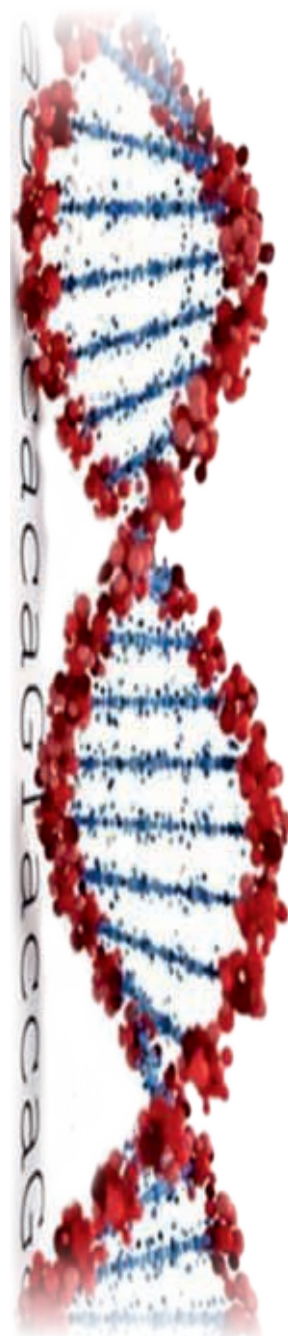
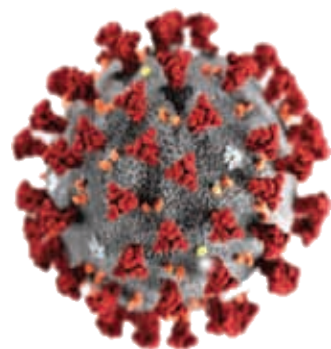




Ministry of Health & Family Welfare



# वार्षिक प्रतिवेदन Annual Report 2019-2020



राष्ट्रीय जैविक संस्थान  
National Institute of Biologicals

# **ANNUAL REPORT**

## **2019-20**



**NATIONAL INSTITUTE OF BIOLOGICALS**

**Ministry of Health & Family Welfare**

**Government of India**

**NOIDA**



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## INTRODUCTION

The National Institute of Biologicals (NIB) had been set up in 1992. NIB is an apex scientific autonomous institute under the administrative control of Ministry of Health & Family Welfare (MoHFW), Government of India. The Institute is located at A-32, Sector-62, NOIDA, Uttar Pradesh in an area of 74,000 Sq. M.

The Institute is performing primary statutory function of Quality Control of Biologicals e.g. Insulin, erythropoietin, blood products, diagnostic kits e.g. HIV, HBV, HCV, therapeutic monoclonal antibodies like Trastuzumab and Rituximab used in cancer treatment etc. in accordance with provisions of Drugs & Cosmetics Act 1940 and Rule 1945 amended from time to time and Medical Device Rules 2017. The Institute is notified Central Drugs Laboratory and Central Medical Device Testing Laboratory under these statutory provisions. The biological products are tested as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms, in the NIB laboratories. The laboratories are also accredited by NABL as per the scope defined. Some of the NIB scientists have also been notified as Government Analysts and Medical Device Testing Officers for biological products as per Statutory Norms.

The scientists of the institute are committed towards their duty and follow the mandates and functions meticulously. Some of them are as hereunder:

- i) to ensure quality of Biological and Biotherapeutic products, both imported and manufactured indigenously moving in the Indian market.
- ii) to contribute in finalizing the specifications for biological products to be incorporated in Indian Pharmacopoeia,

- iii) to prepare National Reference Standards for biological products,

- iv) to train technical personnel in the public and private sectors in the field of Quality Control of Biological products and Haemovigilance programme,

- v) to collaborate with other National and International Scientific Institutions/ organizations in upgrading technologies and keeping abreast of scientific advances made in the field of quality assessment of Biological and Biotherapeutic products.

- vi) to extend technical expertise during joint inspections of manufacturing premises of biological products with the officers of CDSCO

- vii) to implement the Haemovigilance Programme of India to promote safe blood transfusion practices.

The Laboratory and Animal House facility of the Institute, constructed in February, 2006, have 42 Biosafety Level (BSL)-2 laboratories equipped with modern scientific equipment for testing of Biological and Biotherapeutic products. There are 20 walk-in-cold rooms and 03 walk-in-deep freezers (-20°C), and 64 bio-safety cabinets. All equipment are under Annual Maintenance Contract (AMC) or Comprehensive Maintenance Contract (CMC) and are regularly calibrated by a NABL accredited calibration laboratory.

The expenditure made by the Institute on salaries, maintenance, procurement of reagents, chemicals, scientific equipment etc., is met from the grants given by the Ministry of Health & Family Welfare, Govt. of India. The revenue generated from testing of biologicals is deposited in the Consolidated Fund of India with Ministry of Health & Family Welfare, Government of India.

## REPORT FROM THE DESK OF DIRECTOR

It gives me immense pleasure to present the Annual Report of National Institute of Biologicals (NIB) for the year 2019-20 that illustrates the significant work carried out at the Institute.



The institute has affirmed its solidarity with the nation in fighting the COVID-19 pandemic by establishing the COVID-19 testing laboratory and has been declared as High throughput screening laboratory by ICMR. The laboratory was set up in the month of March 2020 for testing the suspected COVID-19 patient samples using cobas 6800 equipment of M/s Roche. The institute formally initiated the testing on 4th April 2020

Immunodiagnostic kit Laboratory of NIB is a WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro diagnostic assays (WHO-CC No. IND-148) and is also “Support Cell” for WHO Prequalification (PQ) Programme for In-vitro Diagnostics (IVD). In this capacity, First WHO-EQAAS Workshop for laboratories in India and select laboratories from South East Asia Region, was organized from 03<sup>rd</sup> to 05<sup>th</sup> December, 2019. A total of 40 participants from laboratories of WHO SEARO including Bhutan, Thailand, Nepal, and India participated in this workshop.

Haemovigilance division of NIB in collaboration with WHO South East Asia Region (SEAR) organized Regional Workshop of National Focal Points of Blood Transfusion Services to Review Implementation of WHO Global Strategy of Safe Blood with an Emphasis on Hemovigilance

which was held from 19th to 22nd August, 2019 at National Institute of Biologicals, NOIDA. About 38 participants from eleven countries had participated in the said workshop.

The state-of-the art laboratories of NIB, was chosen to conduct Six days workshop on “Maintenance and Certification of Biosafety Cabinets” which is a highly specialized technical workshop- the First of its kind in India, organized by WHO- SEARO, CDC, New Delhi and IAMM. NIB extended its support for organizing the workshop from 13<sup>th</sup>-18<sup>th</sup> May 2019 by providing its 4 laboratory facilities with 8 Bio Safety Cabinets for hands on training. The trainers were from NSF International (USA) and Thermo Fisher (USA).

The institute’s global profile has paved way for interaction with international dignitaries from various countries who were interested in capacity building on quality control of biologicals and establishing haemovigilance programme. NIB was honored by the presence of Hon’ble Health ministers of Bangladesh and Bhutan, who had showed keen interest to visit NIB, along with WHO-SEAR dignitaries during their participation in World Conference to Access to Medical Products: Achieving the SDGs 2030 from 19<sup>th</sup> to 21<sup>th</sup> November 2019 at New Delhi.

Thirty one (31) International Delegates from 20 countries, who were undergoing “11<sup>th</sup> international training programme on competence and management systems of laboratories” training at NITS-BIS, NOIDA under the Indian Technical and Economic Cooperation (ITEC) Programme of Ministry of External Affairs, Government of India visited NIB in order to understand and enhance

their knowledge on establishing quality control strategies for biologicals.

The capacity of NIB to test different types of biologicals has increased substantially during the last five years i.e. 262 in 2019-20 from 177 in 2015-16. The Institute evaluated 2014 batches of biological samples in 2019-20 including 1692 batches under Drugs & Cosmetics Act and Rules thereunder, 310 from State Medical Procurement Agencies and 12 vaccine samples from Bangladesh. Out of total samples tested, 3.52% (i.e. 71 batches out of 2014) were found to be of Not of Standard Quality (NSQ) thus highlighting the role of the Institute in protecting and promoting public health

NIB laboratories participated in various International/ National External Quality Assurance Assessment Scheme (EQAAS)/ Proficiency testing by various external agencies like European Directorate for the Quality of Medicines (EDQM) - France, WHO- Geneva, National Serology Reference Laboratory (NSRL) - Australia, Christian Medical College- Vellore in order to assess and strengthen the laboratory's testing performance.

The major contribution towards the quality assurance of various biologicals is emphasized through preparation of various National Reference standards and sera panels. The first National Reference Standards for Blood Grouping Reagents anti-A and anti-B was released officially on 16th April 2019. The institute is also the nodal organization in development and also the sole repository for National Reference Standards for Human Insulin and Insulin Lispro and HIV, HBsAg, HCV and Syphilis performance panel. The collaboration with WHO Collaborating centres like NIBSC for development of International Reference Standards for Biotherapeutics, specifically

Monoclonal Antibodies and plasma derived ones has reiterated the international stature of the institute in the field of quality control of biologicals. The institute has also contributed in developing as well as upgradation of Indian Pharmacopoeia monographs in the field of Biologicals.

National collaboration(s) with reputed national organizations for validation studies of test methods intended for quality evaluation of biologicals and diagnostic kits and reagents and also as subject experts for Joint inspection of manufacturing facilities, brings out the contribution of NIB scientists in strengthening the indigenous development of medical devices, Biotherapeutics and prophylactic medicines. The Scientists have also been invited for sharing their knowledge through expert committee meetings of BIRAC Start Ups, CPCSEA, BIS technical committee etc. and as invited speaker for Haemovigilance Programme of India. The nomination of NIB scientists as faculties for international conferences, meetings and workshops have reinforced the global presence of the institute and its role in strengthening the regulations, testing and manufacturing of biologicals.

NIB has been contributing towards safety of blood transfusion as the National Coordinating Centre for Haemovigilance Programme of India (HvPI) which was launched on 10.12.2012 across the country. This year 15 Continued Medical Education (CMEs)/ National level workshops were conducted for creating awareness on importance of reporting adverse transfusion reactions. A total number of 1638 participants which includes blood bank officials, clinicians, nurses, blood donor motivators and blood bank technical staff were trained in these CMEs/ Workshop organized by HvPI Division of NIB. HvPI is a member of

International Haemovigilance Network (IHN). Further, Head of HvPI- NIB, has been designated as Secretary of IHN Board.

Considering a need of trained and skilled manpower in the country in the area of Quality Control of Biologicals, Diagnostics and Haemovigilance; NIB has trained more than 700 personnel including students, blood bank officials and technical personnel from manufacturing units during this year. The Institute in line with “Pradhan Mantri Kaushal Vikas Yojna”, has been conducting trainings on National Skill Development & Hands- on Training on Quality Control of Biologicals” for Post- Graduate students of Biotechnology, Microbiology, Biochemistry and Pharmacy from Universities of Himachal Pradesh, Jammu, North Eastern States and various National Institute of Pharmaceutical Education and Research (NIPERs). This year NIB has expanded National Skill Development & Hands- on Training program to Post Graduate Students of Tribal Regions of the country i.e. Chhattisgarh and Jharkhand and also to the students of Central University of Kashmir as well as Bodoland University, Assam. With an aim to strengthen the blood services in the country, NIB in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health and Family Welfare, Govt. of India is also organizing Six Days Residential Training Program on “Training of Trainers for Strengthening of Blood Services” for Blood Bank Officials from various parts of the country. More than 800 blood bank officials have been trained since 2016 in various aspects of blood banking, quality management, and haemovigilance and includes a visit to model blood bank.

Apart from the scientific activities, the institute actively participates with other initiatives by Government of India for wellness, environment

protection and Rajbhasha Samiti. On the occasion of 5<sup>th</sup> International Yoga Day on 21<sup>st</sup> June, 2019, Institute organized Yoga Programme under the guidance of a renowned Yogacharya for all the staff. NIB employees, outsourced staff and the trainees enthusiastically participated in the awareness programme on 1- 2 Oct 2019 as a part of “Swatchta Hi Seva Mission -2019” of the Ministry of Health & Family Welfare, Govt. of India with emphasis on plastic waste Collection and management. NIB officials participated in the Official Language Inspection conducted by the Third Sub-Committee of the Parliamentary Committee on Official Language on 22.01.2020.

Further, NIB has generated a gross revenue of Rs. 16.41 crores during the year 2019-20 from various sources i.e. testing fee for evaluation and Quality Control of various biological samples, training fee received from various training programmes, user charges for hostel and guest house and interest on the saving bank account etc. This is deposited in Consolidated Fund of India with Ministry of Health & Family Welfare, Government of India.

NIB continues to strive to fulfil its mandates to become a trendsetter in the field of Quality Control of biologicals in the country and meet the international benchmark. I am grateful to the Ministry of Health & Family Welfare, Government of India, Central Drugs Standards and Control Organization (CDSCO) and Indian Pharmacopoeia Commission (IPC) for their continuous support & guidance and facilitating NIB in fulfilling its endeavors. NIB is making concerted efforts to ensure the quality service in the Healthcare Sector of the country in the area of biologicals.

# SCIENTIFIC ACTIVITIES



## SAMPLE RECEIPT AND REPORT DISPATCH UNIT

### 1. Name of Head:

Ms. Rashmi Shrivastava, Scientist Grade- III  
(till 06.05.2020)

Sh. Harit Kasana, Scientist Grade- II

### 2. Man Power in the Division:

#### I Name of Scientific Staff:

- i. Dr. Swati Shalini, Junior Scientist
- ii. Dr. Anoop Kumar Junior Scientist  
(from 9<sup>th</sup> March 2020 onwards)

#### II No(s). of Outsourced Staff : 10

### 3. Aim and Scope:

SRRDU has been functional as an independent unit since 2008. The unit is main entry point for all the samples that are received in the institute as well as the exit point from where all the reports are dispatched. Samples of various Biotherapeutics, Diagnostics, and Vaccines are received from the National Drug Regulatory authorities as well as several State government Medical Procurement Agencies like Haryana Medical Service Corporation Limited, Rajasthan Medical Services Corporation, Jammu and Kashmir Medical Services Corporation Limited etc. International samples from Bangladesh have also been received for quality evaluation at Vaccine Laboratory. Requisite quantity of all sample received for testing is retained at recommended temperature up to post 3 months expiry.

### 4. Workflow of the Unit

The complete workflow of department has been well documented as per ISO 17025 in approved SOPs for different categories of biologicals and is an ongoing process for continuous improvement in the efficiency of the system. All samples that are received are critically checked with respect to the essential official documents, proper temperature as per label claim, required quantities, testing fee. These checks are always as per the published and revised guidelines uploaded on Institute website.

An In house built software system LIMS (Laboratory Information Management System) was developed and successfully implemented for entering all the information related to sample receipt. The samples were registered, verified, creation of File/ Forwarding No. and Forwarding of samples to Lab was done through LIMS based SRRD portal for Certificates of Analysis (CoA) generation. Thereafter all concerned Laboratories would generate their respective COAs by selecting the File No from drop-down for their respective products tested. Further the CoA were received at SRRDU for the release of test reports both online as well as offline.

### 5. Sample receipt records:

The total no. of biologicals tested at NIB has increased substantially (as shown in Figure 1).



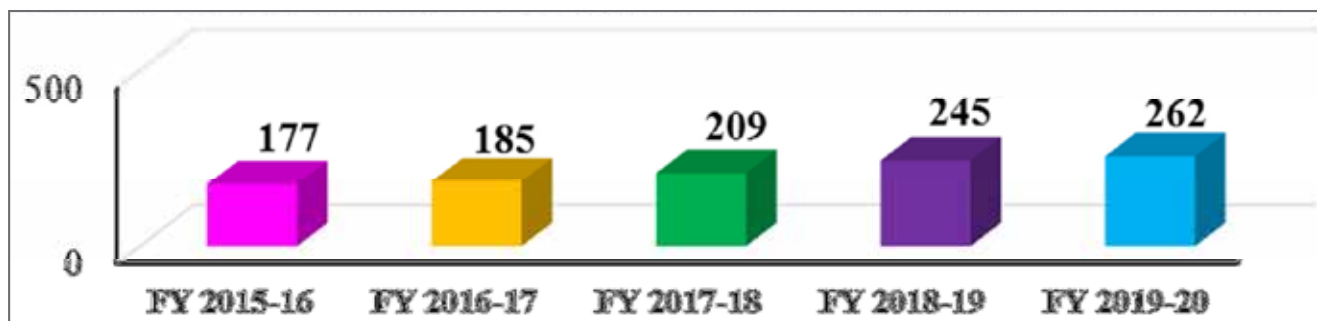


Figure 1: Capacity to test type of Biologicals at NIB during last five financial years

In FY 2019-20 a total of 2065 samples have been received under various product

categories for testing purpose (Figure 2).

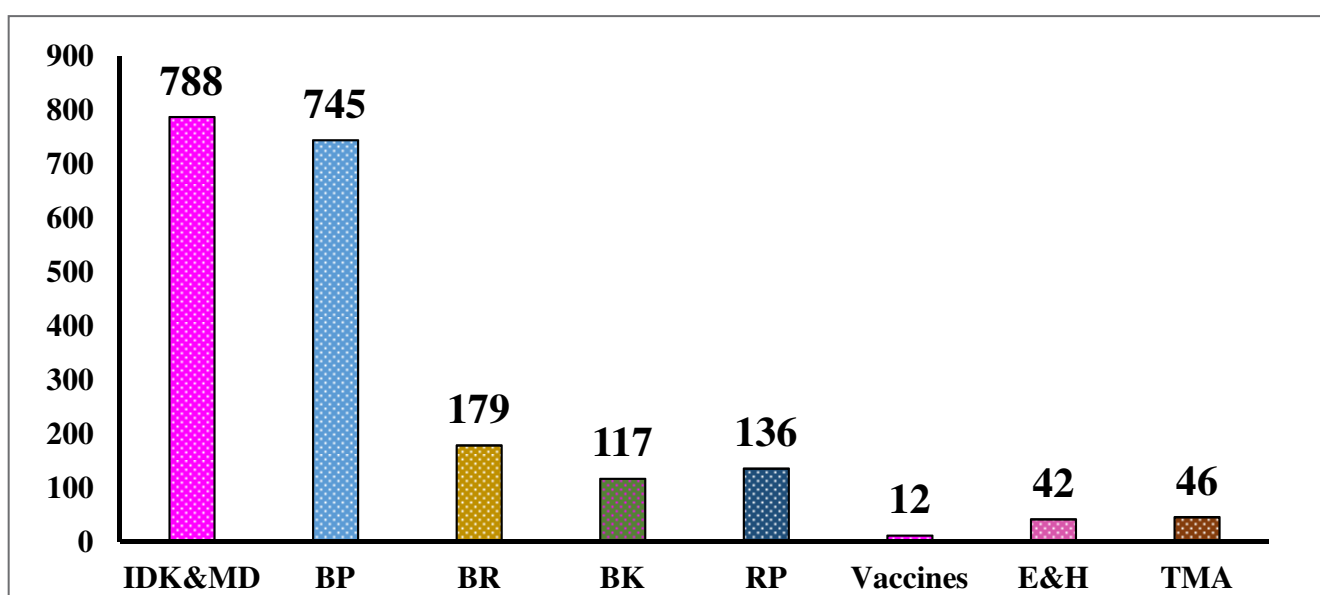


Figure 2: No. of samples received product wise for testing at NIB during year 2019-20

IDK & MD= Immuno diagnostic kit and molecular diagnostic, BP= Blood Products, BR=Blood Reagent, BK= Biochemical Kits, RP= Recombinant Product, E&H= Enzymes and Hormones, TMA= Therapeutic Monoclonal Antibody

Out of the total 2065 samples received at institute in 2019-20, 1778 batches were received under Drugs & Cosmetic Act and Rules, 275 from State Medical Procurement Agencies and 12 vaccines samples from Bangladesh.

## 6. Evaluation of Samples and Release of Test Reports:

A total of 2014 test reports were released in financial year 2019-20. The product wise report release data has been shown in Figure 3.

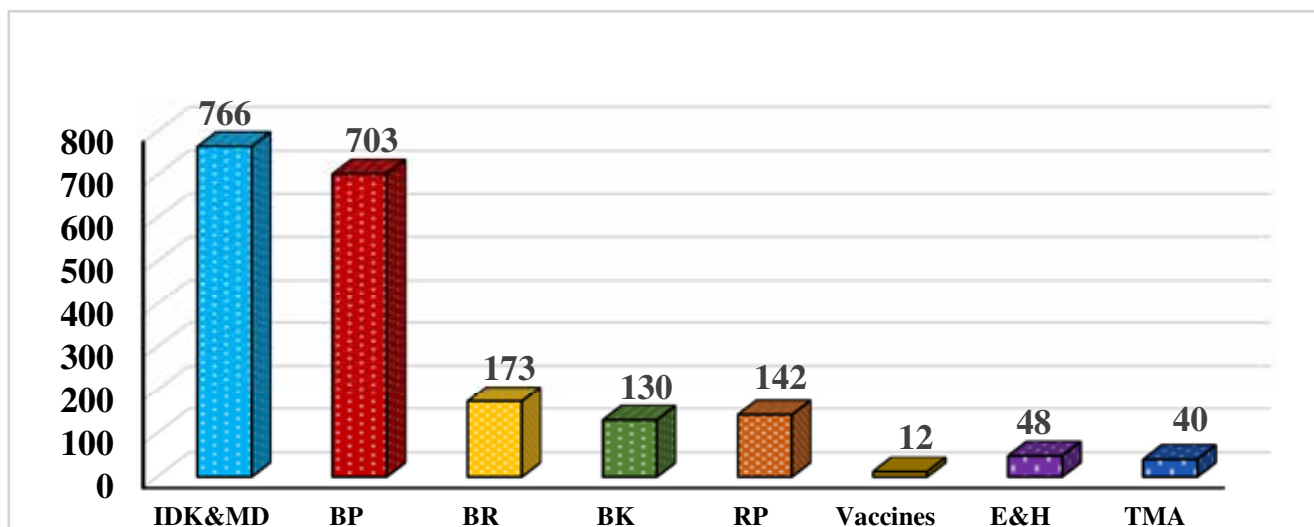


Figure 3: Total reports released product wise from the institute during year 2019-20

Out of total 2014 samples, 71 samples i.e. 3.52% were found to be Not of Standard Quality (NSQ) in 2019-20 as shown in Figure 4.

The no. of NSQ detected has been increased by 1% (from 2.5% to 3.5%) as compared to the previous year.

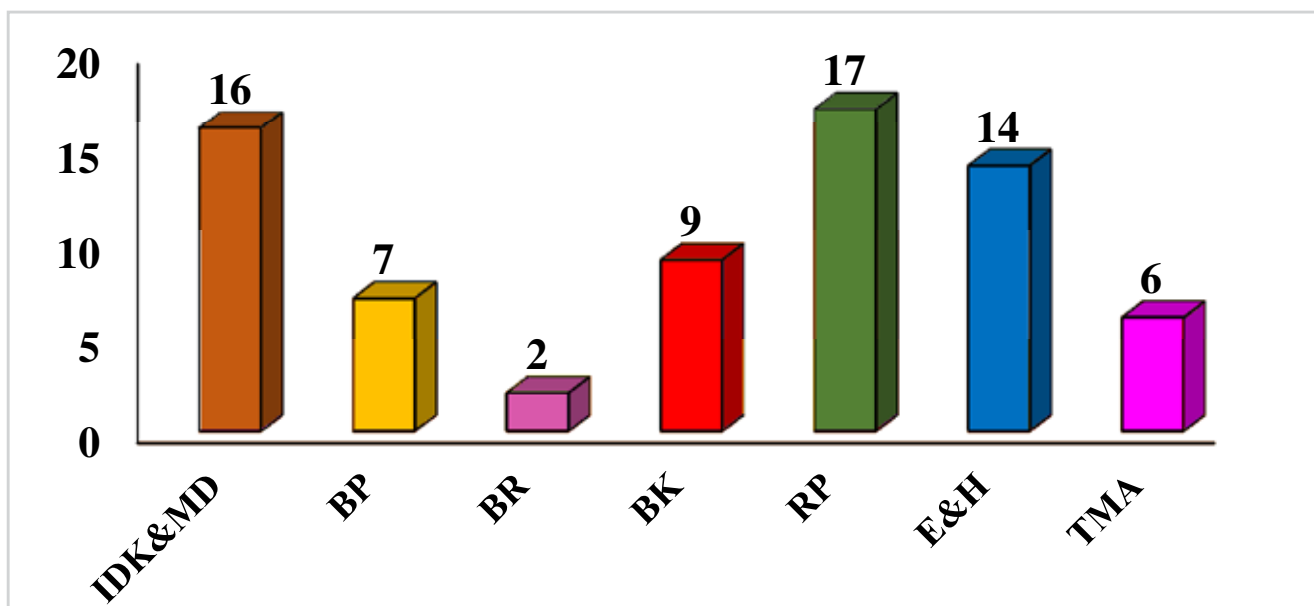


Figure 4: Data for NSQ products released during year 2019-20

## 7. Sample Storage and Record Keeping:

Retained samples are stored frozen, refrigerated or at room temperature as per requirement. There are two dedicated walk-in cold room one each of 2-8°C and -20°C. All the necessary details are entered

in the prescribed register. The samples shall be stored as per the Cold Room Mapping Plan. For security the complete unit is under CCTV surveillance and samples & records are kept under lock and Key.

## **8. Participation in Trainings/ workshop/ conferences:**

Sh. Harit Kasana, Scientist Grade-II and Dr. Swati Shalini Junior Scientist attended training program on “Effective Implementation and Internal Audit of ISO/ IEC 17025: 2017 Laboratory management Systems (LMS) & NABL Criteria” by FICCI Quality Forum at NIB from 20-05-2019 to 23-05-2019.

## **9. Publications:**

Shalini, S., Srivastava, R., Kasana, H., Sharma, M., Sharma, S., Chaudhary, M., Gupta, P., Sharma, C., Rawat, S., Singh, D., Saha, K., & Chhabra, R. (2019). Analysis of market trend of Human Albumin and Coagulation factors in India. International Journal of Biomedical and Advance Research, 10(10), e5268. <https://doi.org/10.7439/ijbar.v10i10.5268>

# IMMUNODIAGNOSTIC KIT & MOLECULAR DIAGNOSTIC LABORATORY

## 1. Name of Head:

Dr. Richa Baranwal, Scientist Grade-III  
(upto 01.05.19)

Dr. Gauri Misra, Scientist Grade-II  
(From 02.05.19 to 24.06.19)

Dr. Harish Chander, Scientist Grade- I  
(From 25.06.19 to 09.02.20)

Dr. Rajesh K. Sharma, Scientist Grade-III  
(From 09.03.20)

## 2. Manpower in the Lab / Division

### I. Name of Scientific Staff:

Mr. N Nanda Gopal, Scientist Grade-III

Dr. Manjula Kiran, Junior Scientist

Mr. P. S. Chandranand, Junior Scientist

Mr. Rajeev Kumar, Junior Scientist

Dr. Anoop Kumar, Junior Scientist

### II. Name of Technical Staff:

Ms. Deepa Sharma, Technical Officer,  
NRL, NACO

Mr. Rahul, Laboratory Technician,  
NRL, NACO (July 15, 2019)

### III. No(s). of Outsourced Staff: 12

## 3. Scientific Activities Undertaken

### a) Collaboration with other Organizations: Networking with blood banks/ hospitals of Delhi/ NCR for collection of plasma bags:

The Laboratory requires infectious plasma bags of HIV, HBV, HCV and syphilis for Preparation of Plasma Panels for Quality Control testing of indigenous and imported Immunodiagnostic and Molecular diagnostic kits received in NIB from offices of Central Drugs Standard Control Organisation (CDSCO). In this regard, DCG (I) has directed various blood banks/ hospitals to provide infectious plasma bags to NIB vide No. Blood Bank/ Misc/ NIB/ 2015-D dated 02.12.2015. During the year 2018-19 a total number of 1056 plasma bags were collected by the Laboratory from the Blood banks/ hospitals enlisted in Table 1. The total number of reactive bags of various markers viz HIV, HCV, HBV & Syphilis were 495, however, 560 bags were non-reactive. However the status of one bag was not known. The details of Plasma Bags collected marker wise are elaborated in Table 2.

**Table 1: List of Blood Banks/Hospitals of different geographical region associated with NIB**

S. No.	Name of Hospital/Blood Bank	S. No.	Name of Hospital/ Blood Bank
1.	Apollo Hospital, New Delhi	5.	Moolchand Hospital, Delhi
2.	Indian Red Cross Society, New Delhi	6.	Kailash Hospital, NOIDA
3.	G.T.B. Hospital, New Delhi	7.	Fortis Memorial, Gurugram
4.	Ganga Ram Hospital, New Delhi	8.	Rajiv Gandhi Cancer Hospital

**Table 2: Total number of Plasma Bags collected during 2018-19:**

Month & Year	New Delhi						Gurugram	NOIDA	TOTAL BAGS PER MONTH
	IRCS	Sir Ganga Ram Hospital	GTB Hospital	Moolchand Hospital	Apollo Hospital	Rajiv Gandhi Cancer Hospital	Fortis Hospital	Kailash Hospital	
Apr 2019	-	29	69	-	-	-	21	-	119
May 2019	14	31	66	5	10	2	-	7	135
Jun 2019	28	2	26	-	-	-	-	12	68
Jul 2019	174	5	32	-	9	-	-	10	230
Aug 2019	15	4	1	-	-	-	32	-	52
Sep 2019	45	-	12	-	-	2	-	15	74
Oct 2019	-	-	23	-	-	-	-	6	29
Nov 2019	66	3	1	-	6	-	-	7	83
Dec 2019	73	2	-	-	-	-	-	7	82
Jan 2020	85	1	4	-	-	-	2	10	102
Feb 2020	60	1	-	-	-	-	-	6	67
Mar 2020	14	-	1	-	-	-	-	-	15
Total →	574	78	235	5	25	4	55	80	1056

**b) CDL Notification:**

The institute is notified Central Drugs Laboratory for Immunodiagnostic Kits (HIV, HCV and HBsAg) since the year 2002 and re-notified in the year 2014. NIB is notified Central Medical Device Testing Laboratory from 1st June 2018, vide Gazette Notification No.S.O.2237 (E).

The institute is accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) in accordance with ISO/IEC 17025 for testing of immunodiagnostic kits and molecular diagnostic kits mentioned in Table 3.

**Table 3: List of Immunodiagnostic and Molecular Diagnostic Kits of HIV 1&2 Antibody, HCV antibody and HBsAg (Rapid, ELISA, CLIA, ELFA, Confirmatory assays) and Syphilis**

S. No.	Name of Marker tested	Specific test or type of test
Serology (N=22)		
1.	HIV 1 & / 2 Antibody	i. Rapid ii. ELISA iii. CLIA iv. ELFA v. Confirmatory

S. No.	Name of Marker tested	Specific test or type of test
2.	HBV	vi. Rapid vii. ELISA viii. CLIA ix. ELFA x. Confirmatory
3.	HCV	xi. Rapid xii. ELISA xiii. CLIA xiv. ELFA xv. Confirmatory
4.	Syphilis	xvi. Rapid xvii. ELISA xviii. CLIA
5.	Anti-HBc Total	xix. ELISA
6.	Anti –HBc IgM	xx. ELISA
7.	HBe Ag/ Hbe Ag-Ab/Anti -HBe	xxi. ELISA
8.	Anti-HBs	xxii. ELISA
<b>Molecular (N=3)</b>		
9.	Blood donor screening multiplex (HBV, HCV & HIV) molecular diagnostic test (Qualitative)	Nucleic Acid Amplification Test (NAT)
10.	Infection Diagnostic test for HIV-1 (Qualitative)	Nucleic Acid Amplification Test (NAT)
11.	Infection Diagnostic test for HCV (Qualitative)	Nucleic Acid Amplification Test (NAT)

### Participation in International level EQAS

#### A) Serology

Immunodiagnostic Kit and Molecular Diagnostic Laboratory has been regularly participating in EQAS since 2009 conducted by NRL Australia- a designated WHO Centre for Diagnostics and Laboratory Support for HIV, AIDS and Blood borne Infections, and fully accredited Proficiency testing provider under ISO 17043: 2010. This strengthen the quality of testing and enhance the credibility of Laboratory. Laboratory has successful participated in three rounds of EQAS 2019 and the Certificate of Participation in NRL EQAS 2019 for Hepatitis serology, HIV

Serology, Syphilis serology has been received from NRL Australia.

#### B) Molecular

This year the Laboratory got enrolled for participated in 2<sup>nd</sup> & 3<sup>rd</sup> Round of EQAS 2020 for Nucleic Acid Testing (NAT) from NRL Australia for the following programmes;

- (i) HBV DNA Viral Load
- (ii) HCV RNA Qualitative & Viral Load
- (iii) HIV-1 RNA Viral Load
- (iv) Multimarker Blood Screening NAT

#### c) Government Analyst:

- i. Under Gazette Notification No. S.O. 4271 (E) published on 26<sup>th</sup> November, 2019,

Dr. Reba Chhabra, Scientist Grade-I & Dr. Rajesh Sharma, Scientist Grade-III are notified Government Analyst for testing of samples received under the Drugs & Cosmetic Act for Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus).

- ii. Under Gazette Notification No. S.O. 3400(E) published on 11<sup>th</sup> July, 2018, Dr. Reba Chhabra, Scientist Grade-I is notified Central Medical Device Testing Officer by Central Government in respect of medical devices (i.e. Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus).

Total 23 samples were received under the Drugs & Cosmetics Act and reported after testing during 2019-20. Out of 23 samples, 21 were reported as Standard Quality (SQ) and 02 were not of standard quality (NSQ) (Table 4)

**Table 4: Samples received and tested under the Drugs & Cosmetics Act during 2019-20**

S. No.	Name of the Kit	No.	SQ	NSQ
1.	HBsAg RAPID	07	06	01
2.	HIV Rapid	07	07	-
3.	HCV Rapid	02	02	-
4.	HBsAg ELISA	03	02	01
5.	HIV ELISA	03	03	-
6.	HCV ELISA	01	01	-

#### e) Publications:

Rajesh K. Sharma, Rajeev Kumar, Brij Bhushan, Tanya Barik, N. Nanda Gopal, Kallol Saha, Ashrat Manzoor and Reba Chhabra. Delhi - National Capital Region: Screening of Plasma for HIV Antibodies. IOSR Journal of Pharmacy and Biological Sciences (IOSR- JPBS). e-ISSN:2278-3008,

p-ISSN:2319-7676. Volume 15, Issue 1 Ser. III (Jan –Feb 2020), PP 34-38.

## 4. Testing of Biologicals:

### 4.1 Quality Control Testing of Immunodiagnostic Kits:

During the year 2019-20, a total of 788 batches of immunodiagnostic and molecular diagnostic kits were received in the Laboratory. Out of 788 batches, total 734 batches were of Immuno-Diagnostic kits & 119 Plasma Pool samples (for TTI testing) and 54 batches were of Molecular-Diagnostic kits (Table 5, Figure 1). Out of 788 batches received 721 batches were evaluated in 2019-20 and 67 batches were under testing. The total No. of batches evaluated during 2019-20 are shown in Table 6. Additionally, reports of 45 batches of 2018-19 year were also released during 2019-20. During 2019-20, total 16 batches were reported as Not of Standard Quality.

**Table 5: Total batches of Immunodiagnostic Kits and Molecular Diagnostic Batches received in the laboratory during 2019-20 month wise.**

Month & Year	IDKL	MDL	Total
Apr 2019	38	4	42
May 2019	45	6	51
Jun 2019	54	5	59
Jul 2019	70	2	72
Aug 2019	70	7	77
Sep 2019	65	4	69
Oct 2019	77	6	83
Nov 2019	38	2	40
Dec 2019	77	7	84
Jan 2020	67	2	69
Feb 2020	73	8	81
Mar 2020	60	1	61
<b>Total</b>	<b>734</b>	<b>54</b>	<b>788</b>

**Table 6: Quality Control evaluation of Immunodiagnostic kits of various marker and Pooled Plasma samples evaluated in the laboratory during 2019-20.**

Name of Biological Tested	Type of Biological	Number of Batches Evaluated		No. of batches found to be of Standard Quality (SQ)	No. of batches found Not of Standard Quality (NSQ)
		Imported	Indigenous		
Immuno-Diagnostic Kits of HIV	RAPID	13	46	56	3
	ELISA	5	27	31	1
	CLIA	30	3	33	0
	ELFA	6	0	6	0
	Confirmatory	2	0	2	0
Molecular Diagnostic Kits of HIV	NAT Qualitative	3	0	3	0
	NAT Quantitative	16	1	15	2
Immuno-Diagnostic Kits of HBV	RAPID	30	111	139	2
	ELISA	14	24	36	2
	CLIA	63	3	65	1
	ELFA	6	0	6	0
	Confirmatory	0	0	0	0
Molecular Diagnostic Kits of HBV	NAT Qualitative	0	0	0	0
	NAT Quantitative	9	1	9	1
Immuno-Diagnostic Kits of HCV	RAPID	18	40	56	2
	ELISA	11	18	28	1
	CLIA	24	3	27	0
	ELFA	4	0	4	0
	Confirmatory	4	0	4	0
Molecular Diagnostic Kits of HCV	NAT Qualitative	2	0	2	0
	NAT Quantitative	9	0	9	0
Immuno-Diagnostic Kits of Syphilis	RAPID	5	21	26	0
	ELISA	2	0	2	0
	CLIA	9	3	12	0
Immuno-Diagnostic Kits of HIV-Syphilis Combo	RAPID	5	0	5	0
Immuno-Diagnostic Kits of HIV, HCV, HBV Combo	RAPID	0	1	0	1
Molecular Diagnostic Kits of Blood Donor Screening (HBV, HCV & HIV)	NAT Qualitative	10	0	10	0
Pooled Plasma	ELISA	0	119	119	0
Total		300	421	705	16
		45 batches of 2018-19 year were also released during 2019-20		45	0
		766		750	16



#### 4.2 Quality Control testing of HBV sub marker kits:

Out of 721 batches evaluated that are received in current financial year, total HBV

sub marker were evaluated were 251 batches. Total 246 batches were reported as Standard Quality and 05 batches were of Non-Standard Quality (Table 7)

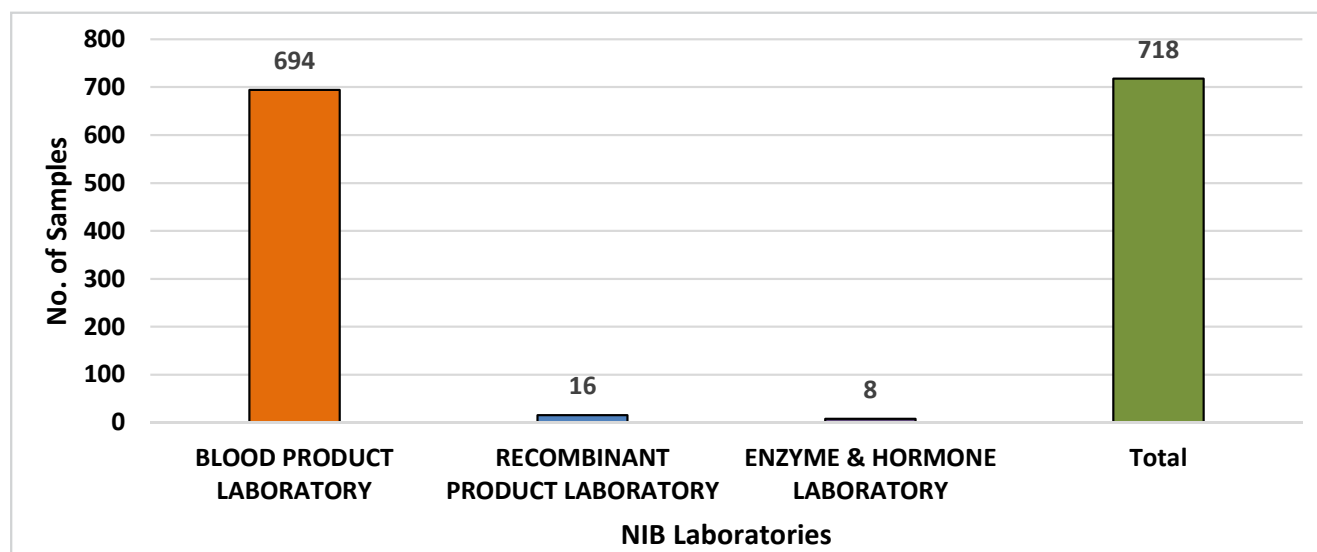
**Table 7: List of HBV sub-markers tested in the year 2019-20**

S. No.	Name of Product/ Marker	No. of Batches Evaluated	No. of batches found to be of Standard Quality (SQ)	No. of batches found Not of Standard Quality (NSQ)
1.	HBsAg	213	209	4
2.	Anti-HBs	11	10	1
3.	HBsAg Quantification	1	1	0
4.	HBc Total	10	10	0
5.	Anti-HBc IgM	7	7	0
6.	Anti- HBe	3	3	0
7.	HBe Ag	6	6	0
<b>TOTAL</b>		<b>251</b>	<b>246</b>	<b>5</b>

#### 4.3 Inter-laboratory testing of Biologicals and Biotherapeutic Samples:

During 2019-20, the laboratory tested 718 batches of biologicals & biotherapeutics received from other NIB laboratories

(Interlaboratory) viz; Blood product laboratory (694), Recombinant product Laboratory (16) and Enzymes & Hormone (8) for Transfusion Transmitted infection (TTIs) (HIV-Ab, HCV-Ab & HBsAg) (Figure-1).



**Figure 1: Number of biologicals & biotherapeutic products tested during year April 2019-March 2020 for TTI testing (Inter-Laboratory Samples tested for TTI during 2019-20)**

## 5. Preparation and Supply of National standards, Sera Panel etc.:

### 5.1 Preparation and characterization of Panel

Characterization and re-characterization of the panel is a continuous laboratory activity to maintain and check quality of the panel member used for the evaluation and supply to the indigenous manufacturer.

### 5.2 Supply of Sera Panel

During 2019-20, the laboratory supplied Performance Panel to 16 indigenous manufacturers as mentioned in Table 8 to strengthen the Quality Control of product during manufacturing of the products. The panel supply boxes comprise of 50 Positive & 150 Negative members for HIV, HCV & HBsAg and 25 positive & 25 Negative members for Syphilis.

**Table 8: Supply of the performance panel from NIB to indigenous manufacturer**

S. No.	Name of Manufacturer	Type of Panel Supplied
1.	Kings Institute, Chennai	HIV, HCV, HBsAg, Syphilis
2.	POCT Services Pvt. Ltd., New Delhi	HIV, HCV, HBsAg, Syphilis
3.	SD BIO-SENSOR HEALTHCARE PVT.LTD	HIV, HCV, HBsAg
4.	Avecon Healthcare Pvt. Ltd, Haryana	HCV
5.	Bhat Biotech India (p)Ltd., Bengaluru	HCV
6.	Voxtur Bio Ltd., Maharashtra	HIV, HCV, HBsAg
7.	Immunoscience(I) Pvt. Ltd.	HIV, HCV, HBsAg
8.	Tulip Diagnostic Pvt. Ltd., Verna, Goa	HCV
9.	Diagnocure (India), Solan, H.P	HIV, HCV, HBsAg
10.	Medsources Ozone, Haryana	HCV
11.	Seloi Healthcare, Mumbai	HIV, HCV, HBsAg, Syphilis
12.	Reckon Diagnostic Pvt. Ltd. Gujrat	HIV
13.	Aspen Lab. Pvt. Ltd., Delhi	HIV, HCV, HBsAg
14.	Biogenix Inc Pvt. Ltd., Lucknow	HIV, HCV, HBsAg
15.	Promea Therapeutics. Telangana	HIV, HCV, HBsAg
16.	Avantor Performance Materials India Ltd, Dehradun	HIV

## 6. Trend in volume of work as compared to previous year:

### 6.1 Trend in volume of work as compared to the previous year for Quality Control Testing of Immunodiagnostic kits:

A total of 766 batches of immunodiagnostic

& Molecular Diagnostic kits were evaluated in the year 2019-20, however, 629 batches were evaluated in the year 2018- 2019. The details of trend for the no. of batches evaluated for immunodiagnostic Kits and Molecular Diagnostic Kits in 2019-20 as compared to that of 2018-19 is given below in figure 2.

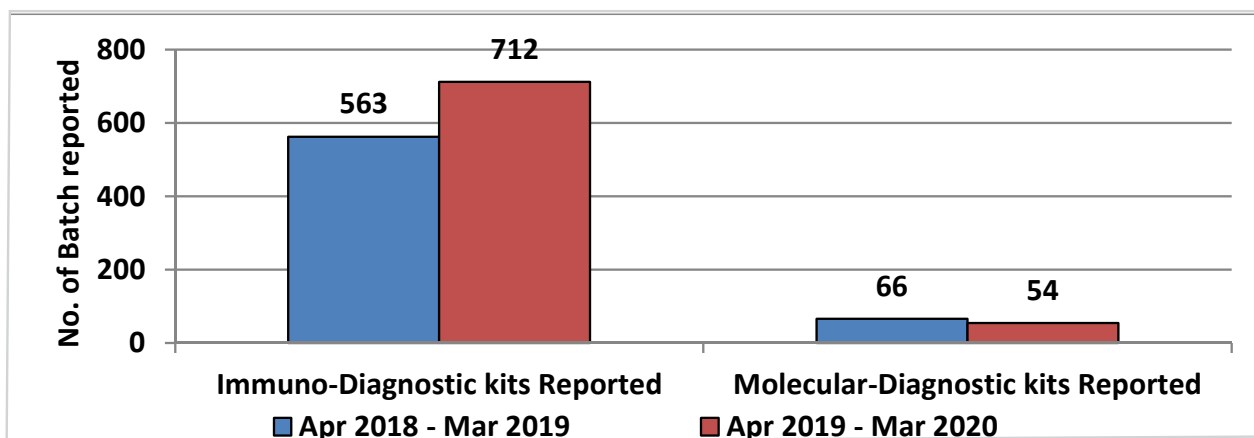


Figure 2: Trend of Immunodiagnostic & Molecular Diagnostic Kits evaluated in 2018-19 as compared to the previous year

### 6.2 Trend in volume of work as compared to the previous year for Inter-laboratory Sample Testing:

A total of 718 lot/ batches of Blood Products, Recombinant Products and Enzymes and

Hormones laboratory were tested during 2019-2020 for the TTI testing of HIV- Ab, HCV-Ab & HBsAg, while in the year 2018-19, 628 lot/batches were tested (Figure 3).

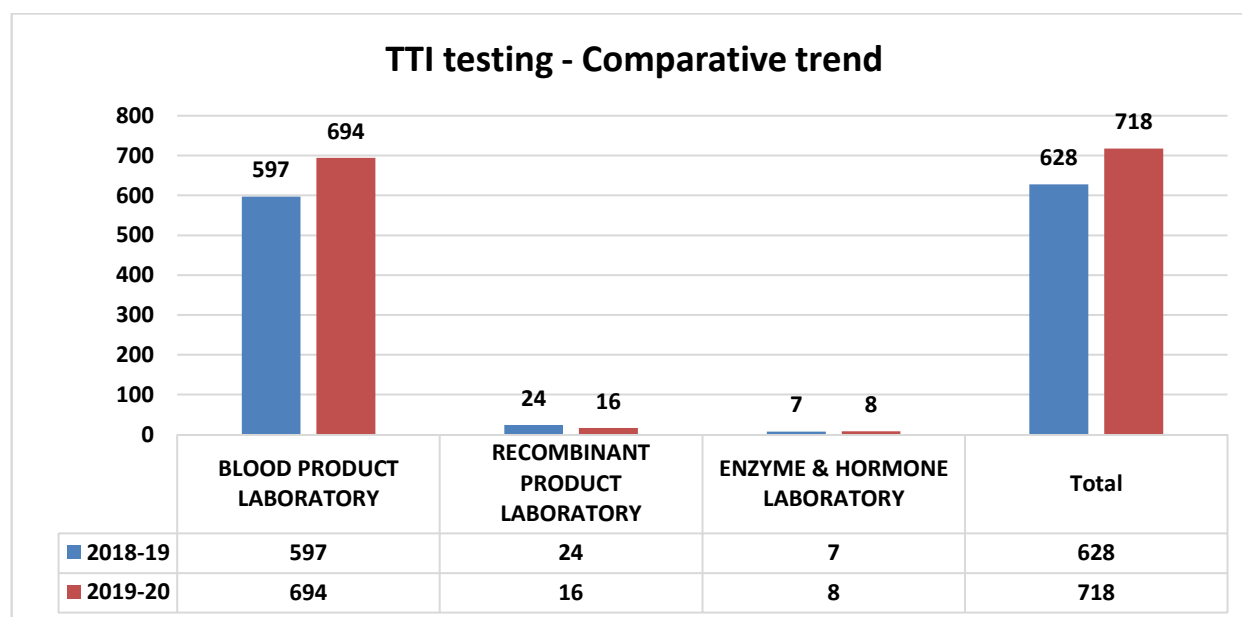


Figure 3: Trend of Inter-Laboratory Sample Testing in 2019-2020 as compared to the previous year

### 6.3 Lot Release testing of HIV-Rapid Diagnostic Kits (RDTs):

dilution panels for HIV-Rapid Diagnostic Kits (RDTs) as per Paul Ehrlich Institut, Germany protocol. A Study protocol conducted on HIV Rapid batches to assess analytical sensitivity

to fix manufacturer specific dilution values. The study has completed using base matrix negative Human plasma along with NIBSC reference standards viz Anti HIV-1, Anti HIV-2, subtypes Anti HIV-C, Anti-HIV-O etc. and presented on 5<sup>th</sup> September 2019.

## 7. Proposed targets for testing of new Biological being undertaken:

7.1 Panel reduction for the markers HIV-Ab, HCV-Ab & HBsAg: The objective is to reduce panel size for Quality Control Testing of HIV-Ab, HCV-Ab and HBsAg Rapid, ELISA and CLIA kits from the existing panel size in accordance to statistical analysis.

## 8. Training/ Workshop/ Conference/ Meeting Organized

### A NRL-NACO, NIB

- i. NIB as a National Reference Laboratory of NACO has successfully organized first time two days interactive meeting by inviting the In charges of 09 SRLs of Uttar Pradesh and 01 SRL of Uttarakhand on 10<sup>th</sup> and 11th October 2019 and completed the 1st round of EQAS Workshop of FY 2019-2020 as per NACO calendar twice in year. 18 participants attended the meeting.



*Photographs of 1st round of EQAS Workshop of Financial Year 2019-2020*



- ii. NRL-NACO-NIB organized One-day workshop for distribution of HIV EQAS panel (Round 2, 2019-20) and training on NACO Prayogshala & Online Data Management On QMS to State Reference Laboratories Of Uttar Pradesh & Uttarakhand by inviting

the Technical officers of all SRLs, SHARE INDIA representative and Assistant Director UPSACS Lab Services on 13<sup>th</sup> February, 2020 at NIB. Total 15 participants attended this training/ workshop.



## B WHO PQ Support Cell, NIB

NIB has been designated as “Support cell for WHO Pre-Qualification Programme” for in-vitro Diagnostics on 22<sup>nd</sup> November 2017.

- i. The Immunodiagnostic Kits and Molecular Diagnostic Laboratory, of the institute has organized 3<sup>rd</sup> meeting with Stakeholders of In-Vitro Diagnostics regarding “Support Cell for WHO Pre-Qualification Programme” on September 1<sup>st</sup> 2019. The laboratory displayed the blank NIB-WHO-PQ template for general discussion with the participants of the meeting. Specific areas of concern as mentioned below from the template, with regard to data received were discussed and addressed in the meeting.

- A. Product Code & No. of Tests per Kit
- B. Type of Assay & Assay Format
- C. Stability Study Data (Real & Accelerated)
- D. Antigen / Antibody Type

- E. Details of Reference Standards used

- F. Type of Panels used (Seroconversion, performance etc.)

- G. Number of Specimens per panel

- H. Source of Panels (Details of Panel Provider)

- I. Cross reactive / Interfering samples used (if any)

- J. Maximum number of tests in one run & Time required

It was mutually decided upon that the suggestions put forth by the industry / stakeholders would be included in the revised pre-filled template in word format by each stakeholder. Data received would be analysed for further strengthening of the stakeholders enabling them towards smoother integration and participation in WHO-PQ programmes.



*Group photograph of Participants of WHO PQ Support Cell Meeting*

### **C WHO Collaborating Centre, NIB**

- NIB has been designated as WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg & Syphilis in-vitro diagnostic assays (WHO CC No.IND-148) on 19<sup>th</sup> September, 2018
- NIB was felicitated with certificate declaring Immunodiagnostic Kits & Molecular Diagnostic Laboratory, NIB as the WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro Diagnostic assays On 15<sup>th</sup> December, 2018,
- i. The First WHO-EQAAS Workshop for Laboratories in India and select laboratories from South East Asia Region was organized by National Institute of Biologicals (NIB), WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis In-Vitro Diagnostic Assay, was held at NIB from 3<sup>rd</sup> to 5<sup>th</sup> December, 2019 at NIB – NOIDA with a view to strengthen the technical performance of Quality Control Testing in Drugs Testing Laboratories.

### **OBJECTIVES:**

The specific objectives of the workshop were:

- (a) To provide support to the participants for improvement in their understanding of External Quality Assessment Assurance Scheme (EQAAS) for TTI testing and chemical testing, and principles of Quality Management System (QMS).
- (b) To prepare a road map to bridge the gaps, strengthen for implementation of EQAAS in CDLs, 03 member states of South-East Asia Region (SEAR) including India and SRLs of National Health Mission and states.
- (c) To discuss challenges in EQAAS and success stories in strengthening EQAAS for CDLs, India and SRLs of National Health Mission, Ministry of Health & Family Welfare, Government of India.

A total of 40 participants from laboratories of WHO SEARO (Bhutan, Thailand, India & Nepal), Central Drugs Laboratory/ Central Drugs Testing Laboratories of India, laboratories from 10 states of India under



National Health Mission (NHM), IPC and NICED participated in the workshop. During the workshop the Hands-on Training was provided in Immunodiagnostic Kits & Molecular Diagnostic Laboratory, WHO Collaborating Centre to share technical information about EQAAS, educate the participants to improve performance and encourage them to enhance self-confidence and credibility of the laboratory.

Dr. Reba Chhabra, Director in- Charge NIB delivered a talk on Significance of EQAAS in

TTI Testing wherein the major components involved and advantages of participating in EQAAS were presented. The participants were apprised of the technical aspects related to EQAAS through a presentation on “Laboratory Capacity building for ensuring quality of test kits”, by Dr. Richa Baranwal, Scientist Grade-III, NIB. The hands on training was provided to the participants by Dr. Rajesh Sharma, Scientist Grade- III and Mr. Rajeev Kumar, Junior Scientist.



*Inaugural Function*



*Technical session*



*Hands on Training on EQAAS TTI Testing in Immunodiagnostic Kits & Molecular Diagnostic Laboratory, WHO Collaborating Centre*



*Group photograph of Participants of WHO EQAAS Workshop*

#### D. Expert Committee Meetings:

The Fifth Technical Expert Committee Meeting was held on 18<sup>th</sup> October, 2019 for strengthening of Molecular Diagnostic activities of the Institute under the Chairpersonship of Dr. Anuradha Chakrabarti, Prof. & Head, Department of Experimental Medicine, PGIMER, Chandigarh.

#### 9 Participations in training/ Workshop/Conference:

During 2019-20, the scientists of the laboratory participated in the training, workshop & meetings as mentioned in the table 9

**Table 9: Training/workshop & meetings attended during 2019-20**

Name of the Scientist Participated	Name of the Training/ Workshop/ Conference	Duration	Place
Dr. Rajesh K Sharma Scientist-III	Expert Resource Person: Two days state level workshop cum TOT on External Quality Assurance Standards (EQAS) and Internal Quality Control Process (IQC) for In-House Laboratory Strengthening under Chief Minister's Free Diagnostic Services Programme	23 <sup>rd</sup> & 24 <sup>th</sup> May, 2019	Guwahati, Assam.
	1 <sup>st</sup> meeting of committee reviewing for up gradation of Microbiology Lab to BSL-2 Lab	22 <sup>nd</sup> June, 2019	DDPR Central Research Institute for Homoeopathy, NOIDA
	Technical Resource Group (TRG) meeting Laboratory Services NACO	24 <sup>th</sup> & 25 <sup>th</sup> June, 2019	New Delhi



Name of the Scientist Participated	Name of the Training/ Workshop/ Conference	Duration	Place
Dr. Rajesh K. Sharma Scientist-III & Dr. Richa Baranwal Scientist -III	Participated in Zoom Virtual Meeting of Working Group 1 on Quality assurance and standards of medical products, including labs for South East Asia Regulatory Network	6 <sup>th</sup> August, 2019	NIB, NOIDA
Dr. Rajesh K Sharma Scientist-III	Indian and European Regulatory Summit 2019 as a panelist for topic Materiovigilance and recall process of Notified Medical Devices and IVD – an Indian Perspective New Delhi.	14 <sup>th</sup> November, 2019	New Delhi.
Mr. N. Nanda Gopal Scientist -III &	Attended a meeting of the Technical Specifications Committee experts to revise Technical Specification of Anti Retro Viral Drugs for Adult and Pediatric ARV formulation under the Chairmanship of Addl. DGHS	26 <sup>th</sup> April 2019	Nirman Bhawan.
	Attended 19 <sup>th</sup> First HUB meeting at BIRAC, Department of Biotechnology	March, 2020	DBT, New Delhi
Mr. P. S. Chandranand Junior Scientist	Delivered a talk on “Increased adoption of emerging technologies like Artificial Intelligence & Robotics in, In-Vitro Diagnostics, at 5 <sup>th</sup> international exhibition & conference on pharmaceutical and medical device industry,	6 <sup>th</sup> March, 2020	Mahatma Mandir, Gandhinagar, Gujarat
	Participated in “Expert Dialog: Indigenous Manufacturing of Biomedical Devices enabled by Research and Ecosystem support”	10 <sup>th</sup> February, 2020	Department of Biotechnology, New Delhi.

### Participation of NIB Scientists in 2019 World Conference on Access to Medical Products Achieving the SDGs 2030

NIB Scientists, Dr Reba Chhabra, Dr Harish Chander, Dr Richa Baranwal and Sh. P. S. Chandranand participated in 2019 World Conference on Access to Medical Products Achieving the SDGs 2030 organized by

Ministry of Health & Family Welfare and WHO from 19-21 November 2019 held at Hotel Taj Palace, Diplomatic Enclave, New Delhi, India. The objective of conference was to accelerate access to medical products for achieving universal health coverage in the context of Sustainable Development Goals.



*Sh. P. Chandranand, Junior Scientist, Immunodiagnostic Kits & Molecular Diagnostic Laboratory presented posters in the conference; (i) Role of NIB as “Support Cell for WHO Pre-Qualification Programme for In-vitro Diagnostics” and (ii) Advantages of an In-House developed Cost Effective Laboratory Information Management System (LIMS) in a Regulatory Environment*

## 10. Outstanding achievements of the Laboratory:

The Laboratory Scientists of IDK&MDL were involved in establishment of initiation of COVID 19 clinical samples testing using

equipment cobas 6800 installed in the Laboratory in collaboration of NIB with ICMR. The laboratory prepared SOPs for COVID 19 testing.

## BLOOD REAGENT LABORATORY

### 1. Name of Head:

Mrs. Kanchan Ahuja, Scientist Grade-III

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific Staff:

Mr. Pankaj K. Sharma, Scientist Grade-III

Ms. Vandana Tandasi, Junior Scientist

#### II. Name of Technical Staff:

Ms. Priya Bhagat, Lab Assistant

#### III. No(s). of Outsourced Staff: 06

### 3. Scientific Activities Undertaken:

#### a) Collaboration with other organizations:

##### I. Collaborative study for the preparation of 1st National Reference Standard for Anti-A and Anti-B in collaboration with 8 stakeholders:

1. M/s Diagast India,
2. M/s Bio-Rad Laboratories Pvt. Ltd.,
3. M/s Lab Care Diagnostics,
4. M/s Agappe Diagnostics Ltd.,
5. M/s Immucor India Pvt. Ltd.,
6. M/s Ortho Clinical Diagnostics India Pvt. Ltd.
7. M/s J. Mitra & Co. Pvt. Ltd.
8. M/s Arkray Healthcare Pvt. Ltd.

##### II. Networking with blood banks/ hospital of Delhi/ NCR for the collection of leftover blood samples:

DCG (I) has directed vide letter No.- No.X-11026/77/14-BD dt 08.05.2014 to various

blood banks/ hospitals to provide non-infective and non-clotted left over blood samples from blood samples from blood banks for carrying out quality control of Blood Grouping reagents, Gel Cards and Microplates.

During the year 2019-2020 a total number of 391 blood samples were collected, out of which 390 were non-infected.

#### b CDL Notification:

The Institute is notified Central Drugs Laboratory (CDL) by Government of India vide Gazette Notification No. G.S.R. 601 (E), dated 27<sup>th</sup> August 2002; Gazette Notification No. G.S.R. 908(E) dated 22<sup>nd</sup> December 2014 and Gazette Notification No. 2237 (E) dated 1<sup>st</sup> June 2018 for Blood Grouping Reagents. The Institute is also accredited by NABL as per the ISO/ IEC 17025:2005 for chemical and biological testing for Blood Grouping Reagents since 2011. The Blood Reagent Laboratory has the infrastructure and expertise for testing 88 different types of Blood Grouping Reagents, Rare Reagents, Gel Cards and Microplates.

#### c Govt. Analyst:

Mrs. Kanchan Ahuja, Head, Blood Reagent Laboratory is a notified Government Analyst for Blood Grouping Reagents as per the Gazette Notification No. S.O.-2393(E) published on 2<sup>nd</sup> Sept, 2015.

Dr. J. P. Prasad. Scientist Grade -I and Quality Manager, NIB is a notified Government Analyst vide Gazette Notification Extraordinary Part-II. Section (3), subsection ii, published on September 2011.

As per the Gazette Notification No. - S.O. 3400(E) dated 11<sup>th</sup> July 2018, Mrs. Kanchan Ahuja and Dr. J. P. Prasad are notified Medical Device Testing Officers under the rule 18 of the Medical Devices Rules, 2017.

**d Development of Monograph:**

A total number of 3 monographs have been prepared and submitted to Indian Pharmacopoeia Commission for review by the Expert Group committee of Blood and Blood related Products for publication in the forthcoming edition of Indian Pharmacopoeia:

1. Anti-D IgG

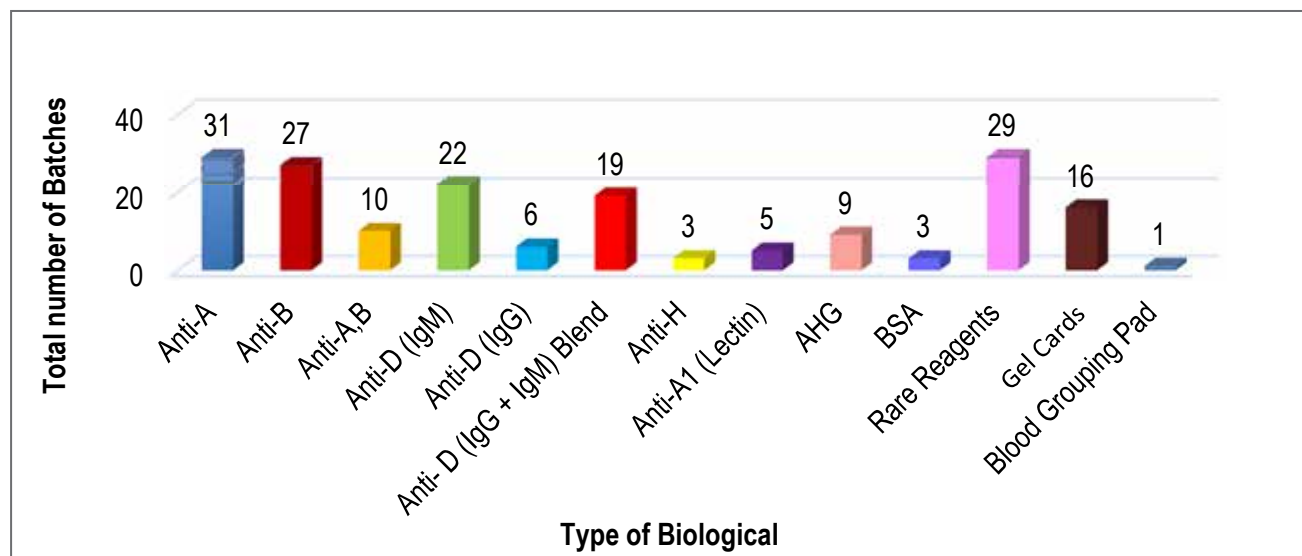
2. Anti D (IgG+IgM)
3. Anti Human Globulin

#### 4. Testing of Biologicals

**4.1** A total of 179 batches of Blood grouping reagents, Gel cards and blood grouping rapid cards were received for Quality Control evaluation. Out of which 133 batches of routine Blood Grouping reagents, 29 were rare blood grouping sera, 16 were rare & blood grouping gel cards and 01 grouping pad. Details are given below in Table 1 and Fig 1.

**Table: 1**

Name of the biologicals tested	Type of biologicals	No. of batches received & evaluated	No. of batches found to be of Standard Quality	No. batches found not to be of Standard Quality	Remarks
Anti-A	Routine Blood Grouping Reagents	31	171+ 08 under the Drugs & Cosmetics Act	02	08 samples of Anti-A, Anti-B, Anti-AB, Anti-D (IgM+IgG), Anti-D (IgM), Anti-D (IgG), Anti-A1 Lectin and AHG under the Drugs & Cosmetics Act received
Anti-B		27			
Anti- D(Blend)		19			
Anti AB		10			
Anti-A1 Lectin		5			
Anti H Lectin		3			
AHG		9			
Anti D (IgM)		22			
Anti D (IgG)		6			
BSA		3			
Rare Blood Grouping Reagents		29			
Gel Cards	Gel Cards	16	179	2	08
Blood Grouping Pad	Grouping Pad	01			
	Total	<b>181</b>			

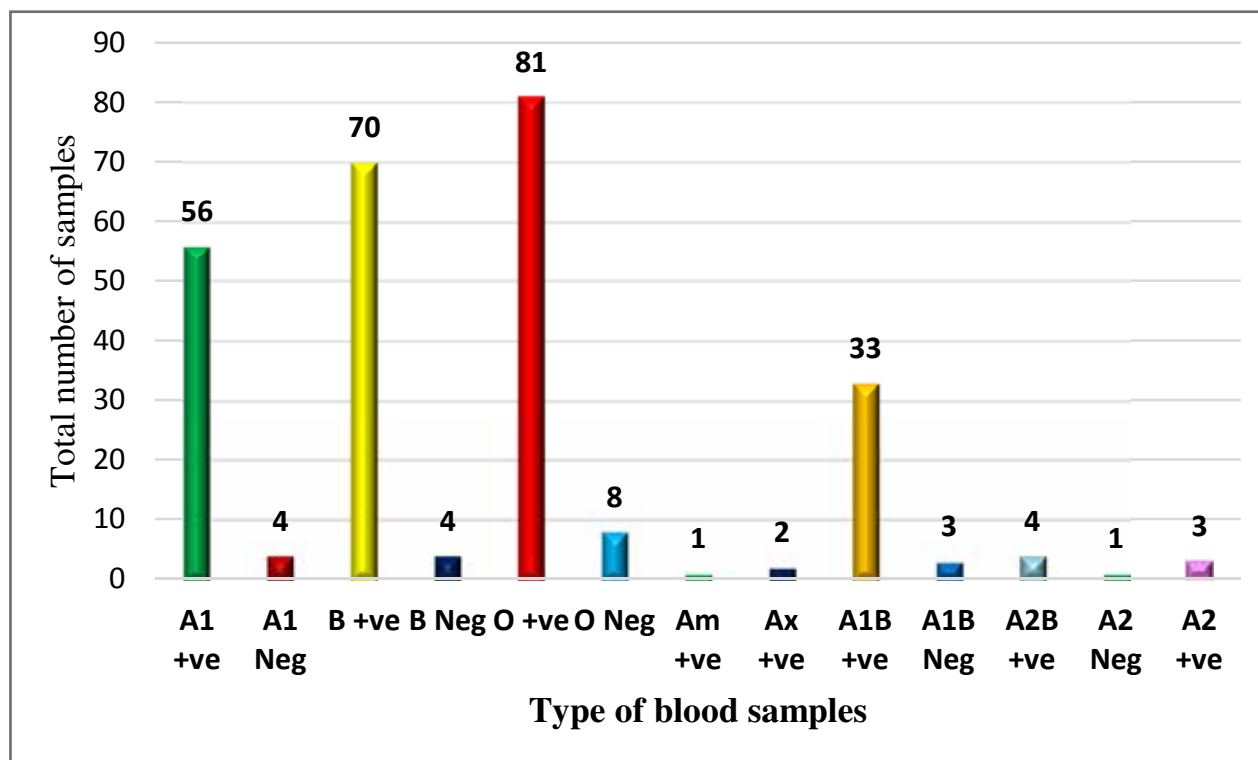


*Fig. 01 Type of Biologicals received for Quality Control Testing 2019-2020*

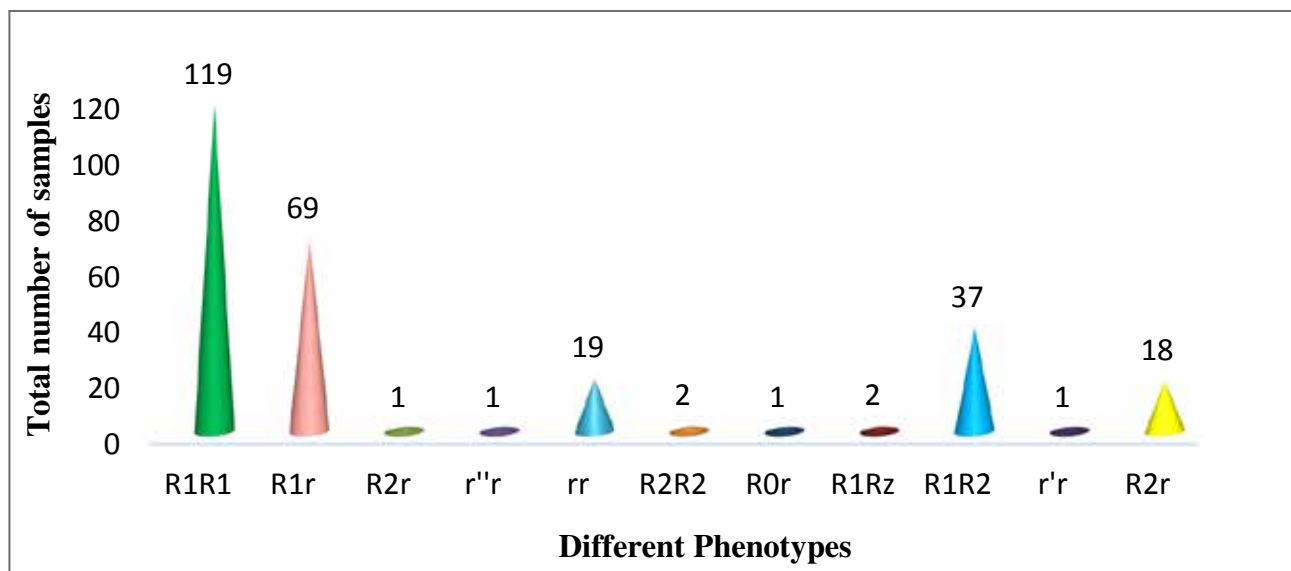
#### 4.2 Collection of samples:

The Laboratory grouped, subgrouped, Rh phenotyped 270 blood samples to be used for

quality control evaluation of blood grouping reagents. The details of the sample collected and Rh phenotyped are given in (Fig.2 & 3).



*Fig.2 Type of blood samples collected in 2019-20*



*Fig.3 Phenotyping of various blood samples collected in 2019-20*

## 5. Preparation and supply of National Standards, Sera panel etc.

a) The laboratory formally released the 1<sup>st</sup>

National Reference Standard for Anti-A and Anti-B blood grouping reagents on 16<sup>th</sup> April, 2019.



b) **Preparation of in-house standards:** Calibration of working standards for Anti-A, Anti-B, Anti-AB, Anti-D (IgM), Anti-D (Blend), Anti Human Globulin, Anti-A1 (Lectin) and Anti-H (Lectin) was done using Secondary Standards (in -house controls)

which were calibrated against International Reference Standards from National Institute of Biological Standards and Control (NIBSC, UK). Details of International Reference standards are given in (table 2).



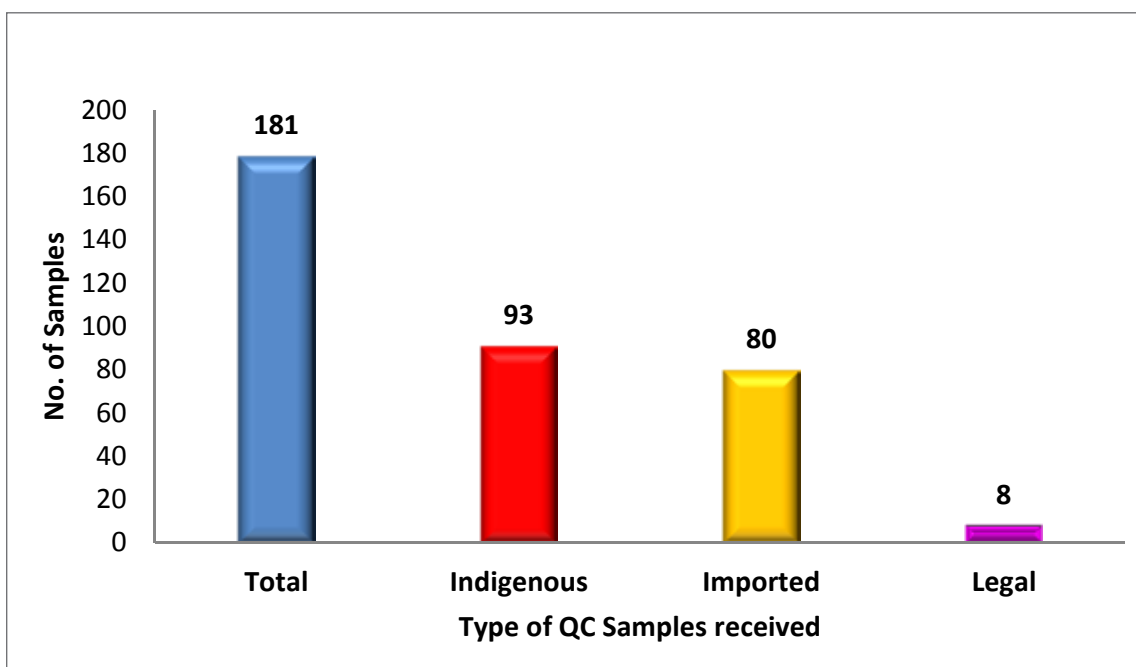
**TABLE 2: Details of the International Reference Standards used**

Name of Reagent	International Reference Standard	Source
Anti-A	03/188, version 2; 11/11/05	NIBSC, UK
Anti-B	03/164, version 2; 11/11/05	NIBSC, UK
Anti-AB	03/188, version 2; 11/11/05 03/164, version 2; 11/11/05	NIBSC, UK
Anti-D (IgM)	99/836, version 2; 20/5/05	NIBSC, UK
Anti-D (IgG+IgM)	99/836, version 2; 20/5/05	NIBSC, UK
Anti Human Globulin	96/666, version 2; 19/04/04	NIBSC, UK

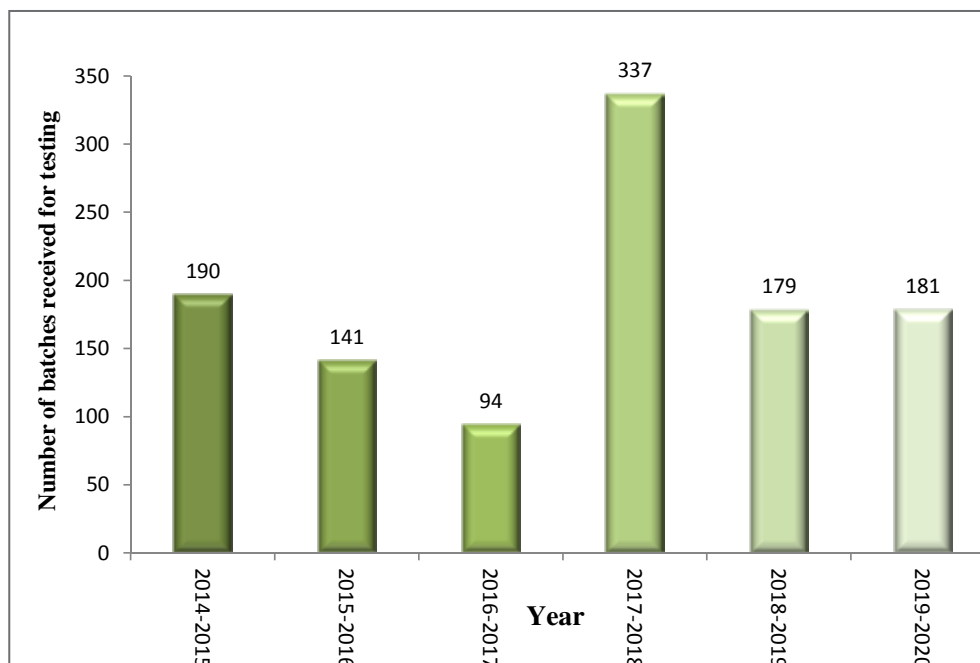
## 6. Trend in volume of work as compared to the previous year:

- a) **No. of samples received:** Total 181 batches were evaluated. Out of which 80 batches were from imported manufacturers and 93

batches were from indigenous manufacturers Fig 4. Total of 181 CoAs were released during 2019-20 as compared to previous years. Details are given in Fig 5.



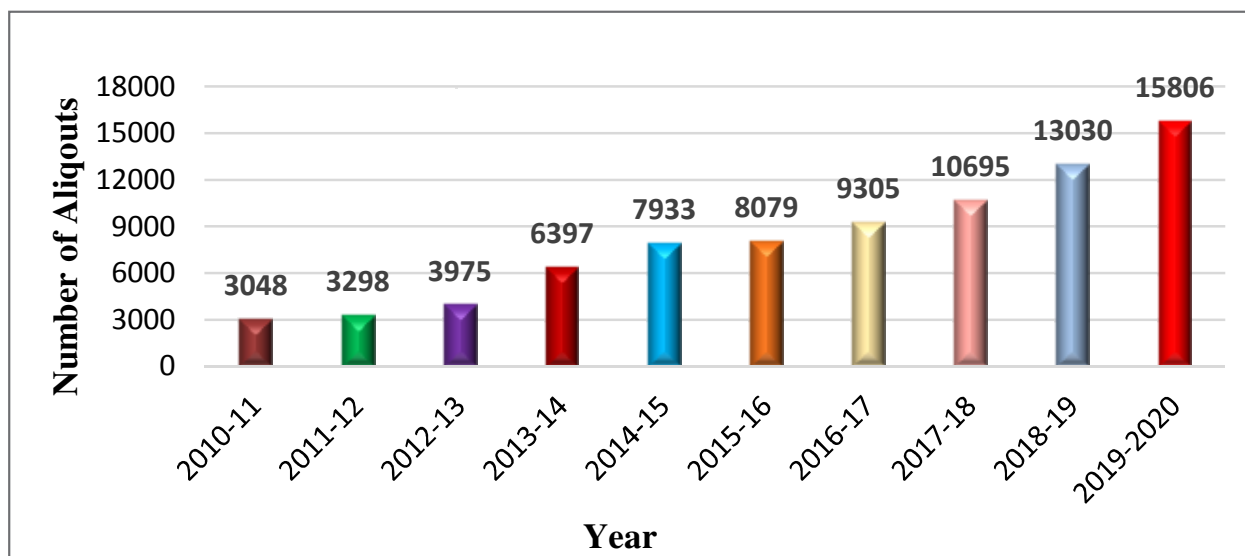
*Fig.4 Batches received from Indigenous & Imported manufacturers in 2019-2020*



*Fig. 5 Trend in volume of work as compared to previous years*

- b) **Cryopreservation of red blood cells:** The laboratory strengthened the repository for cryopreserved panel cells for routine and

rare red blood cells from a total number of aliquots from 13030 to 15806 (Fig.6) . The laboratory prepared repository for newer rare red cells.



*Fig. 6 Status of cryopreservation of Red Blood Cells (2019-2020) stored at 70°C*

- c) **Inter Laboratory Testing of Blood Products**

The Laboratory tested a total number of 160 samples of Blood Products for Anti-A

and Anti-B hemagglutination test parameter Fig. 7.



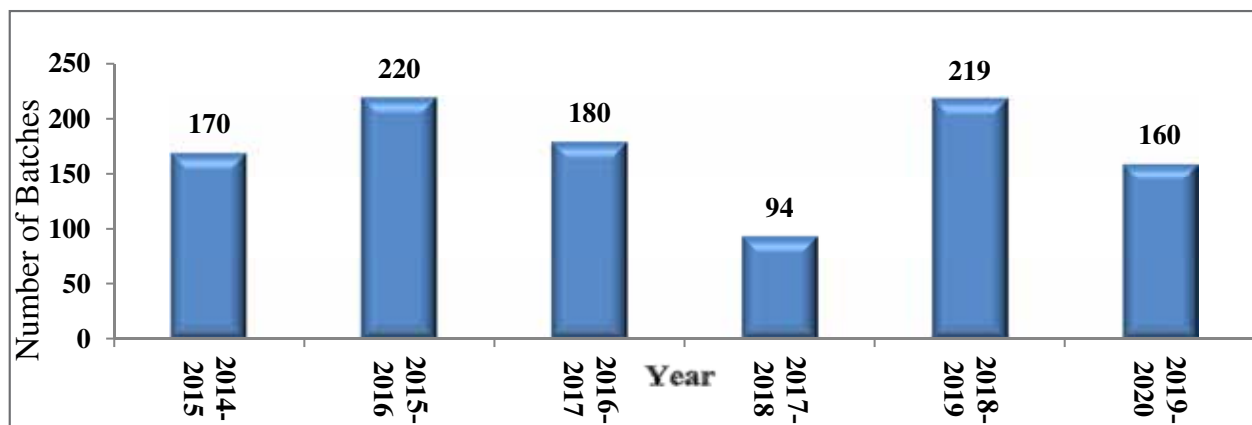


Fig. 7 Interlaboratory testing of Blood Products

## 7. Proposed targets for testing of new biologicals being undertaken:

Reverse with Antibody Screening

## 8. Trainings/workshops/conferences attended:

S. No.	Name	Topic	Venue	Date
1	Ms. Kanchan Ahuja, Scientist Grade-III Shri. Pankaj K. Sharma, Scientist Grade-III	ISO/IEC 17025:2017	FICCI Quality Forum at NIB	20-23 May 2019
2	Ms. Kanchan Ahuja, Scientist Grade-III	4 <sup>th</sup> Expert Group Committee Meeting as an expert for revision of "Guidance Manual for Compliance of Indian Pharmacopoeia Commission"	Indian Pharmacopoeia Commission, Ghaziabad	6 <sup>th</sup> November, 2019

**Training imparted to the stakeholders:** Quality Control Officer from M/s Avecon Healthcare Pvt. Ltd., was trained in Blood Reagent laboratory on 16<sup>th</sup> March 2019 on Quality Control of Blood Grouping Reagents.

Anti-A1 (Lectin) and Anti-D (Blend) blood grouping reagents conducted by Indian Red Cross Society, Delhi on 30<sup>th</sup> Aug 2019. The performance of the staff was found to be 100% satisfactory.

## 9. Outstanding Achievements of the laboratory:

**Participation in proficiency testing:** The staff participated in external proficiency program for Anti-A, Anti-B, Anti-AB,

**Preparation of 1<sup>st</sup> National Reference standard for Anti-A and Anti-B:** The laboratory formally released the 1st National Reference Standard for Anti-A and Anti-B reagents on 16<sup>th</sup> April, 2019

## BIOCHEMICAL KIT LABORATORY

### 1. Name of Head:

Ms. Ajanta Sircar, Scientist Grade III

2. Dr. Ashwini Kumar Dubey,  
Scientist Grade-III

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific Staff:

1. Mr. Tara Chand, Scientist Grade III

#### II. Name of Technical Staff:

Mr. Mohit Sharma, Lab Assistant

#### III. No(s). of Outsourced staff: 04

### 3. Scientific Activities Undertaken:

#### a) Collaboration with other organizations:

S. No.	Title	Collaborating Institutes	Period of Study	Status
1.	Validation studies for Ion Exchange Chromatography Principle-based 'Laboratory Reference Method for estimation of HbA1c' and 'International Guideline' based protocols for various quality control tests/ parameters for evaluating rapid HbA1c assay kits	Department of Endocrinology, AIIMS, New Delhi and Biochemical Kit Laboratory, NIB-NOIDA	29.03.2019-till date	<b>Under Phase –I Activities:</b> <ol style="list-style-type: none"> <li>Biochemical Kit Laboratory has signed a Memorandum of understanding (MoU) with Department of Endocrinology, AIIMS, New Delhi</li> <li>Presently literature review and survey of available test protocols for validation of Ion Exchange HPLC based HbA1c assays is being done.</li> <li>Information regarding the spectrum of Rapid HbA1C assays available in the Indian market is also being done.</li> </ol>

#### b) CDL / CMDTL Notification:

Central Medical Device Testing Laboratory (CMDTL) for Glucose Test Strips and Fully automated analyser bases Glucose Regents vide Gazette Notification S.O.2237 E dated 1<sup>st</sup> June 2018

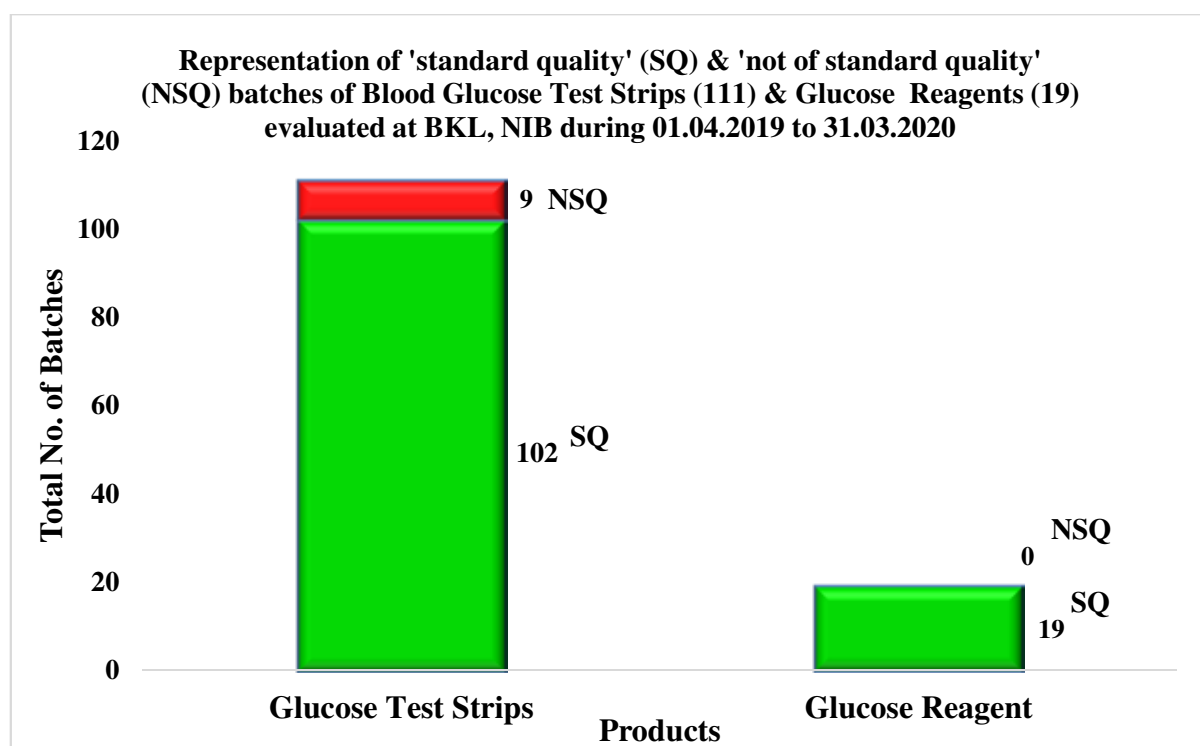
Laboratory is notified Central Medical Device Testing Officer by the Central Government in respect of Medical Device (i.e. Glucose test strips and fully automated analyser based glucose reagents) vide Gazette Notification S.O. 3400(E) dated 11<sup>th</sup> July 2018.

#### c) Govt. Analyst/ Central Medical Device Testing Officer:

Ms. Ajanta Sircar, Head, Biochemical Kit

#### 4. Testing of Biologicals:

Name of Biologicals Tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of Standard Quality	No. of batches found not to be of Standard Quality	No. of Inter-Laboratory sample tested	Remarks
1.	2.	3.	4.	5.	6.	7.
Glucose Test Strips	Glucose Test Strips	111	102	09	Nil	8.1% were found NSQ
Biochemical kit	Fully automated analyser based glucose reagents (closed system chemistry and Open ended system chemistry)	19	19	Nil	Nil	all samples found SQ



#### 5. Trend in volume of work as compared to the previous year:

In the financial year 2019-20, a total of 130 sample batches (111 batches of Blood Glucose Test Strips and 19 batches of Glucose Reagent) were evaluated. The workload had

increased by 10.2% as compared to the previous financial year.

#### 6. Participation in proficiency testing/ EQAS:

The laboratory is presently enrolled in the Association of Clinical Biochemists of India

(ACBI)/ Christian Medical College (CMC) in External Quality Assessment Scheme (EQAS) – 2019 & 2020 for Chemistry II (Glucose, Cholesterol and Triglyceride),

conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore.

## 7. Participation in Training/ Workshop/ Conference:

S. No.	Name of the Laboratory staff	Name of the Programme	Duration	Place of Training	Trainer
i.	1. Ms. Ajanta Sircar, Scientist Gr.-II & Head 2. Sh. Tara Chand, Scientist Gr.-III	Training programme on Laboratory Management System based on ISO/IEC 17025:2017.	May 20-23, 2019	NIB NOIDA	FICCI, New Delhi
ii.	1. Sh. Tara Chand, Scientist Gr.-III 2. Dr. Ashwini Kr. Dubey, Scientist Gr.- III 3. Mr. Mohit Sharma, Laboratory Assistant and 02 outsourced staff	High ended equipment operation training for 'Cobas b123' for Glucose Chemistry by application specialist from M/s Roche Diagnostics India Pvt. Ltd., for the Quality control Evaluation of batches of Glucose reagent samples.	May 10-14, 2019	NIB NOIDA	Application specialist from M/s Roche Diagnostics India Pvt. Ltd.
iii.	1. Sh. Tara Chand, Scientist Grade-III 2. Dr. Ashwini Kr. Dubey, Scientist Grade- III and 01 outsourced staff	High ended equipment operation training for 'Vitros XT7600' for Glucose Chemistry by application specialist from M/s Ortho Clinical Diagnostics, India, for the Quality control Evaluation of batches of Glucose reagent samples.	July 11-16, 2019	NIB NOIDA	Application specialist from M/s Ortho Clinical Diagnostics, India.
iv.	1. Sh. Tara Chand, Scientist Gr.-III 2. Dr. Ashwini Kr. Dubey, Scientist Gr.- III and 02 outsourced staff	High ended equipment operation training for 'Architect c4000' for Glucose Chemistry by application specialist from M/s Abbott Healthcare Pvt. Ltd., India for the Quality control Evaluation of batches of Glucose reagent samples.	September 11-19, 2019	NIB NOIDA	Application specialist from M/s Abbott Healthcare Pvt. Ltd., India

S. No.	Name of the Laboratory staff	Name of the Programme	Duration	Place of Training	Trainer
v.	1. Sh. Tara Chand, Scientist Gr.-III 2. Dr. Ashwini Kr. Dubey, Scientist Gr.- III and 02 outsourced staff	High ended equipment operation training for 'Unicell Dx C800' for Glucose Chemistry by application specialist from M/s Beckman Coulter India Pvt. Ltd., India for the Quality control Evaluation of batches of Glucose reagent samples.	September 16-23, 2019	NIB NOIDA	Application specialist from M/s Beckman Coulter India Pvt. Ltd., India



**Fig.1a: Certificates of training for equipment 'Cobas b123' operation for Glucose Chemistry from M/s Roche Diagnostics India Pvt. Ltd.**



**Fig.2a: Certificates of training for equipment 'Vitros XT 7600' operation for Glucose Chemistry from M/s Orthoclinical Diagnostics India Pvt. Ltd.**



**Fig.1b: Equipment operation training for high ended equipment 'Cobas b123' for Glucose Chemistry by application specialist from M/s Roche Diagnostics India Pvt. Ltd.**

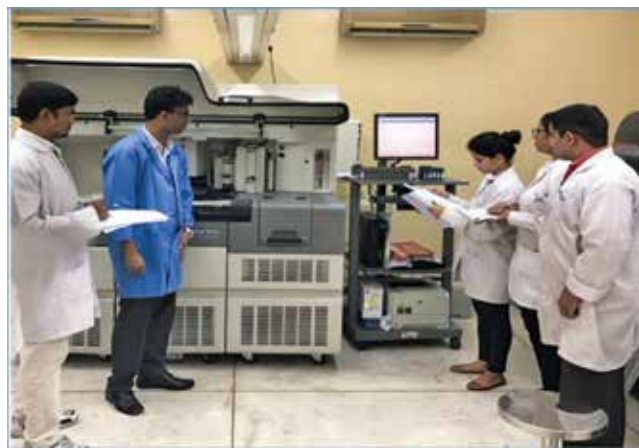


**Fig.2b: Equipment operation training for high ended equipment 'Vitros XT 7600' for Glucose Chemistry by application specialist from M/s Orthoclinical Diagnostics India Pvt. Ltd**





**Fig.3a: Certificates of training for equipment 'Architect c4000' operation for Glucose Chemistry from M/s Abbott Healthcare (I) Pvt. Ltd.**



**Fig.4b: Equipment operation training for high ended equipment 'DxC 800' for Glucose Chemistry by application specialist from M/s Beckman Coulter India**



**Fig.3b: Equipment operation training for high ended equipment 'Architect c4000' for Glucose Chemistry by application specialist from M/s Abbott Healthcare India Pvt. Ltd.**



**Fig.5a. Hands-on training to summer trainee (01 month period) from Gautam Buddha University, Greater NOIDA.**



**Fig.4a: Certificates of training for equipment 'DxC 800' operation for Glucose Chemistry from M/s Beckman Coulter India**



**Fig.5b. In the lab with the participants M. Pharm. Students of Delhi Pharmaceutical Sciences and Research University, Delhi during National Skill development and Hands- On Training Programme on Quality Control of Biologicals.**



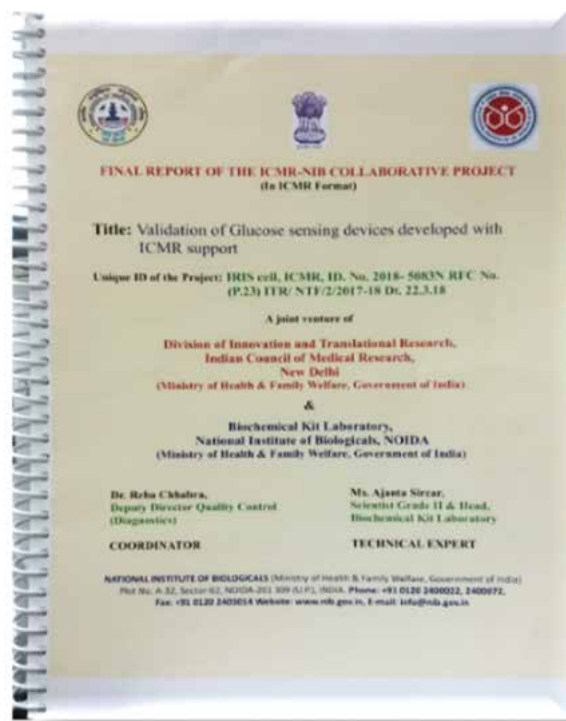
**Fig. 6c. Hands- On Training to the M. Pharm. Students of Delhi Pharmaceutical Sciences and Research University, Delhi**



**Fig. 7. Ms. Ajanta Sircar, Scientist-II and Head of the Biochemical Kit Laboratory demonstrating mobile app based Glucometer device to Prof. Ramesh K. Goyal, Vice-Chancellor of the Delhi Pharmaceutical Sciences and Research University, Delhi during his visit to the laboratory**

## 8. Outstanding achievements of the Lab:

Compilation of the final report ICMR-NIB Project entitled ‘Validation of Glucose sensing devices developed with ICMR support’ (Project Period: 28.07.2017 to 30.06.2019). The ‘Final Report of the ICMR-NIB Collaborative Project (In the ICMR Format)’ compiled by Biochemical Kit Laboratory, National Institute of Biologicals had received by ICMR fraternity with widespread appreciation.



**Figure-8: Final Report of the ICMR-NIB Collaborative Project (In the ICMR Format).**



## VACCINE LABORATORY

### 1. Name of Head:

Mr. Harit Kasana, Scientist Gr. II

### 2. Manpower in the Lab/Division:

#### I. Name of Scientific staff:

- i. Mr. Jaipal Meena, Scientist Gr-III
- ii. Mr. Ajay Kumar Ade, Junior Scientist
- iii. Ms. Archana Sayal, Junior Scientist

#### II. Name of Technical Staff

- i. Mr. Sukhen Majhi (Laboratory Technician)
- ii. Mr. Prdeep (Laboratory Assistant)

#### III. No(s). of Outsourced staff: 09

### 3. Scientific Activities Undertaken:

- a) **CDL notification:** Institute is notified CDL for the BCG Vaccine, Cell Culture Rabies Vaccine, Live attenuated Measles Vaccine, Live Attenuated Rubella Vaccine. (Ref. Gazette Notification No: G.S.R. 250 (E)-Part-II - Section 3 - Sub-Section (i)).

Oral Polio Vaccine (Ref. Gazette Notification No: G.S.R. 249 (E))

#### b) Government analyst

Sh. Harit Kasana, Scientist Grade-II and Sh. Jaipal Meena, Scientist Grade-III are

notified Government analyst (Ref. Gazette Notification No: S.O 4271(E) - dated 26 November 2019) for Bacillus Calmette-Guerin (BCG) vaccine, Live Attenuated Measles vaccine, Live Attenuated Rubella vaccine, Cell Culture Rabies vaccine and Oral Polio Vaccine.

- c) **Development of monograph:** The Third Stakeholder's meeting to include WHO protocol for determination of PRP content of Hib vaccine by HPAEC-PAD in Indian Pharmacopoeia was held at NIB on 10<sup>th</sup> October 2019 under Chairmanship of Dr. Surinder Singh, Director NIB. The said meeting was attended by the representatives of Indian Pharmacopoeia Commission, Indian Vaccine Manufacturers and NIB Scientists. Lab was involved in the preparation of Monograph based on WHO protocol for Determination of PRP Content of Hib in liquid vaccine presentations by HPAEC-PAD for inclusion in Indian Pharmacopoeia. Further, National Institute of Biologicals has prepared a comparative summary sheet of the Indian manufacturers' validation data. Hence, WHO protocol is proposed to include for determination of the PRP content of Hib vaccine in the "Haemophilus Influenzae Type b Monograph" in forthcoming Indian Pharmacopoeia edition.





**d) Publication:**

Estimation of Potency of Hepatitis B immunoglobulin marketed in India to evaluate the manufacturers production consistency: Role of National Control

Laboratory, Jaipal Meena, Shivani Sood, Neha Rani, Roshita Bisht, Manjula Kiran, Reba Chhabra, Surinder Singh and Subhash Chand, Biologicals, Volume 59, May 2019, Pages 72-73. (Impact Factor 1.9).

**4. Testing of Biologicals:**

Name of *Biologicals Tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches found to be of standard quality	No. of Batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Rabies immunoglobulin	Viral vaccine	16	16	0	16	16 Batches tested
Measles Vaccine	Viral vaccine	01	01	0	0	Standardized
Rubella Vaccine	Viral vaccine	01	01	0	0	Standardized
Cell Culture Rabies Vaccine	Viral vaccine	10	10	0	-	10 batches released
Oral Polio Vaccine	Viral vaccine	01	01	0	-	Standardized
Hepatitis B Vaccine	Viral vaccine	02	02	0	-	02 batches released

Name of *Biologicals Tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches found to be of standard quality	No. of Batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Varicella Vaccine	Viral vaccine	00	00	0	-	Under Standardization
Japanese Encephalitis Vaccine	Viral vaccine	02	02	0	-	Under Standardization
Haemophilus influenza type b (Hib) TT conjugate vaccine	Bacterial vaccine	02	02	0	-	Standardized
Hib Pentavalent vaccine(Determination of PRP content by HPAEC-PAD)	Bacterial Vaccine	00	00	0	-	Standardized only for PRP Content
Inactivated Single Serotype (Hikojima) Cholera Vaccine	Bacterial vaccine	01	01	0	-	Standardized
Tetanus Toxoid Vaccine Adsorbed	Bacterial vaccine	02	02	0	-	Under Standardization
Bacillus Calmette Guerin (BCG) vaccine	Bacterial vaccine	02	02	0	-	Standardized

\* MMR vaccine \* MR vaccine \* Rotavirus Vaccine \* Inactivated Polio Vaccine \* Human Papilloma Vaccine \* Hepatitis A Vaccine has also been Standardized

## 5. Preparation and supply of national Standards, Sera Panel etc.:

The laboratory will take up the feasibility study for the reference standard preparation in collaboration with manufacturers and IPC.

## 6. Trend in volume of work as compared to previous year:

S. No.	Name of the product	No. of batches evaluated for the period	
		2018-19	2019-20
1.	Human Rabies Immunoglobulin	14	16
2.	Live attenuated MMR vaccine	02	00
3.	Live attenuated Measles vaccine	01	01
4.	Live attenuated Rubella vaccine	01	01

S. No.	Name of the product	No. of batches evaluated for the period	
		2018-19	2019-20
5.	Cell Culture Rabies Vaccine	21	10
6.	Live attenuated Measles and Rubella Vaccine	00	00
7.	Japanese Encephalitis Vaccine	02 batches under standardization	02 batches under standardization
8.	Human Papilloma Virus vaccine	03	00
9.	Inactivated Polio Vaccine	00	00
10.	Oral Polio Vaccine	00	01
11.	Rotavirus Vaccine	05	00
12.	Hepatitis A Vaccine	00	00
13.	Hepatitis B Vaccine	06	02
14.	Varicella Vaccine	02 batch under standardization	00
15.	Bacillus Calmette Guerin (BCG) vaccine	05	02
16.	Tetanus Toxoid Vaccine	02 batches under standardization	02 batches under standardization
17.	Cholera Vaccine	01	01
18.	Hib Pentavalent vaccine (Determination of PRP content by HPAEC-PAD)	03	00
19.	Haemophilus influenza type b (Hib) TT conjugate vaccine	02	02
20.	Samples for Moisture Content	303 batches tested	314 batches tested

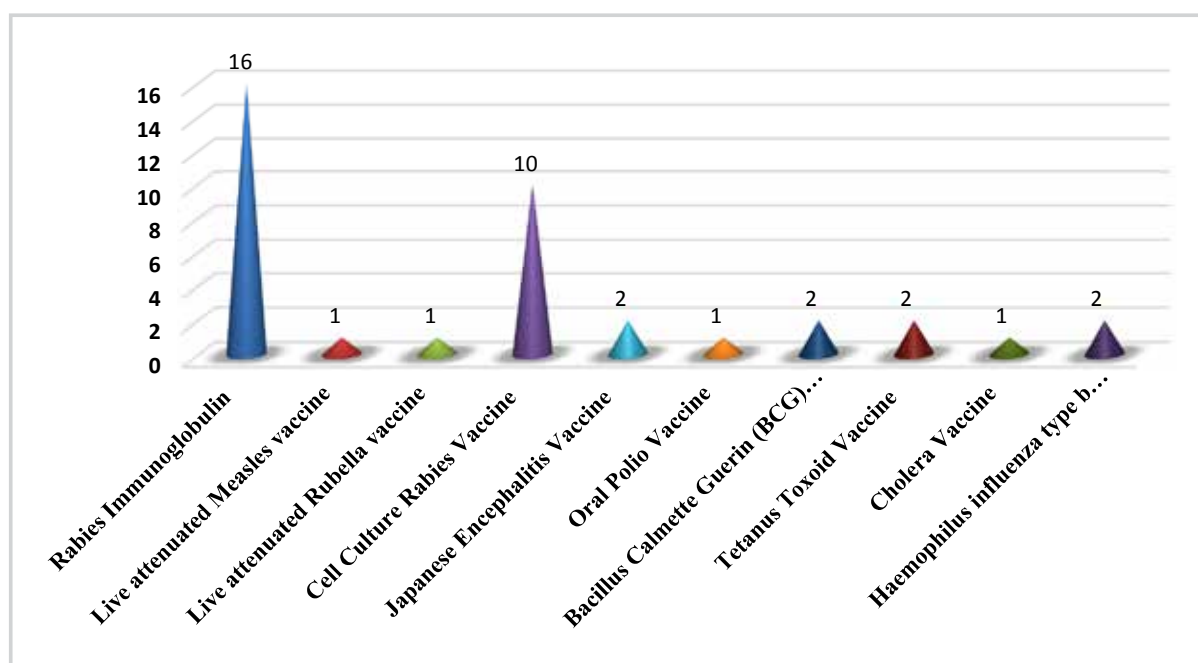


Figure 1: Number of Vaccines & Sera samples evaluated in the period 2019-2020

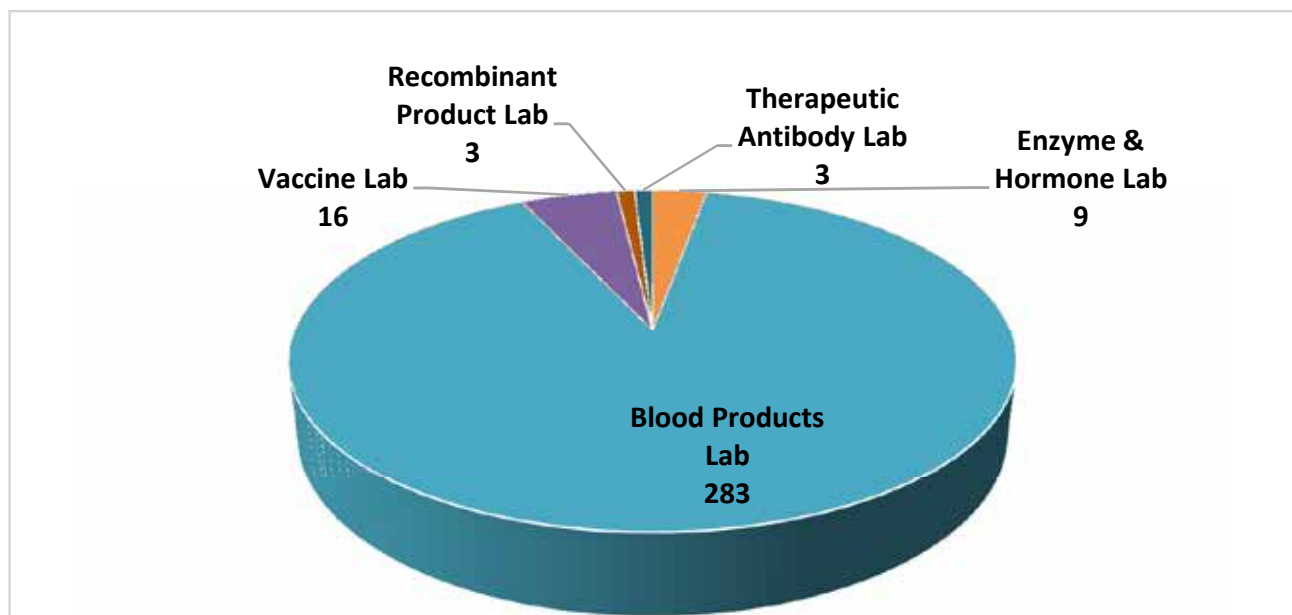


Figure 2: Number of Batches Evaluated for Moisture Content In 2019-2020

## 7. Proposed targets for testing of new Biologicals being undertaken:

S. No.	Product/ test	Timeline
1	Japanese Encephalitis Vaccine (JEV)	March 2021
2	Varicella Vaccine	March 2021
3	Meningococcal Vaccine	March 2021
4	Tetanus Toxoid Vaccine	March 2021

## 8. Participations in training/workshop/conference:

S. No.	Name of Programme	Name of Participant	Duration of training
1.	Training in Glycoprotein detection and Residual Host Cell DNA testing of Rabies Vaccine at Bharat Biotech International Limited, Hyderabad	Mr. Jaipal Meena	Mar 03-07, 2020
2.	Training was provided to Officials of Drug Regulatory Authority Workshop on Capacity Building in Regulation of Vaccines held at Paro, Bhutan.	Mr. Ajay Kumar Ade	Feb 10-14, 2020

S. No.	Name of Programme	Name of Participant	Duration of training
3.	3 <sup>rd</sup> Annual Regulators Conclave for Central and State Regulatory Authorities in India, Jointly organized by CDSCO, Ministry of Health & family welfare, Government of Goa and WHO India held at Hotel Double Tree by Hilton, Panjim, Goa	Mr. Harit Kasana	Aug 21-22, 2019



4.	Meeting with stakeholders on Antisera for Human use held at IPC, Ghaziabad	Mr. Harit Kasana, Mr. Jaipal Meena	02.07.2019
5.	Effective Implementation and Internal Audit of ISO/IEC 17025:2017 Laboratory management systems and NABL criteria at NIB, Noida	Mr. Harit Kasana, Mr. Jaipal Meena	20.05.2019-23.05.2019
6.	Risk/ Benefit Evaluation for representatives of the regulatory authorities in India conducted by CDSCO in collaboration with WHO at New Delhi.	Mr. Harit Kasana, Mr. Ajay Kumar Ade	01.05.2019-02.05 2019
7.	7 <sup>th</sup> Vaccine Expert Group Meeting held at CDL Kasauli	Mr. Jaipal Meena	29.04.19



## 9. Outstanding achievements of the Lab:

9.1 Mr. Ajay Kumar Ade, Junior Scientist, Vaccine and Antisera laboratory attended “Workshop on Capacity Building in

Regulation of Vaccines, Bhutan” held at Paro, Bhutan from 10<sup>th</sup> to 14<sup>th</sup> February 2020. Mr Ajay Kumar Ade participated as trainer and provided training to Officials of Drug Regulatory Authority of Bhutan.



## BLOOD PRODUCTS LABORATORY

### 1. Name of Head:

Mrs. Sudha. V. Gopinath, Scientist-III  
(From 16.11.2018 to 29.04.2019)

Dr. Meena Kumari, Scientist-II  
(From 29.04.2019)

### 2. Manpower in the Lab / Division

#### I. Name of Scientific Staff

- i. Mrs Y. Madhu, Scientist-III
- ii. Mrs Rashmi Shrivastava, Scientist-III (From 06.05.2019 to 09.03.2020)
- iii. Dr. Varun Singh, Junior Scientist
- iv. Mr. Anirban Mukherjee, Junior Scientist
- v. Ms. Apoorva Anand, Junior Scientist (From 14.05.2019)

#### II Name of the Technical Staff:

- i. Ms. Girija L. V., Laboratory Technician (From 01.05.2019)

#### III. No(s) of Outsourced Staff: 12

### 3. Scientific Activities Undertaken:

#### a) Collaboration with Other organizations

- i. Proficiency Testing (PT) Programme: Successful results received for participation in PTS 201, an international PT study organized by European Directorate for Quality of Medicines (EDQM), France for Protein Composition in Human Normal Immunoglobulin for Intra venous use (Study period 16.08.2019– 18.10.2019).
- ii. Proficiency Testing (PT) Programme: Successful results received for

participation in PTS 202, an international PT study organized by European Directorate for Quality of Medicines (EDQM), France for Molecular Size Distribution in Human Normal Immunoglobulin for Intra venous use (Study period 14.11.2019 – 10.12.2019).

- iii. International Collaborative Study: Successfully results received for participation in “International Collaborative Study to calibrate the WHO 3rd International Standard for Thrombin” organized by NIBSC, UK (study period Jan. – Feb.2020).

#### b) CDL Notification:

NIB is notified Central Drug Laboratory vide Gazette of India Extraordinary Part II Section 3-Subsection (ii) S.O. 4271 (E).- published in New Delhi, the 26<sup>th</sup> November, 2019 for the following products:

- i. Human Albumin
- ii. Human Normal Immunoglobulin (Intravenous & Intramuscular)
- iii. Human Coagulation Factor VIII
- iv. Human Coagulation Factor IX
- v. Plasma Protein Fraction
- vi. Fibrin Sealant Kit
- vii. Anti- Inhibitor coagulant Complex

#### c) Government Analyst:

1. Dr. J. P. Prasad, Scientist Grade –I & Divisional Head, Blood Products Laboratory is notified Government Analyst vide Gazette Notification No. S.O. 4271(E).- for testing of plasma

derived products published on 26<sup>th</sup> November 2019.

2. Dr. Meena Kumari, Scientist Grade-II, & Head, Blood Products Laboratory is notified Government Analyst vide Gazette Notification No. S.O. 4271(E).- for testing of plasma derived products published on 26<sup>th</sup> November 2019.
3. Ms. Madhu Erramilli, Scientist Grade-III, Blood Products Laboratory is notified Government Analyst vide Gazette Notification No. S.O. 4271(E).- for testing of plasma derived products published on 26<sup>th</sup> November 2019.

**d) Development of monographs:**

The following are proposed for inclusion

- a. Method verification process of various test parameters for Human Fibrinogen (Freeze dried powder) derived from Human Plasma is under progress for inclusion of Monograph in Indian Pharmacopoeia.
- b. Amendment in General Chapters for Pyrogen Testing in Blood Products has been communicated to IPC, Ghaziabad.

- c. With regard to Deletion of test for Abnormal Toxicity in relevant Monographs for Blood Products to harmonize with European and British Pharmacopoeia as proposed, the General Chapter for Abnormal Toxicity Testing in Blood Products is under revision as discussed and decided in the 3rd meeting of Expert Working Group on Blood and Blood related products held on 20<sup>th</sup> August 2019.
- d. Proposal for inclusion of separate Monograph for product Pentaglobulin- a product containing mixture of IgG, IgA and IgM under Human Normal Immunoglobulin for intravenous use has been discussed and agreed in the 3rd meeting of Expert Working Group on Blood and Blood related products in a meeting held on 20<sup>th</sup> August 2019.
- e. Proposed revision of Monograph for Human Prothrombin Complex with reference to composition of various Factors on the label of the container to IPC, Ghaziabad.

## 4. Testing of Biologicals

**Table 1:**

S. No.	Name of Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)
1	Human Albumin	Blood Products	265	265	00
2	Plasma Protein Fraction	Blood Products	00	00	00
3	Human Normal Immunoglobulin IV	Blood Products	95	88	07



S. No.	Name of Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)
4	Human Normal Immunoglobulin IM	Blood Products	15	15	00
5	Human Normal Immunoglobulin SC	Blood Products	03	03	00
6	Specific Immunoglobulin IM (Hepatitis B immunoglobulin)	Blood Products	06	06	00
7	Specific Immunoglobulin IV (Hepatitis B immunoglobulin)	Blood Products	01	01	00
8	Specific Immunoglobulin IV (Anti-D Immunoglobulin)	Blood Products	01	01	00
9	Specific Immunoglobulin IM (Tetanus Immunoglobulin)	Blood Products	25	25	00
10	Specific Immunoglobulin IM (Anti-D Immunoglobulin IM)	Blood Products	02	02	00
11	Specific Immunoglobulin IM (Rabies Immunoglobulin)	Blood Products	17	17	00
12	Human Coagulation Factor VIII (Plasma derived)	Blood Products	148	148	00
13	Human Coagulation Factor VIII rDNA	Blood Products	17	17	00
14	Human Coagulation Factor IX	Blood Products	26	26	00

S. No.	Name of Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)
16	Human Prothrombin Complex	Blood Products	04	04	00
17	Fibrin Sealant Kit	Blood Products	44	44	00
18	FEIBA (Anti-inhibitor coagulant complex)	Blood Products	11	11	00
19	Human Fibrinogen	Blood Products	02	02	00
		<b>Total</b>	<b>682 (+ 21 previous year) 703</b>	<b>675 (+ 21 previous year) 696</b>	<b>07 (0.94%)</b>

#### 4a Details of testing of samples received under the Drugs & Cosmetics Act:

S. No.	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)
1	Human Albumin	03	03	0
2	Human Normal Immunoglobulin IV	02	02	0
3	Human Tetanus Immunoglobulin (IM)	01	01	0
4	Human Coagulation Factor VIII (Plasma derived)	01	01	0
	<b>Total</b>	<b>07</b>	<b>07</b>	<b>0</b>

### 5. Preparation and supply of National Reference Standards (NRS):

The indigenous biopharmaceutical companies are dependent upon the Primary Reference Standards which are, many a times of limited supply, and as a standard procedure the companies have to develop in-house standards calibrated against the primary standard. NIB being the nodal laboratory for quality control of biologicals

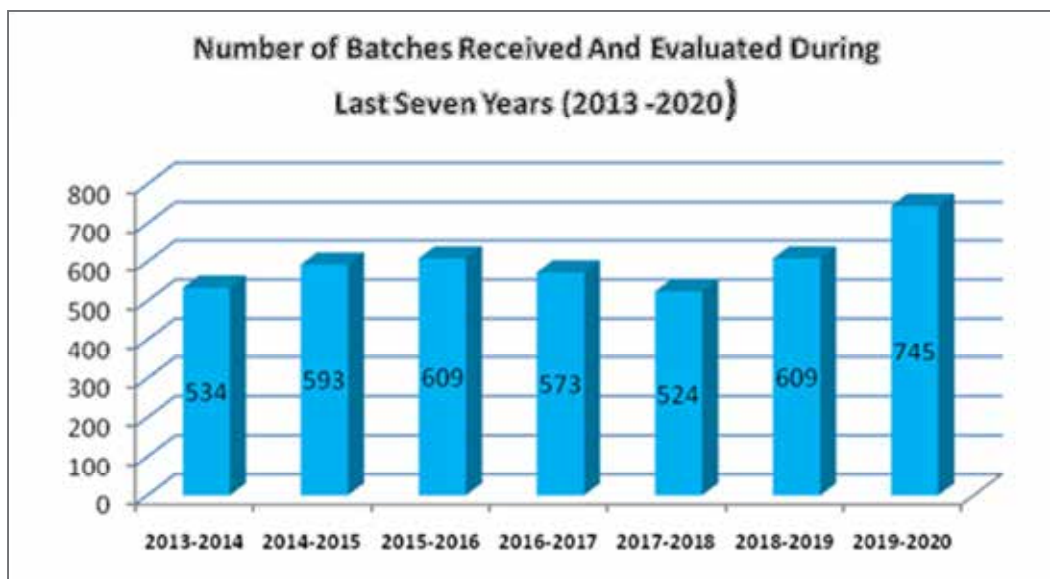
aims to develop National Reference Standard through collaborative studies for supply to the indigenous manufacturers thereby facilitating easy availability of such traceable standards. The laboratory has proposed development of two national reference standards:

- 1<sup>st</sup> National Reference standard for total protein estimation of Human albumin and
- 1<sup>st</sup> National reference Standard for Potency assay of Human Coagulation Factor VIII.

## 6. Trend in volume of work as compared to previous years

The trend in quantum of batches of various

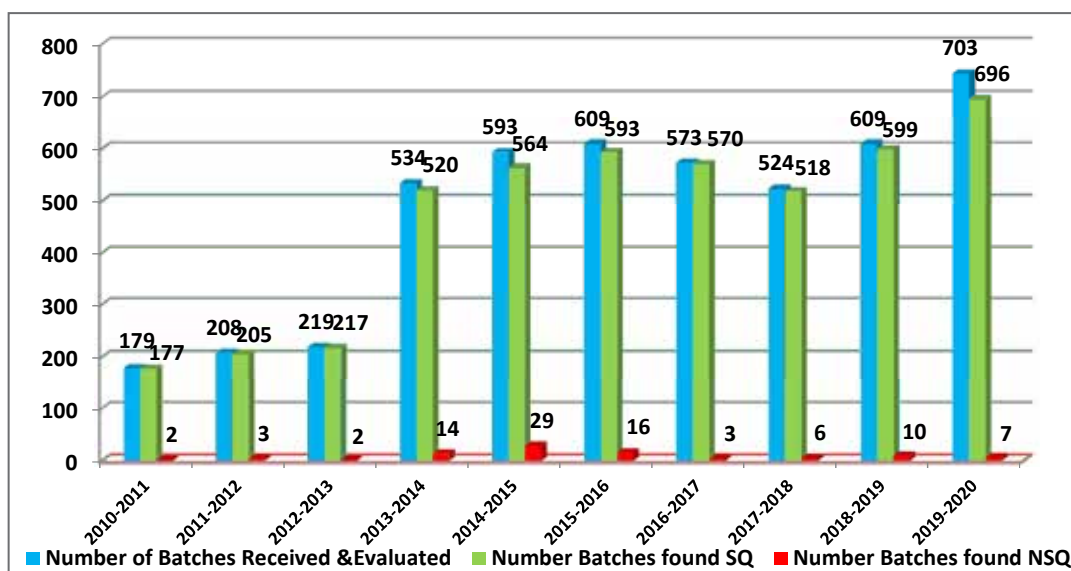
plasma derived products received and tested in last seven years at Blood Products Laboratory, NIB has been depicted in Fig.1 below.



*Fig.1 Quantum of batches received and tested in last seven years (2013 – 2020)*

The results of Quality Control testing and number of batches found not of standard quality in last ten years at NIB have been summarised and shown in Fig 2 below. During this period 2010 -2020, a total of 4,793 batches of various Blood Products have been received and tested.

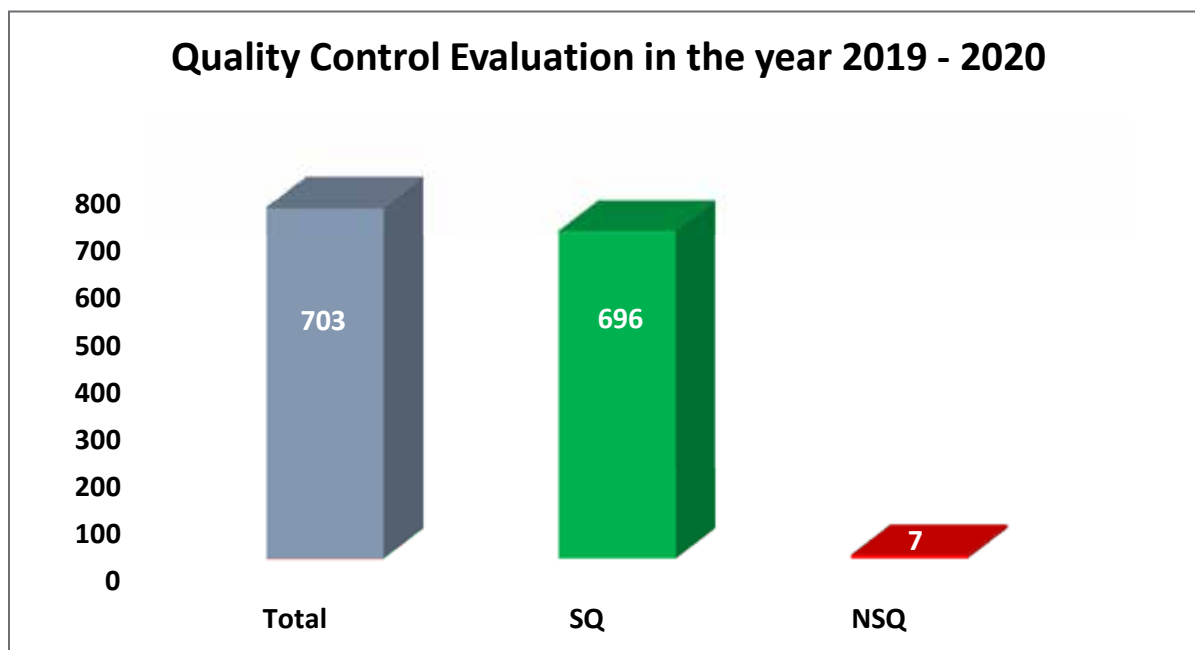
Out of which 92 batches (1.92%) were found Not of Standard Quality (NSQ) due to out of specification results observed in various test parameters like Anti-A and Anti-BHaemagglutinins, PKA, Potency, Total Protein, Protein Composition, etc.



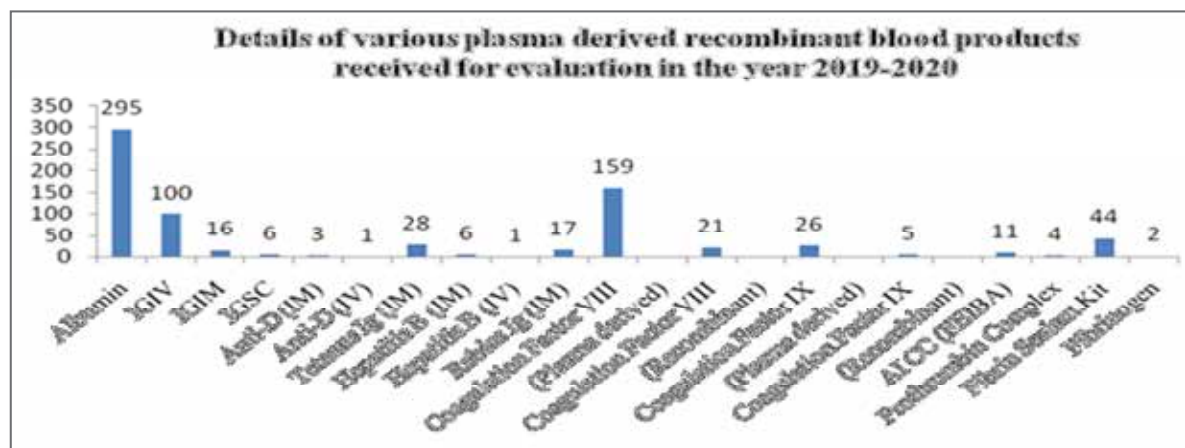
*Fig 2. Quality Control testing of various Blood Products in last ten years (From year 2010 to 2020)*

During the reporting period 2019 -2020, 703 batches of various Blood Products have been evaluated and out of which seven batches of Human Normal Immunoglobulin for intravenous use are found Not of Standard Quality (NSQ) due to out of specifications observed in test for Anti-A and

Anti-B Haemagglutinins as per respective Monograph in IP 2018, which amounts 0.94%. During this reporting period about 18 types of various Blood Products have been received and evaluated. The details are given in Fig 3 & 4 below.



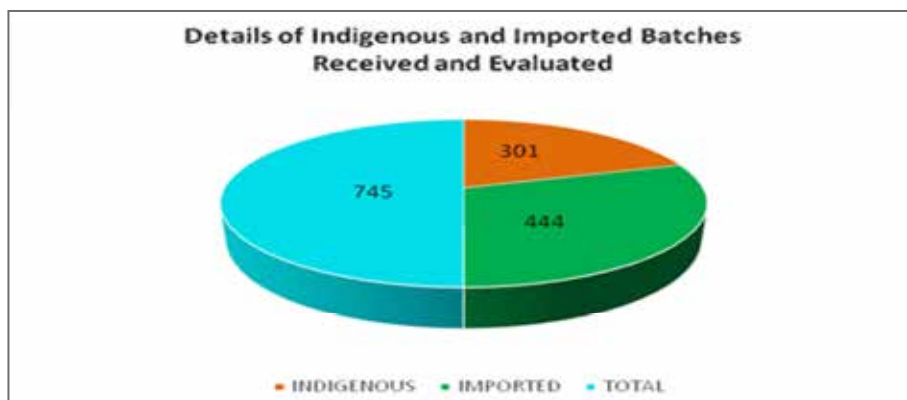
*Fig 3. Quality Control testing of various Blood Products in the year 2019 – 2020*



*Fig 4. Details of various plasma derived recombinant blood products received for evaluation in the year 2019-2020*

During the year 2019 – 2020, out of 745 batches received for evaluation 444 batches (59.65%) are imported and 301 batches

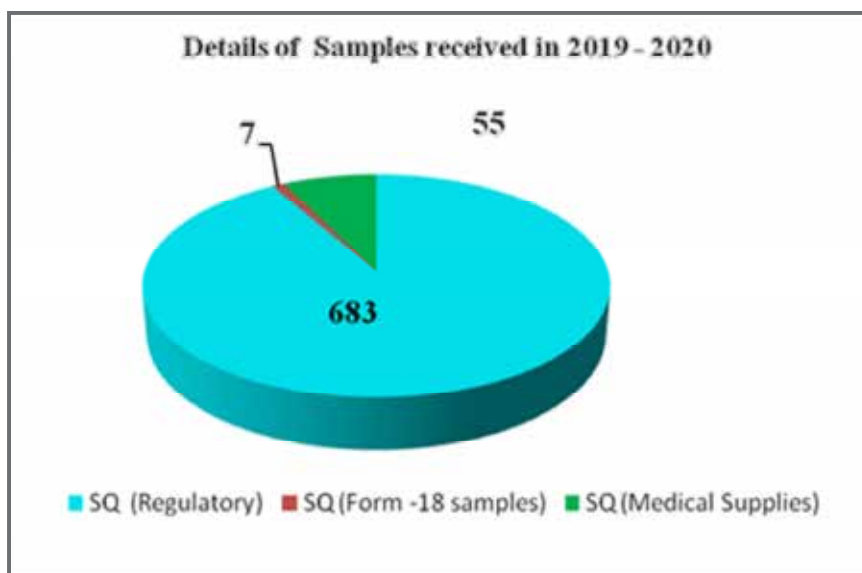
(40.35%) are indigenous as shown in fig.5 below.



**Fig 5. Quality Control testing of Indigenous and Imported Batches of various Blood Products in the year 2019 – 2020**

In the year 2019 – 2020, 7 samples were received on Form 18 and 55 batches were

received from various state medical stores. Details are given in Fig 6 below.



**Fig 6. Details of Samples received on Form 18, from State Medical Stores and routine Regulatory in the year 2019 – 2020**

## 7. Proposed target for testing of new biologicals

- a. The laboratory has received and tested one batch of anti-thymocyte globulin (rabbit), which is imported in to the country for immunosuppressive therapy in kidney transplantation for treatment of patients with kidney failure. Anti-thymocyte globulin (rabbit) is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant. Thymoglobulin

is to be used in conjunction with concomitant immunosuppression.

- b. The laboratory has initiated establishing of Quality Control testing of Human Coagulation Factor IX (Recombinant) as per the monograph in BP / EP. The method verification and establishment for testing of this product is targeted to be completed by July 2020. Once the quality control testing is established, the Monograph will be written and proposed for publication in Indian

Pharmacopoeia.

## 8. Participation in training/ workshop/ conference

- 1) Ms. Sudha V Gopinath Scientist III delivered a talk on “National Lot Release System for Blood Products in India and its difficulties” during the Fourth meeting of National Control Laboratories for Biologicals organized by Ministry of Food and Drug Safety, Republic of Korea held on 27<sup>th</sup> June 2019 at Grand International Parnas, Seoul South Korea. The meeting paved way for understanding the lot release system in the Western Pacific Region including Malaysia, Indonesia, Philippines, Vietnam, Japan, China and South Korea. Various issues like developing Common standards for plasma derived products, collaborative studies for improving their quality, and regulatory harmonization for increase in trade and importance of trend analysis in monitoring the quality of these drugs were discussed. The participation in the meeting strengthened the linkage of the institute with other National Control Laboratories of western pacific region and is expected to further provide information to Government of India on best practices for assuring the quality of these lifesaving medicines thereby promoting public health.
- 2) Dr. Meena Kumari, Scientist-II & Head-attended meeting at IPC, Ghaziabad, as experts for Plasma Derived products for monograph development, monograph verification and revision of monograph, organized by IPC, Ghaziabad on 20<sup>th</sup> August, 2019.
- 3) Dr. J. P. Prasad, Scientist-I & Divisional Head, attended the meeting on “Hearing on the development of product-specific reference

materials for Human Coagulation Factor VIII and Factor IX” held at WHO Headquarters, Salle B, Geneva, on 7<sup>th</sup> & 8<sup>th</sup> November, 2019

- 4) Mrs. Y. Madhu, Scientist-III - Participated in Fourth meeting for Revision of Guidance Manual for compliance of Indian Pharmacopoeia, organized by IPC, Ghaziabad on 6<sup>th</sup> November, 2019.
- 5) Dr. Varun Singh, Junior Scientist, attended BIS-CEN-CENELEC Joint Workshop on “Emerging Challenges in new era of Standardization: Exchange of best practices”, at Bureau of Indian Standards Office, Bahadur Shah Zafar Marg, New Delhi, on 26<sup>th</sup> November 2019.
- 6) Mr Anirban Mukherjee, Junior Scientist. Attended one day CBT course” Driving Rapid Biologics Development- From Cell Line Development to Commercial Manufacturing at IIT Delhi on 10<sup>th</sup> December 2019.
- 7) Ms Rashmi Srivastava, Scientist - III attended three day CBT course series” Empowering Regulatory Leaders in India” at IIT Delhi from 10<sup>th</sup>-12<sup>th</sup> Dec 2019.

## 9. Outstanding achievements of the laboratory:

- i. The laboratory has tested and reported 703 batches of 18 types of various plasma derived products forwarded by the office(s) of the DCG (I), out of which 07 (0.94%) have been found to be Not of Standard quality. The role of laboratory in assuring the quality of such lifesaving drug is reiterated thereby safeguarding public health.
- ii. During the reporting period the laboratory, had tested 7 samples under the Drugs & Cosmetics Act of various plasma derived products, forwarded by the office(s) of the

Drugs Control General of India.

- iii. The laboratory has imparted summer training to fifteen post graduate student to fulfill their post graduate degree. (M.Sc. in various disciplines).
- iv. During this reporting period, the laboratory has successfully participated in Proficiency Testing (PT) Programmes- PTS 201, PT study for Protein Composition in Human Normal Immunoglobulin for Intravenous use and PTS 202, for Molecular Size Distribution in Human Normal Immunoglobulin for Intravenous use - international PT study programmes organized by European Directorate for Quality of Medicines (EDQM), France.
- v. During this period, the laboratory has successfully participated in an International Collaborative Study in “International Collaborative Study to calibrate the WHO 3<sup>rd</sup> International Standard for Thrombin” organized by NIBSC, UK.
- vi. During this reporting period, the laboratory has established Quality Control Testing of three new Biologicals namely Human Fibrinogen, Human Normal Immunoglobulin (Subcutaneous) and Hepatitis B Immunoglobulin (Subcutaneous/ Intramuscular).
- vii. In the year 2019 -2020 the laboratory has actively participated in review / revision / inclusion of five Monographs in IP 2018.



## RECOMBINANT PRODUCT LABORATORY

### 1. Name of Head:

Dr. Charu Mehra Kamal, Scientist Grade-II

### 2. Manpower in the Laboratory/ Division

#### I. Name of the Scientific staff:

- i. Ms. Gurminder Bindra, Scientist Grade III
- ii. Dr Meena Kumari, Scientist Grade III (till 30<sup>th</sup> April 2019)
- iii. Dr. Manoj Kumar, Scientist Grade III (till 20<sup>th</sup> March 2020)
- iv. Dr. Sanjay Mendiratta, Junior Scientist
- v. Dr. Birendra Kumar, Junior Scientist

#### II. Name of the Technical Staff:

- i. Ms. Poonam, Laboratory Technician
- ii. Mr. Mohit Lal, Laboratory Technician

- iii. Mr. Rajeev Srivastava, Laboratory Assistant (till 31<sup>st</sup> January 2020)

#### III. No(s) of outsourced staff: 02

### 3. Scientific Activities Undertaken:

#### a. Collaboration with other organizations:

Preliminary report prepared for Inter Laboratory Collaborative (ILC) Study for development of National Reference Standard (NRS) for Filgrastim for Physico chemical test parameter and assigning potency value. The study has been conducted with 09 participants, including 08 indigenous manufacturers of Filgrastim and United States Pharmacopoeia (USP).

#### b. Central Drugs Lab Notification

The Institute is notified Central Drugs Laboratory (CDL) vide The Gazette of India, Extraordinary, notification No. GSR 908 (E)-Part II-Sec 3 (i) on Dec 22, 2014 for class of products mentioned in Table 1.

**Table 1: CDL Notified recombinant products**

S. No.	Name of Product	Type of Product
1	Recombinant Insulin	Anti-Diabetic
2	Recombinant Insulin Analogues	
3	r-Erythropoietin (EPO)	Growth factors
4	r-Granulocyte colony stimulating factors (G-CSF)	

- c. **Government Analyst:** Two NIB scientists Dr. Charu Mehra Kamal, Scientist-II & Laboratory Head and Ms. Gurminder Bindra, Scientist-III are notified Government Analysts vide Government of India,

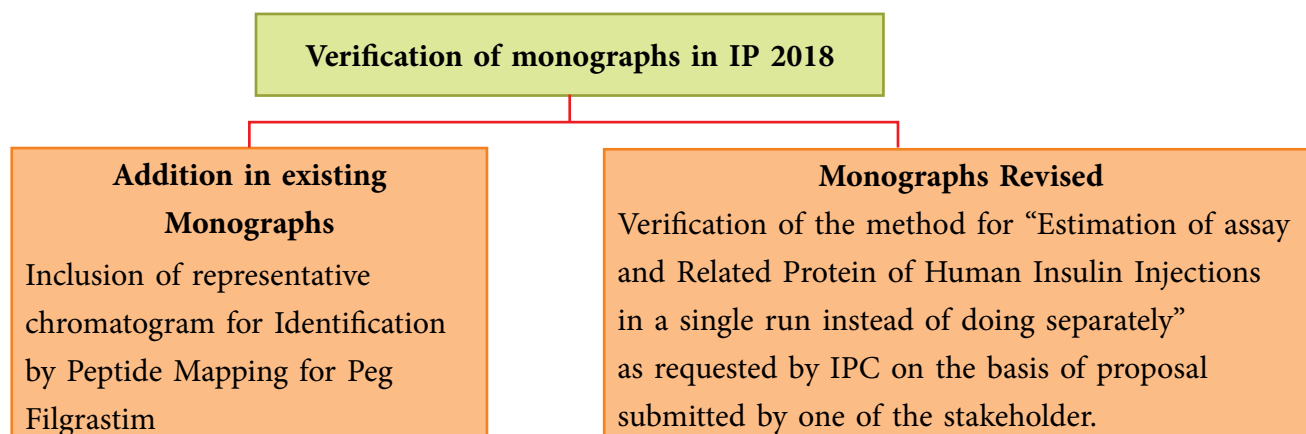
Gazette Notification No: REGD. NO. D. L.-33004/99 dated 26.11.2019 for Recombinant Products: Insulin and Insulin analogues, r-Erythropoietin (EPO) and r-Granulocyte Colony Stimulating Factor (G-CSF).



**d. Development of Monographs:**

verification of monographs as given below

- i. Laboratory has contributed towards



*Figure 1: Contribution of NIB in Development of IP Monographs*

**e. Publication:**

Sharma, Surinder Singh

Role of NIB in connecting science to patients by assuring safe and quality anti diabetic products, published in Journal of Medical Sciences 2019; 22(1):16-20

Gurminder Bindra, Charu Mehra Kamal, Meena Kumari, Sanjay Mendiratta, Preety

**4. Testing of Biologicals**

Laboratory tested a total of 142 batches of antidiabetic insulin, insulin analogues and growth factors. Out of which 17 batches have been found of not of standard quality (Table 2).

**Table 2: Summary of batches tested during 2019-20**

Name of Biologicals	Type of Biologicals	No. of Batches Evaluated	No. of Batches Found to be of Standard Quality (SQ)	No. of Batches Found Not to be of Standard Quality (NSQ)	No. of Inter lab sample tested	Remarks	
i. Insulin Regular	Anti Diabetic - Insulin	13	49	17	311	Medical supplies: 32	
ii. Insulin Biphasic		47					
iii. Insulin NPH		05					
iv. Insulin bulk		01					
i. Degludec /Aspart	Anti Diabetic – Insulin Analogues	02	35	Nil			Medical supplies: 03 Survey: 03
ii. Degludec		02					
iii. Glargine		06					
iv. Aspart		03					
v. Lispro		04					
vi. Biphasic Lispro		10					
vii. Biphasic Aspart		04					
viii. Detemir		01					
ix. Glargine bulk		03					

Name of Biologicals	Type of Biologicals	No. of Batches Evaluated	No. of Batches Found to be of Standard Quality (SQ)	No. of Batches Found Not to be of Standard Quality (NSQ)	No. of Inter lab sample tested	Remarks
i. Filgrastim	Growth Factors	08	36	Nil		Medical supplies: 25
ii. Erythropoietin		24				
iii. Interferon beta 1b		01				
iv. Peg Interferon beta 1a		02				
v. Peg Erythropoietin		01				
i. Teriparatide	Small Peptides	01	05	Nil	Nil	--
ii. GLP - Dulaglutide		04				
<b>TOTAL</b>		<b>142</b>	<b>125</b>	<b>17</b>	<b>311</b>	

## 5. Preparation and supply of National Standards, Sera Panel etc.

### 5.1 Reference Standard Program

The effective implementation of IP monographs on rDNA Biotherapeutic products requires suitable use of Reference Standards. In this regard, laboratory has a

repository of National Reference Standard for Human Insulin and Insulin Lispro which were developed by NIB as a result of collaborative study conducted with Stakeholders and Pharmacopoeial labs. The development of reference standard for Filgrastim is under progress (Table 3).

**Table 3. Development of Reference Standards**

S. No.	National Reference Standard	Study Period	Details
1	Filgrastim (Development in process)	2017-2020	1. Collaborative study of 09 Laboratories (NIB, Filgrastim Stakeholders, & Pharmacopoeia Labs).
			2. Candidate material received from one of the stakeholders was further distributed to all the participating laboratories. The test protocol to be used uniformly was sent along with the candidate material.
			3. The results of the ILC study have been submitted by the participating laboratories. The compiled data upon analysis will be discussed with the participating laboratories to assign a value for Physico chemical test parameter and assigning potency value.

## 5.2 Supply of Reference Standard for Human Insulin (IPRS)

During the year 2019-20, 05 vials of IPRS for Human Insulin have been supplied to one of the indigenous stakeholder M/s Torrent Pharmaceuticals Ltd, Gujarat. The details for supply of IP Reference Standard for Human Insulin (IPRS) are available on NIB website.

## 6. Trend in Volume of Work as Compared to the previous year

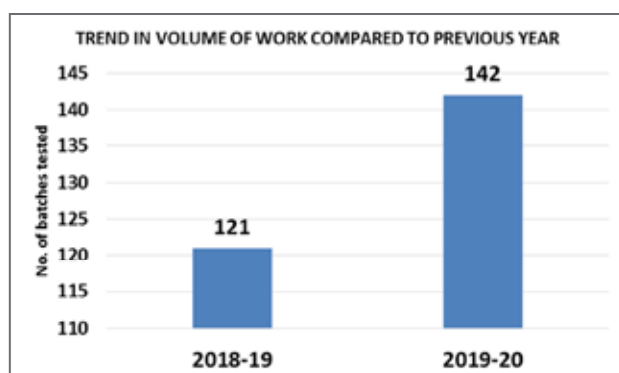


Figure 2a. Trend in number of batches received in the year 2019-2020 compared to 2018-19

## 6.2 Out Of Specification (OOS) results

Lab has reported “Not of Standard Quality” results for 17 batches (36.17%) of Biphasic Human insulin samples on the basis of one QC test parameter “Soluble insulin human



Fig 3: Results for Out Of Specification (OOS) batches of Insulin

## 6.1 Trend in Test and Analysis of Recombinant Biotherapeutic products

The laboratory has capacity and infrastructure to test 500 batches on the basis of complete testing of recombinant products annually. The number of batches received in the laboratory has increased from 121 to 142 batches in current year Figure 2a. The inflow of samples from various sources such as port offices of CDSCO, survey and medical supply of various state medical corporation is shown in Figure 2b.

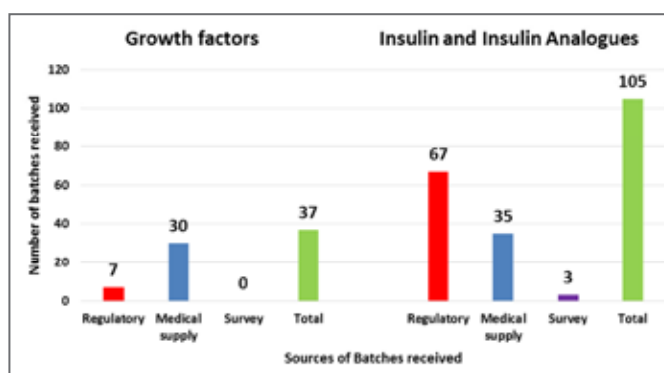


Fig 2b: Batches received from various sources such as Regulatory, Medical supply and Survey.

content” as indicated in the figure 3. All these batches were from one indigenous manufacturer intended for medical supply. This data has also been communicated to office of DCG (I), CDSCO.

### 6.3 Inter-laboratory testing of samples:

As a part of inter laboratory testing, lab has evaluated 311 samples for various parameters such as Particulate matter by Light obscuration method, Osmolality and Bacterial Endotoxin Test ((BET) using

quantitative Kinetic Chromogenic Assay (KCA)) from Blood Products lab (BPL), Therapeutic Monoclonal Antibody lab (TMAb), Vaccine laboratory Lab (ATL) and Enzymes and Hormones Lab (EHL) as shown in figure 4 and table 4.

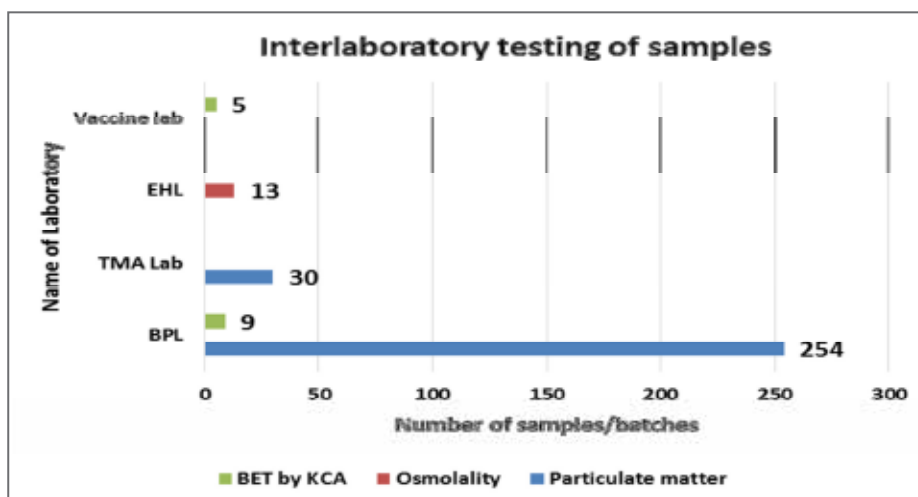


Fig 4: Inter laboratory testing of samples from other labs of NIB

Table: 4 Inter-laboratory testing of samples from other labs of NIB

Laboratory	Parameter	No. of samples tested
Blood products Lab	Particulate Matter	254
TMA		30
Enzyme & Hormone	Osmolality	13
Vaccine Lab	BET(KCA)	05
Blood products Lab		09
Total		311

6.4 Out of total 142 batches of Recombinant Bio-therapeutic products tested 51 were imported products and 91 were indigenous products (Figure 5)

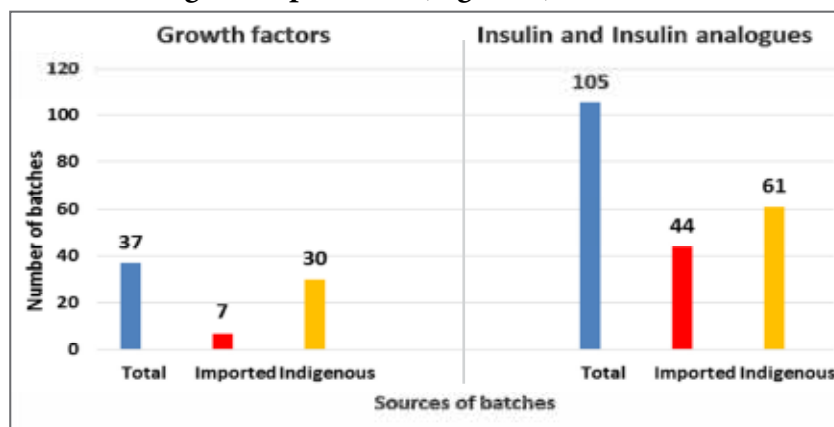


Figure 5: Source of Recombinant Biotherapeutic Products tested in 2019-2020

### 6.5 Samples received on Form 18

- Recombinant Product Laboratory has received 09 samples (08 of Human Insulin and 01 of Filgrastim) on Form 18 for testing from Drugs Inspectors of

CDSCO and State FDA.

- The reports have been released on Form 13 in triplicate. Out of these 09 samples, 06 were found to be NSQ.

## 7. Proposed Target for Testing of New Biologicals and being undertaken

Laboratory has undertaken QC testing of following new products:

S. No.	Product	Pharmacopoeial/ Non-pharmacopoeial	Testing validated/ Established
1.	Insulin Glargine Bulk (Insulin analogue)	Non-pharmacopoeial	Samples received for the first time and testing established as per Indian Pharmacopoeia specifications. Laboratory also established two new QC test parameters Host Cell DNA and Host Cell Protein.
2.	Pegylated Erythropoietin (Growth factor)	Non-pharmacopoeial	Samples received for batch release for the first time and testing established as per Manufacturer's specifications
3.	Human Insulin Injections	Pharmacopoeial	Method verification carried out for "Estimation of assay and Related Protein of Human Insulin Injections in a single run instead of doing separately" as proposed by one of the manufacturer.

## 8. Training/ Workshop/ Conference Organized

**Table 6: Laboratory organized/ participated in following meetings organized at NIB:**

S.No	Meeting For	Date
<b>Monograph development</b>		
1.	Dr. Charu Mehra Kamal, Scientist Grade-II and Head, Recombinant Product Lab attended 9th meeting of Expert working group on-Biologicals and rDNA products along with stakeholders at Indian Pharmacopoeia Commission (IPC), Ghaziabad	27 <sup>th</sup> May 2019

S.No	Meeting For	Date
		

**Institutional Human Ethics Committee**

2.	Dr. Charu Mehra Kamal, Scientist Grade -II and Member Secretary along with Dr. Sanjay Mendiratta, Junior Scientist organized and conducted 10th Institutional Human Ethics Committee meeting at NIB	15 <sup>th</sup> November 2019
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**Presentation**

1.	Dr. Charu Mehra Kamal, Scientist Grade-II and Head Recombinant Product lab gave a talk on “Quality attributes of recombinant products” during the faculty development programme.	1 <sup>st</sup> July, 2019 at Jaypee Institute of Information Technology.
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## ENZYME AND HORMONE LABORATORY

### 1. Name of Divisional Head:

Dr. J.P. Prasad (Scientist Grade- I)

### 2. Name of Head

Dr. Gauri Misra, Scientist Grade- II  
(25.6.2019 onwards)

Dr. Ratnesh Sharma, Scientist Grade-II  
(24.5.2019 to 24.6.2019)

Dr. Akanksha Bisht, Scientist Grade-II  
(till 23.05.2019)

### 3. Manpower in the Lab/ Division

#### I. Name of Scientific Staff

Mr. Paras Jain, Junior Scientist

#### II. Name of Technical Staff

Mr. Brij Bahadur, Lab Technician

Mr. Reetesh Kumar, Lab Technician

Sh. Rajeev Srivastava, Lab Assistant  
(31.01.2020 to till date)

#### III. No (s). of Outsourced Staff: 04

### 4. Scientific Activities Undertaken:

#### A) Collaboration with other organization:

- The laboratory participated in “International Collaborative Study for development of 4th International Reference Standard of Streptokinase” with NIBSC, UK. The study was carried out for potency assay for preparation of 4th International Reference Standard of Streptokinase for Quality Control aspects. The data of the study is under analysis and preliminary report will be sent by the NIBSC, UK for opinion to the laboratory.

- The laboratory participated in “Method Verification of Follicle Stimulating Hormone Injection Monograph IP 2018” with IPC and Stakeholders. The study was in response to the query raised by stakeholders for amendment in potency assay and free subunits by SDS PAGE (non-reducing) in monograph of rFSH, IP-2018. The preliminary analytical report has been sent to IPC vide letter No. 1-10/NIB/EHL/ correspondence/2907 dated: 07.02.2019.

#### B CDL Notification:

NIB is notified Central Drugs Laboratory (CDL) vide the Gazette of India, Extraordinary, and Notification No. : G.S.R. 250 (E) - Part-II - Section 3 - Sub- Section (i) dated 15th March, 2017 for class of products mentioned in Table – 1

**Table 1: CDL notified Enzyme and Hormone products.**

S. No	Name of Products
(a)	Streptokinase (Natural and Recombinant)
(b)	Human Chorionic Gonadotropin (hCG)
(c)	Human Menopausal Gonadotropin (hMG)

- #### C Development of Monograph:
- The laboratory has initiated the experimental work for monographs development of Urokinase Injection for incorporation in Indian Pharmacopoeia.

#### D Publication (s):

Shruti Samlet, Kedar Shedage, Paras Jain, Jay Bajarang Singh, Brij Bahadur, Mohit Kumar and Akanksha Bisht. “Attributes of Bacterial Endotoxin Test (BET) and its comparison with Rabbit Pyrogen Test”, International Journal of Advanced Research, Vol-7, Issue 05, May 2019.

## 5. Testing of Biologicals:

Total 48 batches of Enzymes and Hormones were tested. Out of these 34 were found to be of Standard Quality (SQ) and 14 Not of

Standard Quality (NSQ). Therefore, **29.2% of the total samples received in the lab in 2019-2020 were Not of Standard Quality (NSQ)**. Details as follows in Table2:

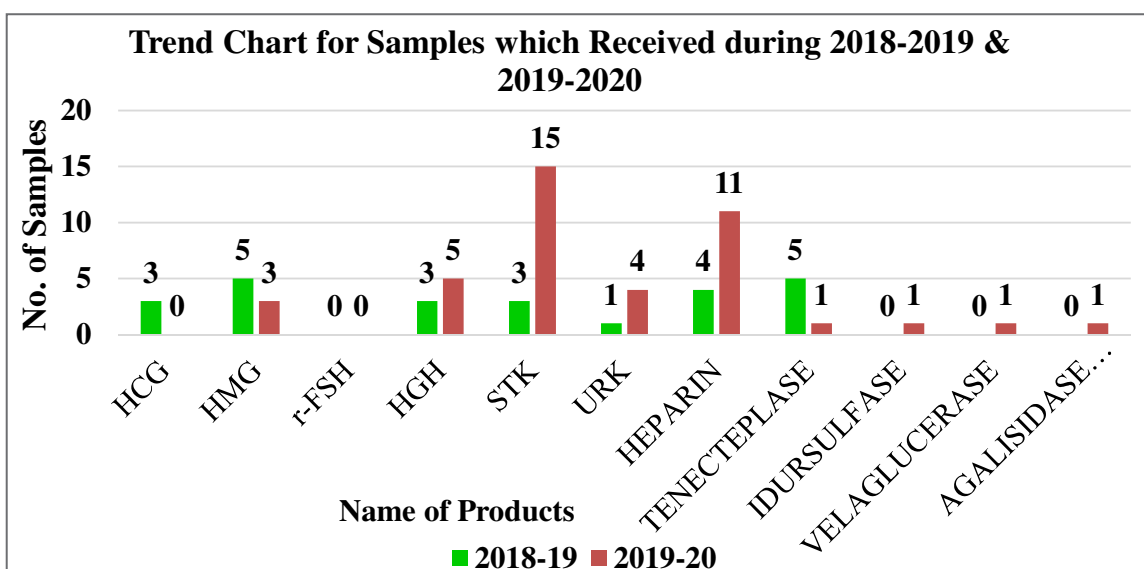
**Table 2: Testing of Biological during 2019-2020**

Name of Biologicals Tested	Type of Biologicals	No. of Batches evaluated	No. of batches found to be of Standard Quality	No. of batches found not to be of Standard Quality	No. of Inter-Lab. Sample tested	Remark
Streptokinase	Enzyme	15	9	6	-----	-----
Heparin Inj.		13	6	7	-----	-----
Urokinase		4	3	1	-----	
Tenecteplase (TNK-t-PA)		2	2	None	-----	
Elaprase		1	1		-----	
Vpriv		1	1		-----	
Replagal		1	1		-----	
Human Chorionic Gonadotropin (HCG) Inj.	Hormone	2	2		-----	-----
Menotropin (HMG) Inj.		4	4		-----	-----
Somatropin Inj. (recombinant)		5	5		-----	-----
Coagulation Factor VIII & Antiheamophilic Factor VIII	Blood Product	---	----	None	21	
Ani-inhibitor Coagulant complex		----	----		10	
Coagulation Factor IX		----	----		05	
Rabies Vaccine	Viral Vaccine Lab	----	----		10	
Total		48	34	14	46	42+46= 88 samples

## 6. Trend in volume of work as compared to the previous year:

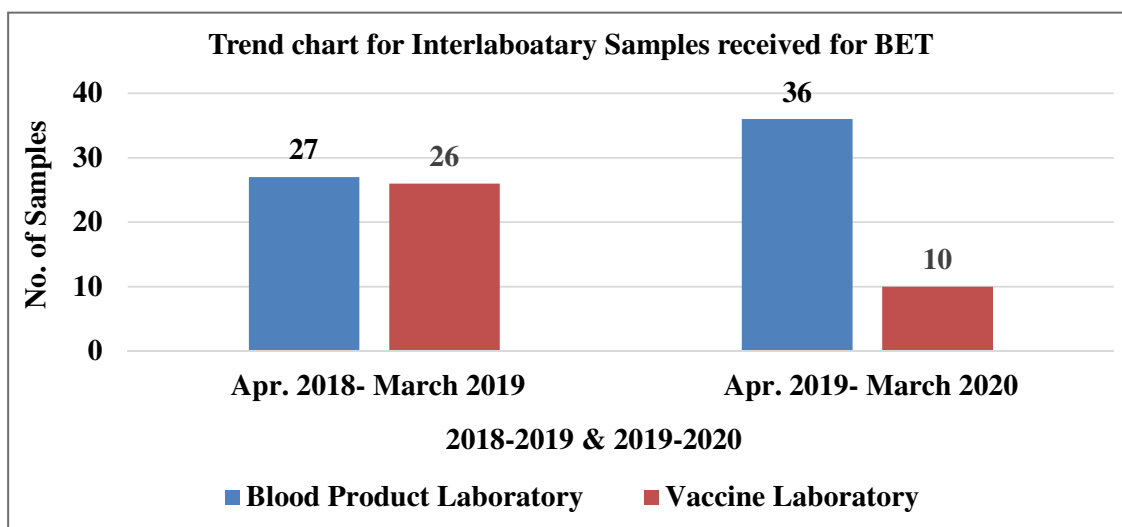
**A. Quality evaluation of Biologicals:** The laboratory has received 42 samples of Enzymes and Hormones received from The Central Drugs Standard Control Organisation (CDSCO), port offices and Government procuring agencies. The

laboratory has a testing capacity of 120 batches of Enzymes and Hormones per year. Also, 46 inter-laboratory samples were tested. The laboratory also has evaluated three new rare disease products namely Elaprase, Vpriv and Replagal. The Trends of samples received for QC evaluation as compared to previous year: Product wise/Total samples are shown in Figure 1.



**B. Interlaboratory Sample testing:** The laboratory has tested 46 samples of Blood Product Laboratory and 10 samples of Viral Vaccine Laboratory for safety test using

Bacterial Endotoxin by Gel Clot Method. The trend of samples received from various laboratory for BET testing by gel clot method is shown in fig. 2.



**C. Establishment of Identification of Urokinase as per manufacturer's method:**

During this year, the laboratory has standardized the identification test by Double Immunodiffusion of Urokinase using manufacturer's protocol.

**D. Methods & Protocols presentation in IAEC:**

The methods and protocols for testing of different test parameter (such as FSH Potency of Hormone, Residual activity of Urofollitropin hormone, HMG potency (FSH activity), HMG potency (LH activity) were presented by Dr. Gauri Misra, SG-II and Head, Enzymes and Hormones Laboratory in IAEC meeting.

**7. Proposed target for testing of new Biologicals being undertaken:**

The laboratory has successfully developed infrastructure for quality control evaluation of rare disease products (new biologicals) and evaluated three new products (Elaprase, Vpriv and Replagal). Now laboratory has started developing of infrastructure for following new biologicals in both categories of Enzymes and Hormones (conventional and

r-DNA origin) for quality control evaluation.

**A. Reteplase for Injection:** The laboratory has been initiated to undertake the Quality evaluation of the Reteplase Injection as per manufacturer's specification.

**B. Enoxaparin for Injection:** The laboratory has start to undertake the Quality evaluation of the Enoxaparin for Injection as per IP 2018.

**C. Recombinant Luteinizing Hormone and Recombinant Gonadotropin Hormone:** Laboratory will initiate to undertake the Quality evaluation as per manufacturer's specification

**8. Participations in Training/ Workshop/ Conference (Name of the Scientist (s), name of Programme, duration and place of training etc.)**

The laboratory staffs attended Training/ Workshop/Conference time to time organised by Institute and also by other institutes. The Training attended by laboratory staffs is tabulated in Table -6.

**Table – 6. Training attended by laboratory staff:**

S. No.	Name of Scientists	Name of the Programme	Duration	Place
1.	1. Dr. Gauri Misra, (Scientist Grade-II) 2. Sh. Paras Jain, (Jr. Scientist)	Effective Implementation and Internal Audit of ISO/IEC 17025:2017 Laboratory Management Systems by M/s FICCI	20 <sup>th</sup> – 24 <sup>th</sup> May 2019	National Institute of Biologicals, Noida
2.	1. Dr. Gauri Misra (Scientist Grade-II) 2. Sh. Paras Jain, (Jr. Scientist)	'Joint meeting Implementation of Indian Pharmacopoeia (I.P.) monograph for Recombinant Follicle Stimulating Hormone (r-FSH) drug substance and drug product.'	22.10.2019	FDA, Bhawan, New Delhi

S. No.	Name of Scientists	Name of the Programme	Duration	Place
3.	1. Dr. Gauri Misra, (Scientist Grade-II) 2. Sh. Paras Jain, (Jr. Scientist)	Technical expert committee (TEC) meeting	25.11.2019	HLL/HITES, Sec 62 Noida
4.	Dr. Gauri Misra (Scientist Grade-II)	03 day CBT course series” Empowering Regulatory Leaders in India”	10 <sup>th</sup> -12 <sup>th</sup> Dec. 2019	IIT New Delhi
5.	Dr. Gauri Misra (Scientist Grade-II)	Invited talk at 8 <sup>th</sup> International Translational Cancer Research Conference: Role of Inflammation and Immune System for Cancer Prevention and Treatment Organized by: Department of Biochemistry, Institute of Science, Banaras Hindu University, Varanasi-221005, INDIA & Society for Translational Cancer Research (STCR)	13-16 February 2020	Banaras Hindu University, Varanasi
6.	1. Dr. Gauri Misra, (Scientist Grade-II) 2. Sh. Paras Jain, (Jr. Scientist)	Use of Artificial Intelligence in Health services- the promising and potential possibilities in near future especially in Diagnostics	25 <sup>th</sup> June, 2019	NIB, Noida

## 9. Outstanding achievements of the Lab:

- I. The laboratory has established Quality control evaluation and tested three new rare disease products namely Elapraxe, Vpriv and Replagal for release in the market.
- II. Extramural funding from ICMR INR **66.56 lakhs**.
- III. 01 research publication published in peer

reviewed journal in reporting year 2019-2020. Shruti Samlet, Kedar Shedage, Paras Jain, Jay Bajarang Singh, Brij Bahadur, Mohit Kumar and Akanksha Bisht. “Attributes of Bacterial Endotoxin Test (BET) and its comparison with Rabbit Pyrogen Test”, International Journal of Advanced Research, Vol-7, Issue 05, May 2019.



# THERAPEUTIC MONOCLONAL ANTIBODY LABORATORY

## 1. Name of Divisional Head:

Dr. J.P. Prasad, Scientist Grade I  
(Till 09.03.2020)

Dr. Harish Chander, Scientist Grade I  
(09.03.2020 onwards)

## 2. Name of the Head:

Dr. Ratnesh K. Sharma, Scientist Grade II  
(25.06.2019 onwards)

Mr. Subhash Chand, Scientist Grade III  
(Till 25.06.2019)

## 3. Manpower in the lab/division:

### I. Name of Scientific Staff:

Md. Daud Ali, Junior Scientist  
14.05.2019 onwards).

Ms. Apoorva Anand, Junior  
Scientist (Till 14.05.2019),

Dr. Richi V. Mahajan, Junior  
Scientist (Till 30.09.2019),

### II. Name of Technical Staff:

Dr. Mohammed Imran, Lab Technician

### III. No(s). of Outsourced Staff: 08

## 4. Scientific Activities Undertaken

### a) Collaboration with other organization:

1. Participation in WHO-NIBSC collaborative study preparation of WHO 1st International Standard (IS) for Bevacizumab: Therapeutic Antibodies Laboratory has participated in WHO-NIBSC Collaborative Study for preparation of WHO 1st International Standard (IS) for

Bevacizumab biological activity. The results of the bioassay performances for the estimation of biological activity have been communicated to NIBSC on 18.12.2019 for further analysis and compilation for assigning the potency value.

2. Participation in WHO-NIBSC collaborative study preparation of WHO 1st International Standard (IS) for Trastuzumab:

Therapeutic Antibodies Laboratory has participated in WHO-NIBSC Collaborative Study for preparation of WHO 1st International Standard (IS) for Trastuzumab biological activity. The results of the bioassay performances for estimation of biological activity have been communicated to NIBSC on 11.03.2020 for further analysis and compilation for assigning the potency value.

### b Upgradation of Centralized Facility for Cell Culture Bioassays for Therapeutic Products:

TAL laboratory has currently having the Centralized Facility for Cell Culture Bioassays for Therapeutic Products which is functional currently at L0048 with two biosafety modules. The said facility is in process of shifting from L0048 to L2028 and upgradation with respect to increase in biosafety modules from 2 to 4 modules considering the increase in workload and to have separate handling of the bioassays involving the infectious agents. The upgradation work of Centralized facility for Cell Culture Bioassays was taken up after

due consultation with the Subject Expert Committee.

**c Govt. Analyst:** Mr. Subhash Chand, Scientist-III is notified Govt. Analyst for Therapeutic Monoclonal antibodies (Rituximab, Trastuzumab, Bevacizumab, Adalimumab) vide Gazette Notification no. 4271(E) dt. 26.11.2019

**d Development of Monograph:**

- i. Therapeutic Antibodies Laboratories, NIB contributed in preparation of General Chapter on Therapeutic Monoclonal Antibodies (mAbs) for human use specifically in framing the guidelines for quality control. The said general chapter is under consideration with Indian Pharmacopoeia Commission (IPC) for inclusion in upcoming edition of Indian Pharmacopoeia.

- ii. NIB Scientists have attended the 3rd Meeting with stakeholders on Blood and blood related products held at IPC Ghaziabad on 20<sup>th</sup> August, 2019 for discussion on preparation of the Anti-D (Monoclonal) Monograph for Indian Pharmacopoeia.

**e Publication (s):**

- i. Subhash Chand, Utpreksha Vaish, Anu Sharma, Nripendra Nath Mishra, J. P. Prasad, Richi V. Mahajan. A reliable assay for ensuring the biological activity of anti T lymphocyte immunoglobulin as an alternate to compendial flow cytometry method. Biologicals. 2020 Mar 6. pii: S1045-1056(20)30012-9. doi: 10.1016/j.biologicals.2020.01.002. (Impact Factor 1.9)

## 5. Testing of Biologicals

S. No.	Name of Biologicals Tested	Type of Biologicals	No. of Batches evaluated	No. of batches found to be of standard quality	No. of batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
1.	Anti-D (Rho) Immunoglobulin	Monoclonal Antibody	21	15	06	-	-
2.	Omalizumab	Monoclonal Antibody	01	01	Nil	-	-
3.	Idarucizumab	Monoclonal Antibody	01	01	Nil	-	-
4.	Bevacizumab	Monoclonal Antibody	03	03	Nil	-	-
5.	Mepolizumab	Monoclonal Antibody	01	01	Nil	-	-
6.	Rituximab	Monoclonal Antibody	02	02	Nil	-	-

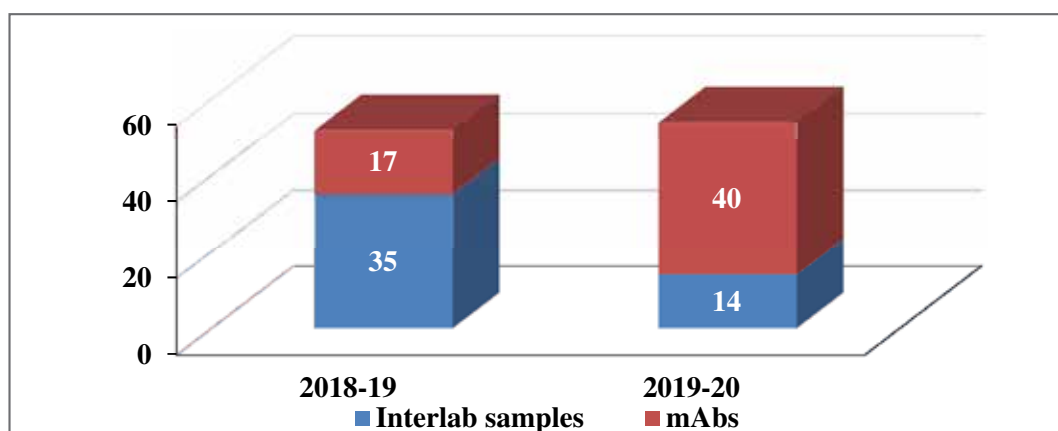
S. No.	Name of Biologicals Tested	Type of Biologicals	No. of Batches evaluated	No. of batches found to be of standard quality	No. of batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
7.	Ranibizumab	Monoclonal Antibody	02	02	Nil	-	-
8.	Cetuximab	Monoclonal Antibody	02	02	Nil	-	-
9.	Obinutuzumab	Monoclonal Antibody	01	01	Nil	-	-
10.	Secukinumab	Monoclonal Antibody	01	01	Nil	-	-
11.	Etanercept	Monoclonal Antibody	02	02	Nil	-	-
12.	Infliximab	Monoclonal Antibody	01	01	Nil	-	-
13.	Aflibercept	Monoclonal Antibody	01	01	Nil	-	
14.	Pembrolizumab	Monoclonal Antibody	01	01	Nil	-	
15.	Filgrastim	Recombinant product	-	-	-	07	Potency Assay
16.	Peg –Interferon $\beta$ -1a	Recombinant product	-	-	-	02	
17.	Interferon $\beta$ -1b	Recombinant product	-	-	-	01	
18.	Teriparatide	Recombinant product	-	-	-	01	
19.	Peg EPO	Recombinant product	-	-	-	01	
20.	JE Vaccine	Viral Vaccine	-	-	-	02	Osmolality test
		Total	40	34	06	14	-

## 6. Preparation and supply of National Standards, Sera panel etc:

1. Roadmap for preparation of Reference Standard for TAL incorporated into the Institutional Development Program (IDP) of NIB which under consideration by Ministry of Health and Family Welfare, Government of India

2. Centralized Bioassay Facility (CFB) of TAL has evaluated the candidate material for preparation National Reference Standard (NRS) for Filgrastim. The reports of the potency assays have been submitted to Recombinant Product Laboratory for further evaluation and assigning the potency value.

## 7. Trend in volume of work as compared to previous year:



## 8. Proposed targets for testing of new biologicals being undertaken:

- i. N=05, new mAb products (Pembrolizumab, Obinituzumab, Omalizumab, Aflibercept, Infliximab) testing capability has been established as per the manufacturer's specifications (Non-Pharmacopoeial Products) in FY 2019-20.
- ii. One new product, Peg-EPO has been standardised for bioassay in Centralized facility for bioassay of TAL.

- iii. New targets undertaken for establishing the testing capability are as below:

S. No.	Product/ test	Timeline
1.	Vedolizumab	September, 2020
2.	Ranibizumab	December, 2020
3.	Anti-Thymocyte globulin (For FACS based potency assay and Anti platelet activity)	March, 2021

## 9. Participations in training/workshop/conference (Name of the scientist, name of programme, duration and place of training etc.):

### 9.1 Scientific Presentations given by NIB Scientist

S. No	Name of the Scientist	Scientific Presentations given
1.	Mr. Subhash Chand, Scientist-III	i) Oral presentation on “Production, Quality Control & Regulation of Biologicals especially mAbs” held at University of Delhi, South Campus; Department of Biochemistry on 15 <sup>th</sup> April, 2019.

## 9.2 Participation of NIB Scientist in training/ workshops/ conferences/ other Scientific activities:

S. No.	Name of the Scientist	Name of the Programme	Duration	Place/ Venue
1.	Mr. Subhash Chand, Scientist-III	Audited the Bioassay Laboratory of Translational Health Science and Technology Institute (THSTI), Faridabad as an Internal Auditor on 13.02.2020 as per the requirements of ISO 17025:2017 standard.	13.02.2020	THSTI, Faridabad.
2.	Mr. Subhash Chand, Scientist-III	19th Annual International Conference on Hemato-Oncology Update, RGCON 2020	7 <sup>th</sup> to 9 <sup>th</sup> Feb., 2020	New Delhi
3.	Dr. Ratnesh K. Sharma, Scientist-II	CBT Course Series-2019 for Regulators.	10 <sup>th</sup> to 12 <sup>th</sup> Dec. 2019	IIT- Delhi
4.	Dr. Ratnesh K. Sharma, Scientist-II Mr. Subhash Chand, Scientist-III	Training on Rapid Fluorescent Focus Inhibition Test (RFFIT) and CVS adaptation at Indian Immunologicals Ltd. (IIL), Hyderabad	18 <sup>th</sup> to 24 <sup>th</sup> October 2019	IIL, Hyderabad
5.	Dr. J. P. Prasad, Scientist-I Dr. Ratnesh K. Sharma, Scientist-II Mr. Subhash Chand, Scientist-III,	Attended the Joint meeting called by CDSCO for grant of permission to manufacturer of recombinant Anti-Rho D Immunoglobulin.	04.09.2019	FDA Bhavan, New Delhi
6.	Dr Harish Chander Scientist-I, Dr. Ratnesh K. Sharma, Scientist-II	3 <sup>rd</sup> Annual Regulators Conclave for Central and State Regulatory Authorities.	21-22 August 2019	Panaji , Goa
7.	Dr. Ratnesh K. Sharma, Scientist-II, Mr. Subhash Chand, Scientist-III, Dr. Richi V. Mahajan, Junior Scientist Md. Daud Ali, Junior Scientist	Use of Artificial Intelligence in Health services- the promising and potential possibilities in near future especially in Diagnostics	25 <sup>th</sup> June, 2019	NIB, Noida





Participation of NIB Scientists, Dr. Harish Chander, Scientist-I, Dr. Ratnesh K Sharma, Scientist-II and Mr. Harit Kasana, Scientist-II attended 3<sup>rd</sup> Annual Regulators Conclave for Central and State Regulatory Authorities held on 21-22 August 2019 at Goa

NIB Scientist- Dr J.P. Prasad, Scientist-I, Dr. Ratnesh K Sharma, Scientist-II and Mr. Subhash Chand, Scientist-III attended the Joint meeting called by CDSCO for grant of permission to manufacturer of recombinant Anti-Rho D Immunoglobulin held on 04.09.2019 at FDA Bhavan, New Delhi



Dr. Ratnesh K Sharma, Scientist-II, NIB, Noida attended CBT Course Series-2019 for Regulators held on 10<sup>th</sup> to 12<sup>th</sup> Dec. 2019 at IIT- Delhi

Participation of NIB Scientists - Mr. Subhash Chand, Scientist-III & Mr. P.S. Chandranand, Junior Scientist, as Auditor in Internal audit as per the requirements of ISO 17025:2017 standard of Bioassay Laboratory of Translational Health Science and Technology Institute (THSTI), Faridabad held on 13.02.2020



## 10. Outstanding achievements of the Lab:

- I. Mr. Subhash Chand, Scientist-III is notified Govt. Analyst for Therapeutic Monoclonal antibodies (Rituximab, Trastuzumab, Bevacizumab, Adalimumab) vide Gazette Notification no. 4271(E) dt. 26.11.2019.
- II. 01 research publications have been published in peer reviewed journal in reporting year 2019-2020.
- III. TAL participated in two WHO-NIBSC Collaborative Studies for preparation of WHO 1st International Standards (IS) for biological activity Bevacizumab & Trastuzumab. search article published in Journal 'Current Science' and 01 book chapter published.

## CLINICAL DIAGNOSTIC KIT LABORATORY

### 1. Name of Head:

Ms. Shalini Tewari, Scientist Grade-III  
(till- 08.03.2020)

### 2. Manpower in the lab/division:

#### I. Name of Scientific Staff:

Mr. Brij Bhushan, Junior Scientist  
(till- 08.03.2020)

#### II. No(s). of Outsourced Staff: 04

### 3. Scientific Activities Undertaken:

- a) Laboratory has submitted Protocol for Bradford method along with supporting data to Indian Pharmacopoeia Commission, Ghaziabad, for inclusion/ addition for protein estimation in phenol containing Allergen Extracts in Allergen Products Monograph in Indian Pharmacopoeia 2018.
- b) Laboratory staff participated in following Training/ Workshop/ Conference:

Name of Scientist	Name of programme	Duration	Organized by
Dr. Achla Prasad Deputy Director (QC)	53 <sup>rd</sup> National Conference of Indian College of Allergy, Asthma and Immunology ICAAICON 2019: Presented "Quality Control of Indigenous Cockroach (P. americana) Allergen Extracts" (Authors: Dr. Achla Prasad, Dr. M. K. Agarwal, Shalini Tewari, Brij Bhushan, Gunjan Sikarwar, Linta Abraham, Aradhna Azad, Dr. Surinder Singh)	7-10 Nov, 2019	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Ms. Shalini Tewari Scientist-III and Mr. Brij Bhushan Junior Scientist	Effective implementation and Internal Audit of ISO/IEC 17025: 2017 Laboratory Management Systems (LMS) & NABL Criteria	20-23 May, 2019	FICCI Quality Forum
Ms. Shalini Tewari Scientist-III	Maintenance and certification of Biosafety Cabinets- sensitization and Hands-on workshop	13-18 May, 2019	WHO-IAMM-CDC-NIB

## ANIMAL FACILITY

### 1. Name of Head:

Dr. Shikha Yadav (Scientist Grade- II, Vet. Pathologist)

### 2. Manpower in the lab/division:

#### I. Name of Scientific Staff:

Dr. Suresh Kumar (Scientist Grade- III, Jr. Vet)

#### II. Name of Technical Staff

Mr. Parminder Kumar, Jr. Animal Care taker

Mrs. Rajendri Devi, Peon

#### III. No(s). of Outsourced Staff: 17

### 3. Scientific Activities Undertaken:

#### a. Collaboration with other organizations:

Animal Facility is a central support unit for all laboratories of NIB. The staff here performs in-vivo tests as per Indian or other Pharmacopoeia for quality control evaluation of biologicals received in the institute. The facility also ensures timely availability of laboratory animals for various in-vivo tests by a planned breeding program and the staff of the facility ensures high quality animal husbandry and care that meets the requirements of animal welfare regulations and guidelines provided by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). We organize request based trainings in the field of Laboratory Animal Science for M.Sc and PhD students, faculty, veterinarians and technicians. We also provide good quality laboratory animals to educational and

research institutes and industry in Delhi-NCR and neighbouring states and generate additional revenue for NIB.

#### Research Projects being continued from previous year:

- Collaboration with Indian Institute of Technology (IIT), Delhi for project titled "Corneal delivery of antifungal-peptide conjugate encapsulated nanoparticle formulation in an experimental animal model of *Fusarium solani*"
- Collaboration with CSIR-Institute of Genomics and Integrative Biology (IGIB), Delhi for project titled "Evaluation of A1 and A2 variants of  $\beta$  casein in cow milk as factors causing allergic airway disease in murine model"
- Collaboration with Jaypee Institute of Information Technology (JIIT), Noida for project titled "Identification and Characterization of miRNAs relevant to cardiac diseases"
- Collaboration with IIT, Delhi for project titled "Nanoformulation-Cell penetrating peptide mediated delivery of Riboflavin to ocular cells"

#### New Research Project Undertaken in 2019-2020

- Collaboration with IIT, Delhi for project titled "Management of bacterial (MRSA) keratitis using novel Stromal Targeting Peptide and its conjugates"



**b. Publication(s):****Research paper****Recent Advances in 3Rs and Laboratory Animal Science: Report on the International Conference of LASA (India)**

Vijay Pal Singh, Shikha Yadav, Himanshu Joshi, Shakthi R. K. Devan, Dinesh K. Yadav and Rana. P. Singh; ALTEX 36(2), 2019 (Online ISSN: 1868-8551; Print ISSN: 1868-596X; Impact Factor 2018: 6.183)

**Poster Presentation**

Saxena S (1), Mathur P (1), **Yadav S (2)**, Singh S (2), Rani V (1) (2019)

“Non Coding Regulatory RNAs from embryonic heart regulates extra cellular matrix remodelling during pathological cardiac hypertrophy”

Presented by first author in The British Society for Cardiovascular Research (BSCR) Autumn Meeting on “Heart Failure- New

Therapeutic Strategies” on 9<sup>th</sup>- 10<sup>th</sup> September 2019 at Emmanuel College, University of Cambridge, UK and abstract published in conference booklet.

**4. Testing of Biologicals:**

*In-vivo* QC evaluation tests i.e. Abnormal Toxicity Test, Pyrogen Test, Potency & Identity Assays & other miscellaneous tests have been performed on a total of 1361 samples of different biologicals forwarded by the laboratories of NIB. A total of 563 samples were tested for Abnormal Toxicity, 707 samples for Pyrogen, 80 samples for Identity and Potency Assay, 11 samples for miscellaneous tests. During the year 2019-20, a total of 13,150 animals were provided by the Animal facility of which 9754 animals were used to conduct the in-vivo QC tests, 20 were used for research and 3376 were sold to other institutes, details of which are provided in Table I.

**4. Testing of Biologicals:****Table 1: Details of Animals used and supplied in 2019-20**

S. No.	Species	Strain	Animal Provided in the Year 2019-20			
			QC Testing	Research	Sold to outside institutes	Total
1.	Mice	Swiss Mice	6017	-	979	6996
		Balb/c/c	1900	-	543	2443
2.	Rats	SD Rats	658	-	976	1634
		Wistar Rats	-	-	842	842
3.	Guinea Pigs	Duncan Hartley	1112	-	36	1148
4.	Rabbits	New Zealand White	67	20	-	87
Total			9754	20	3376	13150
Grand Total			13150			

**Approval of protocols by Institutional**

**Animal Ethics Committee (IAEC):** All the experiments involving animals have to be

approved by the IAEC, constituted by CPCSEA. Three IAEC meetings were organized during the preview period for timely ethical approvals so



that all in-vivo tests could be performed in the designated turnaround time periods. A total of 61 protocols were reviewed by the committee during this period and all relevant records of approvals were maintained as member secretary, IAEC. The IAEC also visited the Animal Facility during these meetings and found it to be meeting all CPCSEA requirements.

**Abnormal Toxicity Test** is conducted to determine the presence of any toxic substance in biological products intended for parenteral administration. The details of number of samples of various products and number of animals used are given in Table 2.

**Table 2: Details of different products tested for Abnormal Toxicity (2019-20)**

Laboratory	Name of Product	No. of Samples 2019-20	No. of Animals used	
			Mice	G. Pigs
Blood Products	Human Albumin	287*	1435	574
	Dried Human Antihemophilic Fraction (Factor VIII)	155	775	310
	Human Specific Immunoglobulin (I/M) (SPIG-IM)	51	255	102
	Human Normal Immunoglobulin (I/M) (IGIM)	21	105	42
	Human Rabies Immunoglobulin (RIg)	17	85	34
Enzymes & Hormones	Human Chorionic Gonadotropin (hCG)	2	10	-
	Streptokinase (STK)	15	75	-
	Urokinase	2	10	-
Vaccines	Human Hepatitis B Immunoglobulin (HBIg)	7	35	14
	Measles, Mumps and Rubella (MMR)	4	20	8
	Varicella	2	10	4
<b>Total</b>		<b>563</b>	<b>2815</b>	<b>1088</b>

\*Including repeat testing

**Pyrogen Test** is conducted to detect the presence of any pyrogenic substance in the biologicals and vaccines intended for parenteral administration and are prescribed in the Indian and other Pharmacopoeia. The details of number of samples

of various products tested for pyrogenicity are provided in Table 3 and a total of 67 rabbits were used in these tests.

**Table 3: Details of different products tested for Pyrogen Test (2019-20)**

Laboratory	Name of Product	No. of samples 2019-20
Blood Products	Human Albumin	287
	Dried Human Antihemophilic Fraction (Factor VIII)	161
	Normal Immunoglobulin (I/V) (IGIV)	105

Laboratory	Name of Product	No. of samples 2019-20
	Normal Immunoglobulin (I/M) (IGIM)	24
	Human Specific Immunoglobulin (I/M) (SPIG-IM)	49
	Human Specific Immunoglobulin (I/M) (SPIG-IV)	3
	Factor-IX	33
	Human Rabies Immunoglobulin (Rig)	17
	Fibrogen	2
Viral Vaccine	Human Hepatitis B Immunoglobulin (HBIG)	7
	Cell Culture Rabies Vaccine (CCRV)	10
	Human Hepatitis B Vaccine (HBV)	7
Enzymes & Hormones	Urokinase	2
<b>Total</b>		<b>707</b>

**Identity and Potency Assay** is done to establish the identity and determine the strength and activity of the products before their use in humans. The details of different product tested for Potency assay are provided in Table 4.

**Table 4: Details of different products tested for Potency Assay (2019-20)**

Laboratory	Name of Product	No. of samples ( 2019-20)	No. of Animals used	
			Rats	Mice
Enzyme & Hormone	hCG	5*	160	-
	r-FSH	1	30	-
	HMG-LH	8	234	-
	HMG-FSH	7*	234	-
Blood Products	Human Rabies Immunoglobulin (RIg)	17	-	2580
Viral Vaccine	CCRV	6	-	492
	Hepatitis B Vaccine (HBV)	5	-	550
Recombinant Product	Recombinant Erythropoietin (r EH)	31	-	1300
<b>Total</b>		<b>80</b>	<b>658</b>	<b>4922</b>

\*Including repeat testing

**Miscellaneous tests performed in Animal Facility (Table 5)**

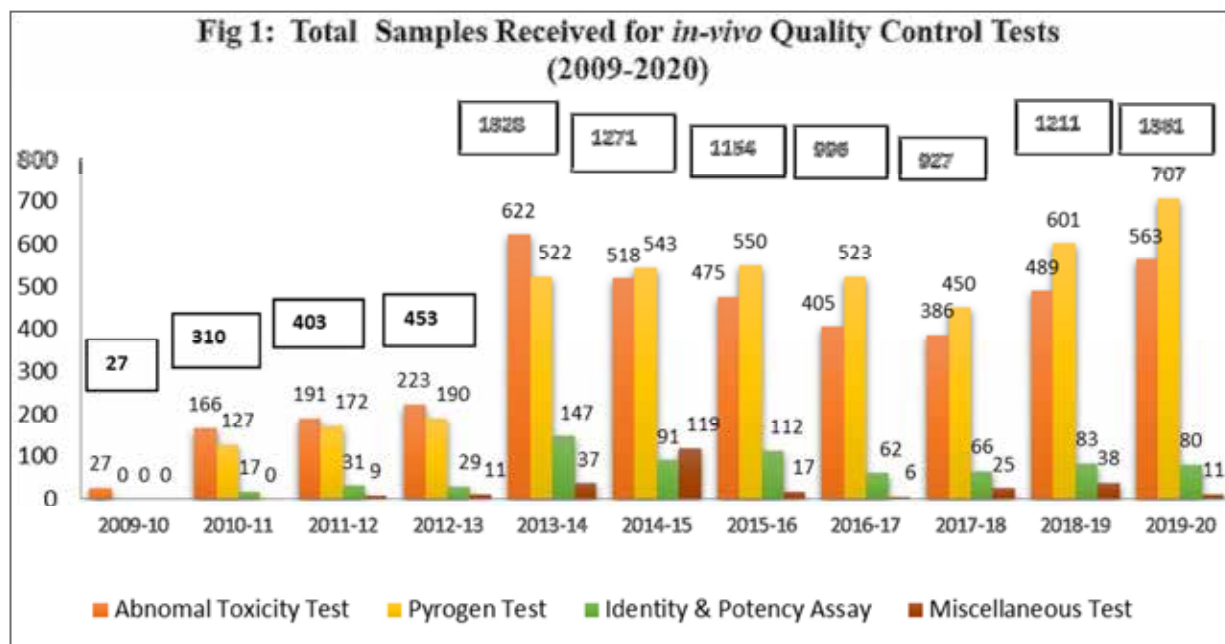
Name of test	No. of Samples	No. of Animals used	
		Mice	G. Pigs
Virulent Mycobacterium of BCG Vaccine	2	-	12
Skin Reactivity for BCG Vaccine	2	-	12
Virus Inactivation for CCRV Vaccine	6	60	-
Tetanus Vaccine Absorbed	1	120	-
<b>Total:</b>	<b>11</b>	<b>180</b>	<b>24</b>

## 5. Trend in volume of work as compared to the previous years:

### Quality Control Testing

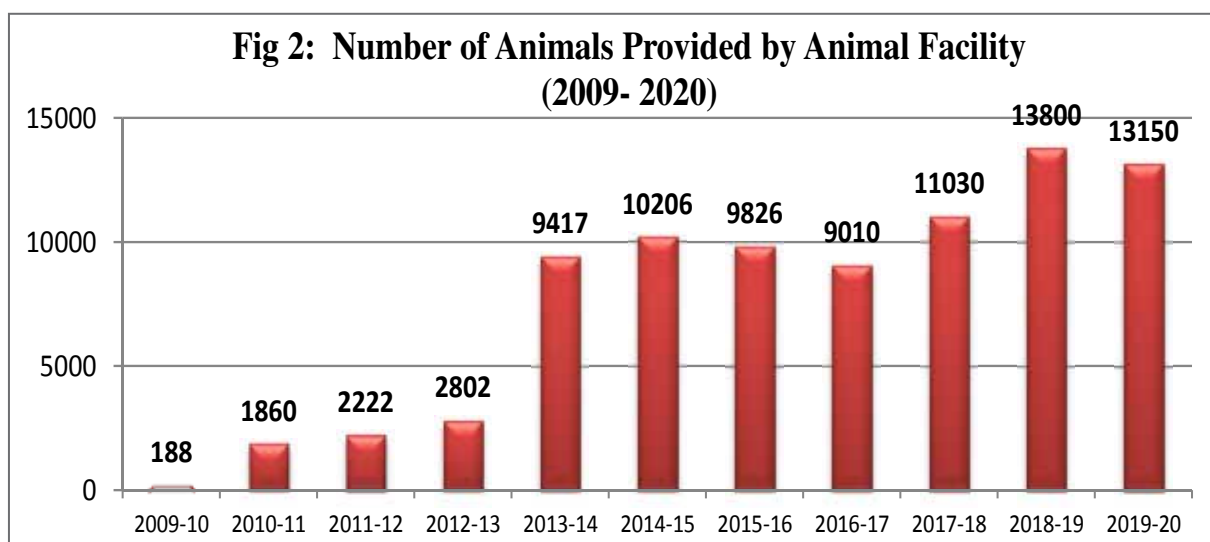
There has been an increase in number samples

received and tested at Animal Facility as compared to previous years and the details are depicted in Figure 1 below:



Further, the details of the number of animals provided by Animal Facility as compared to

the previous years are given in Figure 2.



## 6. Participations in Training/ Workshop /Conference:

Dr. Shikha Yadav, Scientist Grade II & Head, Animal Facility

- Attended as keynote speaker to speak on “The Ethics of Animal Research” in the workshop on “Ethical issues in research” organized by Department

of Biotechnology, Jaypee Institute of Information Technology, Noida on 27<sup>th</sup> July, 2019.

- Attended 4 days training on ISO standard 17025:2017 organized by FICCI at NIB, Noida from 20<sup>th</sup> -23<sup>rd</sup> May 2019.
- Attended as resource person in “Certificate Course in Laboratory Animal Sciences” (CCLAS) at Madras Veterinary College, TANUVAS, Chennai from 26<sup>th</sup> – 28<sup>th</sup> September 2019 to deliver talk on severity assessment and humane endpoints, search on animal alternatives and for evaluation of case presentations and final examination of the participants. This is the only course in the country which has been accredited by the Federation of European Laboratory Animal Scientists Association (FELASA) outside Europe.
- Attended workshops on “Establishing Indian College of Laboratory Animal Medicine (ICLAM)-A specialty program of LASA India and “Critical factors affecting cage processing and Lab animal hygiene” at IISER, Pune on 21<sup>st</sup> November 2019.
- Attended 9th International Conference on “Laboratory Animals in Biomedical Research-The way forward” at IISER, Ministry of Human Resource Development (Government of India), Pune from 22-23<sup>rd</sup> November 2019.
- Delivered a talk on “Pain Assessment and Management in Rodents” in workshop on “Basic Training in Animal Handling & Experimentation” organized by Centre for Comparative medicine, Institute of Liver and Biliary Sciences,

Delhi on 19.2.2020.

- Delivered a talk on “Preoperative care, anesthesia, surgical technique and analgesia” on 20.3.2020 at NIB, Noida for 16 participants comprising of Faculty, PhD students and Post docs of Lala Lajpat Rai University of Veterinary and Animal Sciences, (LUVAS), Hisar, Haryana as part of their training at National Institute of Animal Welfare, Ministry of Fisheries, Animal Husbandry & Dairying, GoI.
- Attended to speak on “General occupational health hazards, personal hygiene and transmission across species boundaries” and “Principles of 3 R’s in Ethical Animal Based Research” at NIAW, Ballabgarh, Faridabad on 21<sup>st</sup> March 2020.

#### **Meetings Attended as Expert or IAEC Member**

- Nominated by CPCSEA (Ministry of Environment, Forests and Climate Change) as Member (Scientist from outside the Institute) of Institutional Animal Ethics Committee (IAEC) of
  - o S.V.P Agricultural University, Meerut and attended their IAEC meeting on 9<sup>th</sup> April 2019.
  - o NIET college of Pharmacy, Greater Noida, UP and attended their meeting on 27<sup>th</sup> December 2019.
  - o IIMT college of Pharmacy, Greater Noida and attended their IAEC meeting on 2<sup>nd</sup> January 2020.
  - o Galgotias University, Greater Noida, UP and attended their meeting on 24<sup>th</sup> January 2020.

**Dr. Suresh Kumar, Scientist Grade- III**

- Nominated by Competent Authority of NIB, Noida as an auditor in the Internal Quality Audit for ISO 17025:2017 scheduled from 14.10.19-16.10.19 for Therapeutic Division of NIB (Blood Products Laboratory, Recombinant Products Laboratory and Sterility Therapeutic Antibody Laboratory).
- Invited as a Resource person on 20<sup>th</sup> February 2020 for conducting a hands on training on “Euthanasia Method & Necropsy Procedure & Handling animal tissues for Histopathological examination” in the workshop on “Basic training in animal handling & experimentation” scheduled from 17<sup>th</sup> -20<sup>th</sup> February, 2020 at the Institute of Liver and Biliary Sciences, New Delhi

**Meetings Attended as Expert or IAEC Member**

- Attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA Main nominee on 17<sup>th</sup> August 2019 at Central Animal Facility, All India Institute of Medical Sciences (AIIMS), New Delhi.
- Attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA Main nominee on 7<sup>th</sup> September 2019 at Animal Facility, Department of Biochemistry, University of Delhi South Campus, New Delhi.
- Attended as an external expert in the CSIR- Assessment Committee constituted in the area of Bioscience and Biotechnology for the assessment of Scientist from Jr. Scientist to Principal Scientist at CSIR Institute of Himalayan

Bioresource Technology (IHBT), Palampur-176061(HP) on dated 17<sup>th</sup> -20<sup>th</sup> September 2019.

**Visit of trainees of National Institute of Animal Welfare (NIAW)**

NIB organised the visit of 16 trainees of National Institute of Animal Welfare (NIAW) comprising of Faculty, PhD students and Post docs of Lala Lajpat Rai University of Veterinary and Animal Sciences, (LUVAS), Hisar, Haryana to NIB, Animal facility to see the working and scientific management of animal house on 20<sup>th</sup> March 2020. This was part of the training organized by National Institute of Animal Welfare (NIAW), Ministry of Fisheries, Animal Husbandry & Dairying, Government of India, on “Management & Welfare of Lab animals for research purposes”, from 18<sup>th</sup>-22<sup>nd</sup> March 2020 at Ballabgarh, Faridabad.

**7. Outstanding achievements of the lab:**

- Annual Inspection of Animal Facility** was performed on 28<sup>th</sup> November 2019 and they appreciated the excellent animal care and systematic record keeping of the Animal Facility and submitted their Inspection Report to CPCSEA, Ministry of Environment, Forest & Climate Change recommending for further renewal of registration of facility for one year.
- Formal Recognition of Competency of Tests Performed by NABL (ISO: 17025):** All in-vivo tests being performed in Animal Facility have been included in the scope of ISO: 17025 and Animal Facility participated in the annual external audit by NABL in



June 2019. There was no nonconformity found in the laboratory thus increasing our confidence on the testing reports released by the laboratory.

**AAALAC International Site Visit:**

On invitation from Dr. Montip Gettayacamin, Senior Director for Southeast Asia, AAALAC International, Thailand, Dr. Shikha Yadav, as an Adhoc Specialist assisted AAALAC International in conducting site visit (audit) of one Animal Facilities (unit) on 14<sup>th</sup> November 2019 at Hyderabad to assess their institutional animal care and use programs for AAALAC

accreditation purposes

c) **Commitment of NIB for implementation of 3R's**

As commitment towards the 3R's, the scientists of Animal Facility and laboratories worked in close coordination to reduce the number of animals used in the quality control testing by testing more than one batch of same product at the same time with a common reference or control group. This enabled us to save 1006 laboratory animals in the year 2019-20, the details of which are provided below;

S. No.	Details of QC Test	Number of Animals Saved
1.	Potency Assay for Rabies Immunoglobulin (RIg)	480 Mice
2.	NIH Potency assay for Rabies Vaccine	204 Mice
3	Potency assay for Recombinant Erythropoietin (r EH)	250 Mice
4.	Potency assay of HMG (FSH & LH)	72 Rats
	<b>Total</b>	<b>1006</b>

## STERILITY TESTING LABORATORY

### 1. Name of Head:

Dr. J. P. Prasad, Scientist, Grade-I

### 2. Manpower in the Lab/Division:

#### I. Name of Scientific Staff:

Sh. Kallol Saha, Junior Scientist

#### II. Name of Technical Staff:

Sh. Narender Kumar, Lab Assistant.

#### III. No(s) of Outsourced Staff- 03

### 3. Scientific Activities Undertaken:

Working on Molecular characterization

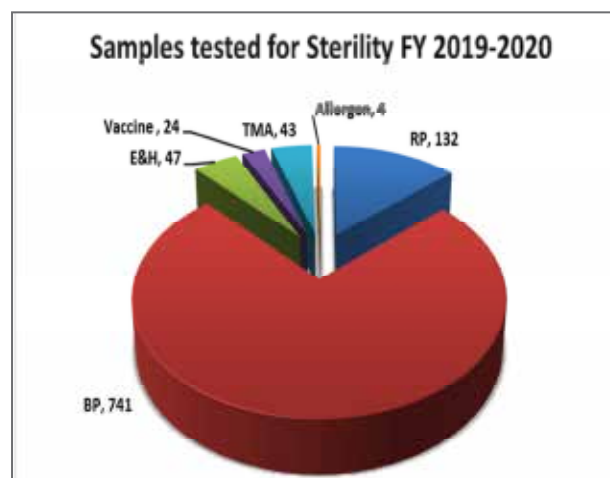
### 4. Testing of Biologicals:

**Table 1: SUMMARY OF VARIOUS BIOLOGICALS TESTED FOR STERILITY**

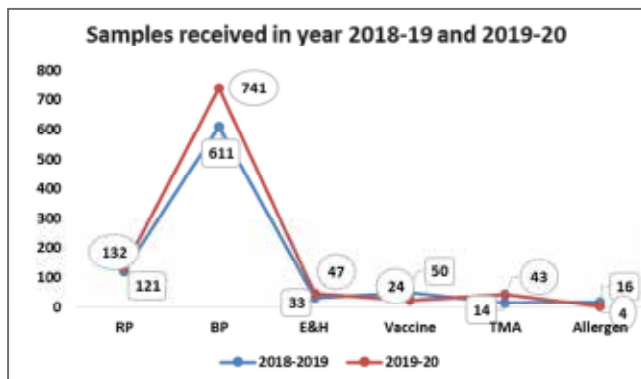
Name of Biological Tested	Type of Biologicals
Recombinant Products	Insulin, Interferon, Erythropoietin, GSF
Blood Products	Albumin, Human Normal Immunoglobulin, Antithrombin, coagulation Factor
Enzymes & Hormones	Streptokinase, hCG, FSH, HMG, Urokinase, Heparin
Viral Vaccines and Immunoserum	Rabies Vaccine, MMR, Measles, Rubella, HPV, Hep. B Immunoglobulin & Rabies Immunoglobulin
Therapeutic Monoclonal Antibody	Trastuzumab, Bevacas, Bevacizumab & Rixubis
Allergen	Cockroach extract, Moth extract

of environmental isolates. Environment monitoring of classified area and isolation of microbes followed by biochemical and molecular characterization using DNA extraction, RT-PCR, Gel electrophoresis and DNA Sequencing. Till now we have isolated and identified *Bacillus megaterium* and *Bacillus aryabhattai* in our classified area.

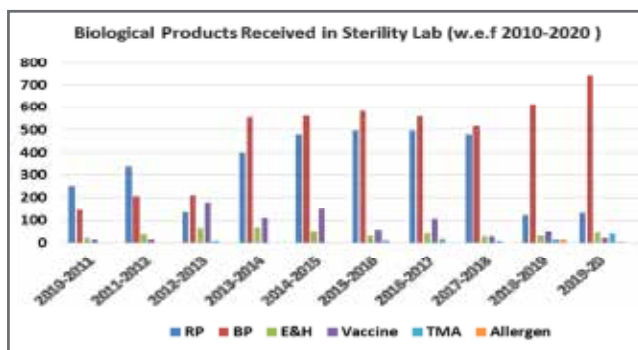
Validation of high increased chemical compatibility, antibiotics and antimicrobial biological products in the aiding of green and red based filter of manufacturer devices.



**5. Trend in volume of work as compared to previous year (2018-2019) including examination of technical dossiers:**



*Fig 2 Samples received in year 2019 - 2020*



*Fig 3 Samples tested for sterility during 2019-2020*

**6. Participation in Training/ Workshop/ Conference (Name of the Scientist(s), Name of the programme, Duration and place of training, etc.):**

Mr. Kallol Saha, Junior Scientist and one outsourced staff participated in One Day seminar on Next Generation DNA Sequencing organized by Thermo Fisher Scientific at Hotel Pullman, New Delhi.

## RENDERING TECHNICAL EXPERTISE THROUGH JOINT INSPECTIONS

The Institute provides technical expertise for enforcement of implementing standards in India through joint inspections of (i) manufacturing premises in coordination with Central Drugs Standards and Control Organization (CDSCO), (ii) GLP- Laboratories conducted by National GLP Compliance Monitoring Authority (NGCMA) DST, and (iii) Animal Facilities

conducted by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).

### cGMP inspections:

Participation of NIB Experts in Joint Inspection of rDNA manufacturing unit under Central Inspection Plan (CIP) 2019:

S. No.	Date and facility	NIB Scientist
1	5 <sup>th</sup> -6 <sup>th</sup> August, 2019 M/s Torrent Pharmaceuticals Ltd., Ahmedabad	1. Dr. Charu M. Kamal, Scientist Grade II 2. Ms. Gurminder Bindra, Scientist Grade III
2	23 <sup>rd</sup> -24 <sup>th</sup> December, 2019 M/s Cadila Pharmaceuticals Ltd., Dholka, and Ahmedabad	1. Dr. Meena Kumari, Scientist Grade-II 2. Dr. Varun Singh, Junior Scientist
3	7 <sup>th</sup> -9 <sup>th</sup> August, 2019 M/s Cadilla Healthcare Ltd. Ahmedabad	Mr. Subhash Chand, Scientist Grade -III
4.	22 <sup>nd</sup> -23 <sup>rd</sup> August, 2019 M/s. Intas Pharma Ltd., Ahmedabad	
5.	7 <sup>th</sup> -9 <sup>th</sup> August 2019 M/s Cadila Healthcare Ltd., Ahmedabad	Dr. Charu M Kamal, Scientist Grade-II
6.	22 <sup>nd</sup> -23 <sup>rd</sup> August 2019 M/s Intas Pharma Ltd., Ahmedabad	

### CPCSEA inspections

1. Dr. Shikha Yadav, Scientist-II and Head Animal Facility was nominated by CPCSEA (Ministry of Environment, Forests and Climate Change) as Member (Scientist from outside the Institute) of Institutional Animal Ethics Committee (IAEC). She attended the IAEC meeting and also conducted annual Inspection of Animal Facility on
  - a. 25<sup>th</sup> May 2019 at PT. BD Sharma PGIMS, PT BD Sharma University of Health Science, Rohtak, Haryana
  - b. 9<sup>th</sup> April 2019 at S.V.P Agricultural University, Meerut.
  - c. 2<sup>nd</sup> January 2020 at IIMT college of Pharmacy, Greater Noida.

**2. AAALAC International Site Visit:** On invitation from Dr. Montip Gettayacamin, Senior Director for Southeast Asia, AAALAC International, Thailand, Dr. Shikha Yadav, as an Adhoc Specialist assisted AAALAC

International in conducting site visit (audit) of one Animal Facilities (unit) on 14<sup>th</sup> November 2019 at Hyderabad to assess their institutional animal care and use programs for AAALAC accreditation purposes.

## QUALITY MANAGEMENT UNIT

### 1. Name of Head :

- i. Dr. J. P. Prasad- Scientist Grade- I & Quality Manager (till 08.03.2020)
- ii. Ms. Shalini Tewari- Scientist Grade- III & Head Quality Management Unit (from 09.03.2020)

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific staff

Mr. Neeraj Malik- Scientist II  
(till 08.03.2020)

Mr. Subhash Chand - Scientist  
III & Deputy Quality Manager  
(till 08.03.2020)

Md. Daud Ali - Junior Scientist & Deputy  
Quality Manager (till 08.03.2020)

Dr. Anoop Kumar - Junior Scientist  
& Deputy Quality Manager  
(till 08.03.2020)

Ms. Archana Sayal - Junior Scientist  
& Deputy Quality Manager  
(till 08.03.2020)

Mr. Brij Bhushan – Junior Scientist

Ms. Rashmi Shrivastava, Scientist  
Grade- III (from 09.03.2020)

#### II No(s). of Outsourced Staff: 05

### 3. Aims and scope of the Unit:

- 3.1 Quality Management Unit (QMU) of NIB ensures the best global practices for quality evaluation of various biologicals at NIB. QMU serves as a laboratory quality management tool with the following objectives to ensure:

3.1.1 appropriate infrastructure, encompassing the organizational structure, procedures, processes, personnel and resources;

3.1.2 taking systematic actions necessary to ensure adequate confidence that quality evaluation at NIB will satisfy given requirements for quality as per the various pharmacopeial guidelines/ or manufacturer's protocol.

3.2 The unit ensures inter-relationship between the laboratories and other technical & administrative departments for compliance of technical and management requirements. In addition, it ensures the vertical relationship between pharmacopeial body and the regulatory system. The objective of Quality Management Unit is continuous improvement in the following areas:

3.2.1 Maintenance, Sustenance & Enhancement of Scope for NABL accreditation in accordance to ISO/ IEC 17025: 2017 requirements & BS OHSAS 18001:2007.

3.2.2 Periodic Assessment by Accreditation/ Certification body.

3.2.3 Preparation & upgradation of Quality System Documentation.

3.2.4 Conducting periodical Internal Quality Audits as and when required.

3.2.5 Conducting and facilitating the Management Review Meetings with technical managers and higher management.



- 3.2.6 Harmonizing the quality control systems and testing among various product testing labs at NIB and assuring the quality of test results

## 4. Accreditation and Certification Activities

### 4.1 Certification as per BS OHSAS 18001:2007

BS OHSAS 18001:2007 is the internationally recognized standard for Occupational Health and Safety Management System. OHSAS stands for Occupational Health and Safety Assessment Series. NIB acquired the BS OHSAS 18001:2007 certification (Certificate No. IND 18.8672U/HS) on 24<sup>th</sup> May, 2018 valid up to 11<sup>th</sup> March, 2021. The first annual surveillance audit for management system of NIB in accordance to BS OHSAS 18001:2007 was successfully completed on 01.02.2019.

The next surveillance audit could not be done in wake of nationwide lockdown due to COVID-19 pandemic.

### 4.2 Accreditation as per ISO/IEC 17025: 2017

ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) is the standard used by testing and calibration laboratories that enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work.

#### 4.2.1 Desktop Surveillance Audit 2018 by NABL

For an accredited laboratory to maintain its accreditation status, it is mandatory that the laboratory continues to comply with the requirements of ISO/IEC 17025 and NABL policies. Once a laboratory has been accredited for the first time, NABL

conducts onsite surveillance visit within the first year of accreditation to verify the continued compliance. In the subsequent accreditation cycles of 2 years, instead of onsite surveillance visits, NABL has evolved a monitoring system for verifying the continued compliance of the laboratory by conducting desktop surveillance.

In June 2019, NIB submitted the application for its continued compliance. The renewal of accreditation is done in September 2019 for biological & chemical test carried out on the various biological products listed in the scope.

#### 4.2.2 ISO/IEC 17025: 2017

NABL is accepting application for accreditation as per ISO/IEC 17025: 2017 by testing and calibration laboratories through their online portal. No hard copy of applications is accepted. NIB has initiated the process of uploading the scope and other related documents on NABL portal for renewal of accreditation in discipline of Chemical & Biological tests in seven different categories mentioned in the portal namely

i. Biotechnology Derived Products	v. Immunological Products
ii. Enzymes	vi. Vaccines
iii. Hormones	vii. Other Specified Tests which include Biochemical Kit
iv. Biopharmaceuticals	

## 5. Quality System Documentation:

5.1 **Review & Revision of Standard Operating Procedures (SOPs) and Manuals** Alert Calendar (Apr 2019- Mar 2020) for timely revision/ review of SOPs issued to all areas of Diagnostic, Therapeutic, Vaccine

Laboratories and Support/ Facilitating Units

5.2 **The Quality Management System of NIB is strengthened with quality documentation procedures as summarized below (Table 1):**

**Table 1: Quality Documentation Procedures**

S. No.	Laboratory / Unit Name	Number of Manual/ SOPs
	<b>Manual</b>	<b>N = 5</b>
1.	Quality Manual-Apex Quality document	01
2.	Biosafety Manual	01
3.	Purchase Manual	01
4.	BS OHSAS 18001:2007 Manual Level I Document Level II Document	02
	<b>Management &amp; Technical System Procedures</b>	
5.	Standard Operating Procedures (SOPs) of various Product Testing Laboratories	<b>N = 705</b>
6.	QMU Approved Formats	<b>N = 1070</b>

### 5.3 Equipment Maintenance

Authorized list of equipment usage is being updated timely with the details of preventive maintenance e.g. AMC / Calibration done with due date. An Alert Calendar for Fixed and Moveable Equipment for Apr 2019-Mar 2020 has been released to all users of the laboratory and the Stores & Purchase Unit which includes activity for: a) AMC, b) Validation and c) calibration. These services are rendered by OEMs of the equipment and NABL accredited external agencies under seven categories viz., Temperature Controlled, Mass/ Volume, UV- Vis Absorbance, Potentiometer Measurements,

Centrifuge, Tele-thermometers, and Mercury Based Thermometers etc.

## 6 Annual Internal Quality Audit :

The annual internal quality audits were conducted as per the requirements of ISO/ IEC 17025:2017 & BS OHSAS 18001:2007 by the Quality Management Unit on 14<sup>th</sup> October -16<sup>th</sup> October, 2019.

## 7 Management Review Meeting

A review of the management system was conducted on 03<sup>rd</sup> January, 2020 (ISO 17025:2017 & BS OHSAS 18001:2007) using a formal agenda whose action was to be taken in time bound manner.

## 8 Trainings/ workshop/ conferences Organized

### Trainings

A Training Calendar has been prepared in coordination with the Training Unit, NIB, for identifying training needs and providing training to the personnel. The training programme is relevant to the present and

anticipated tasks of the laboratory with respect to the requirements of ISO 17025 and On-Job-Specific activities. Scientific and technical persons working in the areas of product testing laboratories, Engineering unit, Stores & Purchase and Quality Management Unit, have been trained in the areas, as enlisted below in Table 2 (Total No. of Internal training= 03)

**Table 2: Management Systems–Laboratory Management System, Occupational Health & Safety: Internal Trainings Organized at NIB**

S. No.	Name of Programme	Programme Attended By	Duration	Organizer
1.	In house training on Laboratory Management System based on revised ISO standard 17025:2017	Scientific Staff & Biologists (N=34)	04 days (20.05.19-23.05.19)	Quality Management Unit & FICCI Quality Forum
2.	Biosafety Practices, Chemical Spillage & sensitization to vaccination schedule	Lab Attendants (N=13)	1 day ( 19.12.2019)	Quality Management Unit & IBSC
3.	Biomedical waste segregation and management	Scientific Staff & Lab Attendants (N=20)	1 day ( 19.12.2019)	Quality Management Unit & IBSC
4.	Laboratory Quality Management System and Internal Audit as per ISI/ ISO/ IEC standard 17025:2017	Scientist (N=1)	04 days (17-20 March 2020)	BIS- NITS, NOIDA

### 9. Visit of Dignitaries:

S. No.	Date of Visit	Name	Designation
1.	08.04.2019	Prof. Bhabatosh Biswas	Chairman, NIPER, Kolkata Member- High level group on Health Sector Fifteenth Finance Commission, Union Finances
2.	08.04.2019	Dr. V. Ravichandiran	Director, NIPER, Kolkata
3.	20.06.2019	Ms. Rita Teatota, IAS	Chairperson, FSSAI
4.	25.06.2019	Dr. Rohini Ahluwalia	Executive Director, Hitachi MGRM Pvt. Ltd.
5.	25.06.2019	Mr. Shishir Kumar	Director, Healthcare: Global Solutions & Innovation at Hitachi Consulting

S. No.	Date of Visit	Name	Designation
6.	31.08.2019	Dr. V. K. Subburaj, IAS	Former Secretary to Department of Pharmaceuticals, Government of India
7.	30.09.2019	Mr. Alex Babu	Assistant Professor of Pharmacy, Government T.D. Medical College, Alappuzha
8.	30.09.2019	Mr. Beesha S Kamal	Assistant Professor of Pharmacy, Government T.D. Medical College, Alappuzha
9.	20.11.2019	Mr. Zahid Maleque	Hon'ble Health Minister, Ministry of Health & Family Welfare, Bangladesh
10.	20.11.2019	Mrs. Dechen Wangmo	Hon'ble Health Minister, Ministry of Health, Bhutan
11.	04.12.2019	Dr. Raman Mohan Singh	Director, Central Drugs Testing Laboratory (CDTL), Mumbai
12.	04.12.2019	Dr. M. Vijay Kumar	Central Drugs Testing Laboratory(CDTL), Mumbai
13.	05.12.2019	Dr. Nabajyoti Choudhary	President, Asian Association of Transfusion Medicine, Delhi (NCR)
14.	05.12.2019	Dr. Joy Mammen	Professor of Pathology, <u>Christian Medical College, (CMC) Vellore</u>
15.	05.12.2019	Dr. Jai Prakash	Senior Principal Scientific officer, Indian Pharmacopoeia, Ghaziabad
16.	05.12.2019	Ms. Binala Joshi	National Medicines Laboratory, Nepal
17.	05.12.2019	Mr. Paisan Pangjuman	Institute of Biological products, Thailand
18.	05.12.2019	Mr. Bhurit Songthanant	Department of Medical Sciences, Thailand
19.	05.12.2019	Mr. Kelzang Wangdi	Senior Pharmacist National Drug Testing Lab Royal Centre for disease control (RCDC), Bhutan
20.	05.12.2019	Dr. Manisha Shridhar, IAS	Regional Advisor WHO Regional Office for South-East Asia (SEARO), New Delhi
21.	05.12.2019	Dr. Madhur Gupta	Technical Officer-Pharmaceuticals, World Health, medical products
22.	08.12.2019	Dr. Mahrukh Petshen	National Biodiversity Centre (NBC), Bhutan
23.	23.01.2020	Dr. Dharmendra Singh Gangwar, IAS	Additional Secretary & Financial Advisor Member of Culture (Ministry of Health and Family Welfare)
24.	03.02.2020	Dr. Arul K	Associate Professor Cops, Govt. Medical College Kottayam

**Visit of International Trainees under Indian Technical and Economic Cooperation (ITEC) Programme of Ministry of External Affairs, Government of India of NITS-BIS- NOIDA on 25.02.2020**

S. No.	Name	Country
1.	Mr. Mohammad Reza Abdullahi	Afghanistan
2.	Mr. Md. Mizanur Rahman	Bangladesh
3.	Mr. Lusie Glenda Silega Coma	Cuba
4.	Mr. Paulo Nicola	Ecuador
5.	Dr. Ayah Muhammed Hassan	Egypt
6.	Mrs. Ghirmawit Ghebregabihier	Eritrea
7.	Mr. Kominist Asmamaw Anley	Ethiopia
8.	Mr. Kitaw Degefa Nayi	Ethiopia
9.	Mr. Yared Mekuria Getachew	Ethiopia
10.	Mr. Tigist Kebede Demisse	Ethiopia
11.	Mr. Hana Fisaha	Ethiopia
12.	Mr. Nicholas Adjetey Sowah	Ghana
13.	Ms. Kpattah Lebene	Ghana
14.	Ms. Noelia Sabrina Gutierrez Bastiani	Guatemala
15.	Dr. Rhwa Hama Ghreeb Qader Tagaran	Iraq
16.	Mr. Meshack Muteti Wambua	Kenya
17.	Dr. Filomeno Aboo Dibaliua Inroga	Mozambique
18.	Mr. Domigos Zunguze	Mozambique
19.	Mr. Naresh Ramgopal	Sri Lanka
20.	Mrs. Joyline Nadanshau Mwinuka	Tanzania
21.	Mr. Eustadius Felican	Tanzania

## 10. Outstanding Achievements:

QMU facilitated for readiness in respect of the pre requisites for COVID-19 testing at NIB to ensure the appropriate procedures are being followed with respect to safety and waste disposal during the COVID-19 patient samples testing along with Institutional Biosafety Committee. The Draft SOPs for Receipt of Samples for COVID-19 testing at National Institute of Biologicals, Entry and Exit

Procedure for COVID-19 Testing Laboratory, Testing of clinical samples for COVID-19 using cobas SARS-CoV-2 on Cobas 6800 system and Procedure for Biomedical Waste Management during COVID-19 Testing were prepared by Immunodiagnostic Kit and Molecular Diagnostic Laboratory for undertaking COVID- 19 Testing at NIB.

## TRAINING UNIT

### 1. Name of Head

Ms. Sudha V. Gopinath, Scientist Grade-III

Ms. Shalini Tewari, Scientist Grade-III  
(In absence of Head Training Unit)

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific Staff:

Sh. Ajay Kumar Ade, Junior Scientist  
(from 4<sup>th</sup> January, 2019 to 27<sup>th</sup> January, 2020)

#### II. No(s). of Outsourced Staff: 05

### 3. Aim and Scope:

The training unit functions with the objective, which is in line with NIB mandate 3.3 as laid down in Memorandum of Association. Besides regulatory officials, manufacturers, academicians, government analysts, blood bank officials, NIB also imparts trainings to graduate and post graduate students for building up the 'National Talent Pool of skilled and trained manpower' to be employed in indigenous manufacturing units for domestic consumption as well as export of biologicals.

The training will help to bridge the gap of trained manpower for Quality Control of Biologicals in Government and Private sector as there is an acute shortage of skilled and hands-on trained manpower in the field of Biologicals

### 4. Training Activities Undertaken:

#### 4.1 Training of Blood Bank Officials in collaboration with Blood Cell, National Health Mission (NHM): Blood Services are

a crucial component of curative healthcare amenities. Adequate and safe supply of blood and blood components is essential to enable care of critical patients in the hospitals. The mission of the Blood Cell, NHM is to develop a coordinated long-term action plan for the development and integration of diverse activities in the area of blood banking with a careful consideration of priorities and optimal use of resources and funds to ensure effective blood services in the country.

NIB in collaboration with Blood Cell, National Health Mission (NHM), conducted a series of Eight training programmes involving "Six Days Residential Training of Blood Bank Officials" with **total 263 participants** for Govt. Blood Bank Officials for technical support in Strengthening Blood Services in India at IDKL, BRL and Hemovigilance Cell, NIB- NOIDA in the following areas:

- i. EQAS for Transfusion Transmitted Diseases and Blood Group Serology.
- ii. Training for Use of Cell counters and Its Quality Assurance.
- iii. Haemovigilance training (BBO/ Clinicians/ Donors)
- iv. Analysis of gaps in Blood Bank Management
- v. Total Quality Management Systems
- vi. To improve the standards of Blood Banks and the Blood services in our country.

This initiative will facilitate in building up a "National Talent Pool of skilled and trained



manpower” to improve better quality, safety and efficacy of blood and blood products, well-equipped blood centers with adequate infrastructure, meeting the requirements of

current good laboratory practices (cGLP) and Strengthen Total Quality Management System.



**Table 1: Six Days Residential Training Programme for “Training of Trainers for Strengthening of Blood Services” in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health & Family Welfare, Government of India.**

S. No.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state of	Duration		No. of Participants
		From	To	
1.	Madhya Pradesh	10-06-2019	15-06-2019	37
2.	Telangana	29-07-2019	03-08-2019	39
3.	Uttarakhand	26-08-2019	31-08-2019	31
4.	Uttar Pradesh	16-09-2019	21-09-2019	27
5.	Telangana	16-12-2019	21-12-2019	40
6.	Maharashtra	20-01-2020	25-01-2020	32
7.	Chhattisgarh	03-02-2020	08-02-2020	35
8.	Uttar Pradesh	02-03-2020	07-03-2020	22
			<b>Total</b>	<b>263</b>

**4.2 Training of Graduate & Post Graduate Students from various Universities at NIB under “National Skill Development & Hands on- Training on Quality Control of Biologicals” programme:** NIB in line with National Skill Development programme under “Pradhan Mantri Kaushal Vikas Yojana (PMKVY)” provided Hands-on Training on “Quality Control of Biologicals”

for M.Sc. Biotechnology, Biochemistry and Microbiology students from Bastar University, Sant Gahira Guru University, Vinoba Bhave University, Kumaun University, Hemvati Nandan Bahuguna Garhwal University, Bodoland University, Motiram Baburam Government Post Graduate College, Kumaun University Campus Bhimtal, Central University of Kashmir, Guru Ghasidas

University, University of Jammu, Tezpur University, Mizoram University, Himachal Pradesh University, Guwahati University, Central Research Institute, Kasauli and M. Pharma students of Delhi Pharmaceutical Sciences and Research University and NIPER Hyderabad.

The objective of this training Programme is to develop and enhance analytical skills and technical knowledge of M. Sc. Biotechnology, Microbiology & Biochemistry students through Hands-on Training in Quality Control of Biologicals including Bio therapeutics, Diagnostics and Vaccines

in NABL accredited and CDL notified laboratories.

The training covers techniques used in quality evaluation like HPLC, Electrophoresis, ELISA, Bacterial Endotoxin Testing, Transfusion Transmitted Infection testing, Blood Serology, Cell culture aseptic handling, sub culturing and maintenance, cell line based potency assays, animal handling, use of laboratory animals etc. in Quality Control testing of Biologicals performed in various labs of NIB and to create awareness about Global scenario of biological testing.



**Table 2: Trainings in line with “National Skill Development & Hands on – Training on Quality Control of Biologicals” programme under Pradhan Mantri Kaushal Vikas Yojana (PMKVY**

S. No.	National Skill Development and Hands on Training in Quality control of Biologicals for Post Graduate students of	Duration		No. of Participants
		From	To	
1.	Bastar University and Sant Gahira Guru University Surguja, Chhattisgarh	01-04-2019	12-04-2019	27
2.	Vinoba Bhawe University, Jharkhand	22-04-2019	03-05-2019	30
3.	Delhi Pharmaceutical Sciences and Research University, Delhi	03-06-2019	14-06-2019	36
4.	National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad	24-06-2019	05-07-2019	30
5.	Kumaun University, Uttarakhand & Hemvati Nandan Bahuguna Garhwal University, Uttarakhand	22-07-2019	02-08-2019	30

S. No.	National Skill Development and Hands on Training in Quality control of Biologicals for Post Graduate students of	Duration		No. of Participants
		From	To	
6.	Bodoland University, Assam and Motiram Baburam Government Post Graduate College, Uttarakhand	23-09-2019	04-10-2019	31
7.	Kumaun University Campus Bhimtal, Uttarakhand	04-11-2019	15-11-2019	27
8.	Central University of Kashmir, Jammu and Kashmir	18-11-2019	29-11-2019	27
9.	Guru Ghasidas University, Chhattisgarh	09-12-2019	20-12-2019	31
10.	University of Jammu, Jammu & Kashmir and Tezpur University, Assam	06-01-2020	17-01-2020	31
11.	Mizoram University, Mizoram and Himachal Pradesh University, Himachal Pradesh	27-01-2020	07-02-2020	32
12.	Guwahati University, Assam and Central Research Institute, Kasauli	17-02-2020	28-02-2020	29
			<b>Total</b>	<b>361</b>

The following lectures as mentioned in Table 3 were delivered by NIB faculties during the above mentioned training programmes:

**Table 3: Lectures delivered by NIB faculties for National Skill Development training programmes for MSc Biotechnology/ Biochemistry/ Microbiology/ M. Pharm students**

S. No.	Topic	Name of the speaker
1.	NIB Overview	<b>Dr. Reba Chhabra,</b> Director I/c
2.	Introduction to Biologicals	<b>Ms Sudha V. Gopinath,</b> Scientist Grade -III, Head Training Unit <b>Ms. Shalini Tewari,</b> Scientist Grade -III, Head CDKL
3.	GLP Regulations: Good Laboratory Practices- pre clinical research & drug development	<b>Dr. Achla Prasad,</b> DD (QC) -T & AF
4.	Biosafety practices in Biomedical laboratories and disposal of Biomedical waste	<b>Dr. Suresh,</b> Scientist Grade -III, AF
5.	Clean Room Procedure Applicable For Biologicals Products	<b>Dr. D. Roy,</b> Consultant (Regulatory) & Former DDC (I), CDSCO
6.	Challenges in QC of Biosimilar	<b>Mr. Subhash Chand,</b> Scientist Grade -III, TMA & DQM
7.	Haemovigilance Program of India, software introduction and Case Studies	<b>Dr. Akanksha Bisht</b> Scientist Grade -II & Head- HvPI

S. No.	Topic	Name of the speaker
8.	Laboratory Quality Management of Systems (LQMS)	<b>Dr. J. P. Prasad,</b> Scientist Grade -I & Quality Manager
9.	Preparation of National Reference Standards	<b>Dr. Richi V Mahajan</b> Junior Scientist
10.	Artificial Intelligence in Bioinformatics: Case Studies	<b>Mr. P.S. Chandranand,</b> Junior Scientist- Bioinformatics
11.	Application of recombinant DNA Technology in Biopharmaceuticals	<b>Dr. Ratnesh Kumar Sharma</b> Scientist Grade-II, Head TAL
12.	Statistics in Health Research	<b>Dr. R.J. Yadav,</b> Consultant
13.	Molecular Basis of Diagnosis	<b>Dr. Harish Chander</b> Scientist Grade -I, Head IDK & MDL

Specific lectures related to laboratories are given by the respective Laboratory Heads

#### 4.3 Training of Graduate/Post Graduate Students from various Universities.

The institute provides 4 to 8 weeks training programme and 3 to 6 months project work in Quality Control of Biologicals in various NIB laboratories to Graduate/ Post Graduate Students of various Universities and Institutes. The training on various analytical platform

makes them proficient, help in their future research endeavours and enable them to get good job opportunities.

**Table 4: List of summer training/ project work conducted at NIB, NOIDA.**

S. No.	Trainings	Duration		No. of Participants
		From	To	
1	Summer Training / Project work of Post Graduate/ Under Graduate students from Life Sciences, Biotechnology, Biochemistry, Microbiology, Pharmacy etc.	April, 2019	March, 2020	89

Details are given in Table 5:

**Table 5: Details of summer training/ project work conducted at NIB, NOIDA.**

S. No	Title	Date		Participant details	Laboratory
		From	To		
1	Detrition of Purity of Human Albumin solution in relation to total protein content composition and monomer content	21.01.2019	05.04.2019	Amity University, Noida	BPL

S. No	Title	Date		Participant details	Laboratory
		From	To		
2	Method validation of a Therapeutic Monoclonal Antibody by Peptide Mapping	21.01.2019	05.04.2019	Amity University, Noida	TMA
3	Method validation for the purity and identification of therapeutic monoclonal antibodies using Capillary Electrophoresis	21.01.2019	05.04.2019	Amity University, Noida	TMA
4	Basics of animal cell culture technology and comparative analysis potency testing of Anti-D monoclonal antibody by agglutination method and flow cytometry	21.01.2019	05.04.2019	Amity University, Noida	TMA
5	Quality Evaluation of Bacillus Calmette Guerin(BCG) Vaccine by determination of count of viable units	21.01.2019	08.04.2019	Jiwaji University	Vaccine
6	Quality Evaluation of Bacillus Calmette Guerin(BCG) Vaccine by determination of count of viable units	21.01.2019	08.04.2019	Amity University	Vaccine
7	Comparison of results for Potency Parameter using Different Diluents	04.02.2019	30.04.2019	Jiwaji University	BRL
8	Standardization and Validation of Varicella Vaccine by In- vitro Microtitration Assay	01.01.2019	03.05.2019	Chandigarh University	Vaccine
9	Standardization of Quality Control Test Parameters of Urokinase Injection	28.06.2018	03.05.2019	NIPER, Guwahati	EHL
10	Determining interference in Plasma Derived products by performing Bacterial Endotoxin Test for Interfering factors as per Indian Pharmacopoeia 2018	28.06.2018	03.05.2019	NIPER, Guwahati	EHL
11	Determination of Reactivity Status of Human Plasma Samples for HBsAg on Various Diagnostic Platforms	04.02.2019	13.05.2019	Jiwaji University	IDKL

S. No	Title	Date		Participant details	Laboratory
		From	To		
12	Inhibition of Proliferation Assay of anti Her -2 Monoclonal Antibody (Pertuzumab) using Breast Cancer cell line	18.12.2019	15.05.2019	Amity University	TMA
13	Bacterial Endotoxin and Interference of Biotherapeutics	18.12.2018	15.05.2019	Amity University	EHL
14	Assessing the Stability of Monoclonal Antibodies using Real-Time and Accelerated Stability Study	07.01.2019	20.05.2019	Gautam Buddha University	TMA
15	Implementation of Laboratory Quality Management System with respect to ISO: 107025 and Certain Parameters for Validation of Laboratory Reference Method of Glucose Estimation	01.01.2019	30.05.2019	Gautam Buddha University	BKL
16	Preparation of In-House Reference Standard for Rituximab CDC Assay	01.01.2019	28.05.2019	Punjab Technical University	TMA
17	Identification Of Filgrastim (G-CSF) Using Analytical Techniques: SDS-PAGE & HPLC	11.02.2019	17.05.2019	Jiwaji University, Gwalior	RPL
18	Standardization and Validation of Varicella Vaccine (By in-vitro Microtitration Method)	15.01.2019	07.06.2019	ITS Institute of Health & Allied science	VVL
19	Comparative study to check the viability of cryopreserved red blood cells when thawed and resuspended in Alsever's solution for a period of four weeks	15.12.2018	14.06.2019	Banasthali University	BRL
20	Determination of Purity and Potency of Recombinant Human Erythropoietin	17.12.2018	14.06.2019	Banasthali University	RPL
21	Potency, Identity and Purity Determination for Quality Control Testing of Insulin Glargine	17.12.2018	14.06.2019	Banasthali University	RPL



S. No	Title	Date		Participant details	Laboratory
		From	To		
22	Preparation of performance panel for HIV diagnostics using various Immunoassay Methodologies and PCR	17.12.2018	17.06.2019	Banasthali University	IDK & MDL
23	Purity of Filgrastim (GCSF) using SDS- PAGE, RP- HPLC & SE- HPLC	17.12.2018	17.06.2019	Banasthali University	RPL
24	Basic Cell Culture Techniques in Quality Control of Vaccines	20.05.2019	19.06.2019	Amity University	Vaccine
25	Basic Cell Culture Techniques in Quality Control of Vaccines	22.05.2019	21.06.2019	Gautam Buddha University	Vaccine
26	Aggregates analysis of the Monoclonal Antibody by size Exclusion Chromatography (SEC – HPLC)”	17.05.2019	24.06.2019	Kalinga institute of Industrial Technology, Bhuwneshwar	TAL
27	Quality Control Testing Of Human Albumin Using Different Analytical Parameters	27.05.2019	27.06.2019	Gautam Buddha University	BPL
28	Grouping, Sub-Grouping, Rh- Phenotyping And Quality Control Of Blood Grouping Reagents	03.06.2019	28.06.2019	Amity University	BRL
29	Basic Cell Culture Techniques in Quality Control Testing of Vaccines	15.05.2019	28.06.2019	Banasthali University	Vaccine
30	Basic Cell Culture Techniques in Quality Control Testing of Vaccines	15.05.2019	28.06.2019	Banasthali University	Vaccine
31	Analytical characterization of Monoclonal Antibody sample using CE-SDS	15.05.2019	30.06.2019	Chandigarh University	TMA
32	Comparative Analysis of Bacterial Endotoxin Test (BET) Qualitative (Gel Clot) Vs. Quantitative (Kinetic Chromogenic Assay) for Insulin Analogue-Insulin Lispro	07.01.2019	28.06.2019	Amity University	RPL
33	Concepts in Laboratory Quality Management System and Certain Quality Control Testing Protocols	27.05.2019	27.06.2019.	Gautam Buddha University	BKL

S. No	Title	Date		Participant details	Laboratory
		From	To		
34	Test for Identification of Monoclonal Antibody Sample by Peptide Mapping using Reverse Phase Chromatography	27.05.2019	27.06.2019	Gautam Buddha University	TMA
35	Sequence Alignment, Phylogenetic Analysis, Structure Visualization and Homology Modelling of Human Insulin, with applications of Cloud Computing and IoT in Diabetes Management	27.05.2019	26.06.2019	Amity University	Bioinformatics
36	Development and Validation of ELISA Method for Determination of Potency In Tetanus Immunoglobulin	17.12.2018	14.06.2019	Banasthali University	BPL
37	Standardization of Quality Control Test Parameters of Idursulfase	19.12.2018	19.06.2019	Banasthali University	EHL
38	Molecular characterization of Plasma Sample for Hepatitis – B Virus (HBV) infection	20.05.2019	28.06.2019	Banasthali University	IDK & MDL
39	Comparison of Different Immunoassay Methodologies	03.06.2019	28.06.2019	Gautam Buddha University	IDK & MDL
40	Basic animal cell culture technique, revival, sub-culturing, growth kinetics, cryopreservation of adherent and suspension cells	03.06.2019	02.07.2019	SRMIST- Tamil Nadu	TMA
41	Comparative analysis of Conventional Streptokinase and its recombinant form	28.05.2019	28.06.2019	Gautam Buddha University	Bioinformatics
42	Molecular characterization of Plasma Sample for Human Immunodeficiency Virus (HIV) Infection	17.05.2019	28.06.2019	Banasthali University	IDK & MDL
43	Study of Conventional and Recombinant Growth Hormone using Bioinformatics Tools	03.06.2019	28.06.2019	Gautam Buddha University	Bioinformatics

S. No	Title	Date		Participant details	Laboratory
		From	To		
44	Analytical characterization of Monoclonal Antibody sample using CE-SDS	03.06.2019	05.07.2019	CCS University	TMA
45	To design the structure based inhibitor of Ubiquitin ligase TRIM 32 that is involved in muscle loss	29.05.2019	02.07.2019	Gautam Buddha University	Bioinformatics
46	Identification of Filgrastim (G-CSF) Using Analytical Technique : SDS Page	11.06.2019	30.06.2019	Banasthali University	RPL
47	Determination of Total PRP (Polyribosyl Ribitol phosphate) & Free PRP Content in Hemophilus Influenzae type -b (Hib) TT Conjugate Vaccine	11.06.2019	05.07.2019	Banasthali University	Vaccine
48	Comparative Study of ELISA and RAPID Based Immunodiagnostic kits used for Detection of Anti - HCV	03.06.2019	02.07.2019	Banasthali University	IDK & MDL
49	Determination of protein concentration of velaglucerase	27.05.2019	05.07.2019	Amity University	EHL
50	Comparison of result for potency parameter of Anti-A, Anti-B, Anti-D (IgM+ IgG) and Anti-D (IgM) blood grouping reagents near expiry and after their specified expiry over the period of sixteen Week	25.01.2019	04.07.2019	Dr. B.R. Ambedkar University Agra	BRL
51	Concepts in Laboratory Quality Management System and Certain Quality Control Testing Protocols	27.05.2019	08.07.2019	Jaypee Institute of Information Technology	BKL
52	Comparative Study of RAPID, ELISA and CLIA Based Immunodiagnostic Kits Used for Detection of HBsAg	11.06.2019	10.07.2019	Banasthali University	IDK & MDL
53	Various Methods of Protein Quantification and Protein Profiling Used in Quality Control of Allergen Products	10.06.2019	10.07.2019	Amity University	ATL

S. No	Title	Date		Participant details	Laboratory
		From	To		
54	Various Method of Protein Estimation and Protein Profiling Used in Quality Control of Allergen Products	11.06.2019	10.07.2019	Hindustan College of Science & Technology Mathura	ATL
55	Quality Control Testing of Human Albumin Using Different Analytical Parameters	11.06.2019	10.07.2019	Gautam Buddha University	BPL
56	Determination of IGA Content in Human Normal Intravenous (IGIV) Immunoglobulins By Using Different Kits	14.01.2019	14.07.2019	Institute of Management studies, Ghaziabad	BPL
57	Basic Animal Cell Culture Techniques: Revival, Sub-culturing, Growth Kinetics, Cryopreservation of Adherent & Suspension Cells	03.06.2019	12.07.2019	Jaypee Institute of Information Technology	TMA
58	Validation of Anti-Complementary Activity using in-vitro Complement Obtained from Pool of 10 Guinea Pig Complement and its Comparison with Kit Methods	15.01.2019	01.07.2019	Chandigarh University	BPL
59	Quality Control Testing of Human Albumin	27.05.2019	15.07.2019	Banaras Hindu University	BPL
60	Quality Control Testing of Human Immunoglobulin	27.05.2019	17.07.2019	Banaras Hindu University	BPL
61	Technical Parameters for Quality Control Testing of Human Albumin and Immunoglobulin	27.05.2019	17.07.2019	Banaras Hindu University	BPL
62	In-vivo testing of Human Normal Immunoglobulin (Gammaglobulin) through Rabbit Pyrogen Test and Abnormal Toxicity Test	11.06.2019	11.07.2019	Amity University	AF
63	Molecular Characterization of Plasma Sample for Hepatitis –C Virus (HCV) Infection	20.05.2019	21.06.2019	Gautam Buddha University	IDK & MDL
64	Protein Estimation and Protein Profiling in Quality Control of Allergen Products	25.01.2019	23.07.2019	Dr. B.R. Ambedkar University Agra	ATL

S. No	Title	Date		Participant details	Laboratory
		From	To		
65	Determination of Protein Composition in Albumin by Horizontal Electrophoresis using Different Buffers	25.06.2019	25.07.2019	Hindustan College of science & technology Mathura	BPL
66	Quality Control Testing Parameter (Repeatability) for Blood Glucose Test Strips and Method Validation Parameters of Laboratory Reference Method for Glucose	25.06.2019	25.07.2019	Raja Balwant Singh Engg. Technical Campus	BKL
67	Characterization of Serological Cross Reactive Plasma Samples of HIV, HBV & HCV by Nucleic Acid Test Method	25.01.2019	25.07.2019	Dr. B.R. Ambedkar University Agra	IDK & MDL
68	Identification of Erythropoietin using Analytical Technique: SDS-PAGE Followed by Immunoblotting	11.06.2019	30.07.2019	CCS University	RPL
69	Grouping, Subgrouping, Phenotyping, Cryopreservation Techniques and Quality Control of Blood Grouping Reagents	01.07.2019	30.07.2019	Assam Down Town University	BRL
70	Grouping, Subgrouping, Phenotyping, Cryopreservation Techniques and Quality Control of Blood Grouping Reagents	01.07.2019	30.07.2019	Assam Down Town University	BRL
71	Determination of Protein Concentration in Peg IFN $\beta$ 1a by reverse Phase HPLC	01.07.2019	30.07.2019	Assam Down Town University	RPL
72	Determination of High Molecular Weight Proteins (HMWP) Content in Peg Interferon $\beta$ 1a Sample	01.07.2019	30.07.2019	Assam Down Town University	RPL
73	Evaluating the Safety of Human Albumin by using in-vivo Quality Control Tests as per Indian Pharmacopoeia 2018	03.06.2019	16.07.2019	Jaypee Institute of Information Technology	AF

S. No	Title	Date		Participant details	Laboratory
		From	To		
74	Evaluating the Safety of Tetanus Immunoglobulin I.P. by Using in-vivo Quality Control Tests as per Indian Pharmacopoeia 2018	03.06.2019	16.07.2019	Jaypee Institute of Information Technology	AF
75	Potency, Identity and Related Proteins determination for Quality Control Testing of Human Insulin	20.06.2019	06.08.2019	NIPER-Mohali	RPL
76	Quality Evaluation of Vaccines by determining PRP content & Antimicrobial Preservative	20.06.2019	06.08.2019	NIPER-Mohali	Vaccine
77	Potency, Identity and Related Proteins determination for Quality Control Testing of Human Insulin	11.06.2019	31.07.2019	Jaypee Institute of Information Technology	RPL
78	Potency Assay of Anti TNF Alpha Antibody and Basic Animal Cell Culture Techniques	20.05.2019	19.07.2019	IIT-Delhi	TMA
79	Determination of Reactivity Status of HBsAg Plasma Samples Using Various Techniques	24.06.2019	06.08.2019	NIET Meerut	IDK & MDL
80	Particulate Matter Testing in Insulin Analogue: Insulin Degludec	11.06.2019	25.07.2019	GLA University	RPL
81	Comparison of Granulocyte-colony stimulating factor (G-CSF) and Recombinant Granulocyte-colony stimulating factor (rG-CSF) using bioinformatics tools	28.05.2019	25.06.2019	Gautam Buddha University	Bioinformatics
82	Identification of Erythropoietin using Analytical Technique: SDS-Page Followed by Immunoblotting	03.06.2019	30.08.2019	CCS University	RPL
83	Bacterial Endotoxin Test (BET) Qualitative (Gel Clot) and Quantitative (Kinetic Chromogenic Assay) for Insulin Analogue Insulin Lispro	03.06.2019	30.08.2019	CCS University	RPL
84	Quality Control Parameters for Allergen Extracts	01.07.2019	22.10.2019	NIMT Institute of Medical & Paramedical sciences	CDKL



S. No	Title	Date		Participant details	Laboratory
		From	To		
85	Quality Control Parameters for Allergen Extracts	01.07.2019	22.10.2019	NIMT Institute of Medical & Paramedical sciences	CDKL
86	Quality evaluation of velaglucerase alfa by western blot and activity assay	01.07.2019	22.10.2019	NIMT Institute of Medical & Paramedical sciences	EHL
87	In-Vitro Techniques for Diagnosis of Transfusion Transmitted Infectious (TTI) Markers: HIV, HCV, HBsAg and Syphilis	20.05.2019	08.07.2019	Gautam Buddha University	IDK & MDL
88	“Basic Animal cell culture techniques and potency assay of Anti TNF alpha mAb sample	08.07.2019	08.01.2020.	Shoolini University	TAL
89	Basic Animal cell culture techniques: Revival, Subculturing, Growth Kinetics, Cryopreservation of Adherent Cells and potency assay of Anti TNF alpha mAb sample	08.07.2019	08.01.2020.	Shoolini University	TAL

#### 4.4 Training to Manufactures/ Stakeholders at Animal facility, NIB:

Topic	Duration	No. of trainees & Trainee details
Ethics, Regulations and Basic Bio Methodologies in Laboratory Animals used for Research and Quality Control Testing	13 <sup>th</sup> to 17 <sup>th</sup> May 2019	4 M. Pharm. of Raj Kumar Goel Institute of Technology, AKTU, Ghaziabad, Noida
Ethics, Regulations and Basic Bio Methodologies in Laboratory Animals used for Research and Quality Control Testing	14 <sup>th</sup> to 18 <sup>th</sup> October, 2019	20 Pharmacology students of NIET Greater Noida, Uttar Pradesh
Ethics, Regulations and Basic Bio Methodologies in Laboratory Animals used for Research and Quality Control Testing	14 <sup>th</sup> to 25 <sup>th</sup> October, 2019	2 Staff of Galgotias University, Greater Noida, Uttar Pradesh

Animal Experimentation	09 <sup>th</sup> to 13 <sup>th</sup> March, 2020	<b>16 Students + 2 Staff + 1 Faculty</b> Biochemistry Department from University of Delhi South-Campus
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#### 4.5 Expert Committee meeting on Training activities:

To advise on training programmes for Skill Development for Life Sciences and Pharmacy students from various Universities/ Institutions across the country in the area of Quality Control and Quality Management System of Biologicals including the Haemovigilance Programme of India, third Meeting of the Expert Committee was held under the Chairmanship of Prof (Dr.) C. K. Kokate, Former, Vice Chancellor of

Kakatiya and KLE Universities and Former President, Pharmacy Council of India, on 27<sup>th</sup> April 2019 at NIB-NOIDA. The objective of the meeting was to review the progress of the training programmes and also to advise various strategies for value addition and effectiveness of this programme with the aim to provide qualified manpower for indigenous Biopharmaceutical industry. Special invitees and representatives from Biopharmaceutical industry as given in Table 5:

**Table 5:**

1.	Prof. (Dr.) C. K. Kokate	Former, Vice Chancellor of Kakatiya and KLE Universities and Former President, Pharmacy Council of India
2.	Dr. USN Murty	Director, NIPER, Guwahati
3.	Dr. Pradeep Das	Scientist G & Director-Rajendra Memorial Research Institute of Medical Sciences, Patna
4.	Dr. J.A.S. Giri	Former President Indian Pharmaceutical Association, Hyderabad
5.	Mr. Suresh Khanna	Honorary Secretary-Indian Pharmaceutical Association and Former President-Karnataka Drugs and Pharmaceutical Manufacturer's Association, Bengaluru
6.	Dr. A. Ramkishan	Dy. Drugs Controller (India), CDSCO, Eastern Zone, Kolkata
7.	Mohd. Yunis	Asst. Drugs Controller (Kashmir division), Drugs & Food Control Organization, Kashmir
8.	Dr. Achla Prasad	Scientist-I & I/c- DD (QC)- TAF & Trg, NIB
9.	Ms. Shalini Tewari	Scientist-III & Head Allergen Testing Laboratory, NIB
10.	Ms. Sudha V. Gopinath	Scientist-III & Head Blood Product Laboratory, & Training unit, NIB



*Expert Committee meeting held at NIB*

Prof (Dr.) C. K. Kokate, Chairman appreciated NIB for its vision to train Pharmacy and Biotechnology Students of the country to ensure availability of readymade trained manpower to industry and contributing to capacity building in the area of Biologicals. Various recommendations were put forward by the members to strengthen the skill development programmes and also to contribute to development of industry-ready work force for boosting indigenous manufacturing of Biologicals.

**4.6 Fourth Expert Committee meeting on Training activities:** The 4<sup>th</sup> Meeting of the Expert Committee to advise on training programmes for Skill Development for Life Sciences and Pharmacy students from various Universities/ Institutions across the country in the area of Quality Control and Quality

Management System of Biologicals including the Haemovigilance Programme of India was held under the Chairmanship of Prof (Dr.) C. K. Kokate, Former Vice Chancellor of Kakatiya and KLE Universities and Former President, Pharmacy Council of India, on 5<sup>th</sup> July 2019 at M/s Hetero Drugs, Hyderabad. The objective of the meeting was to discuss & finalize the policies with respect to the summer training/ winter training and project work for strengthening of academic activities of NIB and also to explore feasibility of establishing a dedicated Training Center with all basic facilities and required equipment for developing skilled manpower in the area of quality control testing of in- vitro diagnostic kits, biopharmaceuticals and Vaccines.

The following members/ officials attended the meeting:

**Table 6:**

1.	Prof. (Dr.) C. K. Kokate	Former, Vice Chancellor of Kakatiya and KLE Universities and Former President, Pharmacy Council of India
2.	Dr. Saranjit Singh	Head Pharmaceutical Analysis, NIPER- Mohali

3.	Dr. K. V. Leela	Professor, Dept. of Microbiology, Government Medical College and Member-Governing Council, The Tamil Nadu Dr. MGR Medical University, Chennai
4.	Dr. J.A.S. Giri	Former President Indian Pharmaceutical Association, Hyderabad
5.	Mr. Suresh Khanna	Honorary Secretary-Indian Pharmaceutical Association and Past President-Karnataka Drugs and Pharmaceutical Manufacturer's Association, Bengaluru
6.	Dr. A. Ramkishan	Dy. Drugs Controller (India), CDSCO, Eastern Zone, Kolkata
7.	Mohd. Yunis	Asst. Drugs Controller (Kashmir division), Drugs & Food Control Organization, Kashmir
8.	Dr. Reba Chhabra	Deputy Director (QC), NIB
9.	Ms. Shalini Tewari	Scientist-III & Head Allergen Testing Laboratory & Member Training Unit , NIB
10.	Ms. Sudha V. Gopinath	Scientist-III & Head Training Unit & Member Secretary, NIB
11.	Mr. PS Chandranand	Jr. Scientist, Bioinformatics Laboratory & Member Training Unit, NIB

#### 4.7 Training on Use of Artificial Intelligence in Health services

Training by Mr. Shishir Kumar “Director–

Healthcare, Global Solutions & Innovation, Hitachi Consulting for NIB Scientists/ Officials on Use of Artificial Intelligence in Health services at NIB on 25<sup>th</sup> June, 2019.





#### 4.8 Show Case of Learning/ Training Support Platform [KLSP]

Presentation by Ankur Gupta for demonstration of learning/ Training support platform [KLSP] tool of HITACHI MGRM NET at NIB, on 5<sup>th</sup> August, 2019. The demonstration was conducted for M-star Learning Support Platform developed by

the firm. It is a comprehensive platform that enables development of course curriculum creation of certification based program and also supports institution function by providing admissions, and others, including performance assessment and system enhancement which strengthens the training management.



**4.9 Meeting to review guidelines for summer/ winter training programmes:** A meeting with Dr. Saranjit Singh, (Head Pharmaceutical Analysis, NIPER Mohali & Expert Committee member) on 24<sup>th</sup> September, 2019 at NIPER, Mohali was convened to review the proposed guidelines on Summer- Winter Training Programs & Four-Six Months Project work undertaken by NIB for students from various Universities. The team led by Dr Reba Chhabra, DD (QC) Diag. & Trg. and members Ms Sudha V Gopinath Scientist-III & Head Training Unit and Ms. Shalini Tewari Scientist-III & Head Clinical Kit Diagnostic

Laboratory visited NIPER, Mohali for this purpose.

**4.10 Publication Skill Developmental Program:** NIB hosted a One-Day Publication Skill Developmental Program for Scientists and research staff, on 3<sup>rd</sup> September 2019, organised by Dr. Bikash Medhi (Professor & Additional Medical Superintendent, (AMS) & his team. The said scientific event was conducted with the basic aim of updating NIB Scientists about the recent standards of publication writing and skill development.

#### 4.11 One-day visit of pharmacy students from Kerala:

NIB hosted One-day Lab visit of 21 pharmacy students along with 02 faculties from College of Pharmaceutical Sciences, Govt. T.D



Medical College, Alappuzha, Kerala on 30<sup>th</sup> September, 2019. The students were given the basic overview of pharmacy related laboratories activities functional here at NIB, and interacted with concerned scientists



**4.12 Two days Pipette leak test workshop for NIB Scientific staff members:** Training unit facilitated Two-Days Scientific Event including Technical Presentations and demonstration of Pipette leak testing organised by M/s BRAND Scientific Equipment Pvt. Ltd. for NIB Scientific staff members, on 05<sup>th</sup> and 06<sup>th</sup> Nov. 2019, here at NIB.



**4.13 One-day visit of pharmacy students from Kerala on 3<sup>rd</sup> February 2020:** NIB hosted One-day Lab visit of 42 B. Pharm students along with 02 Faculty members from College of Pharmaceutical Sciences, (Govt. Medical College, Kottayam, Kerala) on 3<sup>rd</sup> February 2020. The students were given the basic overview of NIB and visited various laboratories, and interacted with concerned scientists



## 5. Visit of delegates:

I. **Visit of Prof Ramesh Goyal, Vice Chancellor, DPSRU:** Facilitated the visit of Prof Ramesh

Goyal Vice Chancellor of DPSRU and interactive session with scientists of NIB and students of National Skill Development



and Hands on Training in Quality control of

Biologicals on 6<sup>th</sup> June 2019.



II. **Visit of Padma Bhushan Prof. Dr. N.K. Ganguly:** Facilitated visit of Padma Bhushan Prof. Dr. N.K. Ganguly Former Director General ICMR and interactive session with students of National Skill Development

and Hands on Training in Quality control of Biologicals from Delhi Pharmaceutical Sciences and Research University on 3<sup>rd</sup> June 2019.



III. **Visit of Ms. Rita Teaotia, IAS:** Facilitated the visit of Ms. Rita Teaotia Chairperson – FSSAI, Ministry of Health & Family Welfare

to NIB and interaction with NIB scientists on 20<sup>th</sup> June, 2019



IV. **Visit of Dr. V. K. Subburaj, IAS, Member:** Facilitated the visit of Dr. V. K. Subburaj (IAS) Member, National Company Law Tribunal and Former Secretary, Department

of Pharmaceuticals, Government of India, visited NIB on 31<sup>st</sup> August 2019, and interacted with the scientists, students and other staff members





V. **Visit of Hon'ble Health Ministers and WHO- SEAR Dignitaries:** Facilitated the visit of Hon'ble Health ministers of Bangladesh and Bhutan and few WHO-SEAR dignitaries visited NIB on 20<sup>th</sup> November 2019. The team visited different labs as well as other facilities of NIB and also interacted with the scientific faculty and other senior



officials. The visit was facilitated by Ministry of Health & Family Welfare (Govt. Of India), coordinated by Mr. Rajiv Kumar (Section Officer-Drugs).

- **Zahid Maleque, Hon'ble Health Minister, Bangladesh**
- **Lyonpo Dechen Wangmo, Hon'ble Health Minister, Royal Government of Bhutan**



VI. **Visit of Dr. Dharmendra Singh Gangwar, IAS:** Facilitated the visit of Dr. Dharmendra Singh Gangwar-IAS (Additional Secretary & Financial Advisor- Ministry of Health &

Family Welfare, Govt. of India), visited NIB on 24<sup>th</sup> January 2020, and interacted with the scientists, and other officials.



VII. **Visit of International Delegates from 20 Countries to NIB:** NIB hosted a Laboratory visit of 31 International Delegates from 20 countries, along with 02 NITS representative officials, on 25<sup>th</sup> February, 2020 from 2:00 PM - 5:30 PM. The delegates were given a presentation on the basic overview of NIB and visited various laboratories, and interacted



with concerned scientists. The said delegates were participating in 11<sup>th</sup> International Training Programme on "Competence and Management Systems of Laboratories" for developing countries being conducted under Indian Technical and Economic Cooperation (ITEC) Programme of Ministry of External Affairs, Government of India at NITS, Noida, India



## HAEMOVIGILANCE DIVISION

### 1. Name of Head:

Dr. Akanksha Bisht, Scientist Grade- II

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific staff:

Mr. Paras Jain, Junior Scientist

#### II. Name of Scientific staff:

Mr. Reetesh Kumar, Lab Technician

#### III. No (s). of Outsourced Staff: 04

### 3. Scientific Activities Undertaken

- a. Implementation and coordination of activities of Haemovigilance Programme of India (HvPI) is one of the mandate's of NIB as per its bye-laws 3.4.1 as approved in the 24<sup>th</sup> Governing Body meeting of NIB held under the Chairmanship of Secretary (Health & F.W.)/ Chairman, Governing Body of NIB on 12<sup>th</sup> Dec, 2014.
- b. 235 new blood centres have been enrolled under this programme during said financial year taking a total 1065 blood centres under this programme. National Institute of Biologicals has a web based reporting system for adverse transfusion reactions and donor reactions via indigenously developed software(s) Haemo-Vigil and Donor-Vigil. A total number of 11,418 Adverse Reaction Reports have been reported via Haemovigilance Software(s) during this financial year out of which 4,281 reports pertain to adverse blood transfusion reactions and 7,137 reports are attributed to reactions during blood donation.

### c. Publication(s)

An Article published as "Haemovigilance Programme of India (HvPI) : Elevation of Safe Blood Transfusion Practices in the Country" published in Journal of the Vivekananda Institute of Medical Sciences, 2019, besides bringing out biannual release of HvPI newsletter to disseminate information about HvPI to health care professionals & other stakeholders.

### 4. Training/ Workshop/ Conference Organized:

NIB under Haemovigilance Programme of India (HvPI) has organized 15 CMEs/ Workshops across the country & trained about 1638 participants which includes Blood bank officials, clinicians, nurses & blood bank technical staff so as to create awareness about the programme.

### 5. Participation in Training/ Workshop/ Conference:

Dr. Akanksha Bisht, Head- HvPI participated as a speaker at:-

- i. CME on Safe blood for all held on 30<sup>th</sup> September, 2019 at Max Super Specialty Hospital, Saket, New Delhi.
- ii. TRANSCON, 2019 held on 1<sup>st</sup> -3<sup>rd</sup> November, 2019 at Punjab Institute of Medical Sciences (PIMS), Jalandhar.
- iii. State level Kerala State AIDS Control Society (KSACS)- workshop on haemovigilance & EQAS held on 29.11.2019 at Thiruvananthapuram.



- iv. BLODCON, 2019 held on 26<sup>th</sup> -28<sup>th</sup> December, 2019 at Bangalore, Karnataka organized by Federation of Indian Blood Donors Organisations- (FIBDO) hosted by Sankalp India Foundation, Bangalore in association with National Blood Transfusion Council (NBTC), MoHFW, Government of India.
- v. CME on current trends & challenges in immunohematology & blood transfusion held on 20<sup>th</sup> February, 2020 at Deen Dayal Upadhyay Hospital, Hari Nagar Delhi.
- vi. 6<sup>th</sup> Asia Pacific Pharmacovigilance Training Course held on 24<sup>th</sup> February to 6<sup>th</sup> March 2020 organized by Indian Pharmacopoeia Commission, Ghaziabad.

- About 38 participants from eleven SEAR countries had participated in the said workshop.

#### Objective of the workshop

- To review the status of regional blood transfusion services (BTS) and implementation of WHO global strategy for blood safety.
- To discuss challenges/ gaps and success stories in strengthening blood transfusion services (BTS) and WHO global strategy for blood safety.
- To prepare a road map to bridge the gaps, strengthen the capacity (with emphasis on hemovigilance), and
- To leverage South-East Asia Regulatory Network for strengthening the quality control of diagnostics testing amongst laboratories.

## 6. Outstanding achievements of the Lab/ Division:

WHO Regional Workshop of National Focal Points of Blood Transfusion Services of 11 Member States of South-East Asia Region (SEAR) i.e. Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor Leste at NIB (19<sup>th</sup> - 22<sup>nd</sup> August, 2019).

- WHO Regional Workshop of National Focal Points of Blood Transfusion Services to Review Implementation of WHO Global Strategy of Safe Blood with an Emphasis on Hemovigilance was held from 19<sup>th</sup> - 22<sup>nd</sup> August, 2019 at National Institute of Biologicals, NOIDA. The participants were from 11 member states of South-East Asia Region (SEAR).



*Group Photograph*



*From Left to Right Dr. Reba Chhabra DD(QC), NIB, Dr. Aparna Singh Shah WHO-SEARO, Dr. Tjandra Yoga Aditama WHO-SEARO, Dr. Surinder Singh Director NIB, Dr. Yu Junping WHO Headquarter Geneva*





*Scientific Session*



*Visit to NIB Laboratories*



*Visit to Blood Bank*

## INFORMATION TECHNOLOGY DIVISION

### 1. Name of Head:

Ms. Sudha V.Gopinath, Scientist-III  
(04.01.2019 onwards)

### 2. Manpower in the Lab/ Division:

#### I. Name of Scientific staff:

Sh. Deepak Mahajan, Computer Officer

#### II. No(s). of Outsourced Staff: 03

### 3. Activities Undertaken:

- 3.1 The IT Division has drafted tender enquiries / online bidding through Govt. E-Marketplace such as Supply of toner cartridges, Desktop Computers, LaserJet Printers, Class III Digital Signature Certificate and Bio-metric Attendance System (BAS) etc. Supply order for supply of toner cartridges, Class III Digital Signature Certificate, and BAS had been awarded to L-1 bidders with the approval of the Competent Authority.
- 3.2 The IT Division has drafted tender enquiry for Operation & Non-Comprehensive Maintenance of Audio Visual System, Audio Video Conferencing, LED Display, All-in-One Computers and e-Podium installed at Conference Hall, Laboratory Block. The work has been awarded to L-1 bidder M/s. Purple Wave Infocom Pvt. Limited, New Delhi in December, 2019.
- 3.3 The Institute has implemented the e-Tendering Services of ITI Limited through its website <https://nib.euniwizarde.com> to make transparency in the tendering process as per Govt. guidelines.
- 3.4 IT Division has also looked after the work of installation and commissioning of Local Area Network in the Laboratory Block, Administration and Library Block. The work has been awarded by the Procurement Division to L-1 bidder M/s. Times IT Solution, New Delhi in July 2019. In addition, IT Division has also looked after the work of installation of Kramer Switcher, Receivers and Network Cabling in the Conference Hall, Laboratory Block for backup solution. The work has been awarded by the Procurement Division to L-1 bidder M/s. Edu Assessment Pvt. Limited New Delhi in April 2019.
- 3.5 The IT Division has implemented the Bio-metric Attendance System for regular as well as contractual staff of the Institute. The BAS has been managed by the IT Team and submitted monthly attendance report to Finance & Accounts Division.
- 3.6 The IT Division has drafted the specification for procurement of 43" LED TV for installation in Animal Facility, Clinical Diagnostic Kit Laboratory and Therapeutic Antibodies Laboratory. The said requirement has been awarded to L-1 bidder M/s. Purple Wave Infocom Pvt. Limited, New Delhi with the approval of the competent authority.
- 3.7 As per the directions of the National Informatics Centre, the Institute has successfully migrated the Institute's website from Shared Server to NIC National Cloud Server, National Data Centre, Shastri Park, Delhi.
- 3.8 The IT Division has also received the quarterly information from various

Laboratories / Divisions / Sections for updating the website of the Institute. The information has been compiled in html pages and reviewed by the Web Committee Members. The same has been updated with the approval of Web Information Manager and Competent Authority.

- 3.9 The IT Division has also managed to update the Intranet LAN Portal of the Institute. The information such as SOPs, Monographs, AMC records, Committees etc. received from Quality Management Unit has been updated time to time as per requirement.
- 3.10 The IT Division has also looked after the IT related services such as renewal of Comprehensive Annual Maintenance Contract of Desktop Computers, Servers, Routers, Laptops, Printers, Local Area Network and Network devices and other peripherals, Multi-functional Digital Photocopiers, Leased Line Connectivity from NIB to CGO, Complex and Shastri Park, PLA and Combistats Software, maintaining the Inventory Module as per requirement of the Institute.
- 3.11 The IT Division has also received tender enquires, corrigendum, tender extension date for hosting on NIB website and e-Publishing on Central Public Procurement Portal for wide publicity etc.
- 3.12 NIB is hosting several National and International meetings, Conferences, Workshops, Trainings and Academic activities for the past few years. The IT Division has also looked after the IT related arrangements in Conference Room, Meeting Room, Class Room and Bioinformatics Centre for the various training programmes and meetings held in the Institute. Beside this, IT Division

has also provided the technical support for arrangements of Telecon and online Webinars etc. held during the year.

- 3.13 IT Division has also received the Indents from Procurement Division for purchase of Desktop Computers, All-in-One PC, Laptop, MS Office Standard 2019, Toner Cartridges and Anti-Virus Software through Government e-Marketplace for the various Divisions / Sections of Institute. During the year, the IT Division has placed the contracts through Government e-Marketplace for the IT related hardware. The estimated expenditure incurred during the financial year on IT hardware is above Rs. 50.00 lakh.

**A. IT enabled services undertaken during the year 2019-2020 are given below:**

- 3.14 **Sample Tracking Invoice Generation Software:** The IT division is maintaining the in-house developed software for Invoice Generation against testing fees received for Quality Control Evaluation of all indigenously produced and imported biologicals products submitted by the manufacturers.
- 3.15 **Other Invoice Generation Software:** The IT division is maintaining the in-house developed software for generation of Other Invoice against payment received other than testing fees of samples such as Sale of Laboratory Animals to CPCSEA Registered Institutes and Reference Standards – Biotech Products, Old Newspapers & Magazines and e-Waste etc. Presently, the Invoice Generation Software's are being used by the Sample Receipt & Report Dispatch Unit and Finance & Account Division of the Institute.

## BIOINFORMATICS DIVISION

### 1. Name of Head

Mrs. Shalini Tewari, Scientist Grade III till 29.05.2019

Dr. Reba Chhabra, DD (QC) from 30.5.2019

Mrs. Sudha. V. Gopinath, Scientist Grade III from 06.12.2019.

### 2. Manpower in the Lab/ Division:

#### Name of Scientific Staff

Mr. P. S. Chandranand, Junior Scientist

### 3. Scientific Activities Undertaken:

3.1 Mr. P. S. Chandranand, Jr. Scientist, delivered a talk on “Increased adoption of emerging technologies like Artificial Intelligence & Robotics in, In-Vitro Diagnostics, in 5<sup>th</sup> international exhibition & conference on pharmaceutical and medical device industry, at Mahatma Mandir, Gandhinagar, Gujarat on 6<sup>th</sup> March 2020.



3.2 Mr. P.S. Chandranand, Jr. Scientist, is an online Expert Reviewer for National Biopharma Mission-BIRAC (NBM-BIRAC), request for proposals (RFP) under Enabling Indigenous Development of Technologies for Affordable Biomanufacturing, reviewed RFP 4, i.e. Develop IT platforms for quality management system in biopharmaceutical Industry. This RFP had FOUR proposals with regard to Laboratory Information Management Systems (LIMS) to be evaluated and reported back to NBM.

3.3 Mr. P.S.Chandranand, Expert member of DBT-Biotechnology Industry Research Assistance Council (DBT-BIRAC - FIRST-HUB) committee, a Facilitation Cell for the Start-ups/ innovators and for those who want to take up R&D in pharma and medical devices. From April 3<sup>rd</sup> onwards, the Committee meets on every Friday to provide NIB's point of view in technical guidance and inputs to start ups engaged in COVID-19 related diagnostic & therapeutic products, testing and standardization activities.

- 3.4 Mr. P.S.Chandranand, Jr. Scientist, Participated and provided suggestions during the “EXPERT DIALOG: Indigenous Manufacturing of Biomedical Devices enabled by Research and Ecosystem support” on 10th February, 2020 in Department of Biotechnology, New Delhi
- 3.5 Procurement portal has been designed and is lined up for necessary testing and validation for integration into the on-going LIMS project of the institute.
- 3.6 Procurement portal has been designed and is lined up for necessary testing and validation for integration into the on-going LIMS project of the institute.
- 3.7 Four post graduate students from Bodoland University (Assam) did their dissertation work in Bioinformatics Division on the following topics.
- a. Prediction of Multi-Epitope Vaccine towards potential development against Japanese Encephalitis Virus (JEV): An Immunoinformatics approach
  - b. Bioinformatic approaches to study the clinical strategy of chimeric antigen receptor T cell therapy
  - c. Evolutionary Study of Coagulation Factor VIII: A Bioinformatics Approach.
  - d. Sequence analysis of Human Immunodeficiency Virus-1 with the aid of comparative genomics in computational biology.



## ENGINEERING DIVISION

### Electro-Mechanical Engineering Works Undertaken:

The NIB campus specifically Laboratory & Animal House Building is complemented by various engineering services/ facilities/ installation to facilitate the day to day scientific activities. The detailed information about the various engineering works/ services/ facilities and installation undertaken during the Financial Year 2019-20 are as under:

1. Supply Installation, Testing & Commissioning of APFC relays, Capacitors, Contactors and repair maintenance of other accessories of Capacitor banks of NIB Noida.
2. Construction for setting up COVID 19 Lab, Gowning, Degowning and Sample Receipt Room, creation of negative pressure, HEPA filters & heating system in Room No. L0142 at ground floor of Lab Building.
3. Repair works of Centrifugal chiller, 750 Tr, M/s Carrier, USA make for HVAC system installed for Laboratory & Animal House building.
4. Administration of various electro-mechanical engineering services/ facilities installation of day to day operation and maintenance & repairing, which are provided/ installed in the various buildings/ areas of NIB Campus.

Apart from the above the Institute has finalized the services contracts for annual operation and maintenance contract, and AMCs/ CMCs of the following Engineering Services/ facilities and fixed scientific equipment during the financial year 2019-20:

i) Operation and Non Maintenance

contract for External & Internal services (Electrical).

- ii) Operation and comprehensive maintenance contract for fire-fighting system, water supply system, water softening plant system, neutralization system including centralized water softening plant of the Institute.
- iii) Operation and maintenance contract for CCTV Surveillance system and Access Control system installed in various building/ locations/ areas of the Institute.
- iv) Operation and maintenance contract for HVAC plant System including Window/ Split Cassette and package type AC units installed in various buildings of the Institute.
- v) Operation & maintenance of 3x2.8T/ Hr at 10.5kg/Sqcm Steam Generating Boiler including Economizers and allied accessories etc.
- vi) Operation and maintenance of 20 Nos. Walk-in-cold Rooms, Constant Humidity Chambers and Environment Rooms, installed in the Laboratory & Animal House Building.
- vii) Operation and maintenance contract for Sterilizers, Glass Washers, Glassware Dryers, Tunnel Washers and Case & Rack Washers installed in the Animal House facility of the Institute.
- viii) Operation and maintenance contract for centralized R. O. Plant system installed in the Laboratory & Animal House.
- ix) Repair and maintenance of the following engineering installation/ facilities/ fixed

scientific equipment under AMC/ CMC contract with OEM or their authorized service agency in India, which are installed in various buildings/ areas of the Institute namely are: Elevators/ Lifts, Centralized UPS system, Electrical appliances, LED Signage, Telecommunication/ EPABX system/ PRI lines services, Bio-Safety Cabinets & Laminar Air Flow Stations, Chemical Fume Hoods, Air Compressor ( Atlas Copco Make), Refrigerators and Bio-waste Disposal

- x) Operation and maintenance of Steam Sterilizers, Washers and other equipment of Steris, USA make installed in laboratory and animal house.
- xi) Operation and Non-comprehensive Maintenance for Fire Alarm/ Detection system & PA System, installed in the Laboratory & Animal House Building” at NIB Noida

### Major Civil works undertaken:

1. Up gradation of existing laboratory infrastructure for setting up COVID-19, sample testing laboratory, in a very short time span of 3-4 days, during nationwide lockdown.
2. Up gradation of existing Lab. for setting up Central Facility for Bioassay.
3. Refurbishing of Library ground floor for setting up Training Unit and IT Cell.
4. Implementation of Swachhta Action Plan in NIB, under which construction of new wash room for workers and replacement of conventional flushers with auto flushers in urinals.
5. Complete support & management of repairs, maintenance and trouble shooting in buildings (area of buildings more than 35000 Sqm.), services and Institute campus to ensure uninterrupted services in the Labs, Guest House, Hotel, Cafeteria, offices etc.
6. Addition & alteration works viz. construction of Store Room for Training Unit, shifting & resetting of Immuno Diagnostic Kit Lab, Project Lab, increase in capacity of meeting room in lab. Building, etc.
7. Monitoring & maintaining of controls, checks, systems and documentation for ISO 17025 and OHSAS 18001:2007
8. Award of fresh Annual Contract for Housekeeping & Cleaning services and providing banners, signage etc. in NIB Campus Noida.
9. Environmental monitoring and filing application for renewal of Consent to Operate (CTO) Air & Water, from UP, Pollution Control Board.
10. Increase in green cover by large scale plantation in NIB campus.
11. Management of annual service contracts viz. maintenance of horticulture, pest & rodent control services etc.
12. Coordination with external agencies CPWD, HSCC etc. for settlement of pending issues.
13. Coordinated condemnation committee proceedings leading to disposal of large quantities of scrap kept in NIB premises.
14. Preparation of Standard Operating Procedure (SOP) for mechanized cleaning of Sewers.
15. Logistic support during National Health Mission Trainings, Skill Development Trainings, Seminars, Meetings etc. conducted in NIB throughout the year.

## REPORT OF THE ADMINISTRATIVE WORK

### Head of the Administration:

Dr. Reba Chhabra, Deputy Director (Admin)

### 1. General Body of the Institute Composition of the General Body:

**Secretary, Health & Family Welfare**

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi.

**Chairperson**

**Secretary**

Department of Biotechnology,  
New Delhi

Member

**Secretary, DHR & DG, ICMR**

Ansari Nagar, New Delhi – 110029

Member

**Director General of Health Services,**

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi – 110011.

Member

**Additional Secretary (Health)**

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi – 110011.

Member

**Additional Secretary & F.A.**

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi – 110011.

Member

**Joint Secretary**

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi – 110011.

Member

**Drugs Controller General (India),**

Directorate General of Health Services,  
F.D.A. Bhawan, Kotla Road  
New Delhi - 110002.

Member

**Secretary**

Health & Family Welfare, H. Block Secretariat,  
Govt. of Andhra Pradesh,  
Hyderabad, Andhra Pradesh

Member

**Secretary**

Health & Family Welfare Department,  
Government of West Bengal,  
Writers Building, Kolkata.

Member

**Chairman**

Serum Institute of India Ltd.,  
212/2 Hadapsar,  
Pune - 411 028

Member

**Director**

Pasteur Institute of India,  
Coonoor – 643 103  
(The Neelgiris)

Member

**The Chairman-cum-Managing Director**

National Dairy Development Board,  
Anand, Gujrat.

Member

**Managing Director**

Haffkine Bio-Pharmaceutical Corpn. Ltd.,  
Acharya Donde Marg, Parel, Mumbai.

Member

**Director,**

NIB, NOIDA

Member Secretary

**Meeting of General Body**

The Meeting of the General Body was held on 11.03.2019

## 1. Governing Body of the Institute

Composition of the Governing Body:

**Secretary (Health & Family Welfare)**

Ministry of Health &amp; Family Welfare

Nirman Bhawan, New Delhi-110011

**Chairperson****Secretary (DBT), Govt. of India**

Block No.2, C.G.O. Complex

Lodhi Road, New Delhi – 110003.

Member

**Secretary, DHR & DG, ICMR**

Ansari Nagar, New Delhi – 110029

Member

**Director General of Health Services**

Directorate General of Health Services,

Nirman Bhawan, New Delhi- 110011.

Member

**Additional Secretary (Health)**

Ministry of Health &amp; Family Welfare

Nirman Bhawan, New Delhi – 110011.

Member

**Additional Secretary & F.A.**

Ministry of Health &amp; Family Welfare

Nirman Bhawan, New Delhi – 110011

Member

**Joint Secretary**

Ministry of Health &amp; Family Welfare,

Nirman Bhawan, New Delhi - 110011.

Member

**Drugs Controller General of India**

Directorate General of Health Services,

Nirman Bhawan, New Delhi- 110011.

Member

**Director,**

NIB, NOIDA

Member Secretary

**Meeting of the Governing Body**28<sup>th</sup> Meeting of Governing Body was held on 11.03.2019



## 2. Standing Finance Committees.

### Composition of the Standing Finance Committee:

#### Additional Secretary

Ministry of Health & Family Welfare,  
Nirman Bhawan,  
New Delhi

Chairperson

#### Addl. DG, ICMR or his nominee

Indian Council of Medical Research,  
Ansari Nagar, New Delhi - 110029.

Member

#### Joint Secretary

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi - 110011

Member

#### Drugs Controller General (I) or his nominee

(Not below the rank of Asstt. Drugs Controller (I))  
FDA Bhawan, New Delhi - 110002

Member

#### Director (IFD)

Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi - 110011.

Member

#### Director,

NIB, NOIDA

Member Secretary

### Meetings of the Standing Finance Committee:

- i. The 30<sup>th</sup> Meeting of Standing Finance Committee was held on 01.06.2019
- ii. The 31<sup>st</sup> Meeting of Standing Finance Committee was held on 05.11.2019

## 3. Promotions, Appointments/ MACPs made/ granted by the Institute during the year 2019-2020

### Promotion

S. No.	Name	Designation
1.	Dr. Reba Chhabra	Deputy Director (QC)
2.	Dr. Achla Prasad	Deputy Director (QC)

S. No.	Name	Designation
3.	Ms. Ajanta Sircar	Scientist Grade-II
4.	Shri J. P. Pant	Administrative Officer
5.	Shri P. K. Mohapatra	Administrative Officer

### Appointments

S. No.	Name	Designation
1.	Dr. Harish Chander	Scientist Grade-I
2.	Dr. Akanksha Bisht	Scientist Grade-II
3.	Dr. Meena Kumari	Scientist Grade-II
4.	Shri Harit Kasana	Scientist Grade-II
5.	Dr. Gauri Misra	Scientist Grade-II
6.	Dr. Ratnesh Kumar Sharma	Scientist Grade-II
7.	Shri Sinto M.V.	Lab Technician

### MACP

S. No.	Name	Designation
1.	Dr. Shikha Yadav	Scientist Grade-II (Sr. Vet.[Path.])
2.	Ms Sudha V Gopinath	Scientist Grade-III
3.	Ms Kanchan Ahuja	Scientist Grade-III
4.	Dr. Rajesh Kumar Sharma	Scientist Grade-III
5.	Ms. Gurminder Bindra	Scientist Grade-III
6.	Ms. Shalini Tewari	Scientist Grade-III
7.	Dr. Richa Baranwal	Scientist Grade-III
8.	Ms. Rashmi Srivastava	Scientist Grade-III
9.	Ms. Y. Madhu	Scientist Grade-III
10.	Sh. Brij Bahadur	Laboratory Technician
11.	Sh. Mohit Sharma	Laboratory Assistant
12.	Ms. Priya Bhatt	Laboratory Assistant
13.	Sh. Rajeev Kumar Shrivastava	Laboratory Assistant
14.	Sh. Prdeep Kumar	Laboratory Assistant
15.	Sh. Mukesh Kumar	Assistant Engineer (Electrical)
16.	Sh. Chandra Pal	Junior Engineer (Mechanical)
17.	Sh. Subhash Chand	Junior Engineer (Electrical)
18.	Sh. Amarjeet Singh	Junior Engineer (Mechanical)
19.	Ms. Savita Rai	Receptionist
20.	Shri Govind Singh Rawat	Staff Car Driver Gr-I
21.	Ms. Rajenderi Devi	MTS

#### 4. Budget & Finance

During the financial year 2019-20, the approved Budget Estimate (BE) allocation was of Rs. 46.40 Crores and the Revised Estimate (RE) was for Rs. 46.15 Crores. The brief details of BE, RE and Expenditure Incurred are as under:

Particulars	Amount (Rs. in Crore)
Budget Estimate (BE)	46.40
Revised Estimate (RE)/Final Estimate	46.15
Expenditure incurred during the year	43.04

Further, the Institute is generating revenue by way of various sources i.e. (i) Fee for Testing of Biological Products (ii) Sale of Reference Standards (iii) Sale of Laboratory Animals (iv) User Charges for Hostel and Guest House (v) Training Fee (vi) Interest on Saving Bank Account etc. During the Financial Year 2019-20, the Institute generated gross revenue of Rs. 16.41 Crore (Including GST). The entire amount of revenue generated in the respective financial year is deposited in the Consolidated Fund of Government of India with the Ministry.

Detail of the expenditure incurred and revenue generated under various heads, may be viewed from the Audited Annual Accounts of the Institute given in the Report.

#### 5. Staff in Position

##### A. Scientific

S. No.	Name	Designation
1.	Dr. Reba Chhabra	Director I/C
2.	Dr. J. P. Prasad	Scientist Grade-I
3.	Dr. Harish Chander	Scientist Grade-I
4.	Dr. Shikha Yadav	Scientist Grade-II (Sr. Vet.[Path.])
5.	Sh. Neeraj Malik	Scientist Grade-II
6.	Dr. Charu Mehra Kamal	Scientist Grade-II
7.	Dr. Akanksha Bisht	Scientist Grade-II
8.	Dr. Meena Kumari	Scientist Grade-II
9.	Sh. Harit Kasana	Scientist Grade-II
10.	Dr. Gauri Misra	Scientist Grade-II
11.	Dr. Ratnesh Kumar Sharma	Scientist Grade-II
12.	Ms. Ajanta Sircar	Scientist Grade-II
13.	Ms. Sudha V Gopinath	Scientist Grade-III
14.	Ms. Kanchan Ahuja	Scientist Grade-III
15.	Dr. Rajesh K. Sharma	Scientist Grade-III

S. No.	Name	Designation
16.	Ms. Gurminder Bindra	Scientist Grade-III
17.	Ms. Shalini Tewari	Scientist Grade-III
18.	Dr. Richa Baranwal	Scientist Grade-III
19.	Ms. Rashmi Srivastava	Scientist Grade-III
20.	Ms. Y. Madhu	Scientist Grade-III
21.	Dr. Suresh Kumar	Scientist Grade-III (Jr. Vet.)
22.	Sh. Subhash Chand	Scientist Grade-III
23.	Dr. Manoj Kumar	Scientist Grade-III
24.	Sh. Jaipal Meena	Scientist Grade-III
25.	Sh. Tara Chand	Scientist Grade-III
26.	Sh. Pankaj Kumar Sharma	Scientist Grade-III
27.	Sh. N. Nanda Gopal	Scientist Grade-III
28.	Dr. Ashwini Kumar Dubey	Scientist Grade-III
29.	Dr. Sanjay Mendiratta	Junior Scientist
30.	Dr. Manjula Kiran	Junior Scientist
31.	Ms. Vandana Tandasi	Junior Scientist
32.	Dr. Varun Singh	Junior Scientist
33.	Dr. Birendra Kumar	Junior Scientist
34.	Sh. P. S. Chandranand	Junior Scientist
35.	Sh. Ajay Kumar Ade	Junior Scientist
36.	Sh. Anirban Mukherjee	Junior Scientist
37.	Dr. Anoop Kumar	Junior Scientist
38.	Ms. Archana Sayal	Junior Scientist
39.	Sh. Rajeev Kumar	Junior Scientist
40.	Md. Daud Ali	Junior Scientist
41.	Dr. Swati Shalini	Junior Scientist
42.	Ms. Apoorva Anand	Junior Scientist
43.	Sh. Paras Jain	Junior Scientist
44.	Sh. Kallol Saha	Junior Scientist
45.	Sh. Brij Bhushan	Junior Scientist
46.	Sh. Subhash Kumar	Junior Scientist

S. No.	Name	Designation
47.	Ms. Girija L. V	Laboratory Technician
48.	Sh. Brij Bahadur	Laboratory Technician
49.	Sh. Sukhen Majhi	Laboratory Technician
50.	Dr. Mohammed Imran	Laboratory Technician
51.	Sh. Reetesh Kumar Prajapati	Laboratory Technician
52.	Sh. Mohit Lal	Laboratory Technician
53.	Ms. Poonam	Laboratory Technician
54.	Sh. Lakhan	Laboratory Technician
55.	Sh. Prem Prasad	Laboratory Technician
56.	Sh. Sinto M. V.	Laboratory Technician
57.	Sh. Mohit Sharma	Laboratory Assistant
58.	Ms. Priya Bhatt	Laboratory Assistant
59.	Sh. Rajeev Kumar Shrivastava	Laboratory Assistant
60.	Sh. Prdeep Kumar	Laboratory Assistant
61.	Sh. Narender Kumar	Laboratory Assistant
62.	Sh. Parminder Kumar	Junior Animal Care Taker

#### B. Administration, Finance, Procurement & Engineering

S. No.	Name	Designation
63.	Sh. S. K. Sharma	Senior Administrative Officer (F)
64.	Sh. J.P. Pant	Administrative Officer
65.	Sh. W. Z. Quazi	Senior Administrative Officer (P)
66.	Sh. P.K. Mohapatra	Administrative Officer (F)
67.	Sh. Sushil Kumar Dixit	Junior Hindi Translator
68.	Sh. Deepak Mahajan	Jr. Programme Officer
69.	Sh. Praveen Kumar Pant	Administrative Assistant
70.	Sh. Pawan Kumar Sharma	Assistant Gr.-I
71.	Sh. Manmeet Singh Bhatia	Section Officer
72.	Sh. R.K. Arora	Stenographer Grade-B
73.	Sh. Pardeep Kumar	Administrative Assistant
74.	Sh. U.N. Sharma	Administrative Assistant



S. No.	Name	Designation
75.	Sh. Dhirender Singh	Administrative Assistant
76.	Sh. Sanjeev Kumar	Administrative Assistant
77.	Sh. Partho Mondal	Administrative Assistant
78.	Sh. Prem Chand Gupta	Assistant -I
79.	Sh. Pardeep Kumar	Administrative Assistant
80.	Ms. Savita Rai	Assistant Gr.-I
81.	Sh. Govind Singh Rawat	Driver
82.	Sh. Ravi Dutt	Driver
83.	Sh. Harinder Singh Chauhan	Driver
84.	Sh. Leela Kishan	Driver
85.	Sh. Bijender Singh	MTS
86.	Sh. Subhash Chand	MTS
87.	Sh. Suraj Pal	MTS
88.	Sh. Rakesh	MTS
89.	Sh. P. C. Diwan	MTS
90.	Ms. Shobha	MTS
91.	Ms. Rajenderi Devi	MTS
92.	Sh. Mukesh Kumar	Assistant Engineer (Electrical)
93.	Sh. R. P. Joshi	Assistant Engineer (Civil)
94.	Sh. Subhash Chand	Junior Engineer (Electrical)
95.	Sh. Chandra Pal	Junior Engineer (Mechanical)
96.	Sh. Amarjeet Singh	Junior Engineer (Mechanical)
97.	Sh. Krishna Kumar	Junior Engineer (Civil)
98.	Sh. H. P. Vashisht	Electrician

## RAJBHASHA (HINDI):

### Aims and Scope:

The aim of the Rajbhasha unit is to educate, train the employees of Institute to use Hindi language in day-to-day official work as per the rules of Rajbhasha. This unit also provides a platform to employees of the Institute to involve themselves and participate in various activities during celebration of the 'Hindi Pakhwara' and other activities organized by Nagar Rajbhasha Bhasha Karyanvyan Samiti, NOIDA.

The constitution of the Rajbhasha Committee of the Institute is as under:-

<b>Dr. Reba Chhabra</b>	<b>Chairperson</b>
Shri W.Z. Quazi	Member
Shri S.K. Sharma	Member
Shri R.P. Joshi	Member
Shri J.P. Pant	Member
Shri Pawan Kumar Sharma	Associate

The Committee has organized various programmes to promote the use of Hindi language in day-to-day official work.

### Miscellaneous Academic activities

1. Shri Pawan Kumar Sharma, Data entry Operator and Smt. Savita Rai, Receptionist, participated in "Hindi essay writing competition" held in V.V. Giri National Labour Institute, Noida on 26.12.2019 organized by Nagar Rajbhasha Karyanvyan Samiti, Noida.
2. Two outsourced staff- Technical Associate and Data Entry Operator- participated in

"39<sup>th</sup> Seminar" held in National Centre for Medium Range Weather Forecasting, Noida on 29.01.2020 organized by Nagar Rajbhasha Karyanvyan Samiti, Noida.

### Participation in Meetings / Workshops

Shri P.K. Mohaptra, Section Officer, Shri Pradeep Kumar, Junior Accountant and Shri Upender Nath Sharma, Cashier participated in "9<sup>th</sup> National official language conference" from 16.01.2020 to 18.01.2020 in All India Institute of Medical Science, Jodhpur

### Hindi Pakhwara

Hindi cell, National Institute of Biologicals, Noida organized "Hindi Pakhwara" from dated 31.08.2019 to 14.09.2019 as per guidelines issued by Rajbhasha Vibhag, Ministry of Home Affairs, and Government of India. In this program talks were delivered by various officials of the Institute. Various types of competitions were also organized in this pakhwara programme for the officials of the Institute.

### Inspection by the Parliamentary Committee on Official Language

Dr. Reba Chhabra, Director (In-charge), participated in the Official Language Inspection being conducted by the Third Sub-Committee of the Parliamentary Committee on Official Language on 22.01.2020 at Ashoka Hotel New Delhi. The committee observed and supervised the Hindi work being done in the office.



## EMPOWERING CONSUMERS: RIGHT TO INFORMATION ACT, 2005

In terms of Section 4(1) (b) and 4(2) of the Right to Information Act, 2005, the Institute has nominated the following officers as PIO and Appellate Authority under the RTI Act, 2005: Sh. W.Z. Quazi, Senior Administrative Officer– Appellate Authority. Sh. P. K. Mohapatra,

Administrative Officer– Public Information Officer (PIO)

During the year (2019-20), the Institute received the following applications to obtain various types of information under the RTI Act: -

	Opening Balance	No. of Applications Received as transfer from other PA u/s 6(3)	Received (including cases transferred to other PAs)	No. of cases transferred to other PAs u/s 6(3)	Decision where request/ appeal Rejected	Decision where request/ appeal Accepted	Registration Fee Collected (in Rs.) u/s 7(1)
<b>Request</b>	0	9	28	0	0	28	160

Particulars	Opening Balance	No. of Applications Received as transfer from other PA u/s 6(3)	Revived (including cases transferred to other PAs)	No of cases transferred to other PAs u/s 6(3)	Decision where request/ appeal Rejected	Decision Where request appeal Accepted	Registration Fee Collected (in Rs.) u/s 7(1)
Request	-	19	28	-	-	-	160/-
First Appeals	-	-	9	-	-	9	-

# AUDITOR'S REPORT NIB



**CHANDIWALA VIRMANI & ASSOCIATES**  
Chartered Accountants

43, IInd Floor, Near Delhi Gate Police Station,  
Daryaganj, New Delhi-110002  
011-43587399  
chandiwalagupta@yahoo.com  
www.chandiwalavirmani.in

## INDEPENDENT AUDITOR'S REPORT

**To**  
**National Institute of Biologicals**  
**A-32, Institutional Area, Sector-62**  
**Noida (Uttar Pradesh)-201307**

### Opinion

We have audited the financial statements of **National Institute of Biologicals (herein after called "NIB")**, which comprise Balance Sheet as at 31st March, 2020, the Income & Expenditure Account and Receipt and Payment Account for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Subject to Emphasis of matters Para below, in our opinion, the accompanying financial statements give a true and fair view of the financial position of the **NIB** as at 31st March, 2020, and of its financial performance for the year then ended in accordance with the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI).

### Basis for Opinion

We conducted our audit in accordance with the Standards on Auditing (SAs) issued by ICAI. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the **NIB** in accordance with the Code of Ethics issued by ICAI and we have fulfilled our other ethical responsibilities in accordance with the Code of Ethics. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Emphasis of Matters

*We draw attention to Note No. 2 of these financial statements which indicates that NIB is procuring certain Fixed Assets through its procurement consultant M/s. HLL Lifecare Ltd. The reconciliation/settlement with M/s HLL Lifecare Ltd. is under process as on the date of Balance Sheet, hence, the Overstatement/Understatement of Capital Assets cannot be quantified. Our opinion is not Qualified in respect of this matter.*

### Other Matters

Attention is also invited to the following:

- Note No. 1 Reconciliation of Property, Plant & Equipment and its physical verification.
- Note No. 5 regarding pending settlement with M/s HSCC (I) Ltd.



Contd..2



- Note No. 10 regarding maintenance of separate Receipt & Payment account of the respective funds for various projects funded by other agencies.
- Note No. 13 regarding utilization of Grants.

### **Responsibilities of Management and Those Charged with Governance for the Financial Statements**

Management is responsible for the preparation of these financial statements that give a true and fair view of the state of affairs, results of operations and cash flows of the **NIB** in accordance with the accounting principles generally accepted in India. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the **NIB**'s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the **NIB** or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the **NIB**'s financial reporting process.

### **Auditor's Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with SAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

### **Chandiwala Virmani And Associates**

**Chartered Accountants**

**Reg. No. 000082N**



**CA Naveen Chand Jain**

**Partner**

**(M. No.: 105433)**

**UDIN: 20105433AAAABL4088**

**Place: Noida**

**Date: 04/09/2020**

NATIONAL INSTITUTE OF BIOLOGICALS  
Ministry of Health & Family Welfare

**BALANCE SHEET AS AT 31st MARCH 2020**

		Amount In ₹	
CORPUS/CAPITAL FUND AND LIABILITIES	Schedule	Current Year	Previous Year
Corpus / Capital Asset Fund	1		
Gross Corpus Fund		2,35,51,06,644.20	2,33,81,88,825.53
Less : Accumulated Depreciation		1,12,49,49,901.03	1,06,02,29,787.10
Net Corpus Fund		1,23,01,56,743.17	1,27,79,59,038.43
Current Liabilities and Provisions	2	9,97,18,680.91	9,32,22,257.52
<b>TOTAL</b>		<b>1,32,98,75,424.08</b>	<b>1,37,11,81,295.95</b>

ASSETS	Schedule	Current Year	Previous Year
Property, Plant & Equipment	3		
Gross Block		2,30,47,39,604.24	2,30,10,44,482.57
Less : Accumulated Depreciation		1,12,49,49,901.03	1,06,02,29,787.10
Net Block		1,17,97,89,703.21	1,24,08,14,695.47
Current Assets, Loans & Advances	4	15,00,85,720.87	13,03,66,600.48
<b>TOTAL</b>		<b>1,32,98,75,424.08</b>	<b>1,37,11,81,295.95</b>
SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS	12		

As per our report of even date attached.

For Chandiwalla Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N



Place: Noida  
Date: 04/09/2020  
UDIN : 20105433AAAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

  
P K Mohapatra  
Admn. Officer (Finance)

  
S.K. Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
(Director i/c)

**NATIONAL INSTITUTE OF BIOLOGICALS**  
Ministry of Health & Family Welfare

**INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

			Amount In ₹
PARTICULARS	Schedule	Current Year	Previous Year
<b>INCOME</b>			
Receipts from Sales & Testing	5	12,76,68,089.00	10,93,64,479.00
Grants/Subsidies Utilized for Revenue Expenditure	6	27,11,74,741.55	24,08,56,157.10
Interest Earned	7	95,05,050.00	49,79,352.00
Other Income	8	51,74,598.00	21,11,734.00
Depreciation (as per contra)		6,47,20,113.93	6,12,46,379.40
<b>TOTAL (A)</b>		<b>47,82,42,592.48</b>	<b>41,85,58,101.50</b>
<b>EXPENDITURE</b>			
Establishment Expenses	9	13,57,74,266.00	11,14,38,100.00
Administration Expenses	10	10,70,39,586.52	9,37,20,785.13
Lab Services - Operation & Maintenance Exp	11	17,07,08,626.03	15,21,52,836.97
Depreciation (as per contra)		6,47,20,113.93	6,12,46,379.40
<b>TOTAL (B)</b>		<b>47,82,42,592.48</b>	<b>41,85,58,101.50</b>
Balance being Surplus/(Deficit) (A-B)		-	-
Less: Prior period Expenses		-	-
Prior period Expenses charged to Grant		-	-
<b>SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS</b>	<b>12</b>		

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N

CA Naveen Chand Jain  
Partner (M.No. 105433)

Place: Noida  
Date: 04/09/2020  
UDIN : 20105433AAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

P K Mohapatra  
Admn. Officer (Finance)

S K Sharma  
Sr. Admn. Officer (Finance)

Dr. Reba Chhabra  
(Director i/c)

**NATIONAL INSTITUTE OF BIOLOGICAL**  
(Ministry of Health & Family Welfare, GOI)  
**RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31ST MARCH 2020**

		Amount in ₹			
RECEIPTS	Current Year	Previous Year	PAYMENTS	Current Year	Previous Year
<b>1. Opening Balance</b>			<b>1. Expenses</b>		
-Cash in Hand	99.00	20,022.00	-Establishment Expenses	11,25,75,766.00	8,71,05,959.00
-Bank Balance	9,45,53,152.45	6,85,94,127.26	-Administrative Expenses	99,92,665.44	79,38,780.51
-Stamps in Hand	2,229.00	7,118.00	-Lab Services- O&M Services	9,47,77,396.21	9,57,81,228.01
			-Transfer for Haemovigilance Programme	-	30,10,000.00
<b>2. Grants Received</b>			<b>2. Payments made against Funds</b>		
-From Government of India	42,84,58,000.00	39,15,88,000.00	-Advance to HILL Lifecare Limited	-	22,00,000.00
			-Advance to HITES Limited	1,18,00,000.00	-
<b>3. Interest Received:</b>			-Advance to IOCL - Supply of HSD for DG /Boilers	1,05,30,000.00	60,00,000.00
-On Super Saving Bank Account	91,04,638.00	48,08,710.00	-Advance to CPWD-Horticulture work	3,75,725.00	-
-Interest Recovered from Scooter, HBA & Computer advance	55,665.00	-	-Advance to Contractors & Suppliers-Net	21,61,832.00	8,20,269.70
			-Expenditure against SERB Project	1,52,970.00	2,24,833.00
<b>4. Other Income</b>			-Fund Transfer to T&W A/c-WHO	6,97,605.00	96,937.00
-Receipts from Hostel/Guest houses	11,81,000.00	10,82,200.00	<b>3. Expenditure on Fixed Assets &amp; Capital-WIP</b>		
-Sale of Tenders Forms	28,560.00	26,320.00	-Machinery & Equipment	3,98,975.00	11,39,344.00
-Sample Testing Receipts & Sale of Ref. Standards	14,23,45,548.28	12,75,15,398.48	-Computers & Computer Software	7,53,894.78	5,74,201.00
-Training fees	3,40,000.02	3,15,000.00	-Furniture & fixture	59,427.00	3,23,101.00
-Miscellaneous Receipts	1,86,998.00	94,077.20	-Office Equipments	62,136.00	1,28,829.00
-Sale of Lab Animals	4,96,840.00	4,93,250.00	-Books	58,055.00	16,438.00
<b>5. Other Receipts</b>			<b>4. Payment of Internal Receipts/Unspent Balances</b>		
-Tour Advance	29,480.00	38,093.00	-To the Government of India	12,77,00,000.00	10,80,00,000.00
-LTC Advance	5,190.00	58,183.00	-Previous Year Receipts Paid to Ministry	84,55,565.00	99,97,711.00
-Departmental Advance	1,25,784.00	35,366.00	<b>5. Other Payments and Advances</b>		
-Advances to Contractors refunded	3,582.00	-	-Medical Advance	-	2,31,200.00
-Advance Received for Reference Standards	17,08,352.00	12,25,600.00	-Computer Advance	-	1,00,000.00
-EMD received during the year	48,02,000.00	74,42,200.00	-Tour Advance	3,23,002.00	1,89,500.00
-Security Deposit/Retention Money Received	1,98,046.20	5,79,765.00	-LTC Advance	2,06,200.00	15,31,440.00
-Claims received -Net	11,53,814.15	15,64,463.00	-Departmental Advance	3,66,848.00	1,64,725.00
-TDS Receivable received	2,64,735.00	33,744.00	-Other Advance	49,155.00	22,18,241.00
-Received from IPC - Haemovigilance	-	30,00,000.00	-Security Deposit released	13,35,174.00	17,96,335.00
-Funds Received from WHO	6,97,605.00	96,937.00	-EMD released	53,11,400.00	60,28,500.00
-Adv. Received from Sale of Lab Animals	2,225.00	-	-Statutory Liabilities paid	2,54,56,607.00	2,34,00,134.00
-Adv. Received from Sale of Scrap Material	8,02,500.00	-	-Payment made for Expense Payable	9,600.00	94,892.00
-Bank deposit for Sale Tax Refunds	24,826.00	-	-Payment to Suppliers of Goods & Services	18,02,40,782.00	15,10,00,390.83
			-Net GST paid	51,63,675.00	39,50,104.44
			<b>6. Closing Balances</b>		
			-Cash in Hand	11,457.00	99.00
			-Bank Balance	8,75,39,184.67	9,45,53,152.45
			-Stamps in Hand	5,772.00	2,229.00
<b>TOTAL</b>	<b>68,65,70,869.10</b>	<b>60,86,18,573.94</b>	<b>TOTAL</b>	<b>68,65,70,869.10</b>	<b>60,86,18,573.94</b>

As per our report of even date attached.

For CHANDIWALA VIRMANI AND ASSOCIATES

Chartered Accountants

(FR No. 000082N)

  
CA Naveen Chand Jain  
Partner  
(M. No. 105433)

Place: Noida

Date: 04/09/2020

UDIN: 20105433AAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

  
P K Mohapatra  
Admn. Officer (Finance)

  
S.K. Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
Director (i/c)



NATIONAL INSTITUTE OF BIOLOGICALS  
Ministry of Health & Family Welfare

## SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2020

SCHEDULE 1 -CORPUS/CAPITAL FUND	Amount in ₹		Amount in ₹	
	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
Balance as at the beginning of the year	2,07,95,79,107.76		2,08,26,01,529.76	
Add: Grant Utilised for Security Deposits	-		-	
Add: Increase in Stock of Fuel for Boilers & D.G Set	13,22,925.00		-30,22,422.00	
Add: Grant Utilised for Security Deposits - Electricity	-		-	
Add: Receipts from Sale of Assets	-	2,08,09,02,032.76	-	2,07,95,79,107.76
Add: Capital Assets Fund				
Balance at the beginning of the year	26,03,87,282.77		22,76,05,084.83	
Addition during the year	6,76,77,807.67		3,27,82,197.94	
Less: Adjustment on account of Capital WIP	-6,10,38,378.00		-	
Less: Adjustment for amount of fixed asset/WIP excess charged in P.Y	-29,44,308.00	26,40,82,404.44	-	26,03,87,282.77
Add/Less: Grant utilised for advances of previous years		-67,83,099.00		-62,83,035.00
Add/Less: Grant Utilized for advances against Assets/Capital items during C.Y		1,18,77,508.00		22,00,000.00
Add/Less: Grant Utilized for advances against Goods & Services during C.Y		49,467.00		20,62,684.00
Add/Less: Adjustment towards advance from Capital WIP		29,44,308.00		-
Add/Less: Grant utilised for Prepaid Expenses Increase/Decrease during the year - Electricity		20,34,023.00		2,42,786.00
<b>BALANCE AS AT THE YEAR END</b>		<b>2,35,51,06,644.20</b>		<b>2,33,81,88,825.53</b>

SCHEDULE 2 -CURRENT LIABILITIES AND PROVISIONS	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
<b>A. CURRENT LIABILITIES</b>				
1. Sundry Creditors				
a) HSCC	1,54,57,028.00		1,54,57,028.00	
b) Goods/Service	2,06,69,964.62	3,61,26,992.62	1,63,13,808.54	3,17,70,836.54
( Including Creditors outstanding for more than one year )				
2. Advances Received				
-Advance Received for Sale of Reference standards	7,400.00		7,400.00	
-Advance Received for Sale of Lab animals	2,225.00		-	
-Advance Received for Sale of scrap	7,048.00		-	
-Fund received for SERB Project	1,69,775.00		3,22,745.00	
-Fund Received From DST- Nanomission	2,70,000.00		2,70,000.00	
-Receipts payable to MOH & FW, GOI	1,46,47,737.00		84,55,565.00	
-Advance to HLL against Equipments	5,74,676.00		-	
- Earnest Money Deposit	22,02,200.00	1,78,81,061.00	27,51,700.00	1,18,07,410.00
3. Statutory Liabilities				
-TDS (Professional)	3,21,871.00		85,584.00	
-TDS (Contractors)	2,36,075.50		2,49,595.00	
-GST (TDS)	2,98,039.50	8,55,986.00	2,82,448.00	6,17,627.00
4. Other Current Liabilities				
-Security deposit / Retention Money	39,23,620.20		37,89,147.00	
-Salary Payable	84,53,140.00		84,00,598.00	
-Expenses Payable	-		33,51,406.67	
-Testing Fees Refundable	28,73,674.00		7,99,483.00	
-Claim Payable	-		49,316.00	
-TDS Payable to NIB-GPF	1,56,123.00		45,311.00	
-Audit Fee Payable	72,000.00		72,000.00	
-Employee Contribution to NPS	1,78,968.00		2,81,318.00	
-Employer Contribution to NPS (Payable)	5,00,503.00		-	
-CGHS Contribution	-		6,25,061.00	
- Grant Payable to MOHFW, GOI (Schedule-6A)	2,13,29,404.09	3,74,87,432.29	2,33,11,701.31	4,07,25,341.98
<b>B. Provisions</b>				
-Gratuity	34,96,446.00		39,86,642.00	
-Accumulated Leave Encashment	38,70,763.00	73,67,209.00	43,14,400.00	83,01,042.00
<b>TOTAL</b>		<b>9,97,18,680.91</b>		<b>9,32,22,257.52</b>



**NATIONAL INSTITUTE OF BIOLOGICALS**  
Ministry of Health & Family Welfare

**SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2020**  
**SCHEDULE-3: PROPERTY, PLANT & EQUIPMENT AS ON 31.03.2020**

FIXED ASSETS	GROSS BLOCK					DEPRECIATION			NET BLOCK					
	Cost as at 01.04.2019	Additions during the year	Transfer From WIP	Transfer In	Sold during the Year	Adjustments	Cost as at 31.03.2020	As at 01.04.2019	Depreciation Adjustment	During the year	Production/Sales /Adjustments	Total up to 31.03.2020	As at 31.03.2019	As at 31.03.2020
LAND	14,61,50,000.00	-	-	-	-	-	14,61,50,000.00	-	-	-	-	-	14,61,50,000.00	14,61,50,000.00
BUILDINGS	85,31,69,788.18	99,39,368.00	-	-	-	-	86,31,09,156.18	17,54,52,192.56	-	1,40,71,999.25	-	18,95,24,131.81	67,79,17,595.62	67,37,85,024.37
A.C.PLANT	39,23,53,532.95	-	-	-	-	-	39,23,53,532.95	38,02,18,810.56	-	1,32,037.89	-	38,03,50,888.45	1,21,34,702.39	1,20,02,664.50
MACHINERY & EQUIPMENT	74,04,98,887.00	3,86,96,032.00	-	-	-	-	77,91,94,919.00	43,45,68,624.09	-	3,87,31,220.39	-	47,32,99,844.48	30,59,31,262.91	30,58,95,074.52
COMPUTER	2,63,46,339.50	1,86,210.00	-	-	-	-	2,65,32,549.50	2,60,72,795.58	-	47,40,083.21	-	3,08,12,878.79	2,71,543.92	(42,80,329.29)
COMPUTER SOFTWARE	1,20,86,418.11	4,34,188.07	-	-	-	-	1,25,10,606.78	81,86,219.52	-	16,63,607.63	-	98,49,887.15	39,00,198.59	26,60,719.63
FURNITURE & FIXTURES	3,40,03,622.47	39,80,377.00	-	-	-	-	3,79,83,999.47	1,44,07,340.24	-	21,68,034.16	-	1,85,75,384.40	1,75,56,262.23	1,84,08,615.07
OFFICE EQUIPMENTS	2,43,15,474.72	1,10,22,914.00	-	-	-	-	3,53,48,388.72	1,32,70,676.43	-	27,12,471.09	-	3,49,83,147.52	1,20,54,798.29	2,01,65,241.20
VEHICLES	7,55,248.00	-	-	-	-	-	7,55,248.00	2,40,918.15	-	71,748.56	-	3,12,666.71	5,14,329.85	4,42,581.29
TYPEWRITERS	2,00,970.64	-	-	-	-	-	2,00,970.64	1,90,922.10	-	-	-	1,90,922.10	10,048.54	10,048.54
BOOKS	68,43,403.00	40,164.00	-	-	-	-	68,83,567.00	65,75,719.10	-	4,22,386.40	-	69,98,125.50	2,67,663.90	(1,14,558.50)
CYCLE Rickshaws	9,000.00	-	-	-	-	-	9,000.00	4,387.50	-	877.50	-	5,245.00	4,612.50	3,735.00
TOOLS	1,19,112.00	-	-	-	-	-	1,19,112.00	41,121.27	-	5,657.84	-	46,779.11	77,590.73	72,332.89
CURRENT YEAR (A)	2,23,70,63,796.37	6,42,89,293.67	-	-	-	-	2,30,13,51,090.04	1,06,02,59,787.10	-	6,47,20,113.93	-	1,12,49,46,901.03	1,17,66,32,009.47	1,17,64,01,189.21
PREVIOUS YEAR	2,21,18,72,284.63	2,51,89,511.94	-	-	-	-	2,23,70,61,796.57	99,80,83,407.70	-	6,08,82,655.40	-	1,06,03,29,787.10	1,21,28,88,876.93	1,17,64,32,699.47

**WORK IN PROGRESS:**

ASSETS	GROSS BLOCK AS AT 31.03.2020				TRANSFER TO FIXED ASSETS	REDUCTIONS DURING THE YEAR	ADJUSTMENTS (NOTE)	TRANSFER FROM WIP	ADDITIONS DURING THE YEAR	OPENING AS AT 01.04.2019	NET BLOCK	
	As at 01.04.2019	During the year	Depreciation Adjustment	Total up to 31.03.2020							As at 31.03.2019	As at 31.03.2020
WIP WORKS	-	-	-	-	-	-	-	-	-	-	-	-
Capital WIP	6,39,82,686.00	31,86,554.00	-	33,88,554.00	-	6,39,82,686.00	-	-	-	6,39,82,686.00	-	33,88,554.00
CURRENT YEAR (B)	6,39,82,686.00	33,86,554.00	-	33,88,554.00	-	6,39,82,686.00	-	-	-	6,39,82,686.00	-	33,88,554.00
PREVIOUS YEAR	6,50,20,472.83	75,92,686.00	-	6,39,82,686.00	86,30,472.83	-	-	-	-	-	-	6,39,82,686.00
GRAND TOTAL (A+B)	2,30,10,44,482.57	6,76,77,807.67	-	2,30,47,39,604.24	-	6,39,82,686.00	-	-	6,47,20,113.93	1,12,49,46,901.03	1,24,06,14,695.47	1,17,97,89,703.21
PREVIOUS YEAR	2,27,68,92,757.46	3,27,62,197.94	-	2,30,10,44,482.57	86,30,472.83	-	-	-	6,08,82,655.40	1,06,03,29,787.10	1,21,28,88,876.93	1,24,06,14,695.47





NATIONAL INSTITUTE OF BIOLOGICALS  
Ministry of Health & Family Welfare

## SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2020

SCHEDULE 4 -CURRENT ASSETS , LOANS & ADVANCES	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
<b>A. CURRENT ASSETS</b>				
1. Cash balances in hand	11,457.00		99.68	
2. Balance with Banks :				
- Super Saving Accounts	8,75,39,184.67		9,45,53,152.45	
3. Stamps in Hand	5,772.00	8,75,56,413.67	2,229.00	9,45,55,481.13
<b>TOTAL (A)</b>		<b>8,75,56,413.67</b>		<b>9,45,55,481.13</b>
<b>B. LOANS, ADVANCES AND OTHER CURRENT ASSETS</b>				
<b>1. Loans &amp; Advances</b>				
Staff Advances				
- Computer Advance	70,500.00		1,29,000.00	
- House Building Advance	16,82,250.00		19,52,250.00	
- LTC Advance	-		16,700.00	
- Motor Car Advance	6,000.00		42,000.00	
- Departmental Advances	5,000.00	17,63,750.00	-	21,39,950.00
<b>2. Advances and other amount recoverable in cash or in kind or for value to be received:</b>				
(a) Other Entities engaged in activities of NIB				
- Advance to CPWD	37,20,278.00		10,00,000.00	
- Advance to DAVP	-		3,582.00	
- Advance to M/s Agarwal Sales Agency	-		3,780.00	
- Advance to HSCC (ETP)	5,69,091.00		5,69,091.00	
- Advance to HSCC (Other work)	6,48,934.91		6,48,934.91	
- Advance to IOCL	18,180.00		42,767.00	
- Advance to HPCL	31,287.00		-	
- Advance to NICSI	47,000.00	50,34,770.91	12,32,061.00	35,00,215.91
(b) On capital Account				
-Advance to HLL against Equipments	-		12,35,107.00	
-Advance to HITES against Equipments	1,01,40,977.00		-	
(c) Deposits				
-Bank Deposit for Sales Tax Registration	-		25,000.00	
-Security Deposit with Balmer Lawrie	3,00,000.00		3,00,000.00	
-Security Deposit with PVVNL-Electricity	79,57,678.00		79,57,678.00	
-Security Deposit with Padam Petroleum	25,000.00		25,000.00	
-Security Deposit with Noida-Water Connection	9,30,750.00		9,30,750.00	
-Security Deposit with Telephone	10,000.00		10,000.00	
-Security Deposit with PNG (IGL)	1,92,000.00		1,92,000.00	
-Security Deposit with Gas (BPCL)	3,550.00	1,95,59,955.00	3,550.00	1,06,79,085.00
<b>3. Claim Receivable</b>		1,02,585.85		2,52,442.00
<b>4. Sundry Debtors</b>		1,05,34,470.00		33,73,795.00
<b>5. Pre-paid Expenses</b>		34,21,533.00		13,87,510.00
<b>6. Stock-Fuel for Boilers &amp; D.G Set</b>		45,92,309.00		32,69,384.00
<b>7. TDS Receivable for previous year</b>		6,08,799.00		2,62,455.00
<b>8. TDS Receivable (2019-20)</b>		13,04,924.00		6,11,079.00
<b>9. GST Recoverable</b>		1,56,06,210.44		1,03,35,203.44
<b>10. Grant Receivable/Payable to MOHFW, GOI</b>		-		-
<b>TOTAL (B)</b>		<b>6,25,29,307.20</b>		<b>3,58,11,119.35</b>
<b>TOTAL (A+B)</b>		<b>15,00,85,720.87</b>		<b>13,03,66,600.48</b>



NATIONAL INSTITUTE OF BIOLOGICALS  
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF INCOME & EXPENDITURE FOR THE YEAR ENDED AS AT 31st MARCH 2020

SCHEDULE 5 - RECEIPTS FROM TESTING & SALES	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
1. Receipts from Testing				
-Sample Testing Receipts		12,59,93,489.00		10,82,74,479.00
2. Receipts from Sales				
-Sale of Reference Standards		16,74,600.00		10,90,000.00
<b>TOTAL</b>		<b>12,76,68,089.00</b>		<b>10,93,64,479.00</b>

SCHEDULE 6 - GRANTS/SUBSIDIES UTILIZED FOR REVENUE EXPENDITURE	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
Grant Adjusted towards Revenue Expenditure:				
Current Year Expenditure	41,35,22,478.55		35,73,11,722.10	
Less: Expenses Adjusted from Current Year Income	14,23,47,737.00	27,11,74,741.55	11,64,55,565.00	24,08,56,157.10
		<b>27,11,74,741.55</b>		<b>24,08,56,157.10</b>

SCHEDULE 6 A - GRANTS/SUBSIDIES	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
Grant Received During the Year		42,84,58,000.00		39,15,88,000.00
Grant unutilized b/f from the previous year		2,33,11,701.31		49,61,493.35
<b>Total</b>		<b>45,17,69,701.31</b>		<b>39,65,49,493.35</b>
Less: Revenue Expenses Adjusted from Current Year Income (Schedule-6)		27,11,74,741.55		24,08,56,157.10
		<b>18,05,94,959.76</b>		<b>15,56,93,336.25</b>
Less: Grant Utilized for purchase of Fixed Assets		40,58,680.67		1,52,92,568.94
Less: Grant Utilized for advances against Assets/Capital items during C.Y		1,18,77,508.00		22,00,000.00
Less: Grant Utilized for advances against Goods & Services during C.Y		49,467.00		20,62,684.00
Less: Current Year Income transferred to MOH & FW		12,77,00,000.00		10,80,00,000.00
Less: Current Year Income Payable to MOH & FW		1,46,47,737.00		84,55,565.00
Add/Less: Stock of Fuel for Boilers & D.G Set		13,22,925.00		-30,22,422.00
Add: Adjustment of Revenue Expenditure from Capital WIP		11,89,595.00		-
Add: Previous Year's Advance adjusted towards Goods & Services		12,31,608.00		8,49,547.00
Add/Less: Prepaid Expenditure		20,34,023.00		2,42,786.00
Add: Advance of Previous Year Refunded/Received During the Year		3,582.00		-
Less: Security Deposits - Electricity		-		-
<b>Grant Payable/(Receivable) to Govt. of India (Refer Schedule-2)</b>		<b>2,13,29,404.09</b>		<b>2,33,11,701.31</b>

SCHEDULE 7 - INTEREST EARNED	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
a) On Saving Accounts		92,20,646.00		48,29,558.00
b) On Loans To Employees/Staff		2,06,896.00		1,49,794.00
c) On Funds Provided to HITES		77,508.00		-
<b>TOTAL</b>		<b>95,05,050.00</b>		<b>49,79,352.00</b>

SCHEDULE 8 - OTHER INCOME	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
a) Usage receipts for Hostel, Guest House & Conference Hall		14,85,900.00		10,84,450.00
b) Sale of Tender Forms		25,500.00		23,500.00
c) Training Fees		3,40,000.00		3,15,000.00
d) Receipts from Sale of Assets		-		-
e) Misc Receipt		11,04,675.00		1,51,567.00
f) Interest on Security Deposit (Electricity)		2,33,881.00		-
g) Sale of Lab Animal		5,00,845.00		4,99,138.00
h) License Fees		68,536.00		38,079.00
i) CGHS		14,15,261.00		-
<b>TOTAL</b>		<b>51,74,598.00</b>		<b>21,11,734.00</b>



NATIONAL INSTITUTE OF BIOLOGICALS  
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF INCOME & EXPENDITURE FOR THE YEAR ENDED AS AT 31st MARCH 2020

SCHEDULE 9 - ESTABLISHMENT EXPENSES	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
a) Salary and Wages		10,34,51,565.00		9,33,95,527.00
b) Allowances and Bonus		47,09,930.00		5,37,952.00
c) Employer's Contribution to NPS/ other Fund		36,83,940.00		30,78,922.00
d) Expenses on Employee's Retirement and Terminal Benefit		1,95,09,804.00		79,68,343.00
e) Others				
-Medical Reimbursement		27,71,519.00		27,53,974.00
-LTC Expenses		2,48,863.00		19,34,458.00
-Reimbursement of Tuition Fees		13,80,645.00		17,59,924.00
-Honorarium		18,000.00		9,000.00
<b>TOTAL</b>		<b>13,57,74,266.00</b>		<b>11,14,38,100.00</b>

SCHEDULE 10 - OTHER ADMINISTRATIVE EXPENSES	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
a) Consultants/Cont. Emp.Payment		4,45,08,568.00		4,07,90,696.00
b) Purchase of office consumables		2,77,371.00		1,40,746.00
c) Office Maintenance		82,80,749.70		76,39,876.30
d) Rent, Rates and Taxes		3,31,926.00		2,39,058.00
e) Vehicles Running and Maintenance		1,97,832.00		1,99,486.00
f) Postage, Telephone and Communication Charges		7,50,927.00		6,83,156.00
g) Printing & Stationary		23,77,176.00		22,81,937.00
h) Travelling and Conveyance Expenses		13,78,142.00		15,08,880.00
i) Expenses on Seminar/Workshops		2,10,200.00		2,38,860.00
j) Hospitality/Staff Welfare Expenses		8,22,070.00		8,34,714.00
k) Auditor's Remuneration		72,000.00		72,000.00
l) Professional Charges		13,69,938.00		11,19,002.00
m) NIB Training		14,03,813.00		-
n) Advertisement and Publicity		48,86,516.00		25,14,458.00
o) Other Expenses:				
- Miscellaneous Expenses		-		334.32
- Security Services expenses		1,98,68,426.00		1,96,89,578.00
- Honorarium (others)		3,13,300.00		5,88,000.00
- House Keeping Charges		1,01,67,747.00		67,78,865.00
- Hiring of Vehicles		57,70,520.00		45,20,475.00
- Hindi Promotion		3,31,103.00		1,18,400.00
- Bank Charges		9,411.44		26,143.51
- Internet Access Charges		10,11,552.00		10,26,719.00
- Travelling (others)		9,47,610.00		12,27,926.00
- Newspapers & Periodicals		2,45,914.00		1,87,043.00
- Other Office Expenditure		7,74,930.38		4,28,828.00
- Cenvat Credit Written Off		-		62,451.00
- Pest Control Charges		1,63,200.00		1,72,041.00
- Recruitment Expenses		2,00,916.00		1,85,569.00
- Freight & Cartage		-		3,226.00
- Consultancy Charges- HLL		1,95,693.00		-
- Swachheta Action Plan (SAP)		1,72,035.00		4,42,317.00
<b>TOTAL</b>		<b>10,70,39,586.52</b>		<b>9,37,20,785.13</b>

SCHEDULE 11 - LAB SERVICES - OPERATION & MAINTENANCE EXP	For Current Year ended on 31.03.2020		For Previous Year ended on 31.03.2019	
a) Electricity and Water Charges		6,71,28,855.00		6,58,61,390.00
b) Repair & Maintenance - Lab Equipments		1,17,29,530.97		1,20,95,654.89
c) Operation & Maintenance - Electrical		68,99,409.00		42,44,196.00
d) Operation & Maintenance - DG Sets		27,47,378.00		54,52,020.00
e) Operation & Maintenance - HVAC Plant		1,45,19,992.00		1,09,08,513.00
f) Operation & Maintenance - Boiler		21,36,598.00		20,46,770.00
g) Operation & Maintenance - Water Supply system		57,19,568.00		51,17,136.00
h) Operation & Maintenance - Air Compressor		33,000.00		97,833.00
i) Operation & Maintenance - Cold Room		33,89,873.00		41,81,887.00
j) Operation & Maintenance - BMS		1,13,369.00		1,19,408.00
k) Operation & Maintenance - Lifts		6,57,089.00		6,37,950.00
l) Operation & Maintenance - Acces Control System		15,36,100.00		16,47,914.00
m) Operation & Maintenance - ETP & STP		11,89,595.00		-
n) Purchase of Lab Consumable		1,57,88,601.00		1,19,73,719.00
o) Purchase of Lab Chemicals		23,47,195.00		18,64,970.00
p) Purchase of Kits & Reagents		2,21,39,171.42		1,79,67,158.47
q) Purchase of Lab Animal		4,34,850.00		60,000.00
r) Lab Misc. Expenses		12,39,265.64		1,03,638.61
s) Bio-Waste Disposal Charges		1,73,811.00		1,90,864.00
t) Consumption of Fuel for Boilers & D.G Set				
Opening Balance of Fuel (HSD)		32,69,384.00		62,91,806.00
Add: Purchases		1,21,08,300.00		45,59,393.00
Less: Closing stock		45,92,309.00		32,69,384.00
<b>TOTAL</b>		<b>17,07,08,626.03</b>		<b>15,21,52,836.97</b>



*Signature*

## NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health &amp; Family Welfare

DETAILS OF GRANT UTILISATION FOR THE

FINANCIAL YEAR 2019-20

Amount in ₹					
PARTICULARS	GIA - SALARY	GIA - GENERAL	GIA - ASSETS	GIA - SAP	TOTAL
<b>RECEIPTS</b>					
Grant unutilized b/f from the Previous Year	-97,03,728.00	1,54,49,643.08	1,75,08,103.23	57,683.00	2,33,11,701.31
Grant in Aid Received From Ministry	14,00,00,000.00	27,70,57,000.00	1,10,00,000.00	4,01,000.00	42,84,58,000.00
<b>TOTAL RECEIPTS (A)</b>	<b>13,02,96,272.00</b>	<b>29,25,06,643.08</b>	<b>2,85,08,103.23</b>	<b>4,58,683.00</b>	<b>45,17,69,701.31</b>
<b>LESS:- EXPENDITURE INCURRED &amp; PROVISION</b>					
Establishment Expenses	13,57,74,266.00	-	-	-	13,57,74,266.00
Administrative Expenses	-	10,68,67,551.52	-	1,72,035.00	10,70,39,586.52
Lab Services-Operation & Maintainance Exp	-	17,07,08,626.03	-	-	17,07,08,626.03
Increase in Stock of Fuel for Boilers & D.G Set	-	13,22,925.00	-	-	13,22,925.00
Payment made for Fixed Assets during the year:					
Additions in Fixed Assets	-	-	6,76,77,807.67	-	6,76,77,807.67
Less: Advance of Previous year Utilized against Fixed Assets	-	-	-37,70,344.00	-	-37,70,344.00
Less: Adjustment for amount of fixed asset excess charged in P.Y	-	-11,89,595.00	-6,27,93,091.00	-	-6,39,82,686.00
Advance against Fixed Assets, Goods & Services (Net)	-	49,467.00	1,48,21,816.00	-	1,48,71,283.00
Less: Advance of Prev. Year Utilized/Refunded against Goods & Services	-	-12,35,190.00	-	-	-12,35,190.00
Add: Grant Utilised for Prepaid Expenses Increase/Decrease	-	20,34,023.00	-	-	20,34,023.00
<b>TOTAL CURRENT YEAR EXPENDITURE / UTILISATION (B)</b>	<b>13,57,74,266.00</b>	<b>27,85,57,807.55</b>	<b>1,59,36,188.67</b>	<b>1,72,035.00</b>	<b>43,04,40,297.22</b>
<b>GRANT RECEIVABLE / PAYABLE TO GOI (A) - (B)</b>	<b>-54,77,994.00</b>	<b>1,39,48,835.53</b>	<b>1,25,71,914.56</b>	<b>2,86,648.00</b>	<b>2,13,29,404.09</b>





**SCHEDULE-12**  
**NATIONAL INSTITUTE OF BIOLOGICALS**  
 (Forming part of Financial Statement as on 31.03.2020)

**(A) SIGNIFICANT ACCOUNTING POLICIES**

**1. Basis of Accounting**

The financial statements have been prepared as prescribed by ICAI in accordance with generally accepted accounting principles. The National Institute of Biologicals (hereinafter referred to as NIB) adopts accrual system of accounting, however, the incomes i.e. receipts from Training Fee received, and Rent received from Hostel/Guest House and Interest on advances are recognized on cash basis.

The accounting policies adopted and applied in the preparation of financial statements by NIB are consistent with those used in the previous years.

**2. Property, Plant & Equipment and Depreciation**

- a) Property, Plant & Equipment (herein after commonly called Fixed Assets) are stated at cost less accumulated depreciation.
- b) Depreciation has been provided to the extent of 95% on S.L.M on the basis of rates as prescribed in schedule XIV of the Companies Act 1956. The depreciation rates applied on various assets is given below –

**RATES OF DEPRECIATION CHARGED ON PROPERTY, PLANT & EQUIPMENT**

Machinery & Equipment	-	4.75%
Office Equipment	-	7.07%
Building	-	1.63%
Furniture & Fixtures	-	6.33%
Typewriter	-	13.91%
Vehicles	-	9.50%
Air Conditioner	-	13.91%
Computer & Computer Software	-	16.21%
Cycle Rickshaws	-	9.50%
Tools	-	4.75%
Books	-	40.00%

- c) The depreciation has been provided for the full year in respect of additions, if any, made during the year in Fixed Assets. In respect of sale/disposal of fixed assets, no depreciation has been provided for in the year of sale/disposal, but it has no financial implication due to this deviation from the prescribed provisions of the ICAI.





**SCHEDULE-12**  
**NATIONAL INSTITUTE OF BIOLOGICALS**  
(Forming part of Financial Statement as on 31.03.2020)

- d) The depreciation has been charged to the grant (Corpus Fund/Capital Fund) and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item as per AS-12 prescribed by the ICAI.
- e) During the year, the depreciation has been charged from the year of original purchase of assets, procured through procurement consultant M/s HLL/HITES irrespective of the year of capitalization in respect of additions in fixed assets.

**3. Grant-in-Aid**

- a) The Grant-in-Aid received from the Ministry of Health & family Welfare (MoHFW), Government of India is accounted for on accrual basis. Accordingly, any deficit/surplus of grant has been shown as Grant Receivable / Payable to the MoHFW.
- b) The grants utilized for the purchase of fixed assets have been shown under the head of Capital Assets Fund.
- c) Further grants utilized for advances against fixed assets, goods & services have also been shown under the head of Corpus/Capital Assets Fund.
- d) A chart for receipt and utilization of Grant according to its grant head has been prepared and shown in Notes on Accounts to the financial statement.

**4. Inventory Valuation**

Stock of Diesel is valued at cost based on First in First Out (FIFO) method.

**5. Employee Remuneration & Benefits**

- (a) All Retirement and other Terminal Benefits such as Gratuity, Leave Encashment and Bonus etc. are not accounted on year to year basis and the same are recognized in the year of occurrence of event.
- (b) For disbursement of the Pension/Family Pension to the ex-employees, the requisite amount is transferred from NIB main account to NIB Pension account and unspent amount including interest earned, is carried forward to next year for discharging the pensioners liabilities.



**SCHEDULE-12**  
**NATIONAL INSTITUTE OF BIOLOGICALS**  
 (Forming part of Financial Statement as on 31.03.2020)

**6. Revenue Recognition**

- a) Income and expenditure are accounted for on accrual basis, as they are earned or incurred, however, the incomes i.e. rent received from Hostel/Guest House, Bank Interest and Interest on Staff Advances are accounted on Cash basis.
- b) The Consultancy charges paid for procurement of Fixed Assets is considered as revenue expenditure

**7. Provision**

A provision is recognized, when an enterprise has a present obligation as a result of past event; it is probable that an outflow of resources will be required to settle the obligation, in respect of which a reliable estimate can be made. Provisions are determined based on best estimate required to settle the obligation at the balance sheet date. These are reviewed at each balance sheet date and are adjusted to reflect the current best estimates.

**8. Contingent Liabilities and Contingent Assets**

A disclosure for a contingent liability is made when there is a possible obligation that may, but probably will not, require an outflow of resources. Where there is a possible obligation or a present obligation but the likelihood of outflow of resources is remote, no provision or disclosure is made.

**(B) NOTES ON ACCOUNTS**

1. NIB maintains Fixed Assets details in computerized format and keeping hard copy of the same for records. The physical verification of fixed assets has been done. The Quantitative adjustment resulting of physical verification yet to be considered.
2. The depreciation of Rs.6,47,20,114/- (includes additional depreciation of Rs. 6,91,097/- in respect of fixed assets procured through M/s HLL Lifecare Ltd. in the different previous years and capitalized during the year) has been charged to the Income and Expenditure account. The reconciliation/ settlement with M/s HLL Lifecare Ltd. is under process as on the date of Balance Sheet.



**SCHEDULE-12**  
**NATIONAL INSTITUTE OF BIOLOGICALS**  
(Forming part of Financial Statement as on 31.03.2020)

3. All liabilities are recognized to the extent information available.
4. NIB transfers all the receipts earned during the year from its various operations to the Ministry of Health & Family Welfare, GOI and already transferred an amount of Rs.12,77,00,000/-out of total receipts of Rs.14,23,47,737/-. The balance amount of Rs.1,46,47,737/- is shown as “Receipts Payable” to MoHFW under the head of “Current Liabilities”.
5. As per NIB records, an amount of Rs.1,54,57,028/- is payable and Rs. 12,18,026/- is receivable from M/s HSCC (I) Ltd for various projects. It is agreed between HSCC and NIB to enter into Memorandum of Understanding (MOU) for final financial settlement of above outstanding for respective projects accounts including third party liabilities.
6. Party’s balances are subject to confirmation due to COVID.
7. Purchase of Diesel to the extent utilized during the year is recognized as expenditure and the balance is shown as stock forming part of Current Assets.
8. TDS receivable during the year of Rs. 13,04,924/- includes the amount Rs.1,64,500/- which is not reflected at Income Tax portal.
9. During the year, The NIB has made efforts to collect information from suppliers/service providers about their status under Micro, Small and Medium Enterprises (Development) Act, 2006. On the basis of information so gathered, no dues payable to Micro, Small and Medium Enterprises as on 31.03.2020 and hence the interest payable, if any, are not recognized.
10. Separate bank accounts are maintained on behalf of other entities by the Institute for various projects/schemes i.e. (i) Haemovigilance Programme of India (HvPI), (ii) Uttar Pradesh State Aids Control Society (UPSACS) and (iii) Training & Workshops. The Receipt & Payment account of the respective funds are given at Appendix-1 to 3.

The Institute maintains separate bank account for disbursement of Pension for the ex-employees. During the year an amount of Rs. 1.60 crores has been transferred in this account and shown as an expenditure under the head ‘Expenses on Employee’s Retirement and Terminal Benefits’ of Schedule-9. The Receipt & Payment account of the Pension fund is given at Appendix-4.



**SCHEDULE-12**  
**NATIONAL INSTITUTE OF BIOLOGICALS**  
 (Forming part of Financial Statement as on 31.03.2020)

11. Internal Audit Committee is functional in order to strengthen the internal audit system.
12. Previous year's figures have been regrouped/ reclassified / rearranged, wherever necessary.
13. The summary of Grants Received and Utilized during the year is as under:


(Amount in Rs.)

Sl. No.	Nature of Grant	Opening Balance	Amount Received	Amount Utilized	Surplus / (Shortfall)
1.	GIA-Assets	1,75,08,103	1,10,00,000	1,59,36,189	1,25,71,914
2.	GIA-Salary	(97,03,728)	14,00,00,000	13,57,74,266	(54,77,994)
3.	GIA-General	1,54,49,643	27,70,57,000	27,85,57,807	1,39,48,836
4.	GIA-SAP	57,683	4,01,000	1,72,035	2,86,648
<b>Total</b>		<b>2,33,11,701</b>	<b>42,84,58,000</b>	<b>43,04,40,297</b>	<b>2,13,29,404</b>

**For Chandiwala Virmani and Associates**  
**Chartered Accountants**  
 (FR No. 000082N)

  
 (CA Naveen Chand Jain)  
 Partner  
 (M. No. 105433)

  
 (P.K. Mohapatra)  
 Admn. Officer (Finance)

**For National Institute of Biologicals**  
  
 (S.K. Sharma)  
 Sr. Admn. Officer (Finance)

  
 (Dr. Reba Chhabra)  
 Director I/c

**Place: Noida**  
**Date: 04/09/2020**  
**UDIN: 20105433AAAABL4088**

**NATIONAL INSTITUTE OF BIOLOGICAL  
NIB- HAEMOVIGILANCE PROGRAMME OF INDIA (HvPI)  
RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

Receipts	Amount	Payments	Amount
Opening Bank Balance (As per Bank Book)	21,11,862.74	Expenditure Incurred During the Year	64,24,118.55
Fund Received from IPC	45,00,000.00	Closing Bank Balance (As per Bank Book)	2,47,842.19
Interest Received	60,098.00		
	<b>66,71,960.74</b>		<b>66,71,960.74</b>

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO: 000082N

  
CA Naveen Chand Jain  
Partner  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

  
P K Mohapatra  
Admn. Officer (Finance)

  
S K Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
Director i/c



## Appendix-2

**NATIONAL INSTITUTE OF BIOLOGICAL**  
**NIB- Uttar Pradesh State Aids Control Society (UPSACS)**  
**RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

Receipts	Amount	Payments	Amount
Opening Bank Balance (As per Bank Book)	1,66,580.00	Fund utilized during the Year	4,85,680.60
Fund Received from NRL/SRL	4,50,000.00	Closing Bank Balance (As per Bank Book)	1,36,228.40
Interest Received	5,329.00		
	<b>6,21,909.00</b>		<b>6,21,909.00</b>

As per our report of even date attached.

**For Chandiwala Virmani & Associates**  
**Chartered Accountants**  
**FRN NO. 000082N**

  
**CA Naveen Chand Jain**  
**Partner**  
**(M.No. 105433)**

**Place : Noida**  
**Date : 04/09/2020**  
**UDIN: 20105433AAAABL4088**

**FOR NATIONAL INSTITUTE OF BIOLOGICALS**

  
**P K Mohapatra**  
**Admn. Officer (Finance)**

  
**S K Sharma**  
**Sr. Admn. Officer (Finance)**

  
**Dr. Reba Chhabra**  
**Director i/c**

**NATIONAL INSTITUTE OF BIOLOGICAL**  
**NHM-Training & Workshop**  
**RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

Receipts	Amount	Payments	Amount
Opening Bank Balance (As per Bank Book)	23,58,495.25	<b>Fund utilized during the Year:</b>	
<b>Fund Received from:</b>		ICMR-Project	2,26,802.00
ICMR	31,53,100.00	NHM-Bihar	1,81,000.00
NHM-Chhatisgarh	6,45,000.00	NHM-Chhatisgarh (Net)	3,79,355.00
NHM-Maharashtra	6,50,000.00	NHM-Jammu & Kashmir	7,965.00
NHM-Madhya Pradesh	6,70,000.00	NHM-Kerala (Net)	4,52,273.00
NHM-Punjab	-	NHM-Maharashtra	4,01,140.00
NHM-Telangana	13,20,000.00	NHM-Madhya Pradesh	6,70,000.00
NHM-Uttar Pradesh	6,45,000.00	NHM-Punjab	3,66,382.00
NHM-Uttarakhand	6,70,000.00	NHM-Telangana	9,99,609.00
WHO	23,05,078.00	NHM-Uttar Pradesh (Net)	6,97,232.00
		NHM-Uttarakhand	6,70,000.00
		WHO	25,18,547.54
		Misc. Expenditure (Bank Charges)	163.55
Interest Received	1,34,576.00	Closing Bank Balance (As per Bank Book)	49,80,780.16
	<b>1,25,51,249.25</b>		<b>1,25,51,249.25</b>

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N

CA Naveen Chand Jain  
Partner  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

  
**P K Mohapatra**  
Admn. Officer (Finance)

  
**S K Sharma**  
Sr. Admn. Officer (Finance)

  
**Dr. Reba Chhabra**  
Director i/c

## Appendix-4

**NATIONAL INSTITUTE OF BIOLOGICAL  
NIB- PENSION FUND  
RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

Receipts	Amount	Payments	Amount
Opening Bank Balance (As per Bank Book)	7,07,471.00	Fund utilized for disbursement of Pension	1,57,37,672.00
Fund Received from NIB	1,60,00,000.00	Closing Bank Balance (As per Bank Book)	10,08,918.00
Interest Received	39,119.00		
	<b>1,67,46,590.00</b>		<b>1,67,46,590.00</b>

As per our report of even date attached.

For Chandiwalla Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N

CA Naveen Chand Jain  
Partner  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAABL4088

FOR NATIONAL INSTITUTE OF BIOLOGICALS

  
P K Mohapatra  
Admn. Officer (Finance)

  
S K Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
Director i/c



# AUDITOR'S REPORT NIB-GPF





**CHANDIWALA VIRMANI & ASSOCIATES**  
Chartered Accountants

43, IInd Floor, Near Delhi Gate Police Station,  
Daryaganj, New Delhi-110002  
011-43587399  
chandiwalagupta@yahoo.com  
www.chandiwalavirmani.in

### INDEPENDENT AUDITOR'S REPORT

#### **The Members,**

General Provident Fund,  
National Institute of Biologicals,  
Ministry of Health & Family Welfare  
Government of India,  
A-32, Sector-62 (Institutional Area)  
Noida-201307

#### **Opinion**

We have audited the financial statements of **National Institute of Biologicals General Provident Fund (hereinafter called NIB-GPF)**, which comprise Balance Sheet as at 31st March, 2020, the Income & Expenditure Account and Receipt and Payment Account for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Subject to Emphasis of matters Para below, in our opinion, the accompanying financial statements give a true and fair view of the financial position of the **NIB-GPF** as at 31st March, 2020, and of its financial performance for the year then ended in accordance with the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI).

#### **Basis for Opinion**

We conducted our audit in accordance with the Standards on Auditing (SAs) issued by ICAI. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the **NIB-GPF** in accordance with the Code of Ethics issued by ICAI and we have fulfilled our other ethical responsibilities in accordance with the Code of Ethics. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### **Emphasis of Matters**

*We draw attention to the Note no.2 regarding non receipt of Interest on Bonds of PSIDC since 2013-14. The accumulated amount of interest receivable upto previous year of Rs.10,86,000/- has been reversed and no provision has been made during the current year in view of critical financial position of PSIDC. NIB has initiated the process of recalling principal amount of bond investment in PSIDC. However, no impairment provision for probable loss in recovery of principal amount of Bond has been made in view that Bonds are secured by the State Government Guarantee. Our opinion is not qualified in respect of this matter.*



Contd...2

## **Responsibilities of Management and Those Charged with Governance for the Financial Statements**

Management is responsible for the preparation of these financial statements that give a true and fair view of the state of affairs, results of operations and cash flows of the **NIB-GPF** in accordance with the accounting principles generally accepted in India. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the **NIB-GPF**'s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the **NIB-GPF** or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the **NIB-GPF**'s financial reporting process.

## **Auditor's Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with SAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

**Chandiwala Virmani And Associates**

**Chartered Accountants**

**Reg. No. 000082N**



**(M. No.: 105433)**

**UDIN: 20105433AAAABN6979**

**Place: Noida**

**Date: 04/09/2020**

**NATIONAL INSTITUTE OF BIOLOGICALS GENERAL PROVIDENT FUND**  
(Ministry of Health and Family Welfare)  
Balance Sheet as at 31st MARCH 2020

Amount in ₹

Liabilities	Schedule	For Current Year ended on 31.03.2020	For Previous Year ended on 31.03.2019	Assets	Schedule	For Current Year ended on 31.03.2020	For Previous Year ended on 31.03.2019
<b>Capital</b>				<b>Investment</b>			
Subscription & Contributions	1	7,98,26,835.00	7,87,14,825.00	Fixed Deposit with Bank	3A	3,03,44,490.00	2,37,18,934.00
				Investment PSU Bond	3B	4,40,00,000.00	4,97,00,000.00
				G.O.I. Securities	3C	40,32,500.00	40,32,500.00
Balance being Excess of Income/Expenditure	2	26,85,085.28	43,14,039.28	<b>Current Assets</b>			
				Advance to Members	4	7,08,312.00	6,74,312.00
				Accrued Interest (Investment)		16,03,541.00	25,92,629.00
<b>Current Liabilities</b>				TDS Recoverable		3,13,730.00	1,89,111.00
Provision- Audit Fee		5,900.00	-	TDS Recoverable-NIB		1,56,123.00	45,311.00
				Claim Recoverables		1,239.00	-
				Bank Balance		13,57,885.28	20,76,067.28
<b>Total</b>		<b>8,25,17,820.28</b>	<b>8,30,28,864.28</b>	<b>Total</b>		<b>8,25,17,820.28</b>	<b>8,30,28,864.28</b>

Significant Accounting Policies and Notes to Accounts

5

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N


  
CA Naveen Chand Jain  
Partner  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAABN6979

For National Institute of Biologicals  
General Provident Fund

  
P K Mohapatra  
Admn. Officer (Finance)

  
S K Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
Director (I/c)

**NATIONAL INSTITUTE OF BIOLOGICALS GENERAL PROVIDENT FUND**  
**(Ministry of Health and Family Welfare)**  
**Income & Expenditure Account for the year Ended 31st MARCH 2020**

Expenditure	For Current Year ended on 31.03.2020	For Previous Year ended on 31.03.2019	Income	Amount in ₹	
				For Current Year ended on 31.03.2020	For Previous Year ended on 31.03.2019
Interest on subscription	62,75,570.00	53,36,478.00	Interest on Investment (Bonds)	45,51,974.00	57,59,421.00
Audit Fees	5,900.00	-	Interest on Saving A/c	95,042.00	1,16,084.00
Misc Exp.	-	2,352.00	Misc. Receipts	5,500.00	13,287.00
Excess of Income over Expenditure	-	5,49,962.00	Excess of Expenditure over Income	16,28,954.00	-
<b>Total</b>	<b>62,81,470.00</b>	<b>58,88,792.00</b>	<b>Total</b>	<b>62,81,470.00</b>	<b>58,88,792.00</b>

Significant Accounting Policies and Notes to Accounts

5

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N

  
CA Naveen Chand Jain  
Partner  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAABN6979

For National Institute of Biologicals  
General Provident Fund

  
P K Mohapatra  
Admn. Officer (Finance)

  
S K Sharma  
Sr. Admn. Officer (Finance)

  
Dr. Reba Chhabra  
(Director I/c)

**NATIONAL INSTITUTE OF BIOLOGICAL**  
**General Provident Fund**  
**RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2020**

		Amount in ₹			
Receipts	Current Year	Previous Year	Payments	Current Year	Previous Year
<b>Opening Balance</b>			<b>Payments made out of GPF Fund</b>		
- Bank Balance	20,76,067.28	22,26,882.28	- Towards Withdrawals	92,30,000.00	32,04,000.00
<b>Contribution Receipts</b>			- Towards Final Settlement	82,23,560.00	-
- Contribution received during the year	1,22,90,000.00	1,10,91,696.00	<b>Payments made towards Investments</b>		
<b>Interest Received</b>			- In PSU bonds	1,00,00,000.00	-
- On Bank deposits	95,042.00	1,16,084.00	- In Government Securities	-	-
- Interest on Investment	53,05,631.00	49,39,465.00	- Fixed Deposit	2,58,44,490.00	1,92,18,934.00
<b>Other Receipts</b>			- Interest paid on Investments	-	-
- Misc. Receipts	5,500.00	13,287.00	Purchased Cum-Interest		
- Advance recovered during the year from members	26,000.00	1,32,000.00	<b>Other payments</b>		
- Refund of Tax Deducted at Source	-	78,023.00	- Advance paid during the year	60,000.00	-
- Receipt from matured PSU Bond	1,57,00,000.00	29,00,000.00	- Bank charges	-	-
- Receipt from matured FD	1,92,18,934.00	30,00,000.00	- Claim Recoverable	1,239.00	-
- Claim Recoverable	-	1,564.00	<b>Closing Balances</b>		
			- Bank Balance	13,57,885.28	20,76,067.28
	<b>5,47,17,174.28</b>	<b>2,44,99,001.28</b>		<b>5,47,17,174.28</b>	<b>2,44,99,001.28</b>

As per our report of even date attached.

For Chandiwala Virmani & Associates  
Chartered Accountants  
FRN NO. 000082N

CA Naveen Chand Jain  
Partner  
New Delhi  
(M.No. 105433)

Place : Noida  
Date : 04/09/2020  
UDIN: 20105433AAAAABN6979

For National Institute of Biologicals  
General Provident Fund

P K Mahapatra  
Admn. Officer (Finance)

S K Sharma  
Sr. Admn. Officer (Finance)

Dr. Reba Chhabra  
(Director I/c)



Schedule - 1 : G P F Accounts Balance Summary as on 31.03.2020							Amount In ₹	
Opening Balance	Subscriptio/ Contribution.	Recovery	Advance	Withdrawal	Final Settlement	Previous Year Adjustments (Excess/Short)	Interest	Closing Balance
7,80,40,513	1,22,90,000	26,000	60,000	92,30,000	82,23,560	-	62,75,570	7,91,18,523
<b>ADD : ADVANCE ADJUSTED SHOWN SEPARATELY</b>								
OPENING ADVANCE: 01.04.2019							6,74,312	
ADD: ADVANCE GIVEN DURING THE YEAR							60,000	
LESS ; ADVANCE RECOVERY DURING THE YEAR							26,000	7,08,312
<b>Total Subscription as per Balance Sheet</b>								<b>7,98,26,835</b>

SCHEDULE - 2 : Excess of Income/Expenditure for the year				Amount In ₹	
Particulars				As on 31.03.2020	As on 31.03.2019
Opening Balance				43,14,039.28	37,65,643.28
Add/Less: Income/Expenditure for the year				-	5,49,962.00
Less: Adjustment of previous year excess/deficit				-16,28,954.00	-1,566.00
<b>Balance Carried forwarded to Balance Sheet</b>				<b>26,85,085.28</b>	<b>43,14,039.28</b>



*[Signature]*

*[Signature]*



**NATIONAL INSTITUTE OF BIOLOGICALS**  
**DETAILS OF GPF INVESTMENT FOR FY 2019-20 (AS ON 31.03.2020)**

Sl No	FDR / Receipt NO	DATE OF INVESTMENT	AMOUNT INVESTED (Rs.)	PERIOD OF DEPOSIT (MM/DD)	RATE OF INTEREST( %)	DATE MATURITY / REDEMPTION	AMOUNT DUE ON MATURITY (Rs.)	REMARKS
A- SHORT TERM DEPOSIT WITH BANK OF BARODA								
1	26290300044370	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863756
	26290300044371	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863757
	26290300044372	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863758
	26290300044373	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863759
	26290300045259	22.03.2019	25,00,000	444 Days	7.00%	08.06.2020	27,19,623	Receipt No. 863969
	26290300041620	29.05.2019	10,68,898	366 Days	6.70%	30.05.2020	11,40,677	Receipt No. 863308
	26290300041621	29.05.2019	10,68,898	366 Days	6.70%	30.05.2020	11,41,119	Receipt No. 863309
	26290300041622	29.05.2019	10,68,898	366 Days	6.70%	30.05.2020	11,41,120	Receipt No. 863310
	26290300041623	29.05.2019	10,68,898	366 Days	6.70%	30.05.2020	11,41,119	Receipt No. 863311
	26290300041624	29.05.2019	10,68,898	366 Days	6.70%	30.05.2020	11,41,120	Receipt No. 863312
	26290300046169	06.06.2019	10,00,000	444 Days	7.00%	23.08.2020	10,87,949	Receipt No. 896113
	26290300046170	06.06.2019	10,00,000	444 Days	7.00%	23.08.2020	10,87,949	Receipt No. 896114
	26290300046171	06.06.2019	10,00,000	444 Days	7.00%	23.08.2020	10,87,949	Receipt No. 896115
	26290300047291	20.09.2019	40,00,000	400 Days	6.75%	24.10.2020	43,03,730	Receipt No. 896308
	26290300048046	26.11.2019	10,00,000	367 Days	6.30%	27.11.2020	10,64,687	Receipt No. 896438
	26290300048047	26.11.2019	10,00,000	367 Days	6.30%	27.11.2020	10,64,687	Receipt No. 896439
	26290300048048	26.11.2019	10,00,000	367 Days	6.30%	27.11.2020	10,64,687	Receipt No. 896440
	26290300048049	26.11.2019	10,00,000	367 Days	6.30%	27.11.2020	10,64,687	Receipt No. 896441
	26290300048050	26.11.2019	10,00,000	367 Days	6.30%	27.11.2020	10,64,687	Receipt No. 896442
2	PSIDC BOND Regd Folio No. PSIDC-XXVIII-N2 Allotment Lt. No. 46 Disbative no. 1420-1439 2010-2nd Series, ISIN 973F09113	17.02.2011	20,00,000		9.05% p.a.	17.02.2019 17.02.2020 17.02.2021	600000 (30%) 600000 (30%) 800000 (40%)	30% end of 8th Year 30% end of 9th Year 40% end of 10th Year
3	IFCI Tier II Bonds Series- I July, 2011	July, 2011	20,00,000	10 YY	10.50% p.a	01.08.2021	10.5 BD 01AG21 FYRS10000 LOA UPTO 259P11	200 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09N37
4	IFCI Tier II Bonds Series- I Application No. 804536	01.11.2011	10,00,000	10 YY	10.50% p.a	31.10.2021	10.5 BD 31OT21 FYRS10000 LOA UPTO 07FB12	100 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09NV2
5	IFCI Tier II Bonds Series- I Application No.	07.02.2012	10,00,000	10 YY	10.50% p.a	28.02.2022	OP-1 10.5 BD 28PB22 FYRS10000 LOA UPTO 26AP12	100 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09OL1
6	KTDFC FDR No.300503 Deposit ID: 001031300503	03.02.2018	10,00,000	36 MM	8.25 % p.a.	03.02.2021	10,00,000	Periodic Interest Rs.20767/-qtr
7	KTDFC FDR No.300824 Dated: 07.04.18	07.04.2018	10,00,000	36 MM	8.25% p.a.	07.04.2021	10,00,000	Periodic Interest Rs.20767/-
8	KTDFC FDR No. 200453	04.03.2019	5,00,000	24 MM	8.50% p.a.	04.03.2021	5,00,000	Periodic Interest Rs. 10700/-
9	KTDFC FDR No. 200454	04.03.2019	5,00,000	24 MM	8.50% p.a.	04.03.2021	5,00,000	Periodic Interest Rs. 10700/-
10	KTDFC FDR No. 200455	04.03.2019	5,00,000	24 MM	8.50% p.a.	04.03.2021	5,00,000	Periodic Interest Rs. 10700/-
Total - 3A			3,03,44,490					
B- INVESTMENT IN PSU BONDS/DEPOSITS								

11	KTDFC FDR No. 200465	12.03.2019	25,00,000	24 MM	8.50% p.a.	12.03.2021	25,00,000	Periodic Interest Rs. 53502/-
12	KTDFC FDR No. 200435	19.03.2019	20,00,000	24 MM	8.50% p.a.	19.03.2021	20,00,000	Periodic Interest Rs. 42802/-
13	KTDFC FDR No. 300823	29.04.2018	10,00,000	36 MM	8.25%	29.04.2021	10,00,000	Periodic Interest Rs. 20767/-
14	TANGEDCO Bond Series-3/2014-15	11.06.2015	10,00,000	10 YY	9.00% (Semi annually)	11.06.2023 (8th Yr) 11.06.2024 (9th Yr) 11.06.2025 (10th Yr)	30%- Rs. 300000/- 30%- Rs. 300000/- 40%- Rs. 400000/- ISIN No. INE340M08145 SR-III 9 BD 11J225 FVSR10 LAC 11th June and 11th December every year ISIN No. INE340M08145	
15	KTDFC FDR No. 200315	21.01.2019	40,00,000	24 MM	8.50%	21-01-2021	40,00,000	Periodic Interest Rs. 85504/-
16	LTC Housing Finance Ltd Deposit Receipt No. 663329 FolioKYC/No. 0031051	28.01.2019	10,00,000	24MM	8.20%	28.01.2021	10,00,000	Non-Cumulative Deposit
17	LTC Housing Finance Ltd Deposit Receipt No. 671457 FolioKYC/No. 0033670	03.06.2019	1,00,00,000	36 MM	8.40%	03.06.2020	1,00,00,000	Non-Cumulative Deposit (Deposit Receipt No. 639737 Renewed from 03.06.2019 for 1 year)
18	TANGEDCO Bond Series-3/2016-17	27.03.2017	10,00,000	10 YY	9.25% (Semi annually)	27.03.2025 (8th Yr) 27.03.2026 (9th Yr) 11.06.2027 (10th Yr)	30%- Rs. 300000/- 30%- Rs. 300000/- 40%- Rs. 400000/- ISIN No. INE340M08178	27th March and 27th September every year
19	KTDFC FDR No. 62894 FNo KTDFC/JUN/2017/132452/TVP	31.05.2017	25,00,000	36 MM	8.50%	31.05.2020	25,00,000	Periodic Interest Rs. 53502/-
20	KTDFC FDR No. 200122 Scheme- BPS GEN	09.06.2017	20,00,000	36 MM	8.50%	09.06.2020	20,00,000	Periodic Interest Rs. 42802/-
21	KTDFC Deposit ID. 002031300113 FDR No. 300113	11.08.2017	20,00,000	36 MM	8.25%	11.08.2020	20,00,000	Periodic Interest Rs. 41534/-
22	PNB Housing Finance Ltd Customer ID. 1322374	19.01.2018	15,00,000	44 MM	7.55%	19.09.2021	15,00,000	Non-Cumulative Deposit
23	HDFC Ltd CP/927912 dated 22.01.2018	19.01.2018	15,00,000	33 MM	7.55%	19.10.2020	15,00,000	Non-Cumulative Deposit
24	KTDFC Deposit ID. 002031300423 FDR No. 300423	19.01.2018	20,00,000	36 MM	8.25%	19.01.2021	20,00,000	Periodic Interest Rs. 41534/-
25	KTDFC FDR No. 300724	05.02.2018	5,00,000	36 MM	8.25%	05.02.2021	5,00,000	Periodic Interest Rs. 10394/-
<b>Total - 3B</b>			<b>4,40,00,000</b>					
<b>C - G.O.I Security</b>								
26	8.28% GOI 2027 Govt. of India Security (Amt paid for Investment Rs 492500)	30.01.2012	4,92,500	15 YY	8.28%	21.09.2027	5,00,000	07012 GOI 21SP27 8.28 FV RS 100 Purchased 5000 no @ Rs. 98.50/100.00 Demat form ISIN No. IN0020070069
27	8.83% GOI 2023 Govt. of India Security (Amt paid for Investment Rs 1000000)	30.12.2013	10,00,000	10 YY	8.83%	25.11.2023	10,00,000	16575 GOI 25NOV23 8.83 FV RS 100 Purchased 10000 no @ Rs. 100/100.00 Demat form ISIN No. IN0020130061
28	9.39% GOI 2023 Govt. of India Security (Amt paid for Investment Rs 1510500)	30.12.2013	15,10,500	10 YY	9.39%	20.11.2023	15,00,000	16575 GOI 20NV23 9.39 FV RS 100 Purchased 15000 no @ Rs. 100.70/100.00 Demat form ISIN No. IN1520130122
29	8.35% GOI 2022 Govt. of India Security (Amt paid for Investment Rs 10 Lacs)	19.01.2016	10,29,500	36 MM	8.35%	14.05.2022	10,00,000	ISIN No. IN0020020072 8.35 FV RS 100 02011 GOI 2022
<b>Total - 3C</b>			<b>40,32,500</b>					
<b>GRAND TOTAL (3A+3B+3C)</b>			<b>7,83,76,990</b>					



**SCHEDULE - 4 : Advances to Members during the year**

Particulars	Amount In ₹	
	As on 31.03.2020	As on 31.03.2019
Opening Balance	6,74,312.00	8,06,312.00
Add: Advances given during the year	60,000.00	-
Less: Advances recovered during the year	-26,000.00	-1,32,000.00
<b>Balance of Advances</b>	<b>7,08,312.00</b>	<b>6,74,312.00</b>



**NATIONAL INSTITUTE OF BIOLOGICALS**  
**SCHEDULE-5 General Provident Fund**  
 (Forming part of Financial Statement as on 31.03.2020)

**A. SIGNIFICANT ACCOUNTING POLICIES**

**1. Method of accounting:**

The accounts have been prepared under the Historical cost convention on accrual basis.

**2. Revenue Recognition:**

The Revenue has been recognized on accrual basis.

**3. Fixed Assets:**

There are no fixed assets.

**4. Investments:**

Investments are Non Trade Investments and are stated at cost and are held in the name of the "National Institute of Biologicals General Provident Fund" (herein after referred to as "NIB-GPF").

**B. NOTES TO ACCOUNTS**


1. Investment in the bonds have been stated at the cost therefore the effect of the change in the value of the bond as on date of balance sheet has not been quantified and considered.
2. The interest on Investment in Punjab State Industrial development Corporation Ltd. (PSIDC), a Punjab State Government Undertaking, bonds is not received since 2013-14. In view of critical financial position of PSIDC, the accumulated amount of accrued interest as outstanding upto previous year was Rs.10,86,000/-, has been reversed and no provision has been made in current year. NIB also initiated the process for getting refund of principal amount invested with PSIDC.
3. TDS Recoverable of F.Y. 2019-20 from NIB is shown as Current Assets.
4. The previous year's figures have been regrouped/reclassified/rearranged, wherever necessary to confirm to the current period presentation.

**For Chandiwalla Virmani & Associates**  
**Chartered Accountants**  
 (FRN: 000082N)

  
 (CA Naveen Chand Jain)  
 Partner  
 (M. No. 105433)

Place: Noida  
 Date: 04/09/2020  
 UDIN: 20105433AAAABN6979

**For National Institute of Biologicals**  
**General Provident Fund**

  
 (P.K. Mohapatra)  
 Admn. Officer (Finance)

  
 (S.K. Sharma)  
 Sr. Admn. Officer (Finance)

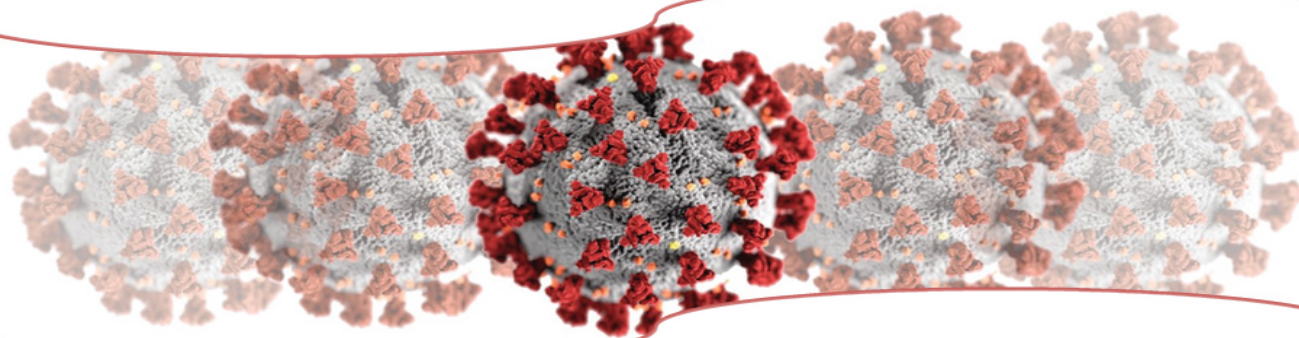
  
 (Dr. Reba Chhabra)  
 Director I/c







# NIB COVID WARRIORS TEAM



## NATIONAL INSTITUTE OF BIOLOGICALS

(Ministry of Health and Family Welfare)

Government of India

Plot No. A-32, Sector-62, NOIDA-201 309 (UP), INDIA

Phone: +91 0120 2400022, 2400072; Fax: +91 0120 2403014

E-mail: [info@nib.gov.in](mailto:info@nib.gov.in); Website: [www.nib.gov.in](http://www.nib.gov.in)

