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Azadi Ka
Amrit Mahotsav



ANNUAL REPORT 2022-2023



जैविक गुणवत्ता पर राष्ट्रीय शिखर सम्मेलन NATIONAL SUMMIT ON QUALITY OF BIOLOGICALS



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27 जनवरी 2023 | विज्ञान भवन, नई दिल्ली
27 JANUARY 2023 | VIGYAN BHAWAN, NEW DELHI



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राष्ट्रीय जैविक संस्थान NATIONAL INSTITUTE OF BIOLOGICALS

Annual Report 2022-2023



NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health & Family Welfare

Government of India

NOIDA

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INTRODUCTION

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. 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 Institute is also accredited by NABL as per ISO/ IEC 17025:2017 for the scope defined.

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.





FROM THE DIRECTOR'S DESK

I am immensely proud to present the Annual Report of National Institute of Biologicals for the year 2022-2023 wherein Institute has progressed incredibly in newer ways of working in the area of Quality Control of Biologicals.

Over the last 30 years since its foundation, the NIB has gradually ascended the success ladder in the highly specialised scientific field of quality control of Biologicals, with its knowledgeable well trained competent and highly motivated staff. Impact of science, scientific research, technological development, globalization on our daily life is vibrant and unavoidable. With this mind, we continue to march steadily towards our aim to work for our Nation's public health safety.

In the last decade, the capacity of NIB to test different types of biologicals has increased substantially from 141 in year 2013-14 to 303 in year 2022-23. The Institute evaluated 2099 batches of biological samples in 2022-23 including batches under the Drugs & Cosmetics Act and Rules thereunder and from State Medical Procurement Agencies as well . Out of total samples tested, 3.61% were found to be of Not of Standard Quality (NSQ) thus highlighting the role of the Institute in protecting and promoting public health.

On 30th June 2022 NIB celebrated our Nation's Azadi Ka Amrit Mahotsav under the theme "Three decades of Service to the Nation". The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar was the Guest of Honour at this prestigious event. Shri Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare & Dr. Balram Bhargava, Secretary, DHR & DG ICMR also graced the occasion along with other dignitaries.

On this auspicious occasion of NIB's 30th Anniversary &

Haemovigilance Programme of India (HvPI's) 10th Anniversary, a Booklet on "30 years of NIB", "Guidance Document for Reporting Blood Donor Adverse Reactions" under the National Blood Donor Vigilance Programme (NBDVP) and a Video on NIB activities were released by The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar. The employees who had completed 25 years of service and contributed to the progress of the institute were felicitated by the dignitaries.

NIB organized the National Summit on Quality of Biologicals on 27th January 2023, to celebrate the 31st Foundation day of NIB, at Vigyan Bhawan, New Delhi, which was virtually inaugurated by Dr. Mansukh Mandaviya, Hon'ble Union Minister of Health & Family Welfare. The Summit provided an integrated platform to different stakeholders, regulators, industry, academia and researchers for the exchange of ideas that can potentially circumvent the present bottlenecks of the Quality regulation of Biologicals. A coffee table book about NIB was also launched by the dignitaries at the event.

This year National Institute of Biologicals (NIB) organized the BLOODCON-2022, the National Conference & Workshop in association with Federation of Indian Blood Donors Organizations (FIBDO) at NIB, NOIDA from 17th to 19th November 2022. The conference was inaugurated by Shri SomParkash, Hon'ble Minister of State, Ministry of Commerce and Industry, Government of India. During the conference a book on "Good Blood Transfusion Practices- Guidance for Rational use of Blood" prepared by NIB was released by Shri Som Parkash, Hon'ble Minister of State, Ministry of Commerce and Industry, Government of India.

Enduring with the Mandate of Training, NIB continued its tradition of conducting National Skill Development & Hands-on Training Programme on Quality Control of Biologicals for M.Sc. Biotechnology Students under "Pradhan Mantri Kaushal Vikas Yojna". Training for 83 Students from Chhattisgarh, Himachal Pradesh, Assam, Manipur has been conducted in the period of this annual report. Also, NIB in collaboration with the Blood Cell-National Health Mission, conducted a six-day residential Hands-on training programme from 09th – 14th January 2023 on "Training of Trainers for Strengthening of Blood Services" for 41 Blood Bank Officials from Chhattisgarh state.

To promote such academic and skill development activities further in the field of Biologicals, NIB, Noida signed a MoU with DPSRU, Delhi on 17th May 2022 to start a Certificate Course on Quality Assurance of Biopharmaceuticals and even welcomed its first batch of students for PhD programme in Aug 2022.

Last but not the least, it gives me immense pride to share that NIB won the prestigious 1st Prof. S.K. Joshi Laboratory Excellence Gold Award in the field of TESTING instituted by the Quality Council of India (QCI) on 6th October 2022.

With the unwavering support and guidance from Ministry of Health & Family Welfare, Government of India, Central Drugs standards and Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC) and Indian Council of medical Research (ICMR), we plan to move forward with a strong commitment for quality of Biologicals, public health and academic excellence. With continuous adhering to the spirit of sharing knowledge and to contribute in evaluating new products, we sincerely hope that in terms of progress and prosperity, year 2023-24 shall live up to all our expectations.

REPORT ON NATIONAL SUMMIT ON QUALITY OF BIOLOGICALS

NATIONAL SUMMIT - 2023

NIB organised the first National Summit on Quality of Biologicals on 27th January 2023, on the occasion of its 31st Foundation day at Vigyan Bhawan, New Delhi. The Summit was virtually inaugurated by Dr. Mansukh Mandaviya, Hon'ble Union Minister of Health & Family Welfare. Dr Bharati Pravin Pawar, Union Minister of State for Health & Family Welfare also addressed the Summit through a video message. Shri Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare addressed the gathering sharing his views on the current practices and future prospects in the field of Quality Control of Biologicals. He emphasized the necessity of active collaboration and support among industry, regulation, research, and academia verticals with respect to Quality of Biologicals in the interest of Public Health. Dr Atul Goel, DGHS, Dr V.K. Paul,

Member, NITI Aayog, and Ms S. Aparna, Secretary, Department of Pharmaceuticals, chaired the three Sessions. Several other eminent dignitaries namely Prof. Y. K. Gupta, President, AIIMS, Bhopal and Dr Pramod Kumar Garg, Executive Director, THSTI along with participation from manufacturers of various Biologicals, medical procurement agencies, IPC, CDSCO etc. also graced the occasion. The Summit provided an integrated platform to different stakeholders, regulators, industry, academia and researchers for the exchange of ideas that can potentially circumvent the present bottlenecks of the Quality regulation of Biologicals. A Coffee Table Book about NIB was also launched by the dignitaries at the event



PROF. S. K. JOSHI LABORATORY EXCELLENCE AWARD

NIB has got the prestigious First Prof. S.K. Joshi Laboratory Excellence Gold Award in the field of Testing on 6th Oct 2022 instituted by the Quality Council of India (QCI) after qualifying several rounds. It is the country's first-of-its-kind Laboratory Excellence Award launched by QCI in Sep 2021. The Award is to recognize Laboratories (Testing, Medical and

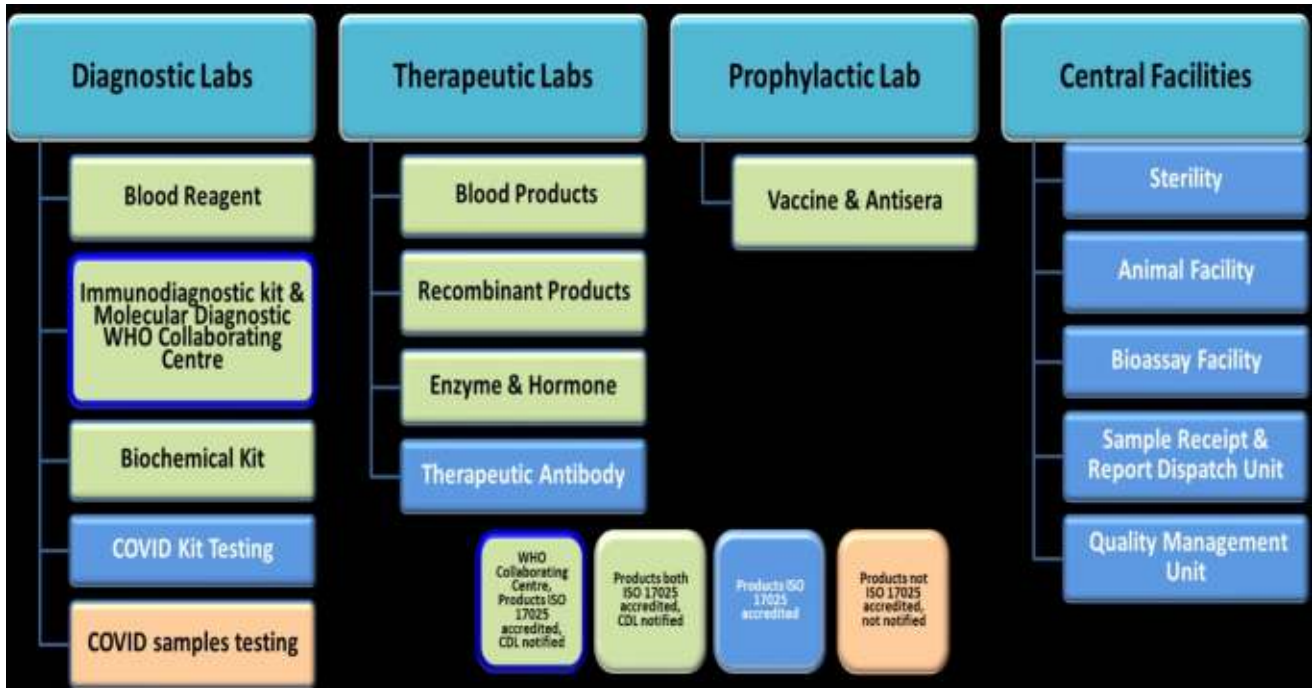
Calibration) that have established outstanding achievements in the field of Quality services and benchmarked in their domain for their best practices. NIB has been playing a pivotal role to ensure that Quality assured Biologicals reach the health system and thereby strengthening Prime Minister's mission to ensure quality health & wellness for all.





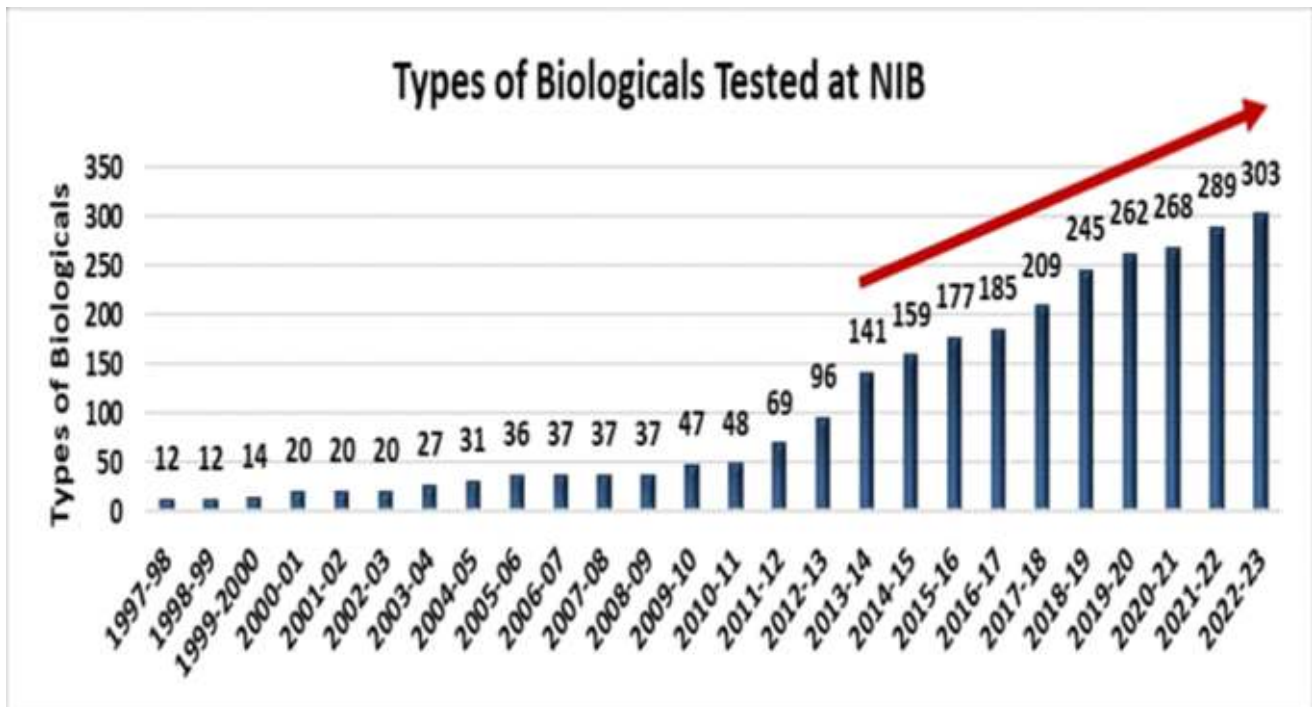
**SCIENTIFIC
ACTIVITIES-
PROTECTING
PUBLIC HEALTH
BY ASSURING THE
QUALITY OF
BIOLOGICALS**

Overview of Quality Control Testing at NIB



Quality Control Evaluation of Biologicals

The total no. of types of biologicals tested at NIB has increased substantially over last 26 years



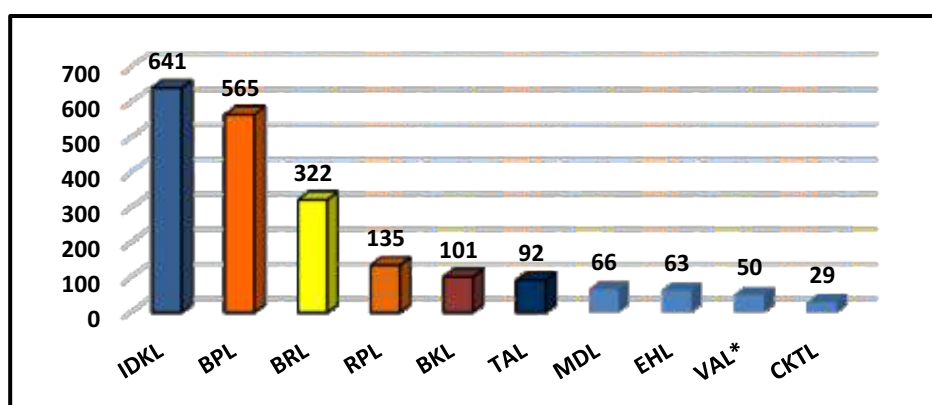
Capacity to test type of Biologicals at NIB

CATEGORY OF BIOLOGICALS TESTED	No. of Biologicals
1. Blood Grouping Reagents	98
2. Immunodiagnostic & Molecular Diagnostic Kits	69
3. COVID-19 Kits	12
4. Biochemical Kits	3
5. Blood Products	25
6. Recombinant Products	37
7. Therapeutic Antibody	25
8. Enzymes & Hormones	20
9. Vaccines	14
Total	303

Samples Received

In FY 2022-23, a total number of 2099 samples (including 35 samples received for parallel testing in addition to CDL, Kasauli) have been received under

various product categories (Fig. 1) (including Govt. samples, Survey samples, Service samples, samples for Standardization) for testing purpose. Out of the total, 303 samples were received from different State Medical Procurement Agencies.



IDKL	Immunodiagnostic kit Lab
BPL	Blood Products Lab
BRL	Blood Reagent Lab
RPL	Recombinant Products Lab
BKL	Biochemical kit
TAL	Therapeutic Antibody Lab
MDL	Molecular Diagnostic Kit
EHL	Enzymes & Hormones Lab
VAL	Vaccine & Antisera Lab
CKTL	Covid Kit Testing Lab

Fig : 1 -Total number of samples received at NIB during FY 2022-23 and their distribution in various categories/ laboratories

*VAL (excluding 35 samples received for parallel testing with CDL, Kasauli)

Release of Test Reports

A total of 2101 (including 30 samples for parallel testing with CDL, Kasauli reported to CDSCO) test reports were released in financial year 2022-23 (Fig. 2). Out of total reports released, 76 samples i.e. 3.61% were found to be "Not of Standard Quality" (NSQ) in 2022-23

(Fig. 3) which is lower than that reported in the previous year 2021-22 (4.30%). Reporting 'Not of Standard Quality' samples shows the Institute's dedication towards protecting and promoting public health and supports the government's aim of a "Healthy India

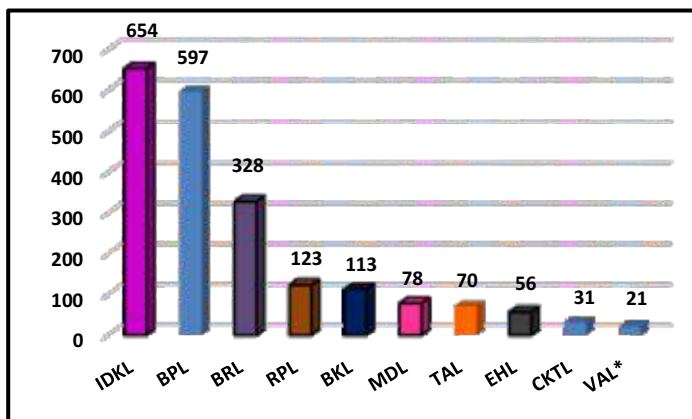


Fig: 2 Lab-wise wise# reports released *VAL (excluding 30 samples for parallel testing in addition to CDL, Kasauli reported to CDSCO)

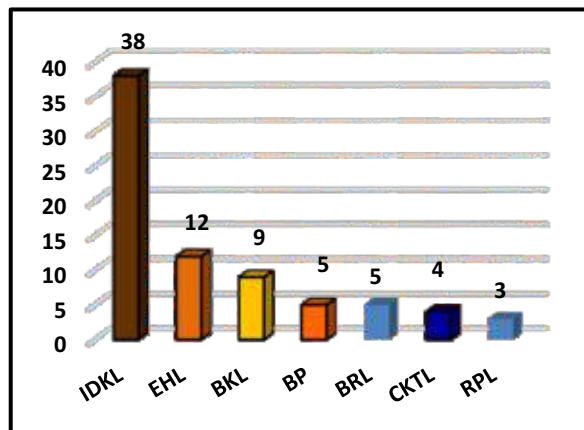


Fig: 3 Lab-wise# number of NSQ reports released

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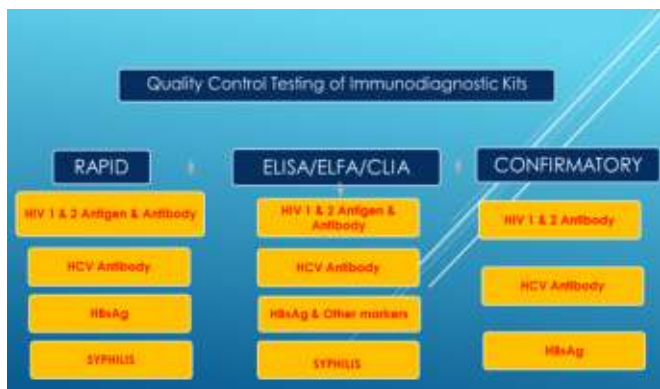
IDKL	Immunodiagnostic kit Lab
BPL	Blood Products Lab
BRL	Blood Reagent Lab
RPL	Recombinant Products Lab
BKL	Biochemical kit
TAL	Therapeutic Antibody Lab
MDL	Molecular Diagnostic Kit
EHL	Enzymes & Hormones Lab
VAL	Vaccine & Antisera Lab
CKTL	Covid19 Kit Testing Lab

NIB LABORATORIES

The Quality Control evaluation of the biologicals are carried at the State-of- the Art laboratories of NIB.

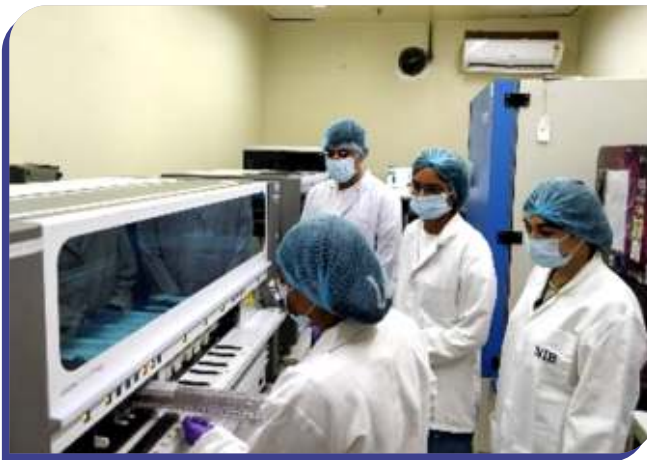
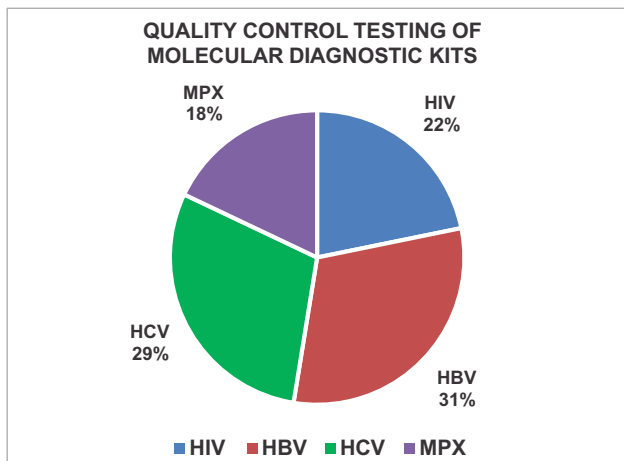
Immunodiagnostic Kit Laboratory (IDKL) is a WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis In-Vitro Diagnostic Assays and Support Cell for WHO Pre-Qualification Programme for In-Vitro Diagnostics and carries out Quality Control

testing of indigenously manufactured and imported kits viz. Rapid, ELISA, Confirmatory, CLIA & ELFA Kits for HIV, HCV, HBsAg & syphilis. The Laboratory has a repository of HIV, HBV, HCV and syphilis Plasma Panels for Quality Control testing of indigenous and imported Immunodiagnostic and Molecular diagnostic kits. In this regard, DCG(I) has directed various blood banks/ hospitals to provide infectious plasma bags to NIB.



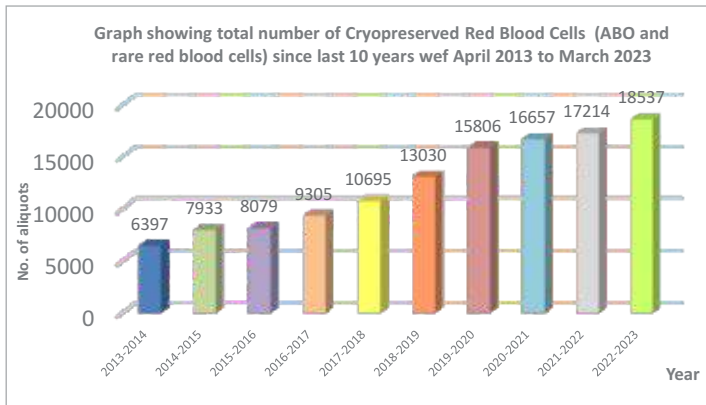
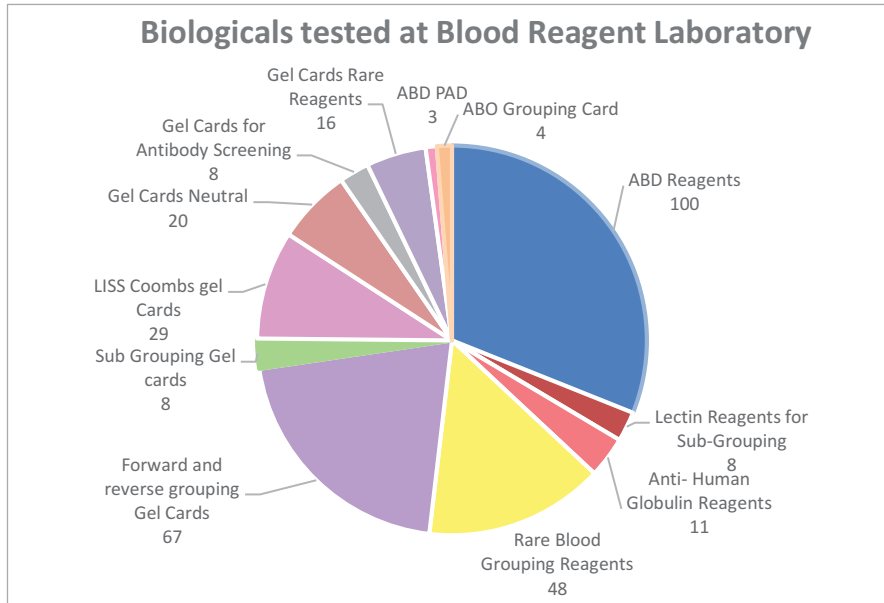
Molecular Diagnostic Kit Laboratory (MDL), Molecular Diagnostic Laboratory (MDL) has been conducting Quality Control testing of indigenously manufactured and imported molecular diagnostic test

kits intended to be used for blood donor screening and viral load monitoring of Human Immunodeficiency Virus (HIV), Hepatitis-B Virus (HBV) and Hepatitis-C Virus (HCV).



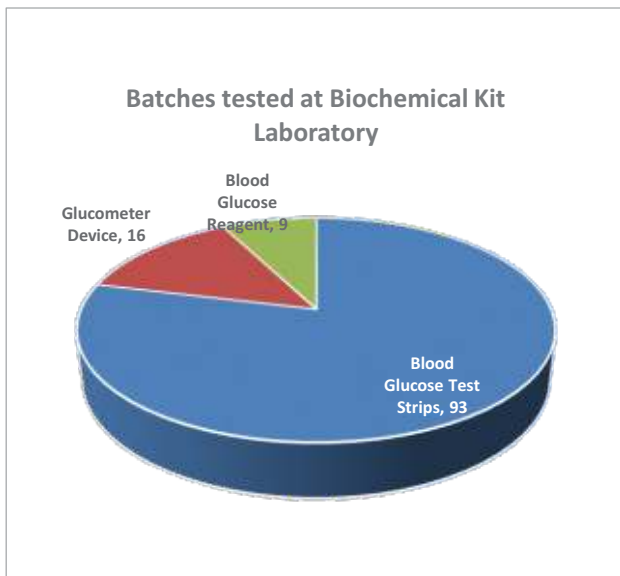
Blood Reagent Laboratory (BRL) carries out quality control evaluation of Blood Grouping Reagents. The laboratory has the infrastructure and expertise for testing different types of Blood Grouping Reagents and Gel cards for safe blood transfusion. DCG (I) has directed to various blood banks/ hospitals to provide non- infective and non-clotted left-over blood samples from blood banks for carrying out quality control of

Blood Grouping reagents, Gel Cards and Microplates. The laboratory maintains and strengthens the repository for cryopreserved panel cells for routine and rare red blood cells from the left-over samples collected from various blood banks. The lab has taken up Quality Control testing of the new biologicals viz. Gel cards for Starter pack for preparing Coombs Control cells, Gel cards for DC-Screening II and ABO Sub Grouping.



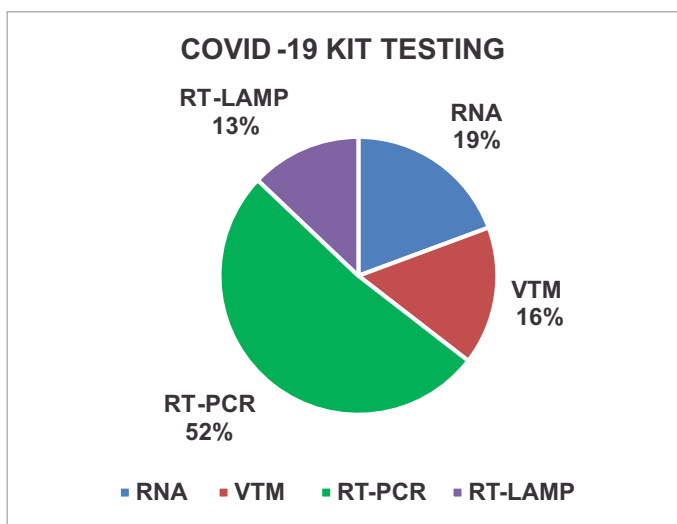
Biochemical Kit Laboratory (BKL) is engaged in the evaluation of batches of Self-Monitoring of Blood Glucose (SMBG/ Glucometers) specific- Blood Glucose test Strips, and fully automated analyzer-based Glucose reagent. The laboratory has initiated to

perform the quality control evaluation of new product, viz., Glucometer Device. The staff is trained in High ended equipment operation for the Quality control Evaluation of batches of Glucose reagent samples, Blood Glucose Meter with App based Smartphone.



COVID-19 Kit Testing Laboratory (CKTL) : NIB is one of the 24 centers in the country identified in the ICMR-DCGI GUIDELINES FOR VALIDATION AND BATCH TESTING OF COVID-19 DIAGNOSTIC KITS dated 4th June 2020 at ICMR’s website. In view of this NIB established a **COVID-19 Kit Testing Laboratory (CKTL)** for QC evaluation of SARS CoV-2 diagnostic kits to promote and safeguard public health. The laboratory is responsible for QC evaluation of RT-

PCR Kits, Covid-19 RT-LAMP (Loop-mediated isothermal amplification) Kits, Viral RNA Extraction Kits, VTM (Viral Transport Medium) & Swabs directed from ICMR’s online portal. Performance of these kits is satisfactory or non – satisfactory based on the sensitivity and specificity as defined by ICMR. The laboratory was operationalized by release of batch validation certificate of the kit on 06.08.2020.



Vaccine & Antisera Laboratory (VAL) was established to ensure that the vaccines produced, distributed and imported into the country are safe, efficacious and potent with the mandate to evaluate and ensure the quality of Biologicals referred to it. The Laboratory also contribute for development of new monographs and revisions of existing monographs in the Indian pharmacopeia regularly.

these batches to DCGI. In this regard three other vaccine products i.e. Hepatitis-B vaccine, Rotavirus vaccine and Japanese Encephalitis vaccine are under validation study. With reference to the DCGI letter F.No. X-11026/15/2022-BD dated 17.11.2022, the lab has received 03 batches each of CDL notified products viz: BCG vaccine, Rabies Vaccine and OPV vaccine from different manufacturers in order to perform parallel testing. The lab has completed the parallel testing for received products.

Two days’ joint inspection of Vaccine and Antisera Lab has been conducted on 10th and 11th May, 2022. On the basis of CDL Audit report, the lab has received three batches of each product - MR vaccine, HIB-TT vaccine, Covaxin, Covishield, ZyCoV-D, Hepatitis-B vaccine, Rotavirus vaccine and JE vaccine. And Lab has submitted the validation and parallel testing data of

Three members team from M/s Popular Pharmaceuticals Ltd, Bangladesh visited Vaccine and Antisera Laboratory, NIB on 01.12.22 for discussion & technical assistance regarding quality control testing of Rotavirus vaccine & other vaccine manufactured by them

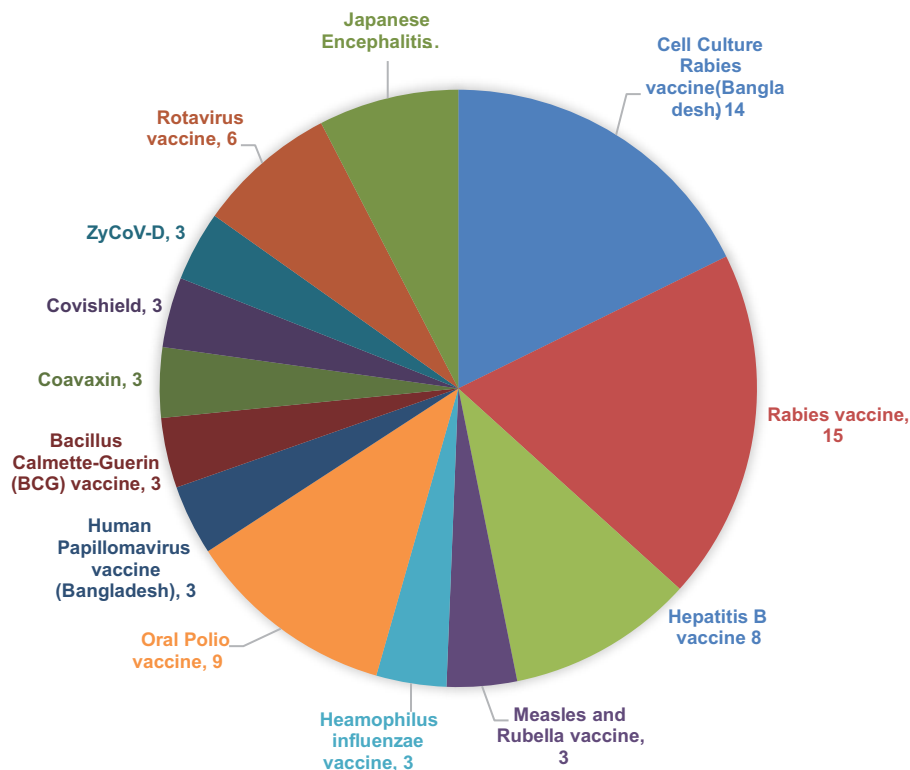


Visit of delegates from M/s Popular Pharmaceuticals Ltd, Bangladesh



Joint Inspection for CDL notification

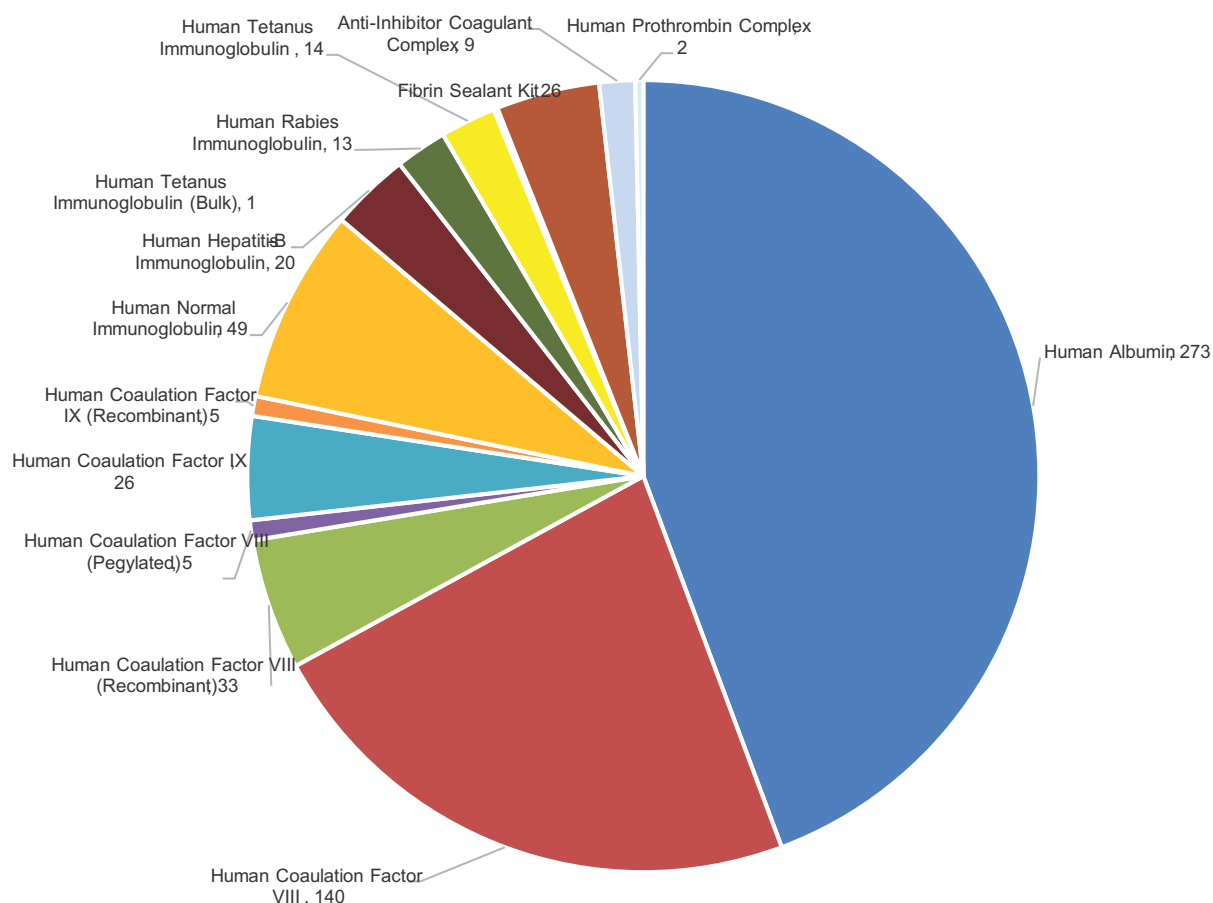
BIOLOGICALS TESTED AT VACCINE AND ANTISERA LAB IN 2022-2023



Blood Product laboratory (BPL) The Blood Products Laboratory is a notified Central Drugs Laboratory (CDL) by Government of India for quality control evaluation of Blood Products. Since these biological therapeutics are inherently complex and variable, a vigilant monitoring is required to ensure the quality as well as safety of such products. Presently, Blood Products Laboratory is testing twenty five different plasma derived biological products as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms



Biologicals Tested at Blood Products Lab



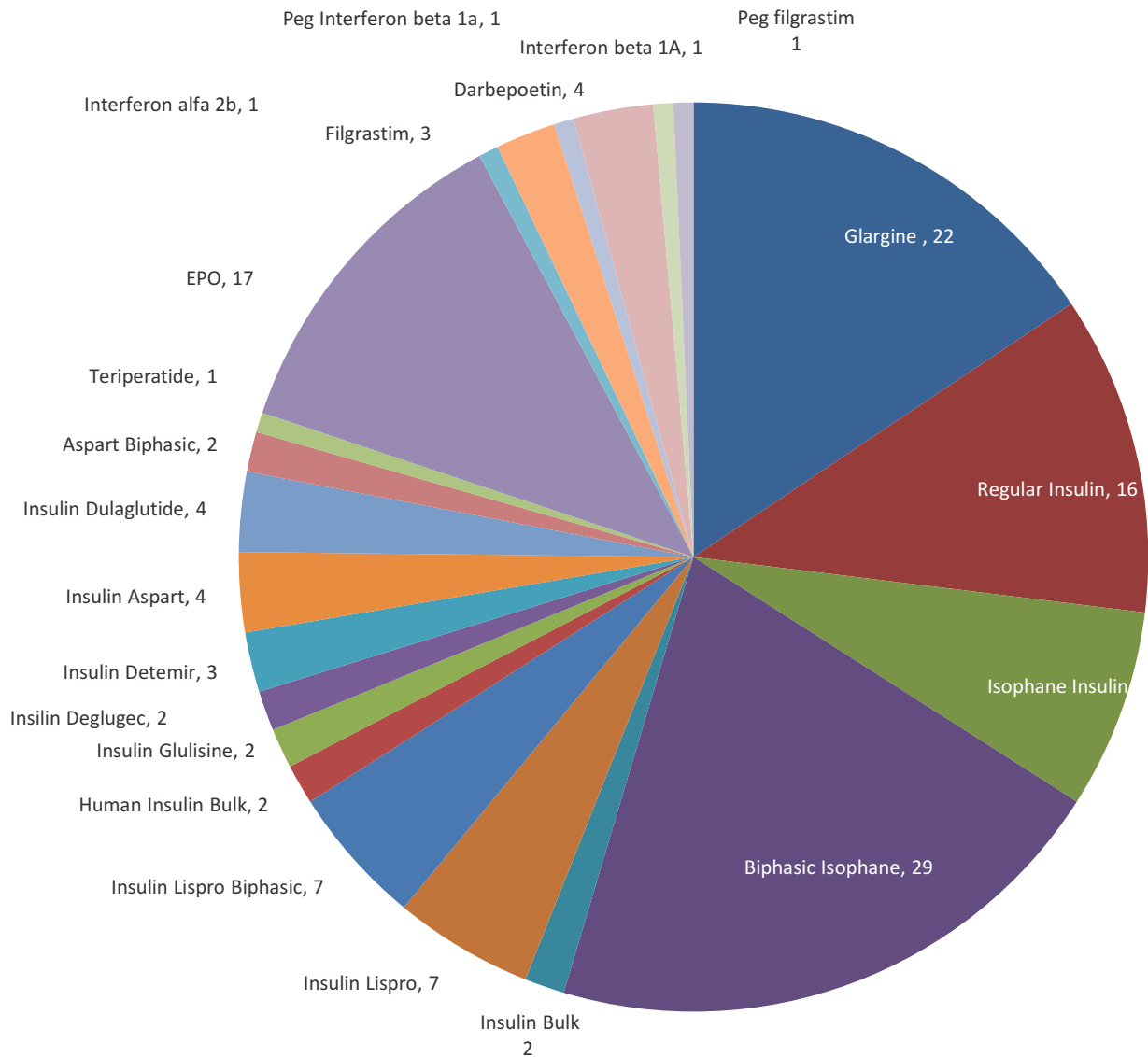
Recombinant Product Laboratory (RPL) contributes to the Regulatory functions of recombinant biotherapeutic products under the class of: Insulin, Insulin Analogs, Growth Factors, Cytokines and Peptides which are intended for therapeutic indications for the treatment of diabetes (Type 1 and Type 2), viral hepatitis, chronic kidney disease, cancer, osteoporosis.

RPL has received a new biological Darbepoietin alpha which is a non pharmacopoeial product from three different indigenous manufacturers (01 batch each) for the purpose of QC evaluation. Accordingly, lab has carried out method verification and established test methods for various QC parameters.

Development of IPRS of Insulin and Insulin Lispro By Recombinant Products Laboratory



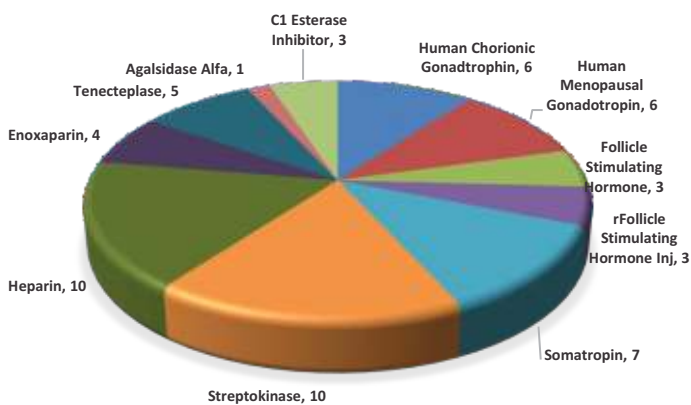
Recombinant biologicals received in RPL for QC testing



Enzyme & Hormone Laboratory (EHL) is involved in Quality control (QC) testing of various therapeutic

Enzymes and Hormones viz Streptokinase, Urokinase, fertility hormones, rare disease therapeutics etc.

BIOLOGICALS TESTED AT ENZYMES AND HORMONES LAB

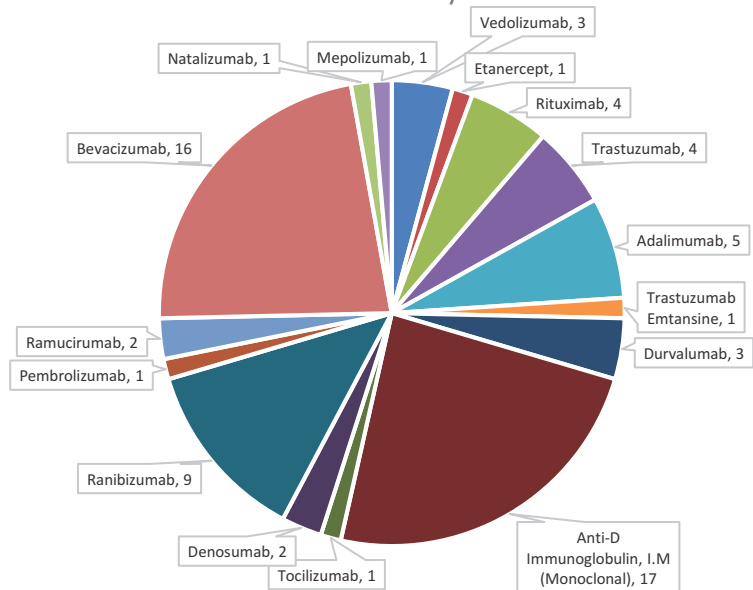


Meeting with CDSCO, IPC & Industry on Testing of Follicle Stimulating Hormone (rFSH) injection as per IP 2022 held on 3rd November 2022 at NIB.

Therapeutic Antibody laboratory (TAL) carries out Quality control testing of therapeutic monoclonal antibodies viz. Rituximab, Trastuzumab, Adalimumab, Anti-D Immunoglobulin, Bevacizumab etc. The lab has also taken up Quality Control testing of the new biologicals viz. Cetuximab, Tocilizumab, Durvalumab,

Denosumab, Trastuzumab Emtansine, Vedolizumab, Mepolizumab, Infliximab, Pembrolizumab, Natalizumab, Omalizumab, Obinutuzumab, Ranibizumab, Ramucirumab, Pertuzumab and Etarnercept.

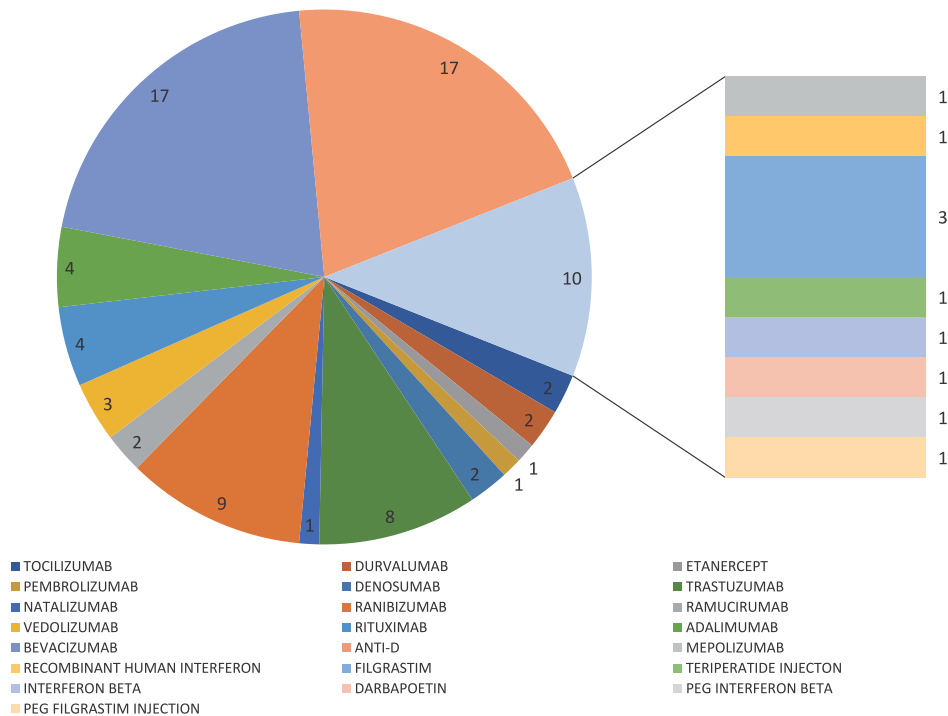
Biologicals tested at Therapeutic Antibodies Laboratory



CENTRAL FACILITIES

Centralized Bioassay Facility with four biosafety modules was set up to cater the cell-based bioassays as a part of quality control evaluation of Therapeutic Antibodies and various recombinant products like peg-

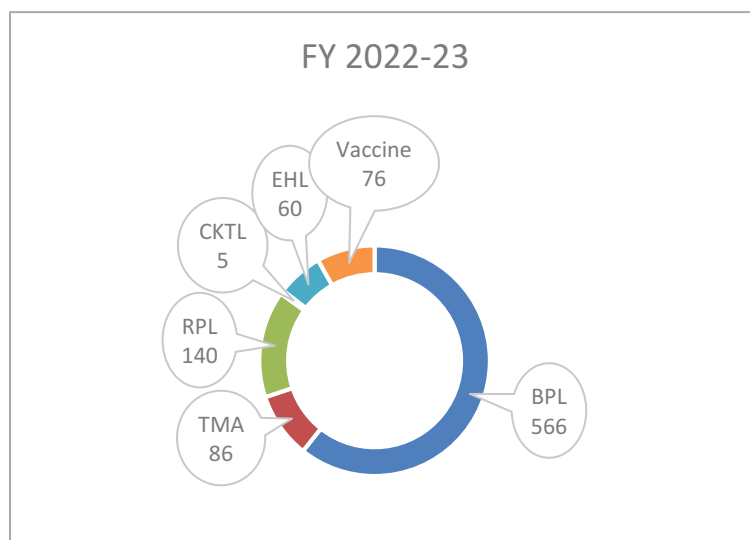
Erythropoietin, Filgrastim, Interferon, Parathyroid hormone, Anti-D Immunoglobulin etc. referred by various product testing laboratories at NIB.



Sterility Testing Laboratory (STL) is a Central Facility well equipped with required equipment viz laminar air flow cabinet in cleanroom, dedicated walk-in incubators at temperatures specified by the pharmacopoeial method for each test media, autoclaves etc. to test the various Biological products referred to it for sterility testing by either of the two

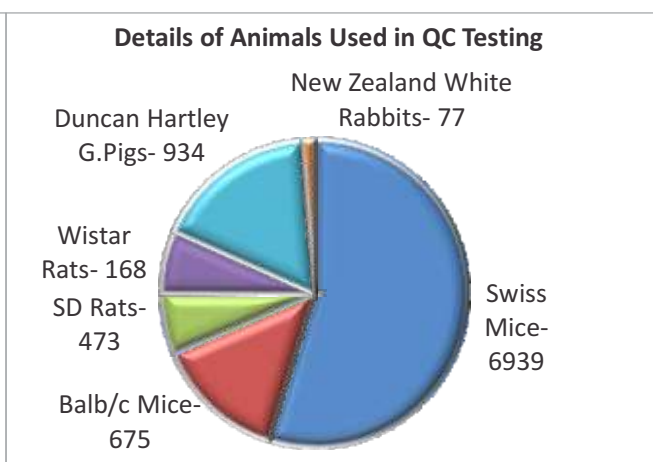
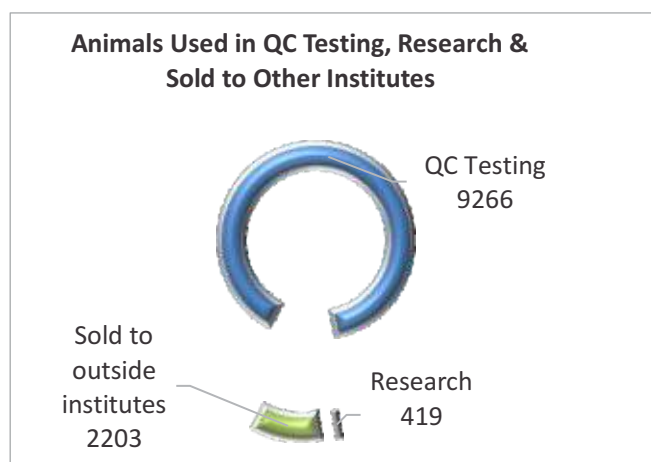
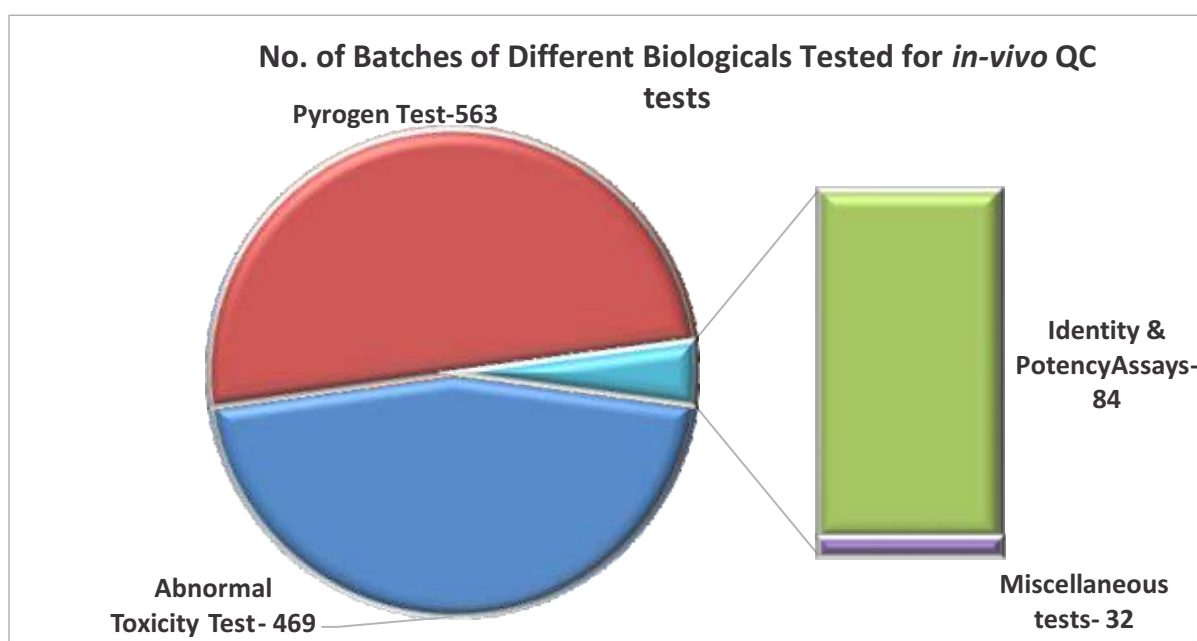
Sterility Testing Techniques viz Direct - Inoculation or Membrane Method (Closed Sterility Test Method) in accordance with the pharmacopoeial method. It also has Environmental microbiology lab for isolation & biochemical characterization of Clean room environmental isolates and handling & maintenance of reference strains of bacterial & fungal strain

Total No. of biological samples tested/ evaluated for sterility:



In-Vivo Bioassay Laboratory & Animal Facility (IVBL & AF) is a central support unit for all laboratories of the Institute. The facility is engaged in performing the *in-vivo* tests (i.e. Abnormal Toxicity Test, Pyrogen Test, Potency & Identity Assays and other miscellaneous tests) as per Indian or other Pharmacopoeia for quality control evaluation of biologicals received in the institute. The facility also ensures timely availability of small laboratory animals viz Mice (Swiss Mice, Balb/c Mice); Rats (Sprague Dawley Rats, Wistar Rats); Guinea pigs (Duncan Hartley); and Rabbit (New Zealand White) 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 Control and Supervision of Experiments on Animals (CCSEA). Facility also provides good quality laboratory animals to educational and research institutes and industries in Delhi-NCR and neighboring states and generate additional revenue for the Institute. Besides using small laboratory animals for performing QC tests on different biologicals, they are also used for research purposes. All the test protocols for use of animals in QC testing and research are approved by Institutional Animal Ethics Committee (IAEC).



Commitment of NIB for implementation of 3R's: As commitment towards the 3R's, the scientists of IVBL & AF 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 the

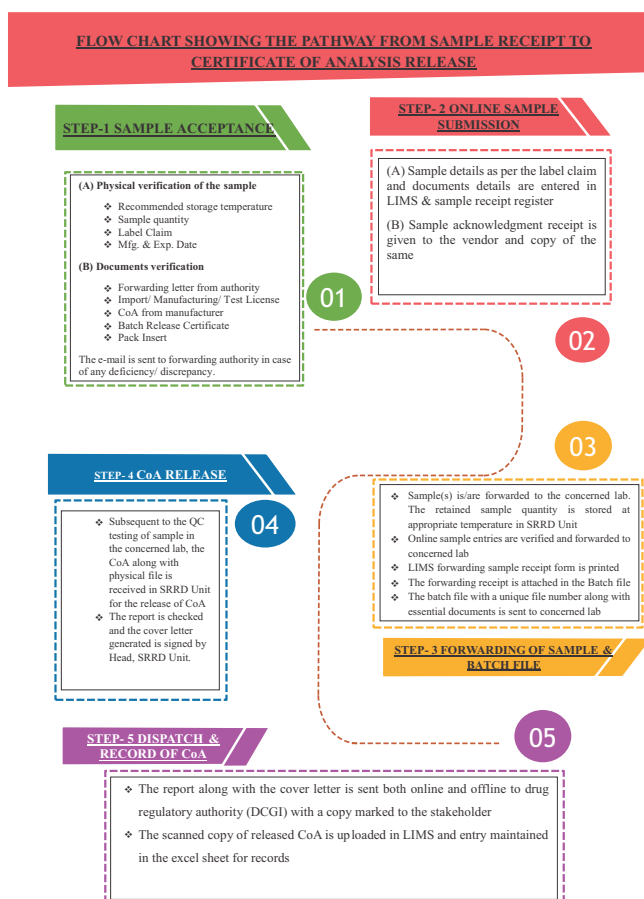
same product at the same time with a common reference or control group. This enabled us to save 1878 laboratory animals in the year 2022-23, the details of which are provided below:

S. No.	Details of QC Test	Number of Animals Saved
1.	Potency Assay for HMG- FSH	18 rats
2.	Potency Assay for HMG-LH	18 rats
3.	Potency Assay for r-FSH & Urofollitropin	15 rats
4.	NIH Potency assay for Rig	400 mice
5.	Potency assay for Recombinant Erythropoietin (r EPO)	175 mice
6.	Potency assay for Cell Culture Rabies Vaccine (CCRV)	1232 mice
7.	Potency assay for Japanese Encephalitis (JE) Vaccine	20 mice

Sample Receipt and Report Dispatch Unit (SRRDU) is the 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 biologicals namely Biotherapeutics, Diagnostics, and Vaccines are received from the National Drug Regulatory authorities (CDSCO) as well as several State Governments Medical Procurement Agencies. International samples of Vaccines from Bangladesh have also been received for quality evaluation. Requisite quantity of all samples received for testing are retained at recommended temperature up to 3 months’ post expiry. Retained samples are stored at frozen/refrigerated/room temperature as per their recommended storage requirement. There are

two dedicated walk-in cold rooms, one each of 2-8°C and -20°C for storage of samples and the details are documented. For security, the complete unit is under CCTV surveillance, samples and documents are kept under lock and key.

An in-house built software system is used to generate Certificate of Analysis (CoA) to enter all the information related to sample receipt. The samples are registered and verified. Creation of File/ Forwarding No. and Forwarding of samples to respective laboratories is done through this portal. The CoAs are received at SRRDU for the release of test reports either online or offline and emailed to the sample sender (ADC (I)/ stakeholder) and DCG (I).



GOVERNMENT GAZETTE NOTIFICATION(S)**CENTRAL DRUGS LABORATORY:**

The Institute is notified Central Drugs Laboratory vide Gazette notification No(s). G.S.R. 249 (E), G.S.R. 908 (E) and G.S.R. 250 (E) - Part-II - Section 3- Sub-Section (i) dated 4th April, 2002; 22nd December, 2014 and 15th March, 2017 for i) Oral polio vaccine, ii) Blood grouping reagents, iii) Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, iv) Blood products- (a) Human Albumin; (b) Human Normal Immunoglobulin (intramuscular and intravenous); (c) Human Coagulation Factor VIII; (d) Human Coagulation Factor IX; (e) Plasma Protein Fractionation; (f) Fibrin Sealant Kit; (g) Anti Inhibitor Coagulation complex; v) Recombinant products such as- (a) Recombinant Insulin and Insulin analogues; (b) r-erythropoietin (EPO); (c) r-Granulocyte Colony Stimulating Factor (G-CSF); vi) Biochemical kits- (a) Glucose Test Strips; (b) Fully automated analyser-based glucose reagents; vii) Enzyme and Hormones such as- (a) Streptokinase (Natural and Recombinant); (b) Human Chorionic Gonadotropin (hCG); (c) Human Menopausal Gonadotropin (hMG); viii) Bacterial vaccine such as- (a) Bacillus Calmette-Guerin (BCG) vaccine; ix) Viral vaccines such as- (a) Live attenuated Measles vaccine; (b) Live attenuated Rubella vaccine; (c) Cell culture Rabies vaccine.

A. The Central Government, vide The Gazette of India Notification No. S.O. 4206(E) dated 24th November, 2020 notified the National Institute of Biologicals, Noida, to perform the function of Central Drugs Laboratory as an additional facility in respect of COVID-19 vaccine, in addition to its existing functions.

CENTRAL MEDICAL DEVICE TESTING LABORATORY: The Institute is notified Central Medical Device Testing Laboratory vide Gazette notification No. S.O.2237 E dated 1st June 2018 under sub-rule (2) of rule 19 of the Medical Devices Rules, 2017 for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory for the purposes of —

- (a) testing and evaluation
- (b) functioning as an appellate laboratory; and
- (c) to carry out any other function as may be specifically assigned to it by the Central Government, in relation to the In-Vitro Diagnostics for human

Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent.

GOVERNMENT ANALYST(S):

NIB scientists are notified Government Analysts vide Gazette notification No. S.O. 2213 (E) dated 26 September 2011 for Diagnostic kits for HIV, HCV, HBsAg; Blood Grouping Reagents; S.O. 2393 (E) dated 2 September 2015 for Blood Grouping Reagents; Blood products- (i) Human Albumin (ii) Human Normal Immunoglobulin (Intramuscular and intravenous) (iii) Human Coagulation Factor VIII (iv) Human Coagulation Factor IX (v) Plasma Protein Fraction (vi) Fibrin Sealant Kit (vii) Anti-Inhibitor Coagulation Complex; Recombinant products such as- (i) Recombinant Insulin and Insulin analogues; (ii) r-Erythropoietin (EPO); (iii) r-Granulocyte Colony Stimulating Factor (G-CSF) and Biochemical kits- (i) Glucose Test Strips; and (ii) Fully automated analyser based glucose reagent; S.O. 4271(E) dated 26th November, 2019 for Blood products- (i) Human Albumin (ii) Human Normal Immunoglobulin (Intramuscular and intravenous) (iii) Human Coagulation Factor VIII (iv) Human Coagulation Factor IX (v) Plasma Protein Fraction (vi) Fibrin Sealant Kit (vii) Anti-Inhibitor Coagulation Complex; Recombinant products such as- (i) Recombinant Insulin and Insulin analogues (ii) r-erythropoietin (EPO) (iii) r-Granulocyte Colony Stimulating Factor (G-CSF); (i) Rituximab (ii) Trastuzumab (iii) Adalimumab (iv) Bevacizumab; Bacterial vaccine such as- (i) Bacillus Calmette-Guerin (BCG) vaccine, Viral vaccines such as- (ii) Live Attenuated Measles vaccine (iii) Live Attenuated Rubella vaccine (iv) Cell Culture Rabies vaccine (v) Oral Polio Vaccine; Blood Grouping Reagents; Biochemical kits- (i) Glucose Test Strips; and (ii) Fully automated analyser based glucose reagent; diagnostic kits for (i) Human Immunodeficiency Virus (ii) Hepatitis B Surface Antigen (iii) Hepatitis C Virus.

Following NIB scientists are notified Government Analysts:

1. Dr. Charu M. Kamal,
2. Ms. Ajanta Sircar,
3. Dr. Rajesh Kumar Sharma,



4. Dr. Meena Kumari,
5. Sh. Harit Kasana,
6. Ms. Kanchan Ahuja,
7. Ms. Gurminder Bindra,
8. Ms. Madhu Erramilli,
9. Sh. Subhash Chand,
10. Sh. Jaipal Meena,

MEDICAL DEVICE TESTING OFFICER(S): NIB scientists are notified Medical Device testing

Officer(s) vide Gazette Notification S.O. 3400(E) dated 11th July 2018 for Human Immunodeficiency Virus (HIV), Hepatitis B surface Antigen (HBsAg), Hepatitis C Virus (HCV), Blood grouping reagents, Glucose test strips and fully automated analyser-based glucose reagents.

Following NIB scientists are notified Medical Device Testing Officers:

1. Ms. Ajanta Sircar,
2. Ms. Kanchan Ahuja,
3. Dr. Rajesh Kumar Sharma

QUALITY MANAGEMENT SYSTEM

The Quality Management System of NIB is woven into the fabric of its operations and ethos, ensuring that it delivers the level of service in respect of testing of biological products. NIB was accredited in accordance with International Standard ISO/ IEC 17025- General Requirements for the competence of testing and calibration laboratories for the first time in the year 2011 in the disciplines of biological testing and chemical testing enabling laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work. NIB's Quality Management System is externally assessed against international standards from time to time in line with the requirement of accreditation, which gives confidence to stakeholders of its reliability. NIB's stakeholders can therefore rest assured of the consistent quality of the services provided by NIB, as well as its commitment to not only maintain but also continuously improve quality standards for its activities. The scope of testing has increased in the disciplines of biological testing and chemical testing from 390-1102 due to addition of new products and segregation of previous products as directed by NABL. The Quality Management Unit (QMU) coordinates the development and maintenance of the NIB's quality management systems, which aim to continually improve NIB services in the field of testing biological products.

As part of the NIB's efforts to drive continuous improvement, the QMU coordinates accreditation activities, performs quality audits, and regularly circulates the Alert Calendars for timely revision/ review of SOPs issued to all areas of Diagnostic, Therapeutic, Vaccine Laboratories and Support/ Facilitating Units. It coordinates between Labs, Procurement and Vendors to facilitate the smooth functioning of Equipment (about 400). The authorized list of equipment usage is being updated timely with the details of preventive maintenance e.g. AMC/ Calibration done with the due date. These services are

rendered by OEMs of the equipment and NABL accredited external agencies under various categories viz., Temperature Controlled, Mass/ Volume, Centrifuge, etc.

Internal Audit of NIB Laboratories/ Units as per ISO/IEC 17025:2017 for renewal of NABL accreditation was organized from 7th-14th November 2022 to assess the compliance to the ISO: 17025: 2017 requirements

NIB has Successfully completed the Desktop Surveillance and received a decision letter dated 6.8.2022 issued by NABL stating the grant of continuation of accreditation in accordance with ISO/IEC 17025:2017 in the discipline of Chemical and Biological testing for the existing scope.

QMU coordinates with Laboratories and IT department to regularly update the Testing fee document on institute's website. The Unit prepares an Annual Training calendar keeping in view the requirements of the staff for due upgradation in the field of relevant applicable standards like ISO 17025:2017 as well as scientific knowledge including biosafety practices. The Unit Prepared write-up to showcase scientific achievements of NIB and its activities in the souvenir published in the National Convention and Science Conference of Vigyan Bharati held on 25-26 June 2022 at Lucknow. A book highlighting the glorious 30 years of NIB was prepared meticulously and published along with two Videos (Hindi & English) on NIB and were launched by Hon'ble State Health Minister Dr Bharti Pravin Pawar on 30th June 2022 at NIB. A coffee table book was conceptualized, designed, prepared and published depicting the NIB profile and achievements, which was launched on the occasion of 31st Foundation day during National Summit on Quality of Biologicals at Vigyan Bhawan on 27 Jan 2023. A complete time line of NIB since 1992 was prepared for display highlighting the major events in chronological order

COLLABORATIONS

1. Collaborated with Indian Pharmacopoeia Commission- Ghaziabad for contribution in development of new pharmacopoeial monographs and also revision of existing pharmacopoeial monographs for Blood grouping reagents.
2. WHO-NIBSC Collaborative Study for 1st International Standard (IS) for Golimumab (Bioactivity).
3. Networking with blood banks/ hospitals of Delhi/ NCR for collection of plasma bags: Immunodiagnostic Kit 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 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. Laboratory routinely collects plasma bags reactive for HIV, HCV, HBsAg & Syphilis and which are non-reactive.
4. Collaboration with various blood banks/ hospitals of Delhi/ NCR for collection of non- infective and non-clotted left-over blood samples as per the approval of Institutional Human Ethics Committee and letter of authorization from DCG (I) to various blood banks/ hospitals to provide non- infective and non-clotted left- over blood samples for carrying out quality control of Blood Grouping reagents.

PARTICIPATION IN PT / ILC / EQAS-NATIONAL / INTERNATIONAL

- A. Biochemical Kit laboratory is presently enrolled in the Association of Clinical Biochemists of India (ACBI)/ Christian Medical College (CMC) in External Quality Assessment Scheme (EQAS) – 2022 & 2023 for Chemistry II (Glucose, Cholesterol, Triglyceride, Creatinine, Uric acid & Albumin) conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore.
- B. Blood Product Laboratory participated in PT Study on Albumin Molecular-size distribution "PTS234" organized by EDQM France.
- C. Blood Product Laboratory participated ILC ON "WHO Collaborative study to assess the Candidate 3rd International Standard for Rabies Immunoglobulin" organized by NIBSC, UK, 2022.
- D. Blood Reagent Laboratory participated in external proficiency program for Anti-A1 (Lectin), Anti- H (Lectin) and Bovine Serum Albumin blood grouping reagents conducted by Indian Red Cross Society, Delhi on 06th July, 2022. The performances of all the staff were found to be 100% satisfactory.
- E. Immunodiagnostic Kit Laboratory has been regularly participating in External Quality Assessment Scheme (EQAS) since 1999. Laboratory has enrolled and participated in Multimarker Blood Screening EQA Program (MMBS4310) with National Serology Reference Laboratory, (NSRL) Australia, a NATA-accredited proficiency testing provider, complying with ILACG13:08/2007 and also a World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections and fully accredited Proficiency testing provider under ISO 17043: 2010. This program meets the highest international quality standards. Laboratory successfully participated thrice in this duration with NRL, Australia EQAS- 2022-23. The results were concordant with reference results.
- F. Molecular Diagnostics Laboratory has successfully participated in the International External Quality Assessment Scheme (EQAS) conducted by NRL-Australia for Event-1 (March) 2023 NAT Proficiency Testing for Qualitative Multimarker Blood Donor Screening and Viral Load Monitoring of HBV, HCV and HIV.
- G. Recombinant Products Laboratory participated in the "LAL Proficiency Testing Program (PTP) for Bacterial Endotoxin Test" by Gel Clot Method and Kinetic Chromogenic method conducted by M/s Charles River Laboratories (Quarter 1). Laboratory has secured a "PASS" result in this study.
- H. Vaccine and Antisera Laboratory has participated in EDQM Collaborative study (BSP-148) for the standardization of an in -vitro assay for the potency control of human rabies vaccine by ELISA, conducted by Department of Biological Standardization, OMCL Network & Healthcare, EDQM, Council of Europe. Laboratory has completed testing and results were communicated to EDQM. In this regard EDQM has shared the report for review on 31.03.2023 and Laboratory has reviewed the report and comments to be incorporated in report has been shared with EDQM. As informed by EDQM, the phase 3 study will be initiated soon.
- I. Staff of Quality Management Unit Participated in Webinar on NABCB Accreditation for Inspection Bodies, and its Benefits to Industry & Government Bodies on 30 August 2022 organised by National Accreditation Board for Certification Bodies, Quality Council of India, New Delhi

EXPERT COMMITTEE MEETINGS

1. Four **Institutional Animal Ethics Committee meetings** were organized by Dr. Shikha Yadav, Member Secretary, IAEC during the preview period for timely ethical approvals so that all in-vivo QC tests could be performed for the biologicals received at NIB in the designated turnaround time periods. All the experiments involving animals have to be approved by the IAEC, constituted by CCSEA. A total of 56 protocols were reviewed by the committee during this period and all relevant records of approvals as well as compliance were maintained by the Member Secretary of IAEC.
 - a. 60th Institutional Animal Ethics Committee (IAEC) meeting- 20th June 2022.
 - b. 61th Institutional Animal Ethics Committee (IAEC) meeting- 28th October 2022.
 - c. 62th Institutional Animal Ethics Committee (IAEC) meeting- 21st December 2022.
 - d. 63rd Institutional Animal Ethics Committee (IAEC) meeting- 6th February 2023.
 - e. The annual inspection of Animal Facility was also conducted by IAEC on 20th June 2022 and the inspection report was submitted to the Committee for Control and Supervision of Experiments on Animals (CCSEA), Ministry of Fisheries, Animal Husbandry & Dairying by their main nominee in the Committee.
2. **Institutional Human Ethics Committee**, NIB reviews all types of study proposals/protocols involving human subjects' samples with a view to safeguard the dignity, rights, safety and well being of all actual or potential human subjects submitted by different laboratories of NIB. The type of study proposals involves utility of Human samples for the purpose of Quality control Testing of Biologicals, The IHEC, National Institute of Biologicals take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non- maleficence and Justice are taken care of in study protocols. The Committee review the proposals before start of the studies as well as monitor the study throughout until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not. Dr. Charu M Kamal, Scientist -I, Member and Dr. Sanjay Mendiratta, Scientist -III, Member Secretary Ethics Committee convened the thirteenth Institutional Ethics Committee Meeting at NIB NOIDA for review of proposals using human material on 21.03.2023. The Committee reviewed the progress of a total of Sixteen ongoing proposals in this meeting.
3. **IBSC Institutional Biosafety Committee (IBSC):**

The 2nd meeting of Institutional Biosafety Committee (IBSC) was held under the chairmanship of Dr. Harish Chander, DD (QC), NIB on 15 th March, 2023 on hybrid mode to review the routine and R&D activities related to biosafety. The committee reviewed two ongoing R&D projects progress report presented by Principal Investigators/ Co-Principal Investigators. IBSC team along with the engineering and biomedical waste management took a laboratory round for biomedical waste management related activities covering various Biotherapeutic, diagnostic and vaccine laboratories, STP and ETP waste management area. The visit also covered biomedical waste disposal route from collection points up to final vendor pick up area
4. The first **Meeting of the Expert Committee for strengthening the Quality Control testing by diagnostic laboratories** of NIB held in hybrid mode was held on 10.06.2022 at NIB under the chairmanship of Dr. V. M. Katoch, President JIPMER Puducherry & AIIMS Madurai and Former Secretary, Department of Health & Research and DG, ICMR.
5. Dr. Meena Kumari, Scientist-II & Head BPL:
 - a. Invited as an examiner for conducting the Practical/Oral Examination for B.Tech. 4th Semester BT on 14.07.2022 at University Institute of Engineering & Technology, Kurukshetra.
 - b. Nominated as a member of "Expert Working Group-Blood & Blood Related Products" by Indian Pharmacopoeia Commission.
6. Dr. Meena Kumari, Scientist-II, Ms. Madhu, Scientist-III, Dr. Manoj Kumar, Scientist-III, Mr. Tara Chand, Scientist-III participated in 6th Meeting of the Expert Working Group- Blood and Blood Related Products in hybrid mode on 17th August, 2022, organized by Indian Pharmacopoeia Commission, Ghaziabad.



7. Dr. Meena Kumari Scientist-II, Ms. Y. Madhu, Scientist-III & Mr. Tara Chand, Scientist-III attended of 'Equipment Specifications Expert Group Committee meeting', under Chairmanship of Dr. R. S. Sharma held on 07.02.2023 at NIB.
8. Dr. Meena Kumari Scientist-II, Madhu, Scientist-III, Dr. Manoj Kumar, Scientist-III & Mr. Tara Chand, Scientist-III attended 7th Meeting of the Expert Working Group- Blood and Blood Related Products conducted by IPC on 20.02.2023 to discuss the action taken report of 6th EWG meeting – Blood and blood related products.
9. Ms. Kanchan Ahuja, Scientist -III attended meeting of the 6th Expert Working Group- Blood and Blood Related Products on 6th August, 2022 organized by Indian Pharmacopoeia, Ghaziabad to discuss on proposed amendments in IP monographs for Anti-A blood grouping reagent, Anti-Human Globulin reagents and Blood Products.
10. Dr. Charu M. Kamal, Scientist –I, Ms. Sudha V. Gopinath, Scientist -II and Mr. N. Nanda Gopal, Scientist -III organized a meeting Chaired by Dr. Harish Chander, Dy. Director (QC) with representatives from CDSCO, IPC & Industry on testing of Follicle Stimulating Hormone (rFSH) injection as per IP 2022 conducted by NIB on 3rd November 2022 at NIB
11. Dr. Gauri Misra, Scientist.-II:
 - a. Expert Committee Member to conduct Clinical Performance Evaluation for New In-vitro Diagnostic (IVD) product " Breath Analyzer along with sample card (Filter card) for detection of COVID-19," held on 23.08.2022 through virtual mode.
 - b. Invited to discuss the queries of the innovators as an External Expert in First Hub Meeting by BIRAC held virtually on 08.04.2022, 08.07.2022 & 03.02.2023
 - c. Participated in Expert committee Meeting to examine the revised NAT Specifications based on the Comments received from GAP (Global Advisory Panel) held on 01.09.2022.
 - d. Provided expert comments for Grant of Permission to Manufacturer for sale / distribution of new in-vitro diagnostic medical device i.e. RT-PCR Test Kit for diagnosis of Kyasanur Forest Disease Virus (KFDV) on 11.10.2022.
 - e. Attended virtual meeting as external expert to review and revise the technical specification of Tab. Buprenorphine used for OST programme under NACP on 06.02.2023.
- f. An external examiner in M.Sc. Biochemistry II semester practical examination at Department of Biochemistry, School of Life Sciences, Khandari Campus, Agra held on 22.07.2022
- g. An External Examiner at Amity University, Noida from 22.06.2022 to 24.06.2022.
12. Dr. Ratnesh Kumar Sharma, Scientist–II, Mr. Subhash Chand, Scientist–III and Dr. Saurabh Sharma, Scientist–III attended Expert Committee Meeting to discuss various modalities for establishment of BSL-3 held on 22.07.2022 at NIB.
13. Dr. Harish Chander, DDQC, Dr Charu M Kamal, Scientist-I, Ms. Sudha V. Gopinath, Scientist-II, Ms Gurminder Bindra, Scientist-III, Mr. Subhash Chand, Scientist-III and Mr. N. Nanda Gopal, Scientist-III attended 12th Meeting of the Expert Working Group - Biologicals and rDNA Products held on 2nd May, 2022 through Video Conferencing for development and discussion on new monographs on Monoclonal Antibodies , Recombinant Products and Enzymes and Hormones .
14. Dr Charu M Kamal, Scientist-I, Ms. Sudha V. Gopinath, Scientist-III, Ms Gurminder Bindra, Scientist-III, Mr. Subhash Chand, Scientist-III and Mr. N. Nanda Gopal, Scientist-III, Dr. Saurabh Sharma, Scientist-III, Dr. Paras Jain, Junior Scientist attended 13th Meeting of the Expert Working Group- Biologicals and rDNA Derived Therapeutic Products held on 28.03.2023 through video conferencing organized by Indian Pharmacopoeia Commission.
15. Dr. Hemant Kumar Verma, Scientist-II nominated as Member (Expert) of the committee constituted by ICMR for Development of portal for access and sharing of Research Facilities of ICMR institutes.
16. Dr. Rajesh K. Sharma, Scientist -III attended online Technical Resource Group (TRG) for Lab Services Division under NACP, NACO meeting on 26.04.2022.
17. Dr. Rajesh K. Sharma, Scientist-III attended Apex Laboratory Meeting of NACO at NARI, Pune on 25.08.2022.
18. Dr. Rajesh K. Sharma, Scientist-III attended Technical Specification Committee meeting at NCDC, New Delhi on 04.10.2022.
19. Recombinant Products Laboratory organized a Scientific discussion on the subject "Stakeholders

meeting for discussion on proposed amendment in Pegfilgrastim IP 2018 monograph and Pegfilgrastim injection draft monograph" on 19.10.2022. The Pegfilgrastim stakeholders, Indian Pharmacopoeia Commission (IPC) representatives and NIB staff participated in the meeting.

20. Dr. Shikha Yadav, Scientist-I:

- a. Nominated as member of Institutional Animal Ethics Committee meeting of Galgotias University, Greater Noida by CCSEA, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India and attended their IAEC meeting on 2nd August 2022.
- b. Attended Institutional Animal Ethics Committee meeting of Jawaharlal Nehru University, Delhi on 8th August 2022.
- c. Attended IAEC meeting of Biomed Pvt. Ltd. Ghaziabad on 31st August 2022.
- d. Invited as a member of the Selection Committee for six vacancies of Scientist 'C' at ICMR-NARFBR, Hyderabad, interviews for which were held from 12-14th October, 2022 at ICMR Hqrs, Delhi.
- e. Invited as special invitee in the 2nd Expert working group Meeting for Alternatives to Animal Methods organized by Indian Pharmacopoeia Commission (IPC), Ghaziabad on 28th November 2022.

21. Dr. Suresh Kumar, Scientist Grade-III:

- a. Attended the Institutional Animal Ethics Committee (IAEC) meeting as a CCSEA- Main nominee to review the research protocols on 2nd April 2022, 12th May 2022 and 3rd September 2022 at All India Institute of Medical Sciences (AIIMS), Delhi.
- b. Attended the meeting as an expert member to facilitate the setting up a nude mice facility on

11th April 2022 at University of Delhi, South Campus, New Delhi, Delhi.

- c. Participated as an external expert in the committee to revise and reframe the regulations under the purview of Minimum Standard of Veterinary Education Degree Course Curriculum - B.V.Sc. & A.H. Regulations for Veterinary College in the context of Laboratory Animal Science and Medicine organised by Veterinary Council of India (VCI), Minister of Fisheries, Animal Husbandry and Dairying on 30.08.2022.
 - d. Attended IAEC meeting as a CCSEA- Main nominee to review the research protocols on 12th October 2022 at University of Delhi South Campus, Delhi.
 - e. Attended IAEC meeting as a CCSEA member-Scientist from outside institute to review the research protocols on 2nd November 2022 at National Institute of Immunology, Delhi.
 - f. Visited Centre of Excellence in Pharmaceutical Sciences (CEPS) at Guru Gobind Singh Indraprastha University, Dwarka, Delhi as an expert member on 10th November 2022 to give expert opinions for their newly established Animal Facility.
22. Dr Harish Chander, Deputy Director (QC)
- a. participated as expert member in an online meeting of National Bidesign consortium Steering Committee of DBT on 9th November 2022.
 - b. participated as a panel member in 14th CII Global MedTEch Summit on 7th September 2022 at New Delhi
 - c. Participated as guest speaker and delivered a lecture on Key role of Invitro diagnostic stakeholders in Materiovigilance Programme of India organized by IPC on 22nd July 2022

Thirteenth Institutional Ethics Committee Meeting at NIB NOIDA for review of proposals using human material on 21.03.2023



The 2nd meeting of Institutional Biosafety Committee (IBSC)



Institutional Animal Ethics Committee meeting



ORGANIZATION/ PARTICIPATION IN CONFERENCE/ WORKSHOP/ SYMPOSIA/SEMINARS/ CMES/ LECTURES DELIVERED / TRAINING IMPARTED

1. Dr. Harish Chander, DD(QC) invited as a speaker and delivered a lecture on recent issues of National Lot release for the seventh WPR NCL workshop held on 06.09.2022 which is organized by Global Bio Conference, Ministry of Food and Drug Safety, South Korea.
2. Dr. Shikha Yadav, Scientist Grade-1
 - a. Participated in the "NC3Rs workshop: Implementing the 3Rs in WHO guidelines - understanding the impact on quality control and batch release testing of biologicals in Asia" on 28th April 2022 organized by National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs), UK to better understand the potential impact of these changes on manufacturers and regulators globally, based on which they would make recommendations to WHO and reduce the barriers for their implementation by the Expert Committee on Biological Standardization (ECBS).
 - b. Invited as faculty to deliver talks on "Ethical Evaluation- International Perspective" and "Severity Assessment and Humane End Points" in the Certificate Course on FELASA Accredited Training programme in Laboratory Animal Science at Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Chennai from 23rd to 24th June 2022 and 15th July 2022.
 - c. Delivered talk on "Pain Assessment and Management in Rodents" on 4th November 2022 in the 4th Workshop on Basic Training in Animal Handling & Experimentation organized by Institute of Liver and Biliary Sciences (ILBS), Delhi.
 - d. Invited to speak on "Severity Assessment - A Practical Approach to Implement Refinement in Experiments Involving Laboratory Animals" on 14th November 2022 in Conference on "Defining Ethics and Welfare (DEW-2022) in Preclinical Research" & Chaired the workshop on "Preparing B- Forms and the conduct of IAEC" on 15th November 2022 at Sree Chitra Tirunal Institute for Medical Science and Technology, Thiruvananthapuram, Kerala.
 - e. Delivered scientific lecture on "Perioperative care, anesthesia, analgesia and refinement of experiments" in the Workshop for Handling and Care of Laboratory Animals at CLAR, School of Life Sciences, Jawaharlal Nehru University (JNU), Delhi on 17th November 2022.
 - f. Delivered a talk on "Scientific and Ethical Practices to Minimize Pain During Aseptic Surgeries in Laboratory Animals" on 18th November 2022 in a 3-day Continuing Education Program (CEP) on "Ethical Issues and Practices in Animal and Human Experimentation" organized by DIPAS, DRDO, Ministry of Defense, Delhi.
 - g. Delivered a scientific lecture on "3Rs – Concept in Laboratory Animal Experimental Designing" on Nov 30th, 2022 in the "workshop on "Basic Biotechnology of Laboratory mice and rats" being organized by National Center for Biological Sciences (NCBS), TIFR, Bengaluru.
 - h. Invited to deliver a scientific talk on "Perioperative Care & Analgesia" on 8th February 2023 in the 2 weeks Certificate Course in Laboratory Animal Science (CCLAS) that was organized by National Brain Research Centre (Under Department of Biotechnology), Ministry of Science & Technology, Manesar, Haryana.
 - i. Invited to deliver a scientific talk on "Perioperative Care, Anesthesia, Surgical Techniques; Analgesia and Pain: Its Causes, Category Monitoring and Distress in Laboratory Animals" on 22.2.23 in the 4 days workshop on Handling and Care of Laboratory Animals organized by School of Life Sciences (SLS) Jawaharlal Nehru University (JNU), Delhi.
3. Dr. Manoj, Scientist-III & Dr. Varun Singh, Scientist-III attended "IPC Conference 2022" addressing Medicine Quality for Future on 01.07.2022 at Vigyan Bhawan, New Delhi.
4. Sh. Anoop Kumar, Junior Scientist, BP Lab has attended a workshop on "The Center of Excellence for Biopharmaceutical Technology (CEBT) Course Event" at Indian Institute of Technology, Delhi from 13.12.2022 to 15.12.2022.
5. Mrs. Apoorva, Junior Scientist, has attended Sun Pharma Science Foundation's International Symposia in collaboration with Tata Memorial



- Center Mumbai "Cell Therapy Comes of Age in India" Date: 7th and 8th January, 2023.
6. Sh. N. Nanda Gopal, Scientist-III attended NABL assessor training on ISO/IEC 17025:2017 from 4th -8th July 2022 organized by Quality Council of India at Gurugram and Qualified as NABL Assessor.
 7. Ms. Sudha V Gopinath, Scientist-II & Dr. Sanjay Mendiratta Scientist-III participated in training program on "ISO 17034:2016, General requirements for the competence of Reference material producers" at Mumbai on 02nd to 04th February 2023 organized by NABL.
 8. Dr. Gauri Misra, Scientist-II
 - a. Delivered a lecture on "Quality Management Systems in Biologicals Industries" in 38th NRL workshop, Melbourne, Australia on 12th October 2022 through virtual mode.
 - b. Invited for 6th Convocation of AcSIR on 12th May 2022 at CSIR-National Physical Laboratory Auditorium, New Delhi.
 - c. Attended "National Conference on Research in Health and Biomedical Sciences" at Symbiosis International (Deemed University) Pune, held from 3rd – 5th November 2022.
 - d. Participated as an Invited Speaker and reviewer in the Bangalore Health Care Summit-2022 on 7th World Cancer Congress-2022 held during 19th – 20th Nov 2022 in Bengaluru, Karnataka.
 - e. Delivered lecture titled 'Multifaceted Science Visionary Sir J.C. Bose: Past and Present' at International Conference on Contributions of Acharya Jagdish Chandra Bose: A Satyagrahi Scientist held from 30th Nov to 1st Dec 2022 at IUAC, New Delhi.
 - f. Delivered lecture on 'Briefing on molecular diagnostics of Malaria', for Hands-on training on 'In-house developed qPCR-based detection of non-human Malaria parasites, *Plasmodium cyanomolgi* and *Plasmodium knowlesi*' on 7th Dec 2022 at NIMR-ICMR New Delhi.
 - g. Attended meeting for technical discussion and sample collection related to Dengue serotype & COVID-19 panel from 14th -16th Dec 2022 at NIV, Pune
 - h. Committee Member of Research and Academic committee of NIB, has attended online meeting of AcSIR with Prof. Manoj Kumar Dhar, Director AcSIR, on 3rd Feb 2023.
 - i. Nominated by DBT as an ethical committee member for an interaction meeting with foreign delegates on 1st March 2023 at MedTherapy India Pvt. Ltd., Noida.
 - j. Nominated to attend "Chintan Shivir" organized by Quality Council of India (QCI) held on 23rd March 2023 at Lucknow (U.P.).
 - k. Attended Eleventh Meeting of Medical Biotechnology and Nanotechnology Sectional Committee, MHD 20 through video conferencing on 29th March 2023 .
 9. Dr. Gauri Misra, Scientist-II & Dr. Ashwini Kumar Dubey, Scientist-III has attended a workshop on 'Methodology for writing a systematic Review' organized by Cochrane Affiliate Centre-ICMR, New Delhi on 14th Feb 2023 through online mode.
 10. Rashmi Shrivastava, Scientist III was Invited as Guest speaker for Panel discussion On Global Regulatory Perspective for Biosimilars– Strategies & Challenges at 2nd Edition India BioPharma Leaders Conclave held on the 26th and 27th May, 2022 in Hyderabad.
 11. Dr. Anoop Kumar, Jr. Scientist was invited as a speaker to deliver a lecture on "Real Time PCR & Its application in disease diagnosis" in a workshop entitled "Hands-on-training on Biological and Molecular Techniques" in the Department of Zoology, MMV, Banaras Hindu University, Varanasi from 20th -23rd Mar 2023
 12. Dr. Ratnesh Kumar Sharma, Scientist-II participated in "Management development program on administrative vigilance role of enquiry officer/presenting officer" from 22nd August to 26th August, 2022 at Shillong, Meghalaya.
 13. Dr. Ratnesh Kumar Sharma, Scientist-II attended the training programme on Preventive Vigilance and Disciplinary Proceedings from 20th to 25th March, 2023 at Cochin cum Lakshadweep organized by Delhi Productivity Council.
 14. Dr. Hemant Kumar Verma, Scientist-II, attended one-day conference "Pharma Anveshan-2023" as invited guest on 6th March, 2023 in New Delhi organized by Pharmacy Council of India, New Delhi.
 15. Dr. Harish Chander, Deputy Director (QC), Mr. Harit Kasana, Scientist-II, Dr. Pankaj K. Sharma, Scientist-III, , Mr. Subhash Chand, Scientist-III, have participated in the Bodoland International Festival at Bodoland University, Kokrajhar, Assam, held from 27th February to 2nd March 2023.



16. Dr Harish Chander DD(QC) , Mr Subhash Chand , Scientist-III organized One-Day workshop; Intellectual Property Rights (IPR) Under "Azadi ka Amrit Mahotsav" (an Initiative of Govt. of India) on 25th June 2022 at NIB
17. Dr. Rajesh K. Sharma, Scientist-III organized CME under Haemovigilance Programme of India at Hind Institute of Medical Sciences, Ataria, Sitapur (UP) and also delivered a lecture on Haemovigilance Programme of India & Networking on 24th March 2023.
18. Dr. Richa Baranwal, Scientist III, took the session on "Performance evaluation/ Clinical Evaluation of In-vitro Diagnostic Kits" on 26th Sep 2022 during three days training program on "Preparedness for Transition to licensing under medical Devices Rules (MDR) for Drug Inspectors/ Medical devices officers organized by National Institute of Health and Family Welfare (NIHFW) in collaboration with Central Drugs Standard Control Organization at New, Delhi.
19. Staff of RPL attended lecture on "Basics of Liquid Chromatography" as a part of Skillsets Enhancement Activities of Analytical teams conducted by M/s Waters India Pvt. Ltd. at NIB on 18th July 2022
20. Ms. Shalini Tewari, Scientist Grade-III & Head QMU gave a lecture on the Quality Management System of the institute on 12th Dec 2022 during in-house training for the newly recruited Assistant-I and Assistant-II.

CONTRIBUTION IN DEVELOPMENT OF PHARMACOPOEIA MONOGRAPH

1. The **Blood Reagent laboratory** prepared and published a total number of 09 monographs in the Indian Pharmacopoeia till date.

A total of 05 amendments of old monographs of following reagents have been done in the year 2022-2023.

- i. Anti- A Blood Grouping Reagent
- ii. Anti-B Blood Grouping Reagent
- iii. Anti-AB Blood Grouping Reagent
- iv. Anti-D (IgM) Monoclonal Blood Grouping Reagent
- v. Anti-Human Globulin (AHG) reagent

2. Blood Products laboratory

- a) Proposal submitted for amendment in following monographs
 - i. Fibrin Sealant Kit w.r.t. test for Water (to add limits).
 - ii. Human Coagulation Factor-VIII w.r.t. test for Water (to add limits).
 - iii. Human Normal Immunoglobulin (IV) w.r.t. to test for Anti-D antibodies.
- b) IPC, Ghaziabad accepted amendment of an alternative method to existing method by Horizontal Zone Electrophoresis for Protein Composition in Human Albumin Monograph (IP. – pg 4536 Protein Composition 2.4.12, IP 2022)

3. Recombinant Products laboratory

- a) Lab communicated the testing status of method verification done for "Identification by SDS PAGE" in draft monograph for Pegfilgrastim injection to IPC on 29th April 2022.
- b) Lab communicated the results for "Biological Identity and Potency" to IPC for proposed monograph on Pegfilgrastim injection as per the draft monograph submitted by one of the stakeholders on 06.06.2022
- c) Lab communicated its consent to Indian Pharmacopoeia Commission (IPC) for participating in the study for development of new lot of Teriparatide IPRS on 21.09.2022
- d) Proposal submitted for amendment in following monographs
 - i. Aspart injection w.r.t. concentration
 - ii. Insulin injection w.r.t. verification of the single method for potency identity and related proteins

4. Vaccine and Antisera Laboratory

Vaccine and Antisera Laboratory initiated the preparation of Monograph based on WHO protocol for "Estimation of Total and free PRP content of Haemophilus Influenzae type b vaccine using High performance Anion Exchange Chromatography with Pulsed Amperometric detection (HPAEC-PAD). The method got published in Indian Pharmacopoeia 2022 as general chapter 2.7.15 "Tests on vaccines".

PREPARATION AND SUPPLY OF NATIONAL REFERENCE STANDARDS/ SERA PERFORMANCE PANELS

A. Collection of plasma bags: During the year 2022-2023, a total number of 485 plasma bags were collected by the Laboratory out of which 260 were reactive for HIV (173), HCV (27), HBsAg (58)

& Syphilis (02) and 225 were non-reactive. The list of blood bank/ Hospitals and details of plasma bags collected are elaborated in the Table below

S. No.	Name of Hospital/ Blood Banks	S. No.	Name of Hospital/ Blood Banks
1.	Indian Red Cross Society, New Delhi	8.	LIONS Blood Bank, Delhi
2.	Sir Ganga Ram Hospital, New Delhi	9.	Deen Dayal Upadhyay Hospital, Delhi
3.	Guru Teg Bahadur Hospital, Delhi	10.	Shri Balaji Action Hospital, New Delhi
4.	Medanta Hospital, Gurugram	11.	HOLY Family Hospital, Okhla Road, New Delhi
5.	Fortis Escort Okhla, New Delhi	12.	BLK Max Superspeciality Hospital, New Delhi
6.	Lok Nayak Hospital, New Delhi	13.	District Civil Hospital, Karnal
7.	RML, Hospital, New Delhi		

B. 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

C. Supply of Sera Panel:

During 2022-23, the laboratory supplied 26 Performance Panel to 13 indigenous manufacturers to strengthen the Quality of product during manufacturing of the products.

D. Preparation and Cryopreservation of Red Cell Panel:

The laboratory collected, Grouped, Subgrouped, Rh phenotyped 344 blood samples to be used for quality control evaluation of blood grouping reagents.

The laboratory maintains and strengthens the repository for cryopreserved panel cells for routine and rare red blood cells from the left over samples collected from various blood banks. The laboratory cryopreserved 288 aliquots of red blood cells in the year 2022-2023 and the total number of aliquots increased from 18249 to 18537.

E. Development of National Reference Standard for Insulin Glargine:

i. Inputs have been received from 03 study participants for finalization of the study protocol for development of National

Reference Standard for Insulin Glargine by NIB through Interlaboratory Collaborative Study (ILC).

ii. A meeting was organized for "Finalization of study protocol for development of First National Reference Standard (NRS) for Insulin Glargine" on 01/09/2022 in virtual mode to discuss the following:

- a. Inputs from study participants in the study protocol was discussed across board so as to maintain uniformity in the study (Testing methodology , Reference Standard usage, number of performances, number of vials to be used etc)
- b. To finalize the material donor for NRS preparation.
- c. Assignment of value for NRS

iii. In continuation to the meeting held for development of First National Reference Standard (NRS) for Insulin Glargine, NIB had sent a request mail to one of the participating labs for supply of candidate material so that ILC could be facilitated. NIB is in receipt of acceptance from the innovator for providing the candidate material so that ILC can be initiated.

F. Supply of reference standard: 03 vials of Human Insulin IPRS purchased from NIB by M/s Torrent Pharmaceuticals Ltd, Gujarat.

PUBLICATIONS

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RESEARCH & DEVELOPMENT

I. Initiation of PhD programme

As a step towards higher excellence, a Memorandum of understanding (MoU) was signed between NIB & AcSIR on 28th February 2022. In pursuance, the institute had its first batch of 7 PhD students in August 2022 session and further 5 PhD students for the January 2023 session

I. Intramural and Extramural Research Projects

The scientists of NIB are undertaking scientific research as per their laboratory work in the field of biologicals. There are N=24 intramural research projects ongoing with NIB funding and the scientists also secured extramural funding and in the current reporting year, there are N=3 extramural projects. NIB also welcome collaborative research or studies from various organizations like NIBSC, EDQM, etc.

A. Extramural Research Projects

S. No.	Name of Project (Extramural)	Funding Agency	PI & Co-PI
1.	Evaluating the potential of new chromone derivatives against human Great wall kinase for cancer therapy using comparative cell based and proteomics investigations	ICMR	Dr Gauri Misra Scientist-II
2.	Harmonization of COVID-19 RT-PCR kits efficiency data towards enhancing their specificity and sensitivity for different strains of SARS-CoV-2.	ICMR	Dr Gauri Misra Scientist-II
3.	Development of in-vitro bioassay for biological activity of anti-HER2 therapeutic monoclonal antibodies based on variability in the expression of HER2 in breast cancer cell lines.	ICMR	Dr. Harish Chander, DD(QC) & Mr. Subhash Chand, Scientist -III

B. Ramalingaswami Fellowship Project

S. No.	Name of Project	Funding Agency
1.	Structure-function characterisation of novel Glycosyl transferases of Mycobacterium tuberculosis as potential therapeutic targets	DBT, Ministry of Science and Technology

C. Intramural Research Projects

S. No.	Name of Project (Intramural)	Laboratory
1)	Development of National Reference Standard Program for Insulin Glargine	Recombinant Products Lab
2)	An Alternative method to animal testing for Quality Control testing of Erythropoietin	Recombinant Products Lab
3)	Development and Validation of Cell line-based Assays to determine Biological Activity of Recombinant Follicle Stimulating Hormone (rFSH)	Enzymes & Hormones Lab
4)	Estimation of potency of Urokinase assay by Chromogenic method for replacement of existing bioassay.	Enzymes & Hormones Lab
5)	Development of an alternate kit-based method for Potency Assay in Human Rabies Immunoglobulin (IM)	Blood Products Lab

S. No.	Name of Project (Intramural)	Laboratory
6)	To replace Barbital Buffer with an alternate suitable buffer in test for "Protein Composition" in Human Albumin and Human normal/ specific Immunoglobulins.	Blood Products Lab
7)	Analytical and functional characterization of Anti-CD20 monoclonal antibody biosimilars marketed in India	Therapeutic Antibody Lab
8)	Spectrophotometric evaluation of biological activity of Vedolizumab as an alternative to FACS	Therapeutic Antibody Lab
9)	Analytical profiling of Anti-HER2 monoclonal antibody biosimilars marketed in India.	Therapeutic Antibody Lab
10)	Development of National Reference Standard (NRS) for Biological Activity of Trastuzumab	Therapeutic Antibody Lab
11)	Development of National Reference Standard (NRS) for Biological Activity of Rituximab	Therapeutic Antibody Lab
12)	Detection of Spike Protein Expression of SARS COV-2 by immune-fluorescence and immune-blotting for quality testing of viral vector-based vaccines	Vaccine & Antisera Lab
13)	Comparison of various pharmacopeia methods with ion-selective electrode potentiometry for measurement of sodium content in human albumin preparation.	Vaccine & Antisera Lab
14)	Comparative study for viability of cryo-preserved Red Blood Cells when thawed and re-suspended in Alsever's Solution for a period of four weeks.	Blood Reagent Lab
15)	Comparison of protein content in human normal / specific immunoglobulins by Kjeldahl and Biuret method.	Blood Products Lab
16)	Comparison of protein content in human normal Albumin by Kjeldahl, Biuret method and HPLC.	Blood Products Lab
17)	Aluminium content in Human serum Albumin using Atomic Absorption spectrophotometer (AAS)	Blood Products Lab
18)	vWF content in Factor VIII by Antigen binding method	Blood Products Lab
19)	An alternate kit based method for "Anti complementary activity" (ACA) test for Human Normal Immunoglobulin for intra-venous use.	Blood Products Lab
20)	Evaluation of SDS-PAGE for determination of Protein Composition in Human Albumin - A comparative study between SDS-PAGE and Horizontal Zone Electrophoresis.	Blood Products Lab
21)	Rapid microbiological Method for Sterility testing of Biotherapeutics based on cAMP assay.	Sterility Testing Lab
22)	Method validation of PRP content of Hib in Pentavalent vaccine by High Performance Anion Exchange Chromatography with Pulsed Amperometry detection.	Vaccine & Antisera Lab
23)	Determination of virus content and identification of adenoviral vector backbone by infectivity assay (cell culture based) and qPCR in ChAdOx1-nCoV-19 samples on different cell lines	Vaccine & Antisera Lab
24)	In-vitro evaluation of anticancer effect of natural and synthetic compounds on various breast cancer cell lines	Vaccine & Antisera Lab

RENDERING TECHNICAL EXPERTISE THROUGH JOINT INSPECTIONS

The Institute provides technical expertise for the enforcement of implementing standards in India through joint inspections of (i) manufacturing premises in coordination with the Central Drugs Standards and Control Organizations (CDSCO), (ii) Animal Facilities conducted by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and (iii) Association for Assessment and Accreditation of

Laboratory Animal Care International (AAALAC) and as NABL assessor for testing laboratories in India.

1. GMP Inspections:

Participations of 04 NIB Scientists as subject experts in Join Inspection of 05 bio therapeutic manufacturing units in India alongwith the CDSCO and state drug control officials.

NIB scientists involved in Joint inspections

S. No.	NIB Scientist	Designation
1.	Dr . Charu M Kamal	Scientist-I
2.	Dr. Ratnesh Kumar Sharma	Scientist-II
3.	Dr. Hemant Kumar Verma	Scientist-II
4.	Ms Gurminder Bindra	Scientist-III

2. CPCSEA Inspections:

Dr. Shikha Yadav, Scientist-I participated in CPCSEA Inspections of 03 Animal Facilities to ensure the compliance with the CPCSEA regulations.

3. AAALAC International Site Visit:

Dr. Shikha Yadav was selected by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) as an Adhoc Specialist in 2017. In the year 2022-23, she was invited as an Adhoc Specialist by Dr Montip Gettayacamin, Regional Director for Southeast Asia, AAALAC International for assisting AAALAC in conducting site visits of 4 Units/Institutes in

India with the AAALAC Council Members to assess their Institutional Animal Care and Use Program for AAALAC accreditation purposes.

4. Inspection of Animal Biosafety Level 3 Facility

Dr. Suresh Kumar, Scientist-III inspected 02 Animal Biosafety Level 3 facility of two Institutes at New Delhi.

5. NABL Assessor:

Sh. N. Nanda Gopal, Scientist-III was nominated by NABL as Assessor for audit of State Food Water and Excise Laboratory.



TRAININGS AT NIB

1. Aim & Scope:

Focusing on Skill Development in "Quality Control of Biologicals", NIB imparts Hands-on Training to Post –Graduate students of Biotechnology, Microbiology, Biochemistry from Universities of Himachal Pradesh, Jammu & Kashmir, North Eastern States and also to students from universities of Tribal Regions of the country i.e. Chhattisgarh, Jharkhand, Assam. NIB in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health and Family Welfare (Govt. of India) organize Residential Training Program on "Training of Trainers for Strengthening of Blood Services" for Blood Bank Officials from various parts of the country. The institute also provides 6 weeks' summer training programme and 4 -6 months' Project Work in Quality Control of Biologicals in various NIB laboratories to Graduate and Post Graduate Students of various universities to enhance their technical capabilities, that would help in their future research endeavors. With an aim to disseminate knowledge in the field of Biologicals, NIB has launched different training programmes including lab specific structured training of One-Two-weeks tenure. The Training Unit plays a major role in organizing these training programmes and also developing new programmes as well as strengthening the training activities of the Institute

2. Training Activities Undertaken:

2.1 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 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.

National Institute of Biologicals in collaboration with Blood Cell, National Health Mission (NHM), conducted "Six Days Residential Training of Blood Bank Officials" for 41 participants of Chhattisgarh state held from 09-01-2023 to 14-01-2023 at NIB NOIDA for technical support in Strengthening Blood Services.

Hands-on training for Govt. Blood Bank Officials at NIB (IDKL, BRL and Hemovigilance Cell), provides technical support in Strengthening Blood Services in India 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.

The initiative will help to bridge the gap of trained manpower to improve better quality, safety and efficacy of blood and blood products, meeting the requirements of current good laboratory practices (cGLP) and strengthen Total Quality Management System.

Training of Blood Bank Officials from the state of Chhattisgarh



2.2 Training of M.Sc. Biotechnology Students from various Universities at NIB under “National Skill Development & Hands-on Training programme”:

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 Biotherapeutics, 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. The three training batches conducted under this programme, are given in Table 1:

Table 1: Two-weeks residential training in line with National Skill Development & Hands-on Training on Quality Control of Biologicals programme.

Trainings	Duration		No. of Participants
National Skill Development Hands on Training for M.Sc. Biotechnology students of Sant Gahira Guru Vishwavidyalaya Chhattisgarh and Bodoland University Assam.	06-06-2022	17-06-2022	32
National Skill Development Hands on Training for M.Sc. Biotechnology students of Himachal Pradesh University Shimla, HP and Shaheed Mahendra Karma Vishwavidyalaya, Chhattisgarh.	12-09-2022	23-09-2022	30
National Skill Development Hands on Training for M.Sc. Biotechnology students of Manipur University Imphal, Manipur.	05-12-2022	16-12-2022	22
Total			84

Sant Gahira Guru Vishwavidyalaya and Bodoland University



Himachal Pradesh University Shimla, HP & Shaheed Mahendra Karma Vishwavidyalaya



Manipur University, Canchipur, Imphal



2.3 Training of Graduate/Post Graduate Students from various Universities.

The institute provides six weeks’ summer training and also four-six months’ project work training in Quality Control of Biologicals in different 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 2: Summer training and project work conducted at NIB, NOIDA.

S. No.	Trainings	Duration		No. of Participants	Total
		April, 2022	March, 2023		
1.	Summer Training of Post Graduate/Under Graduate students from subject Biotechnology, Biochemistry, Microbiology, Pharmacy etc	April, 2022	March, 2023	16	41
2.	Project work of Post Graduate students from subject Biotechnology, Biochemistry, Microbiology, Pharmacy etc	April, 2022	March, 2023	25	

2.4 Conduction of Weekly Seminar for the Project Work trainees of Session-2022-2023

In order to sensitize the students (involved in six-months project work for Session 2022 at NIB),

with the key focal technical parameters being performed at NIB, a weekly seminar was carried out involving all laboratories of NIB.

2.5 Structured customized short-term Laboratory based Training Courses

Table 3:- Details of Newly launched Structured Training Courses

S. No.	Training Title	Duration	Participants	Laboratory
1.	05-days training course on “Ethical Use & Care of Laboratory Animals in Research and Regulatory Testing”	18-04-2022 to 22-04-2022	11	In-Vivo Bioassay Laboratory & Animal Facility
		19-12-2022 to 23-12-2022	20	
2.	05-days “Short -term training course on RT-PCR including RNA extraction”	04-07-2022 to 08-07-2022	1	COVID-19 Kit Testing Laboratory
3.	05-days training course on “Cell Culture Based Techniques for evaluation of Biologicals and Vaccines”	04-07-2022 to 08-07-2022	3	Vaccine & Antisera Laboratory
4.	05-days training course on “Quality Control of Blood Products using Atomic Absorption Spectrometry”	22-08-2022 to 26-08-2022	3	Blood Products Laboratory

S. No.	Training Title	Duration	Participants	Laboratory
5.	05-days training on "Internal Quality Control and method validation Basics"	05-09-2022 to 09-09-2022	1	Biochemical Kit Laboratory
6.	05-days training on "Application of Reverse Phase Liquid Chromatography (RP-HPLC) for identification and potency testing of Human Insulin"	26-12-2022 to 30-12-2022	2	Recombinant Products Laboratory
Total			41	

Ethical Use & Care of Laboratory Animals in Research and Regulatory Testing (April 2022)



Cell Culture Based Techniques for evaluation of Biologicals and Vaccines (July 2022)



Quality Control of Blood Products using Atomic Absorption Spectrometry (August 2022)



Internal Quality Control and method validation Basics (September 2022)



Application of Reverse Phase Liquid Chromatography (RP-HPLC) for identification and potency testing of Human Insulin"



2.6 MoU Signing Ceremony of NIB-DPSRU for Scientific Collaboration

The MoU Signing Ceremony of NIB and DPSRU, was held on **17th May 2022** at NIB. The Hon'ble Vice Chancellor - Prof. Ramesh K Goyal along with Senior Officials of Delhi Pharmaceutical Sciences and Research University (DPSRU) and

Director, NIB - Dr. Anup Anvikar and Senior Scientists and Officials participated in this ceremony. The representative members of the two institutes signed the modalities of collaboration through formal Memorandum of Understanding MoU, including a "Certificate programme on Quality Control of Biopharmaceuticals



2.7 Internal Training Programme on Western Blotting by Recombinant Products Laboratory:

Organized 02-Days Internal training course on

"Western Blotting" at Recombinant Products Lab NIB for the Scientists and Lab Technicians, scheduled in two batches from 17 - 18 May, 2022 & 02 - 03 June, 2022



2.8 Orientation Training Programme on "Building Effective Team"

Organized a training cum-Orientation Programme on "Building Effective Teams" on 23rd February

2023 here at NIB. The training was imparted by two officials: Dr. Nidhi Phutela (Officiating Director) and Dr. Priya Grover (Associate Professor) from the Symbiosis Centre for Management Studies SCMS Noida.



VISITS TO NIB LABORATORIES

3.1 Visit of Hon'ble Minister of State – Ministry of Health & Family Welfare

National Institute of Biologicals (NIB-Noida), Ministry of Health and Family Welfare, celebrated the 'Azadi Ka Amrit Mahotsav', occasion on **30th June 2022** under the theme "**Three decades of Service to the nation**". Honorable Minister of State (MoS) **Dr. Bharati Pravin Pawar** was the Guest of Honour of this prestigious event. Shri Rajesh Bhushan, Secretary- Ministry of Health and Family Welfare, Dr. Balram Bhargava, Secretary- DHR & DG ICMR, Prof Rajender Singh Sangwan- Director ACSIR, Dr

Rajani kant Srivastava- Director RMRC-ICMR, Dr Shalini Singh- Director NICPR, Dr Kiran Kumar Karlapu- Deputy Secretary- MOHFW, Dr. Rubina Bose –Deputy Drugs Controller CDSCO & Dr Mallika Gope- Director NABL, graced the occasion. The employees who had completed 25 years of service and contributed to the progress of the institute were felicitated by the dignitaries. Honorable Minister of State, in her key note address highlighted NIB's role in promoting and safeguarding public health and appreciated its substantial Contribution to the Nation's Drug Regulatory system



Visit of Hon'ble Minister of State – Ministry of Health & Family Welfare

3.2 Visit of International Delegates from 17 Countries to NIB:

National Institute of Biologicals-NIB hosted a **Laboratory visit of 33 International Delegates** from **17 countries** along with 02 NITS representative officials on **14th February, 2023** from 2:00 PM - 5:30 PM. The delegates

were given the basic overview of NIB and visited various Laboratories, and interacted with concerned Scientists. The said delegates were participating in 13th International Training Programme on "Competence and Management systems of Laboratories" for developing Countries being conducted at NITS, Noida, India



3.3 One Day Technical Tour of NABL Officers to NIB;

NIB hosted One Day Technical Tour of National Accreditation Board for Testing and Calibration Laboratories (NABL) 47 officers to NIB on **16th September 2022**. The officers were given the basic overview of NIB, Training facility and quality management system. The officials visited various laboratories, and interacted with concerned scientists.

3.4 Laboratory visit of PGDCR students from AHERF New Delhi;

NIB hosted a laboratory visit of **12 PGDCR students and accompanying Faculty** from Apollo Hospitals Education and Research Foundation (**AHERF New Delhi**) on **28th June 2022**. The students were given the basic overview of NIB and visited various laboratories, and interacted with concerned scientists.

3.5 Laboratory visit of pharmacy students from Kerala, on 13th July 2022;

NIB hosted a Laboratory visit of 38 B. Pharm students alongwith 04 Faculty members from College of Pharmaceutical Sciences (Govt. Medical College Kottayam, Kerala) on **13th July 2022**. The students were given the basic overview of NIB and visited various laboratories, and interacted with concerned scientists.

3.6 Laboratory visit of M.Sc. Clinical Research students from IIPH- Delhi;

NIB hosted laboratory visit of 07 M.Sc. Clinical Research students along with 02 Faculty members from **IIPH Indian Institute of Public Health Delhi** (Public Health Foundation of India) on **14th October 2022**. The students were given the basic Overview of NIB, Training facility and Quality Management System, and visited various Laboratories, interacted with the Concerned Scientists.



Pharmacy students from Kerala



M.Sc. Clinical Research students from IIPH- Delhi



PGDCR students from AHERF New Delhi

HAEMOVIGILANCE PROGRAMME OF INDIA (HvPI)

Scientific Activities Undertaken:

- a. Implementation and coordination of activities of Haemovigilance Programme of India (HvPI) is one of the mandates of NIB as per its bye-laws 3.4.1 as approved in the 24th Governing Body meeting of NIB held under the Chairmanship of Secretary (Health & F.W.)/ Chairman, Governing Body of NIB on 12th Dec, 2014.
- b. 189 new blood centers have been enrolled under this programme during said financial year taking a total of 1428 blood centers 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 15,725 adverse reaction reports have been reported via Haemovigilance Software(s) during this financial year out of which 5,772 reports pertain to adverse blood transfusion reactions and 9,953 reports are attributed to reactions during blood donation.
- c. **Publication(s)**
 - An article on "First Decade of implementation of Haemovigilance Programme in India" has been published in Transfusion Today, Number 131, April 2022 Issue of International Society of Blood Transfusion (ISBT).

Training/ Workshop/ Conference Organized:

- NIB under Haemovigilance Programme of India (HvPI) has organized 03 virtual CMEs/ Workshops/ Conferences across the country so as to create awareness about the programme & trained about 360 participants which includes Blood centre officials, clinicians, nurses, blood donor motivators, blood centre technical staff, PG students & officials from drugs control department.
- A webinar for 50 blood centres w.r.t. Severity Grading Tool (SGT) study under National Blood Donor Vigilance Programme (NBDVP) was organized by Haemovigilance Division of NIB on 06th April, 2022. Apart from participating centres, experts from transfusion medicine department also attended the said webinar.
- National Workshop on "Blood Safety Roadmap for Blood Transfusion Services in India" organized by

Directorate General of Health Services (DGHS), with support of WHO Country Office and National Institute of Biologicals (NIB) on 14th & 15th July, 2022 at NIB, NOIDA. The Head HvPI was the resource person as well as speaker and gave the presentation on the topic of "Haemovigilance Programme of India" in the said workshop.

- Federation of Blood Donor Organizations of India (FBDOI) & NIB have jointly organized the National CME & Workshop on Voluntary Blood Donation, Haemovigilance & Donor Vigilance at NIB, NOIDA on 01st & 02nd December, 2022. 100 participants including voluntary blood donors, donor motivators, blood center officials & Government officials across the country attended the said CME & Workshop.
- Continuing Medical Education (CME) on Haemovigilance Programme of India organized by National Institute of Biologicals (NIB), NOIDA in collaboration with Hind Institute of Medical Sciences (HIMS) Sitapur, Uttar Pradesh on 24th March, 2023 at HIMS Sitapur, Uttar Pradesh. About 180 participants including blood bank officials, clinicians, technicians, nurses, PG students & officials from Drugs Control Department attended the said CME.

Participation in Training/ Workshop/ Conference:

National: -

- Participation via virtual mode in 2nd North East Workshop on Haemovigilance, Blood Donor Vigilance & Voluntary Blood Donation organized by Barak Valley Voluntary Blood Donor's Forum central committee & supported by Federation of Blood Donor Organizations of India (FBDOI) held on 20th -21st May, 2022 at Silchar, Assam.
- Participation via virtual mode in the Federation of Indian Blood Donors Organizations (FIBDO) West Bengal State Conference- 2022 organized by FIBDO, West Bengal held on 28th - 29th May 2022 at Barasat Rabindra Bhawan in North 24 Parganas.
- Participation in the CME on Update on Screening for Transfusion Transmissible Infections organized by Department of Transfusion Medicine, Institute of Liver and Biliary Sciences (ILBS) held on 22nd July 2022 at ILBS, New Delhi.

- Participation in the 1st Annual Conference, PED-OBGY-FUSION 2022 under the aegis of ISBTI organized by Department of Transfusion Medicine and Co-organized by Department of Pediatrics, Obstetrics and Gynecology, Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly on 10th and 11th September, 2022 at Ramnagar Uttarakhand.

International

- Participation via online mode in the IHN General Assembly & IHN SHOT Hybrid Symposium 2022 held from 6th to 8th July, 2022 in Brighton. The General Assembly was also held during the IHN-SHOT Hybrid symposium 2022 on 6th July, 2022.
- Participation in the Virtual Regional meeting of NBTS focal points to review the implementation of "WHO action framework to advance universal access to safe Blood and Blood products 2020 (GPHG)" held from 26th to 27th July, 2022 organized by WHO Regional Office for South East Asia, New Delhi.

Outstanding achievements of the Lab/ Division:

BLODCON-2022, National Conference & Workshop in association with NIB from 17th - 19th November, 2022

Federation of Indian Blood Donor Organizations

(FIBDO) & NIB have jointly organized BLODCON-2022, the National Conference & Workshop at NIB, NOIDA from 17th to 19th November, 2022. The conference was inaugurated by Shri Som Parkash, Hon'ble Minister of State, Ministry of Commerce and Industry, Government of India. Hon'ble Minister appreciated the noble endeavor being done by the FIBDO towards Voluntary Blood Donation movement in the country and congratulated NIB for conducting & hosting this conference.

Dr. Anup Anvikar, Director NIB welcomed the august gathering and briefly apprised about the activities done at NIB & also encouraged the delegates to participate actively in the conference.

80 participants including Voluntary Blood Donors, Donor Motivators, Blood Centre Officials & Government Officials of across the country attended the said Conference & workshop.

Document Release

- During the conference document on Good Blood Transfusion Practices- Guidance for Rational use of Blood prepared by NIB was released by Shri Som Parkash, Hon'ble Minister of State, Ministry of Commerce and Industry, Government of India.



INFORMATION TECHNOLOGY DIVISION

1. Laboratory Information Management Software (LIMS): IT Cell is currently maintaining and updating in-house developed LIMS software. During the year, IT Cell has updated Sample Tracking Invoice Generation Software and Other Invoice Generation Software and merged in LIMS Software. This software facilitates for generation of invoices pertaining to testing fee received from manufacturers and for other services such as Sale of Animals, Biotech Products, eWaste, and Old Newspapers etc.
2. In addition, IT Cell has also updated the CoAs under Part-A and Part-B, deletion and shifting of testing parameters, changes in database along with the testing fees, inclusion of disclaimer in all CoAs released w.e.f. 01.04.2022 for various laboratories in LIMS Portal.
3. IT Cell has updated the LAN Intranet Portal using dot net technology and deployed in IIS Server. IT Cell has also updated the information received from Quality Management Unit such as SOPs, Monographs, AMC records, Committees etc. on LAN Portal.
4. IT Cell has procured the Secured Socket Layer Certificate through GeM Portal and bind with nib.gov.in to keep sensitive information sent across the Internet encrypted so that only the intended recipient can access it.
5. DHCP Server configured in Network Security Firewall, implementation of web and application policy for securing the network to strengthen the IT related services.
6. IT Cell has also completed the Security Audit of New Dynamic Website of the Institute in May, 2022.
7. NIB is hosting National Summit on Quality of Biologicals, National and International meetings, Conferences, Workshops, Trainings and Academic activities for the past few years. The IT Cell has provided IT related support in Conference Room, Meeting Room, Class Room and Bioinformatics Centre for various online as well offline training programmes and meetings held in the Institute. Beside this, IT Cell has also provided the technical support for arrangements of virtual meetings held during the year.
8. IT Cell has got Delegated Admin access from NIC for management of email accounts.
9. IT Cell has registered the Institute name on IGOT Karmayogi and Govt. Land Information System (GLIS) Portal.
10. Design and developed the data-base structure in Aadhaar Based Attendance Portal of NIC and compatibles machines have been installed at the Institute.
11. The IT Cell has initiated the tender enquiry for implementation of Laboratory Information Management System (LIMS) and currently is under process.
12. The IT Cell has initiated the process for implementation of eOffice (Lite) & eOffice (SPARROW) and request for issue of Proforma Invoice has been raised to M/s. NICSI. In this regard, Scanning and Digitization of records, Digital Signature Certificate, and Multi-Functional Printers have been provided to various laboratories / divisions.

ENGINEERING DIVISION

Engineering Activities:

The NIB campus specifically Laboratory & Animal House building is complemented by various engineering services/facilities/installation to facilitate the day to day scientific activities. Details information about the various engineering works/services/facilities and installations undertaken during the Financial Year 2022-2023.

Electro Mechanical Engineering Works Undertaken:

Proposal/Works have been initiated for the following works viz :-

- i. Work for "Repairing & overhauling of 08MVA, 33/11kV, HT Power Transformer No.2 of M/s. Crompton Greaves make {bearing S.No.6058/2} installed at NIB Noida.
- ii. Renovation work of walk-in-cold rooms installed in Basement of Administrative Building.
- iii. Ongoing process to repair works of Centrifugal chiller, 200 Tr, M/s TRANE, USA make for HVAC system installed for Administrative & Cafeteria Building.
- iv. Conversion of Boilers from HSD to Natural Gas (NG) basis.
- v. 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.
- vi. Renovation work Firefighting System underground pipelines with CPWD.
- vii. Work for "Supply, Replacement, Installation, Testing and Commissioning of 03 Nos. Cooling Towers (Capacity: 3 x 930 TR)" which are connected with the HVAC system installed exclusively for Laboratory & Animal House, NIB, Noida.
- viii. Work for Supply, Installation, Testing, Commissioning (SITC) Cooling & Heating Coils with humidity & temperature controllers and dismantling the existing (Cooling Coils & Heating coils) in Air Handling Units for HAVC system installed for Laboratory and Animal House building at NIB, Noida.
- ix. Tendering and award the contract for Supply, Installation, Testing & Commissioning of Centrifugal Chiller (Water cooled) with allied accessories & complete job in respectively and also the buyback with dismantling of existing chiller No.-3(Out of order) in Laboratory & Animal House Building at NIB, Noida by M/s HIETES, Noida.

Apart from the above, the Institute has finalized/ongoing the services contracts for annual operation and maintenance contract and AMC/CMCs of the following engineering services/facilities and fixed scientific equipment during the Financial Year 2022-2023.

1. Operation & Comprehensive Contract of 20 Nos. Walk-in-cold Rooms, Environmental Rooms, Incubators installed in Lab. & Animal house Building, NIB, Noida.
2. Operation and comprehensive maintenance contract for firefighting system, water supply system, water softening plant system, neutralization system including centralized water softening plant of the Institute.
3. Operation and maintenance contract for 3 x 2.8T/Hr at 10.5kg/sqcm steam generating boiler including Economizers and allied accessories etc.
4. Operation and maintenance contract for centralized R.O. Plant system installed in the Laboratory & Animal House Building.
5. AMC of 17 Nos. Fume Hoods (M/s Kewaunee) installed in Lab. & Animal House Building, NIB, Noida.
6. Supply, Installation of 24 Nos. Fire House Boxes and 48 Nos. Fire Hose pipes in NIB campus, Noida.
7. Operation and Non Maintenance contract for External & Internal services (Electrical).
8. Operation and maintenance contract for HVAC plant System including Window/ Split Cassette and package type AC units installed in various buildings of the Institute.
9. 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.
10. 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, Air Compressor (Atlas Copco Make), Refrigerators and Bio-waste Disposal.

11. Operation and maintenance of Steam Sterilizers, Washers and other equipment of Steris, USA make installed in laboratory and animal house.
12. Operation and Non-Comprehensive Maintenance for Fire Alarm/ Detection system & PA System, installed in the Laboratory & Animal House Building" at NIB Noida.
13. To make provision for supply, installation, testing and commissioning separate Air Conditioning Unit to control the Humidity and temperature in Existing Sterility Clean Room" in NIB Campus, Noida.
14. Validation of Sterility Testing Clean Room twice in a year as per WHO guidelines in Laboratory" at NIB, Noida.
15. Award of contract for "Operation & Comprehensive Maintenance of ETP & STP".
16. Facilitated in signing of MoU between NIB and CPWD, for permanent solution of water leakage problem in corroded Stainless Steel (SS) piping network of Lab & Animal House.
17. Environmental monitoring of Stacks (ETP, STP, Chimney flues, Noise, Soil etc.) through NABL accredited agency for obtaining Air & Water consent orders from UP, Pollution Control Board.
18. Process for setting up of QMU Office and Renovation of Office in Animal Facility started by inviting bids.
19. Logistic support during various programmes such as National Health Mission Trainings, Skill Development Trainings, Seminars, Meetings, visits of dignitaries etc. to the Institute from time to time.
20. Renovation of Office Room No. S-0126 and Room

No. S-0127 in Animal House" in NIB Noida.

21. Setting up Quality Management Unit (QMU) at ground floor of Administrative Building in NIB, Noida.

Civil Engineering

1. Setting up of dedicated QMU Office in Admn. Building Hall.
2. Renovation of office Room No- S0126 & S0127 in Animal House.
3. Replacement of worn out galvanised sheet roofing of outdoor boiler machines.
4. Mechanised cleaning of entire sewerage & drainage system in campus, under Swachhatta Action Plan.
5. Environmental monitoring of Stacks (ETP, STP, Chimney flues, Noise, Soil etc.) through NABL accredited agency for obtaining Air & Water consent orders from UP, Pollution Control Board.
6. Monitoring & maintaining of controls, checks, system and documentation as per ISO 17025 and OHSAS 18001-2007 requirements.
7. Activities pertaining to creation of space, upkeep & cleanliness of office undertaken during special campaign 2.0
8. Carried out Non-Destructive Testing of RCC structure of overhead & underground water reservoirs to check the integrity of the structure.
9. Up-gradation of NIB Main Sign Board at North-West corner of campus.
10. Provided set up for permanent display of "Constitution of India "in the office.
11. Complete management of repairs & maintenance works and troubleshooting related to maintenance complaints in 19 buildings (area of buildings more than 35000 Sqm.), services and Institute campus to ensure uninterrupted services in the Labs, Animal Facility, Guest House, Hostel, Cafeteria, Offices etc.
12. Complete management of annual service contracts viz. maintenance of Horticulture, Pest & Rodent Control and Housekeeping etc.

Report of the Administrative Work

Head of the Administration: Sh. Q. W. Zaheeruddin, Sr. Admin. Officer

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. Director , NIB, NOIDA	Member Secretary

2. Governing Body of the Institute

Composition of the Governing Body: Secretary (Health & Family Welfare) Ministry of Health & 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 & 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 of India Directorate General of Health Services, Nirman Bhawan, New Delhi- 110011.	Member
Director , NIB, NOIDA	Member Secretary

Meetings of the Governing Body:

32nd Meeting of Governing Body was held on 27.08.2022

33rd Meeting of Governing Body was held on 14.02.2023

3. Standing Finance Committees.

Composition of the Standing Finance Committee:

Additional Secretary Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi	Chairman
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:

The 34th Meeting of Standing Finance Committees was held on 14.11.2022

4. Promotions, Appointments/ Superannuation/ Quit from Services / granted by the Institute during the year 2022-23:-

Appointments

S. No.	Name of Employee	Designation
1.	Ms. Nisha Dhillon	Assistant-I on 07.09.2022
2.	Sh. Akshat Sabherwal	Assistant-I on 27.09.2022
3.	Sh. Nitesh Kumar	Assistant-I on 07.10.2022
4.	Ms. Saroj Verma	Assistant-I on 14.12.2022
5.	Sh. Praveen Kumar	Assistant-I on 27.12.2022
6.	Sh. Alok Verma	Assistant-II on 15.09.2022
7.	Sh. Rohit Kumar Singh	Assistant-II on 23.09.2022
8.	Ms. Komal Parkash	Assistant-II on 27.09.2022
9.	Sh. Nikhil Pratap Singh	Assistant-II on 13.10.2022

Promotions

S. No.	Name of Employee	Designation
1.	Dr. Harish Chander	Deputy Director (Quality Control) On 30.08.2022
2.	Dr. Shikha Yadav	Scientist Grade-I (Vet) On 30.08.2022
3.	Dr. Charu M. Kamal	Scientist Grade-I On 30.08.2022
4.	Ms. Sudha V. Gopinath	Scientist Grade-II On 03.01.2023
5.	Sh. Brij Bahadur	Jr. Scientist On 16.01.2023

Employees extended premature retirement

S. No.	Name of Employee	Designation
1.	Sh. J.P. Pant	Administrative Officer (31.08.2022)

5. Staff in position**PERSONNEL****A. Scientific**

S. No.	Name	Designation
1.	Dr. Anup Anvikar	Director (Additional Charge)
2.	Dr. Harish Chander	Deputy Director (Quality Control)
3.	Dr. Shikha Yadav	Scientist Grade-I (Vet)
4.	Dr. Charu M. Kamal	Scientist Grade-I
5.	Sh. Neeraj Malik	Scientist Grade-II
6.	Dr. Akanksha Bisht	Scientist Grade-II
7.	Dr. Meena Kumari	Scientist Grade-II
8.	Dr. Hemant Kumar Verma	Scientist Grade-II
9.	Sh. Harit Kasana	Scientist Grade-II
10.	Dr. Gauri Misra	Scientist Grade-II
11.	Dr. Ratnesh K. Sharma	Scientist Grade-II
12.	Ms. Ajanta Sircar	Scientist Grade-II
13.	Ms Sudha V. Gopinath	Scientist Grade-II
14.	Ms. Kanchan Ahuja	Scientist Grade-III
15.	Dr. Rajesh K. Sharma	Scientist Grade-III
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 (Jr. Vet)	Scientist Grade-III
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.	Dr. Pankaj K. Sharma	Scientist Grade-III
27.	Sh. N. Nanda Gopal	Scientist Grade-III
28.	Dr. Ashwini Kumar Dubey	Scientist Grade-III
29.	Dr. Sanjay Mendiratta	Scientist Grade-III
30.	Dr. Varun Singh	Scientist Grade-III



31.	Dr. Saurabh Sharma	Scientist Grade-III
32.	Dr. Manjula Kiran	Jr. Scientist
33.	Ms. Vandana Tandasi	Jr. Scientist
34.	Dr. Birendra Kumar	Jr. Scientist
35.	Sh. Ajay Kumar Ade	Jr. Scientist
36.	Sh. Anirban Mukherjee	Jr. Scientist
37.	Dr. Anoop Kumar	Jr. Scientist
38.	Ms. Archana Sayal	Jr. Scientist
39.	Sh. Rajeev Kumar	Jr. Scientist
40.	Md. Daud Ali	Jr. Scientist
41.	Dr. Swati Shalini	Jr. Scientist
42.	Ms. Apoorva Anand	Jr. Scientist
43.	Dr. Paras Jain	Jr. Scientist
44.	Sh. Brij Bhushan	Jr. Scientist
45.	Sh. Subhash Kumar	Jr. Scientist
46.	Dr. Supriya Saini	Jr. Scientist
47.	Sh. Anoop Kumar	Jr. Scientist
48.	Ms. Sanchi Goel	Jr. Scientist
49.	Sh. Brij Bahadur	Jr. Scientist
50.	Ms. Girija L.V.	Lab Technician
51.	Sh. Sukhen Majhi	Lab Technician
52.	Dr. Mohammed Imran	Lab Technician
53.	Sh. Reetesh Kumar	Lab Technician
54.	Sh. Mohit Lal	Lab Technician
55.	Ms. Poonam	Lab Technician
56.	Sh. Lakhan	Lab Technician
57.	Sh. Prem Kumar Prasad	Lab Technician
58.	Sh. Sinto M.V.	Lab Technician
59.	Sh. Mohit Sharma	Lab Assistant
60.	Ms. Priya Bhatt	Lab Assistant
61.	Sh. Rajeev Kumar Srivastava	Lab Assistant
62.	Sh. Prdeep	Lab Assistant
63.	Sh. Narender Kumar	Lab Assistant
64.	Sh. Parminder Kumar	Jr. Animal Caretaker

B. Administration, Finance, Procurement & Engineering

S. No.	Name	Designation
1.	Sh. W.Z. Quazi	Senior Administrative Officer (P)
2.	Sh. P.K. Mohapatra	Administrative Officer (F)
3.	Sh. Deepak Mahajan	Jr. Programme Officer
4.	Sh. Manmeet Singh Bhatia	Section Officer
5.	Sh. U.N. Sharma	Section Officer
6.	Sh. Sanjeev Kumar	Section Officer (On deputation)
7.	Sh. Pradeep Kumar	Administrative Assistant
8.	Sh. Dhirender Singh	Administrative Assistant
9.	Sh. Praveen Kumar Pant	Administrative Assistant
10.	Sh. Varun Pandey	Administrative Assistant
11.	Sh. Partho Mandal	Administrative Assistant
12.	Sh. Pradeep Kumar Mehta	Administrative Assistant
13.	Sh. Pawan Kumar Sharma	Administrative Assistant
14.	Sh. R.K. Arora	Stenographer Grade-B
15.	Sh. Prem Chand Gupta	Assistant-I
16.	Ms. Savita Rai	Assistant-I
17.	Ms Nisha Dhillon	Assistant-I
18.	Sh. Akshat Sabherwal	Assistant-I
19.	Sh. Nitesh Kumar	Assistant-I
20.	Ms Saroj Verma	Assistant-I
21.	Sh. Praveen Kumar	Assistant-I
22.	Sh. Alok Verma	Assistant-II
23.	Sh. Rohit Kumar Singh	Assistant-II
24.	Ms Komal Parkash	Assistant-II
25.	Sh. Nikhil Pratap Singh	Assistant-II
26.	Sh. Govind Singh Rawat	Driver
27.	Sh. Harinder Singh	Driver
28.	Sh. Leela Kishan	Driver
29.	Sh. Bijender Singh	M.T.S
30.	Sh. Subhash Chand	M.T.S
31.	Sh. Suraj Pal	M.T.S
32.	Sh. Rakesh	M.T.S
33.	Sh. Prem Chand Diwan	M.T.S
34.	Smt. Shoba	M.T.S
35.	Smt. Rajendri Devi	M.T.S
36.	Sh. Mukesh Kumar	Assistant Engineer(Electrical)
37.	Sh. R.P. Joshi	Assistant Engineer(Civil)
38.	Sh. Subhash Chand	Jr. Engineer (Electrical)
39.	Sh. Chander Pal	Jr. Engineer(Mechanical)
40.	Sh. Amarjit Singh	Jr. Engineer(Mechanical)
41.	Sh. Krishna Kumar	Jr. Engineer (Civil)
42.	Sh. H.P. Vashisth	Electrician

Rajbhasha Cell

Implementation of Official Language Policy

In pursuance of the Official Language Policy of the Government of India, a Rajbhasha Cell is in place at NIB. In order to ensure the progressive use of Hindi in day to day official work as well as to see that the prescribed targets, as set in Annual Programme of Official Language for the year 2022-23, for use of Hindi are achieved, various measures and initiatives had been taken in the Institute during the year under review. Chiefly, these measures and initiatives included the extending of full help for translation of material from English to Hindi and vice versa, making standard drafts in Hindi/bilingual form available, conducting of Hindi Workshops on regular basis and all other activities which are otherwise essential for implementation of Official Language Policy of Government of India in the Institute. During the year 2022-23, a Hindi Pakhwada, from 14-29 September, 2022, was also organised in the Institute containing various competitions for the employees therein. This also included a Hindi Kavi-Goshti, organised during celebration of Hindi Pakhwada.

NIB was honoured with Consolation award by TOLIC for doing excellent work in the implementation of Official Language during the year 2021-22. It is a matter of pride to mention that two Scientists of the Institute- Ms. Sudha V. Gopinath, Scientist-II and Dr. Ashwini Kumar Dubey, Scientist-III were awarded First Prize in Hindi Essay Writing Competition, in each of the categories of Non Hindi Speaking and Hindi Speaking employees, held under the aegis of Town Official Language Implementation Committee for the officials of its Member Offices by V.V. Giri Labour Institute, NOIDA.

Quarterly meetings of the Official Language Implementation Committee

Quarterly meetings of the Official Language Implementation Committee were regularly held in each quarter under the Chairmanship of Director, NIB. In these meetings, progress of use of Hindi in official work was reviewed and necessary actions were suggested

for further improvements in this regard.

Participation in other meetings/ workshops/ seminars

The concerned officials of the Institute attended/ participated in the review meetings and workshops held by the Ministry of Health and Family Welfare, Government of India in virtual mode. Director, NIB along with other officials of the Institute attended the meeting held by the Town Official Language Implementation Committee, NOIDA. Two Officers of the Institute did also attend the 2nd All India Rajbhasha Sammelan, held in Surat, Gujarat by the Department of Official Language, Ministry of Home Affairs, Government of India.

Other activities

- The website of the Institute is in bilingual and also updated in Hindi from time to time.
- All the standard forms are in bilingual form and have been uploaded on website of the Institute.
- All the computers which are in use are with facility to work in Hindi. Hindi font "Mangal Unicode" is effectively uploaded in all of these computers.
- Hindi/bilingual standard drafts of routine letters have also been made available to all the concerned units so that the volume of correspondence in Hindi be increased.
- To make the officials proficient in Hindi, with the association of Hindi Teaching Scheme, Department of Official Language (Ministry of Home Affairs), Govt. of India, an In-house "Parangat" Hindi Training Course (Session January-May, 2023) was started in the Institute.
- The Institute is taking all necessary steps to achieve the targets as set in the Annual Programme for the implementation of Official Language, issued by the Department of Official Language, Ministry of Home Affairs, Govt. of India.

Events

1. **Azadi Ka Amrit Mahotsav - Three Decades of Service to the Nation**

National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, celebrated the 'Azadi Ka Amrit Mahotsav', on 30th June 2022 under the theme "Three decades of Service to the nation". The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar was the Guest of Honour for this prestigious event. Shri Rajesh Bhushan, Secretary- Ministry of Health and Family Welfare, Dr. Balram Bhargava, Secretary- DHR & DG ICMR, Prof Rajender Singh Sangwan- Director ACSIR, Dr Rajani Kant Srivastava- Director RMRC-Gorakhpur, Dr Shalini Singh- Director NICPR, Dr Kiran Kumar Karlapu- Deputy Secretary- MoHFW, Dr. Rubina Bose –Deputy Drugs Controller-CDSCO and Dr Mallika Gope- Director NABL, graced the occasion.

A Booklet and a Video on 30 years of NIB along with a Guidance Document for Reporting Blood Donor Adverse Reactions under the National Blood Donor Vigilance Programme (NBDVP) were released by the Hon'ble Minister of State, Ministry of Health & Family Welfare. The employees who had completed 25 years of service and contributed to the progress of the institute were felicitated by the dignitaries. The Honourable Minister of State, in her keynote address, highlighted NIB's role in promoting and safeguarding public health and appreciated its substantial Contribution to the Nation's Drug Regulatory system.

2. **Celebrations of International Yoga Day on 21.06.2022**

With great enthusiasm, NIB celebrated International Yoga day on 21st June 2022 under the guidance of Yoga Acharya Vijaya Kumar, Chairman & CEO, Universal Yoga Group, Gurugram. He emphasised the purpose of the Yoga and its impact on individual/s health and

asked everyone to introduce yoga in their daily activity.

3. **Celebrations of Hindi Pakhwada 2022:**

NIB celebrated Hindi Diwas and Hindi Pakhwad from 14.09.2022 to 29.09.2022. Various competitions have been organised to encourage the use of Hindi language in routine office practices.

4. **Observance of Constitution Day**

NIB organized a talk given by Dr. P K Atul, Scientist-F, National Institute of Malaria Research, ICMR, Delhi on the occasion of the Constitution Day of India on 28.11.2022. He presented about the salient features of our Constitution in detail.

5. **One day Hindi Karyashala**

One Day Hindi Karyashala has been organized on 30.11.2022, at NIB to sensitize staff members about the significance of Hindi Language use in routine office work. Dr. Vandana Sharma, Assistant Director (Rajbhasha), NMR, ICMR, Delhi briefed about the same.

6. **Training on Gender Sensitization and the Posh Act**

As part of a special drive by the Ministry of Women and Child Development, Government of India, NIB organized training on Gender Sensitization and the POSH (Protection of women from Sexual Harassment Act, 2013) Act on 21.12.2022. Dr. Mansi Mishra, Head, Research & Knowledge Manager, CSR, India was invited as a special guest and she briefed about the Act in detail.

7. **Women's Day Celebrations**

NIB celebrated International Women's Day with a great enthusiasm and spirit by organizing various competitions and cultural activities on 13th March, 2023.

8. Organization of recreational activities in the event of NIB's 30 years of inception

S.No.	SPORTS NAME	WINNER	RUNNER	3rd POSITION
1.	BADMINTION - MEN'S	MR. AJAY	MR. JYOTIRAJ	DR. SANJAY MENDIRATTA
2.	BADMINTION - WOMEN'S	DR. RICHA	MS. SHEETAL	MS. PALLAVI
3.	TABLE TENNIS - MEN'S	MR. ANIRBAN MUKHERJEE	MR. KUNAL	Dr. SUBASH CHAND
4.	TABLE TENNIS -WOMEN'S	MS. SHAREEN	DR. MANJULA	MS. GUNJAN
5.	CHESS - MEN'S	DR. SANJAY MENIDIRATTA	MR ANIRBAN Mukherjee	MR. HARIT KASANA
6.	CHESS - WOMEN'S	MS. RASHMI SRIVASTAVA	MS. ARCHANA SAYAL	MS. DIVYANI SHARMA
7.	CARROM - MEN'S	MR. PAWAN Kr SHARMA	MR. JAIPAL MEENA	Dr. SUBASH CHAND
8.	CARROM - WOMEN'S	PRIYANKA GUPTA	POONAM	MS. SIDRA
9.	VOLLEYBALL- WOMEN'S	NIB-LAB (06 PLAYERS)	NIB-ADMIN (06 PLAYERS)	
10.	VOLLEYBALL- MEN'S	NIB-NIGHT RIDERS	NIB-CHALLENGERS	SRRD
11.	CRICKET	ADMIN-XI	NIB-WARRIORS	NIB-LAB
12.	SPORTSMAN OF THE TOURNAMENT	MR. ANIRBAN MUKHERJEE		
13.	SPORTSWOMEN OF THE TOURNAMENT	Ms. SHAREEN		

Photos of events

1. Azadi Ka Amrit Mahotsav - Three Decades of Service to the Nation



2. Celebrations of International Yoga Day on 21.06.2022



3. Celebrations of Hindi Pakhwada 2022



4. Observance of Constitution Day



5. One day Hindi Karyashala



6. Training on Gender Sensitization and the Posh Act



7. Women's Day Celebrations



8. Sports events





EMPOWERING THE CITIZENS : 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) & Sh. Harit Kasana, Scientist Grade-II as Public Information Officer (Scientific Activities)

During the year (2022-23), the Institute received the following applications to obtain various types of information under the RTI Act: -

**Status of RTI Applications Received during the Financial Year 2022-23
(up to 31st March, 2023)**

Particulars	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)
Request	5	2	53	0	0	0	160
First Appeals	0	0	15	0	0	15	0



NIB AUDIT REPORT



Independent Auditor's Report

To
The Members of,
M/s National Institute of Biologicals
(Ministry of Health and Family Welfare, Government of India)
A-32, Sector-62 (Institutional Area),
Noida, U.P.-201309

Report on the Audit of the Financial Statements

Opinion

We have audited the accompanying Financial Statements of M/s National Institute of Biologicals ("the NIB"), which comprise the **Balance Sheet as of March 31, 2023 and the Income & Expenditure Account and Receipt & Payment Account for the year then ended**, and notes to the financial statements, including a summary of the significant accounting policies and other explanatory information.

In our opinion, and to the best of our information and according to the explanations given to us the aforesaid financial statements give a true and fair view of the financial position of the NIB as at March 31st, 2023 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 have conducted our audit of the Financial Statements in accordance with the Standards on Auditing (SA's) 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 the Institute of Chartered Accountants of India 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 audit opinion on the Financial Statements.

Emphasis of Matter

We draw attention to the following Notes of the financial statements:



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Tel. No.: 0120-4266194, M. 9810500901/9810355174 E-Mail: co.agmsca@gmail.com Website: www.agmsca.com

a. Note No. 2 of these financial statements 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.

b. **Note No. 7:** Reversal of GST of Rs. 2,29,11,941/- along with payment of interest of Rs. 21,89,863/- through cash / credit ledger on account of common credit during GST Audit / Reconciliation & filing of annual return for the FY 2020-21 of the NIB under CGST Act, 2017.

Further, Input credit have not been claimed from the FY 2021-22 onwards. It has resulted in increase of expenditure thereby excess utilization of grant.

c. **Note No. 8:** GST is not being deposited in the month of advance received against supply of services of testing and sale of reference standards which are contrary to subsection (2) of Section 13 of CGST Act, 2017 and which attract interest liability on delay payment of GST.

Our opinion is not modified in respect of these matters.

Other Matters

Attention is also invited to the followings:

- **Note-1:** Reconciliation of Property Plant & Equipment and its physical verification has not been prepared.
- **Note No. 10:** Regarding maintenance of separate Receipt & Payment account of the respective funds for various projects funded by other agencies.
- **Note No. 11:** Internal Audit needs to be more strengthened.
- **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 also includes maintenance of adequate accounting records for safeguarding the assets of the **NIB** and for preventing and detecting frauds and other irregularities; selection and application of appropriate accounting policies; making judgments and estimates that are reasonable and prudent; and design, implementation and maintenance of adequate internal financial controls, that were operating effectively for ensuring the accuracy and completeness of the accounting records, 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

- A. As part of an audit in accordance with SAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:
- i. Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
 - ii. Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control systems.
 - iii. Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
 - iv. Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the NIB's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Financial Statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the NIB to cease to continue as a going concern.
 - v. Evaluate the overall presentation, structure and content of the Financial Statements, including the disclosures, and whether the Financial Statements represent the underlying transactions and events in a manner that achieves fair presentation.
- B. Materiality is the magnitude of misstatements in the Financial Statements that, individually or in aggregate, makes it probable that the economic decisions of a reasonably knowledgeable user of the Financial Statements may be influenced. We consider quantitative materiality and qualitative factors in



(i) planning the scope of our audit work and in evaluating the results of our work; and (ii) to evaluate the effect of any identified misstatements in the Financial Statements.

- C. We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

For A G M S & Co.
Chartered Accountants
Firm Registration No.: 021141N


CA Sunil Kumar Gupta
Partner
M. No. 096342



UDIN: 2309634286YP047135

Place: NoIDA

Date: 03-OCT-2023

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare
DETAILS OF GRANT UTILISATION FOR THE
FINANCIAL YEAR 2022-23

PARTICULARS	Amount In ₹				TOTAL
	GIA - SALARY	GIA - GENERAL	GIA - ASSETS	GIA - SAP	
RECEIPTS					
Grant unutilized by/ from the Previous Year	-52,31,360.00	2,29,850.22	66,85,671.56	5,033.00	16,89,194.78
Grant in Aid Received From Ministry	17,50,00,000.00	38,57,70,000.00	7,98,14,000.00	4,95,000.00	64,10,79,000.00
TOTAL RECEIPTS (A)	16,97,68,640.00	38,59,99,850.22	8,64,99,671.56	5,00,033.00	64,27,68,194.78
LESS:- EXPENDITURE INCURRED & PROVISION					
Establishment Expenses	17,20,96,887.00	-	-	-	17,20,96,887.00
Administrative Expenses	-	15,71,49,932.38	-	3,84,090.00	15,75,34,022.38
Lab Services-Operation & Maintenance Exp	-	22,25,32,668.18	-	-	22,25,32,668.18
Increase in Stock of Fuel for Boilers & D.G Set	-	6,80,984.00	-	-	6,80,984.00
Grant Utilised for Security Deposits - Electricity	-	-	-	-	-
Payment made for Fixed Assets during the year:					
Additions in Fixed Assets	-	-	3,81,30,421.68	-	3,81,30,421.68
Less: Advance of Previous year Utilized against Fixed Assets	-	-	-	-	-
Less: Adjustment for amount of fixed asset excess charged in P.Y	-	-	-	-	-
Advance against Fixed Assets, Goods & Services (Net)	-	31,34,986.00	2,59,42,000.00	-	2,90,76,986.00
Less: Advance of Prev. Year Utilized/Refunded against Goods & Services	-	-	-	-	-
Add: Grant Utilised for Prepaid Expenses Increase/Decrease	-	-72,415.00	-	-	-72,415.00
TOTAL CURRENT YEAR EXPENDITURE / UTILISATION (B)	17,20,96,887.00	38,34,26,155.56	6,40,72,421.68	3,84,090.00	61,99,79,554.24
GRANT RECEIVABLE / PAYABLE TO GOI (A) - (B)	-23,28,247.00	25,73,694.66	2,24,27,249.88	1,15,943.00	2,27,88,640.54






NATIONAL INSTITUTE OF BIOLOGICALS

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