

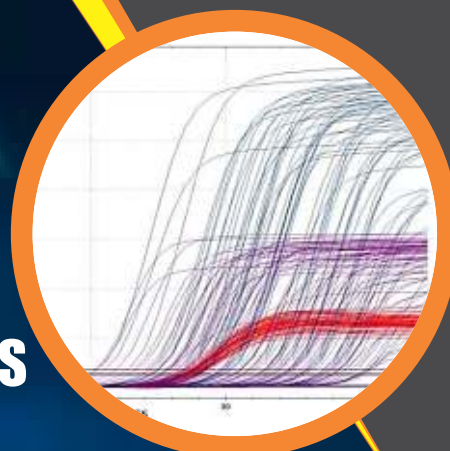


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Years

1992- 2022



# ANNUAL REPORT 2021-2022

राष्ट्रीय जैविक संस्थान  
NATIONAL INSTITUTE OF BIOLOGICALS



# Annual Report 2021-2022



**NATIONAL INSTITUTE OF BIOLOGICALS**

Ministry of Health & Family Welfare

Government of India

NOIDA



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राष्ट्रीय जैविक संस्थान, स्वास्थ्य एवं परिवार कल्याण मंत्रालय,  
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## INTRODUCTION

The National Institute of Biologicals (NIB) had been set up in 1992. NIB is an apex scientific autonomous institute under the administrative control of the 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.

NIB is positioned and functions through a translational interface between policymakers, CDSCO and facilitates safeguarding public health through weeding out "Not of Standard Quality" Biologicals reaching the end-users. The mission of the institute is to ensure the protection of human health in the country by promoting access to good quality biological products and healthcare. Not of Standard Quality Biological products are a threat to public health. Had the same been released to the market without being tested, it could have adversely affected public health. Based on the reports issued by the Institute, "Not of Standard Quality" (NSQ) biologicals are not allowed to enter the market. This way NIB plays a crucial role in promoting and protecting public health.

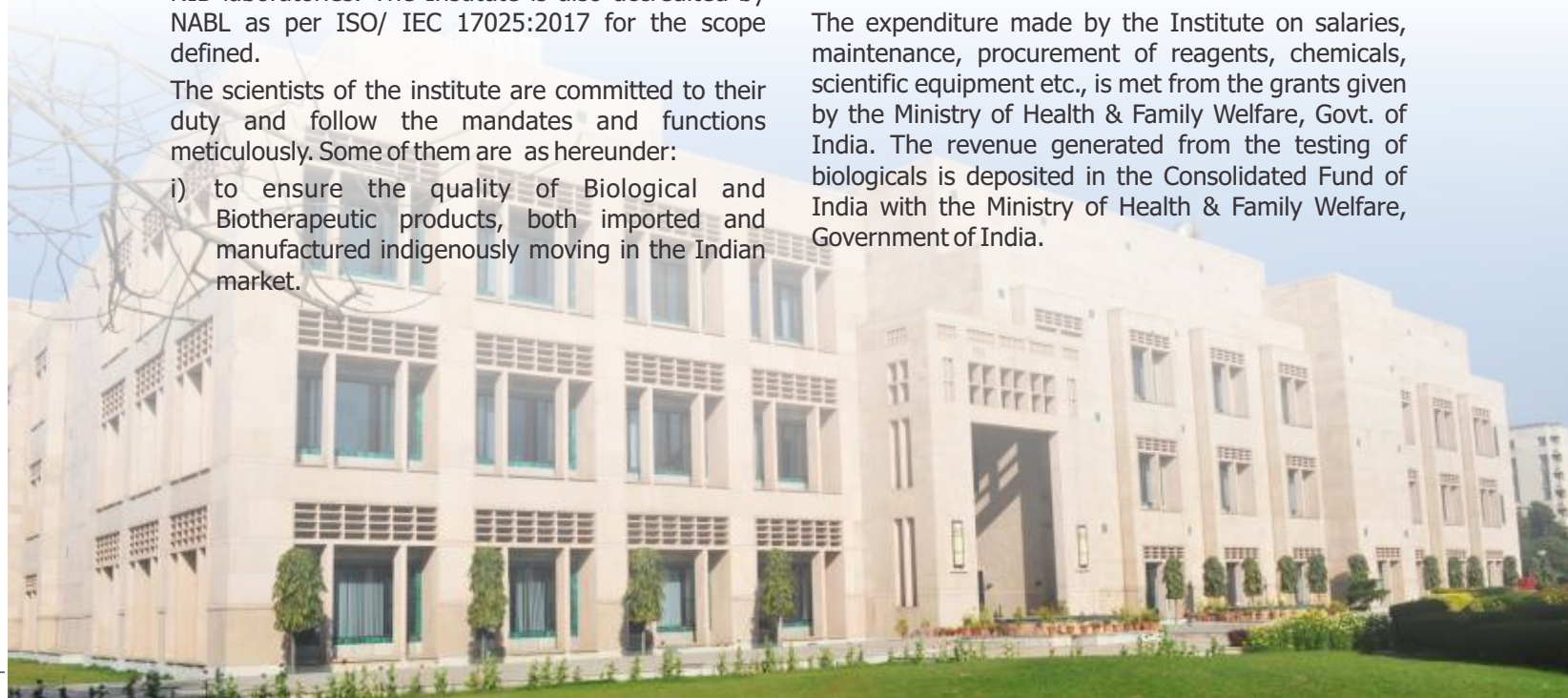
The Institute is performing the primary statutory function of Quality Control of Biologicals e.g. Insulin, erythropoietin, blood products, diagnostic kits e.g. HIV, HBV, HCV, therapeutic monoclonal antibodies like Trastuzumab and Rituximab used in cancer treatment etc. Under the provisions of the Drugs & 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 to their duty and follow the mandates and functions meticulously. Some of them are as hereunder:

- i) to ensure the quality of Biological and Biotherapeutic products, both imported and manufactured indigenously moving in the Indian market.
- ii) to contribute to 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 the 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 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 the testing of biologicals is deposited in the Consolidated Fund of India with the Ministry of Health & Family Welfare, Government of India.





## FROM THE DIRECTOR'S DESK

It gives me immense pleasure to present the Annual Report of the National Institute of Biologicals (NIB) for the year 2021-22 which illustrates the significant work carried out at the Institute.

The institute has affirmed its solidarity with the nation in fighting the COVID-19 pandemic by establishing the high throughput COVID-19 testing laboratory and tested over 2.5 lakh clinical samples from various states.

The capacity of NIB to test different types of biologicals has increased substantially during the last five years *i.e.* 289 in 2021-22 from 209 in 2017-18. The Institute evaluated 2069 batches of biological samples in 2021-22 including batches under the Drugs & Cosmetics Act and Rules thereunder, from State Medical Procurement Agencies. Out of total samples tested, 4.3% (*i.e.* 89 batches out of 2069) were found to be of Not of Standard Quality (NSQ) thus highlighting the role of the Institute in protecting and promoting public health.

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

The institute is also the nodal organization in the development and also the sole repository for National Reference Standards for Human Insulin and Insulin Lispro and HIV, HBsAg, HCV and syphilis performance panels. The collaboration with WHO Collaborating

centres like NIBSC for the development of International Reference standards for Biotherapeutics has reiterated the international stature of the institute in the field of quality control of biologicals. The institute has also contributed to the development as well as up-gradation of Indian Pharmacopoeia monographs in the field of Biologicals.

National collaboration(s) with reputed national organizations for validation studies of test methods intended for quality evaluation of biologicals and diagnostic kits and blood reagents and also as subject experts for Joint inspection (virtual) of manufacturing facilities, brings out the contribution of NIB scientists in strengthening the indigenous development of medical devices, Biotherapeutics and prophylactic medicines. The nomination of NIB scientists as faculties for international conferences, meetings and workshops has reinforced the global presence of the institute and its role in strengthening the regulations, testing and manufacturing of biologicals.

NIB has been contributing to the safety of blood transfusion as the National Coordinating Centre for Haemovigilance Programme of India (HvPI). This year 04 virtual Continuing Medical Education (CMEs)/ National level conference were conducted for creating awareness of the importance of reporting adverse reactions associated with blood transfusion & blood donation. A total number of 4283 participants which includes blood centre officials, clinicians, nurses, blood donor motivators and blood centre technical staff were trained in these CMEs/ Conference organized by the HvPI Division of NIB. HvPI is a member of the International Haemovigilance Network (IHN). Further, the Head of HvPI- NIB, has been designated as Secretary of the IHN Board.

To strengthen the blood services in the country, NIB in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health and Family Welfare, Govt. of



India also organised Six Days Residential Training Program on "Training of Trainers for Strengthening of Blood Services" for Blood Bank Officials from various parts of the country. In addition, NIB has also imparted training to postgraduate students on Quality Control testing of biologicals.

In order to strengthen capacity building, NIB started structured training programmes in the field of Quality Control of biologicals. As a step toward enhancing the academic activities of the institute, a Memorandum of Understanding (MoU) was signed between NIB and the Academy of Scientific and Innovative Research (AcSIR) to collaborate and recognize NIB as its Associate Academic Center for its PhD program.

Further, NIB has generated gross revenue of Rs. 17.41 crores during the financial year 2021-22 from various sources *i.e.* testing fees for evaluation and Quality Control of various biological samples, training fees received from various training programmes, user charges for hostel and guest house and interest on the

saving bank account etc. This is deposited in the Consolidated Fund of India with the Ministry of Health & Family Welfare, Government of India.

NIB continues to strive to fulfil its mandates to become a trendsetter in the field of Quality Control of biologicals in the country and meet the international benchmark. To meet tomorrow's challenges and demands in the interest of public health we are ready to include more and more biologicals under NIB's umbrella. More biological standards also will be made available to researchers and manufacturers to support 'Make in India'.

I am grateful to the 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) for their continuous support & guidance and for facilitating NIB in fulfilling its endeavours. NIB is making concerted efforts to ensure quality service in the Healthcare Sector of the country in the area of biologicals.



**NATIONAL INSTITUTE OF BIOLOGICALS**

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

## GOVERNMENT GAZETTE NOTIFICATION(S)

### CENTRAL DRUGS LABORATORY:

- A. 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.
- B. The Central Government, vide The Gazette of India Notification No. S.O. 4206(E) dated 24th November 2020 and S.O. 5139(E) dated 10th December 2021 notified the National Institute of Biologicals, Noida, to perform the function of the 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 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. J.P. Prasad,
2. Dr. Charu M. Kamal,
3. Ms. Ajanta Sircar,
4. Dr. Rajesh Kumar Sharma,
5. Dr. Meena Kumari,
6. Sh. Harit Kasana
7. Ms. Kanchan Ahuja,
8. Ms. Gurminder Bindra,
9. Ms. Madhu Erramilli,

10. Sh. Subhash Chand,

11. Sh. Jaipal Meena

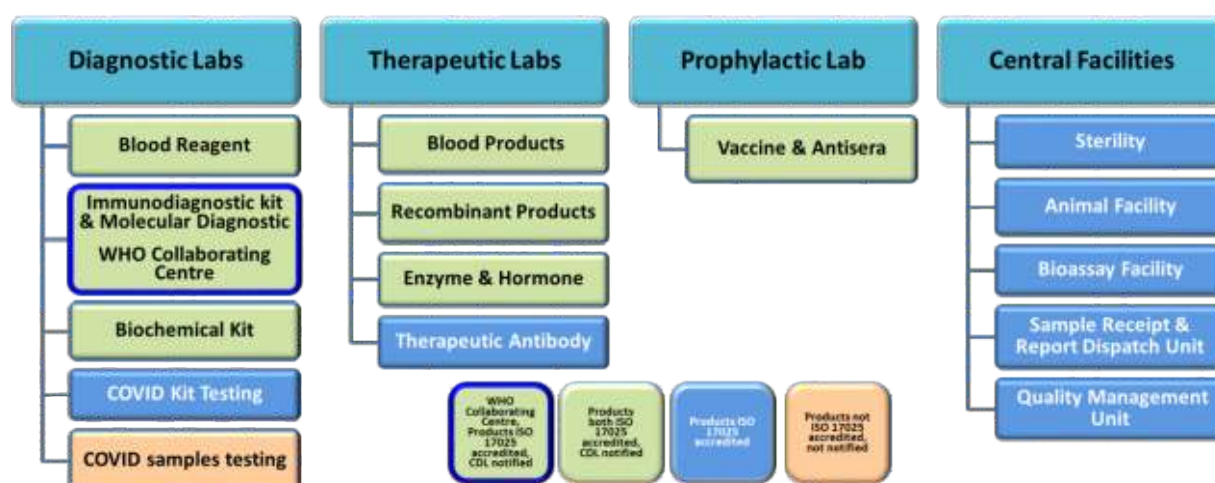
**MEDICAL DEVICE TESTING OFFICER(S):** NIB scientists are notified Medical Device Testing Officer(s) vide Gazette Notification S.O. 3400(E) dated 11th July 2018 for Human Immunodeficiency Virus (HIV), Hepatitis B surface Antigen (HBsAg), Hepatitis C Virus (HCV), Blood grouping reagents, Glucose test strips and fully automated analyser-based glucose reagents. Following NIB scientists are notified Medical Device Testing Officers:

1. Dr. J.P. Prasad,
2. Ms. Ajanta Sircar,
3. Ms. Kanchan Ahuja,

## NIB LABORATORIES AND CENTRAL UNITS

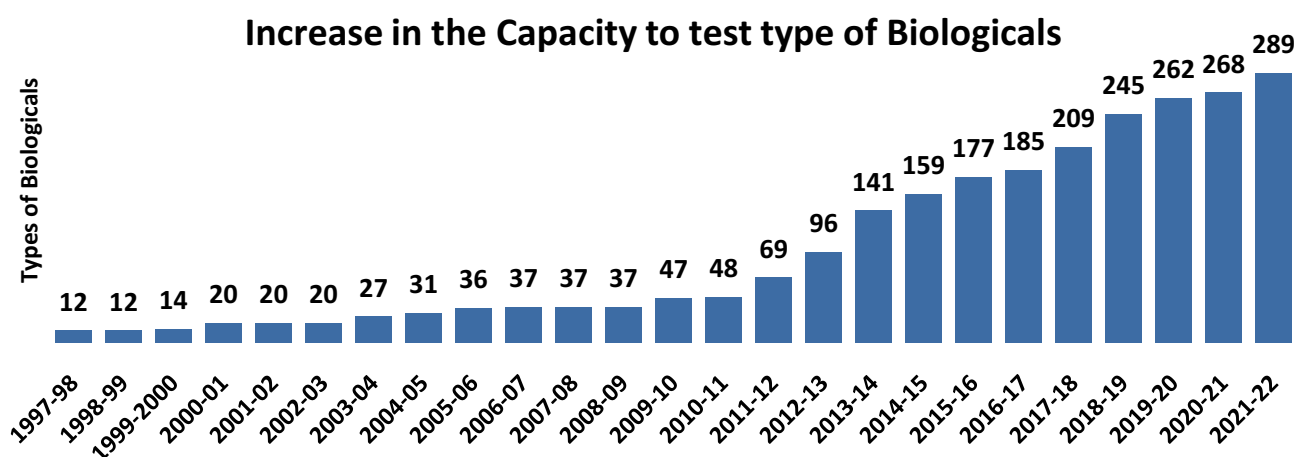
Since Biological products are derived from sources such as living cells or purified components of human blood which are very complex in nature, their production cannot be controlled the way it can be controlled for chemical-based drugs. As a result, biological products are subjected to extensive testing of the final product which is critical to ensure the quality of the biological product that is manufactured. The testing is aimed at keeping public health at the

forefront of all decisions related to the quality of biological products to ensure that each dose administered is safe and effective before CDSCO releases it onto the market for human use. Each biological product forwarded to NIB undergoes rigorous testing as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms at the state-of-the art laboratories of NIB.



### Quality Control Evaluation of Biologicals

The total no. of types of biologicals tested at NIB has increased substantially.





CATEGORY	BIOLOGICAL PRODUCTS	NO. OF TYPES
Diagnostics	1. Blood Grouping Reagents	95
	2. Immunodiagnostic & Molecular Diagnostic Kits	69
	3. COVID-19 Kits	10
	4. Biochemical Kits	03
Therapeutics	5. Blood Products	24
	6. Recombinant Products	34
	7. Therapeutic Antibody	20
	8. Enzymes & Hormones	21
Prophylactics	9. Vaccines	13
	<b>Total Biologicals</b>	<b>289</b>

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

The **Blood Reagent Laboratory (BRL)** performs the quality control evaluation of Blood Grouping Reagents. The laboratory tests various types of Blood Grouping Reagents- including routine and rare reagents, Gel cards and blood grouping cards for safe blood transfusion. The laboratory also collects non-infective and non-clotted left-over blood samples from various blood banks/ hospitals as per the approval of DCG (I) and the Institutional Human Ethics Committee (IHEC) 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 that are collected on a regular basis for QC testing. The laboratory has taken up Quality Control testing of the new biologicals viz. Rh Phenotype Card with Anti-D, Gel card for ABO/Rh for Patients, Anti-Lu<sup>a</sup> Reagent and Anti-Lu<sup>b</sup> Reagent.

The **Biochemical Kit Laboratory (BKL)** is engaged in the quality control evaluation of Blood Glucose Test Strips, Glucometers and Fully Automated Analyzer based Glucose Reagents. QC protocols are based on

International guidelines such as ISO15197: 2013, CLSI EP9-A2, CLSI EP6-A and CLSI EP5-A2 for evaluating the performance-related parameters such as; Precision, System Accuracy, Bias, Linearity and Analytical Measurement Range of the different Product Batch samples.

This year Biochemical Kit Laboratory infrastructure has been expanded by the procurement of a TOSOH HLC-723G8 HbA1c Analyzer for taking up 'Rapid HbA1c Test Kits' as a 'Product' for QC Testing.

**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 for Human Immunodeficiency Virus (HIV), Hepatitis-B virus and Hepatitis-C virus.

**COVID-19 Kit Testing Laboratory (CKTL)** carries out QC evaluation of SARS CoV-2 diagnostic kits to promote and safeguard public health. The laboratory is responsible for QC evaluation of RNA extraction kits and VTMs/ 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 **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. Staff of Vaccine laboratory received training of testing of COVID-19 vaccine at CDL Kasauli. The Laboratory has completed the Quality Control evaluation of COVID-19 vaccine COVAXIN, COVISHIELD and ZyCoV-D received from M/s Bharat Biotech- Hyderabad, M/s Serum Institute of India- Pune and M/s Zydus Cadilla, Ahmedabad respectively. The testing has been



standardized as per manufacturer specifications. The lab has received 3 batches of COVAXIN and COVISHIELD for the parallel testing and the results have been communicated to CDSCO and CDL Kasauli. The lab has also standardized Rabies Immunoglobulin (Equine) received from M/s Popular Pharmaceuticals LTD, Bangladesh.

The **Blood Product laboratory (BPL)** was set up with the aim of assuring the quality plasma-derived products marketed in India viz Human albumin, Immunoglobulins, Coagulation factors, Fibrin sealant kits etc. Since these biological therapeutics are inherently complex and variable, vigilant monitoring is required to ensure the quality as well as safety of such products.

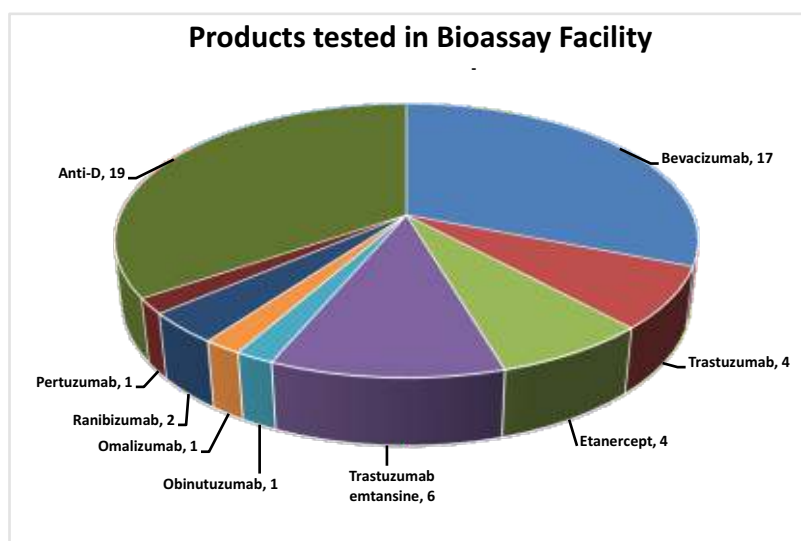
The **Recombinant Product Laboratory (RPL)** contributes to the Regulatory functions of recombinant biotherapeutic products under the class of Insulin, Insulin Analogs, Growth Factors, Cytokines and Peptides which are intended for therapeutic indications for the treatment of diabetes (Type 1 and Type 2), viral hepatitis, chronic kidney disease, cancer, osteoporosis and multiple sclerosis. The emerging biosimilars in market makes it imperative to carry out QC testing of these biologicals to ensure availability of safe, efficacious and potent biomolecules to safeguard public health.

The **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. The laboratory is also a support facility for Bacterial Endotoxin test (BET) for Blood

products & Vaccines. In the year 2021-22, the laboratory has also developed capability for Quality control testing of Human C1-esterase Inhibitor as per the manufacturer's specifications/ European Pharmacopoeia 10.0

The **Therapeutic Antibody Laboratory (TAL)** carries out Quality control testing of therapeutic monoclonal antibodies viz. Rituximab, Trastuzumab, Adalimumab and Bevacizumab, Anti-D immunoglobulin (monoclonal) etc. The laboratory has also established the testing capability of Ranibizumab, Obinutuzumab, Omalizumab, Vedolizumab, Inotuzumab, Trastuzumab emtansine, Infliximab and Etanercept.

The **Central Bioassay Facility** with four biosafety modules was set up to cater the cell-based bioassays as a part of quality control evaluation for various recombinant products like peg-Erythropoietin, Filgrastim, Interferon, Parathyroid hormone, Therapeutic Antibodies, anti-D Immunoglobulin etc. and other therapeutic proteins referred by various product testing laboratories at NIB. It is equipped with workstations Class II type B2 Biosafety cabinets, Centrifuges, CO<sub>2</sub> incubators, Refrigerators/ Freezers, Microscopes, Cell counters, Cryopreservation equipment and Multi-mode plate reader for detection mode of absorbance, luminescence, fluorescence, and time-resolved fluorescence (TRF) for cell-based immunogenicity assays and bioassays including Anti-Proliferation assays, Complement dependent cytotoxicity (CDC), anti-PD1 reporter gene assay, Antibody-dependent cell-mediated cytotoxicity (ADCC), Apoptosis assays, Reporter gene assays, Neutralization assays.

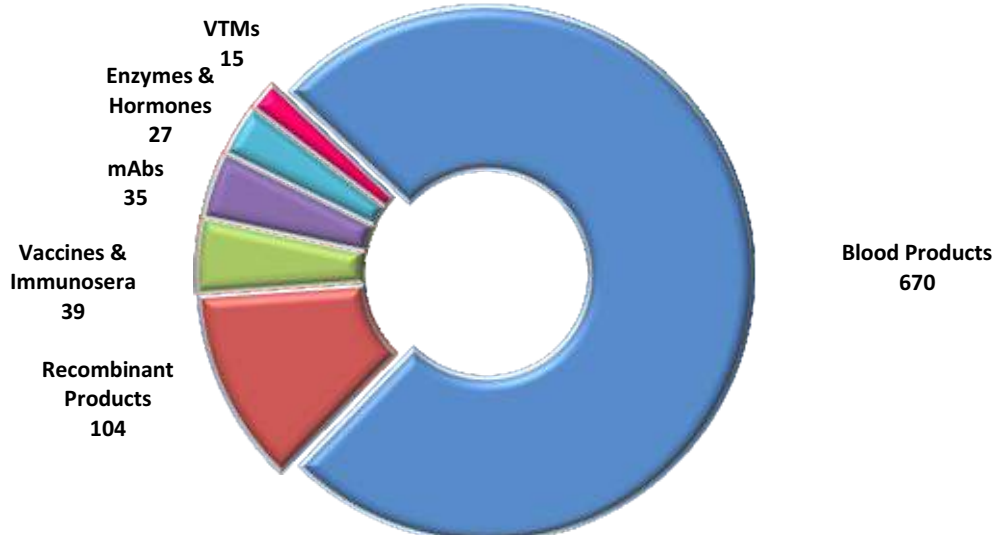




The **Sterility Testing Laboratory** is a Central Facility well equipped with required equipment viz laminar air flow cabinet in cleanroom, dedicated walk-in incubators at temperatures specified by the pharmacopoeial method for each test media, autoclaves etc. to test the various Biological products 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

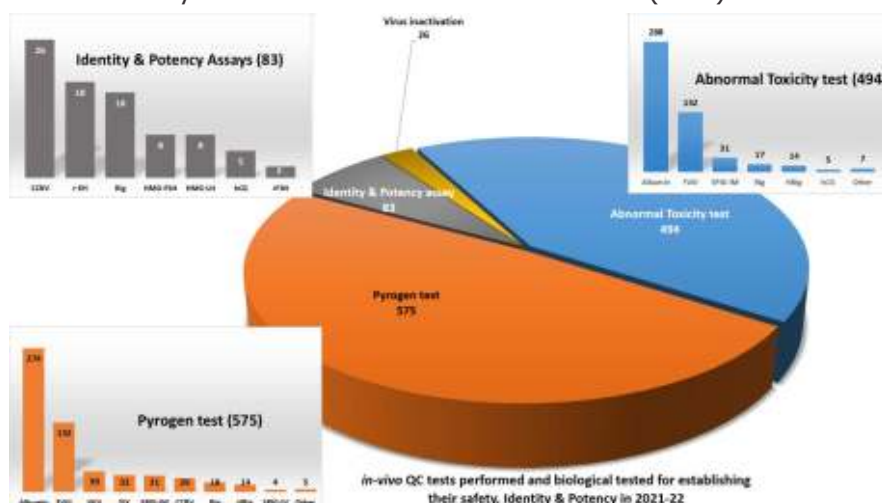
has environmental microbiology lab for isolation & biochemical characterization of clean room environmental isolates and handling & maintenance of reference strains of bacterial & fungal strains. The samples of various biological products currently referred for sterility testing are Recombinant Products, Blood Products, Enzyme and Hormones, Vaccines/Immunosera, Therapeutic Antibodies and VTMs.

### Products tested in Sterility Laboratory

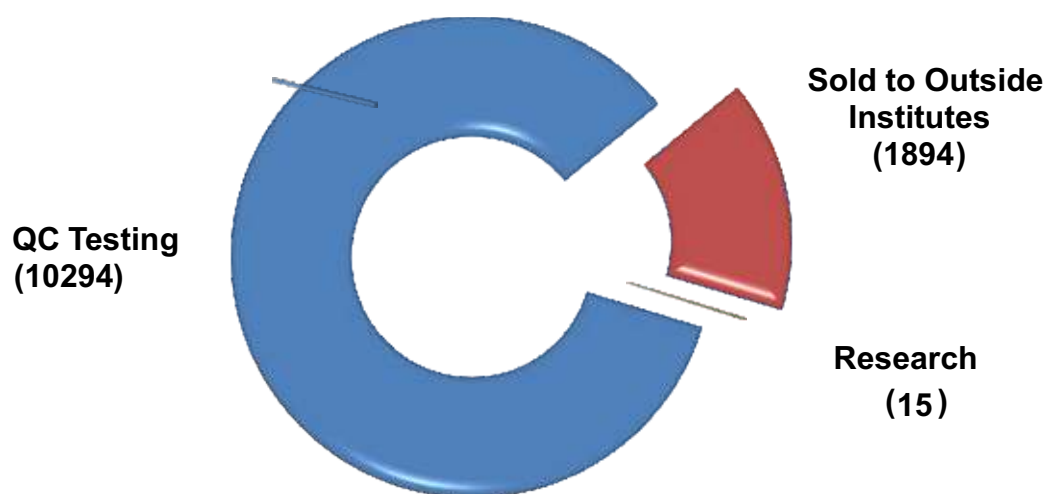


**Animal Facility** is a central support unit of the institute where the *in-vivo* quality control tests are performed to establish the safety, identity & potency of biologicals as per Indian or other Pharmacopoeias. The facility also ensures timely availability of the required laboratory animals viz Mice (Swiss Mice, Balb/c); Rats (Sprague Dawley Rats, Wistar Rats); Guinea pigs (Duncan Hartley) and Rabbits (New Zealand White) for various *in-vivo* tests by maintaining a planned breeding program. The staff of the facility ensures high-quality animal husbandry and care that meets the

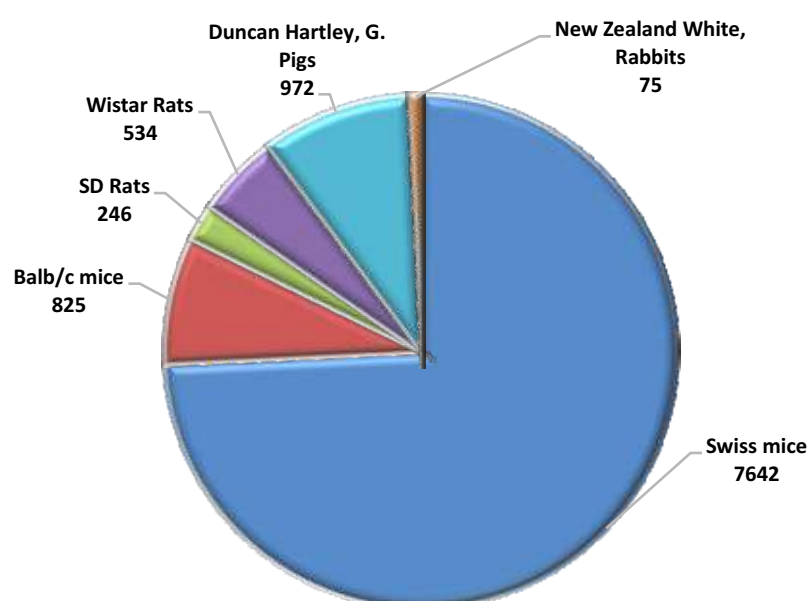
requirements of animal welfare regulations and guidelines provided by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). The facility also provides good quality laboratory animals to educational and research institutes and industries in Delhi-NCR and neighbouring states and generates additional revenue for the Institute. All the test protocols that require the use of animals in QC testing, as well as research, are approved by the Institutional Animal Ethics Committee (IAEC).



### No. of lab animals used in QC testing, research & sold to other



### No. of Lab Animals of various species used in QC testing



**Commitment of NIB for implementation of 3R's:** As a commitment towards the 3R's, the scientists of the Animal Facility and laboratories worked in close coordination to reduce the

number of animals used in the quality control testing and details of animals saved in the year 2021-22 are provided below :

S. No.	Details of QC Test	Number of Animals Saved
1.	NIH Potency assay for Rabies Vaccine	1104 Mice
2.	Potency assay for Recombinant Erythropoietin	75 Mice
3.	hCG	16 Rats
	<b>Total</b>	<b>1195 (Mice &amp; Rats)</b>

**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 Authority (CDSCO) as well as several State governments' Medical Procurement



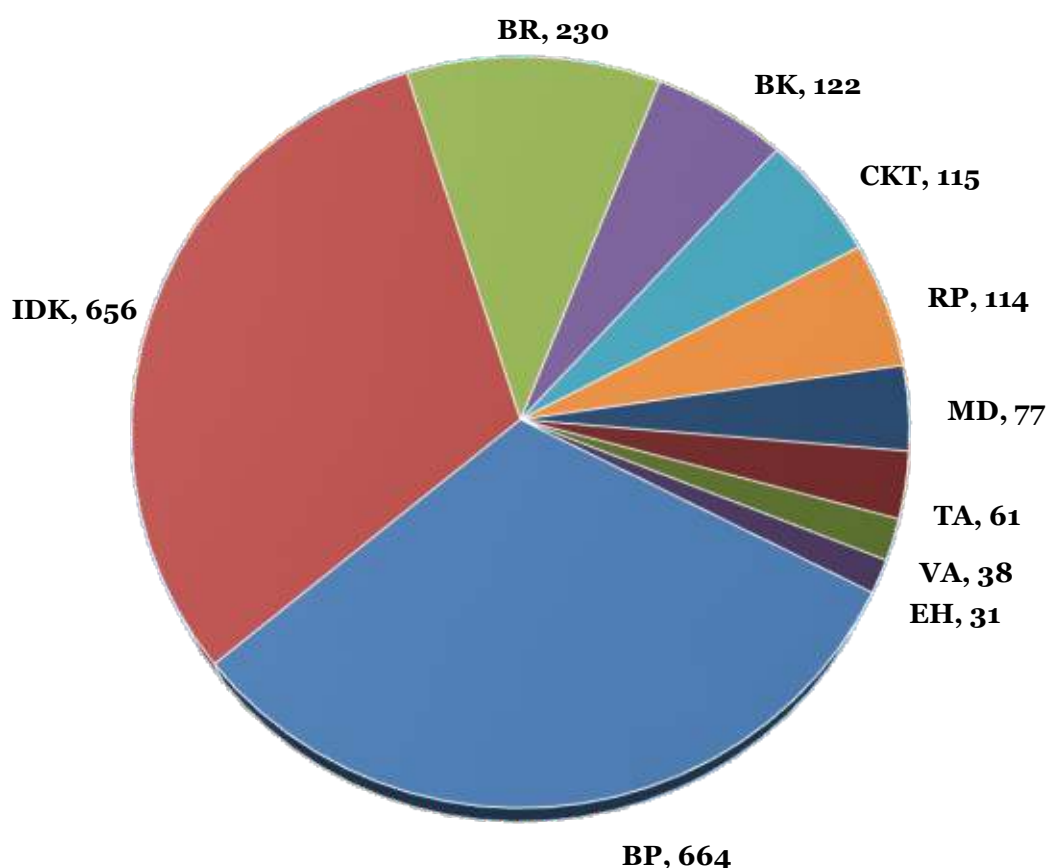
Agencies. International samples of Vaccines from Bangladesh have also been received for quality evaluation. The requisite quantity of all samples received for testing is retained at recommended temperature up to 3 months post expiry. Retained samples are stored frozen/refrigerated/room temperature as 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 LIMS (Laboratory Information Management System) has been developed and successfully implemented for entering

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 LIMS based SRRD portal for Certificate of Analysis (CoA) generation. 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).

In FY 2021-22, a total number of 2108 samples have been received under various product categories (including Govt. samples, Survey samples, Service samples, samples for Standardization, Under the Act) for testing purposes. Out of the total, 222 samples were received from different State Medical Procurement Agencies.

## Distribution of total 2108 samples received



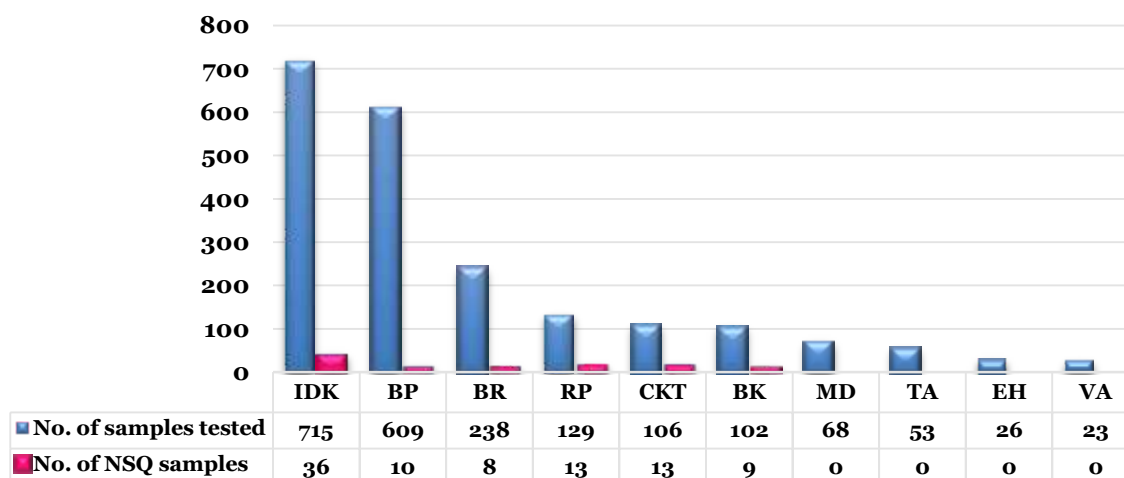
Total number of samples received at NIB during FY 2021-22 and their distribution in various categories/ laboratories  
BP: Blood products; IDK: Immunodiagnostic kits; BR: Blood grouping reagents; BK: Biochemical kits; CKT: COVID-19 Kits;  
RP: Recombinant Products; MD: Molecular Diagnostic Kits; TA: Therapeutic antibodies; VA: Vaccine & Antisera; EH: Enzymes & Hormones

## Evaluation of Samples and Release of Test Reports

A total of 2069 test reports were released in the financial year 2021-22. Out of total reports released, 89 samples i.e. 4.30% were found to be "Not of

Standard Quality" (NSQ) in 2021-22 which is higher than that reported in the previous year 2020-21 (3.52%). Reporting 'Not of Standard Quality' samples after testing thus highlights the role of the Institute in protecting and promoting public health.

Distribution of 2069 Samples tested and 89 Not of Standard Quality (NSQ) reported



BP: Blood products; IDK: Immunodiagnostic kits; BR: Blood grouping reagents; BK: Biochemical kits; CKT: COVID-19 Kits; RP: Recombinant Products; MD: Molecular Diagnostic Kits; TA: Therapeutic antibodies; VA: Vaccine & Antisera; EH: Enzymes & Hormones

**Quality Management Unit (QMU)** 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 343 to 390. 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.

The unit prepares an Annual Training calendar keeping in view the requirements of the staff for due up gradation in the field of relevant applicable standards like ISO 17025:2017 or OHSAS 18001 as well as scientific knowledge. Training(s) are organised in coordination with the IT Unit, for proper execution. Scientific and technical persons working in the areas of product testing laboratories, Engineering unit, Stores & Purchase and Quality Management Unit, have been trained in the areas, as enlisted below in Table

S. No.	Title	Attended by	Organizer/ Trainer
1.	Method Development & Validation of Procedure for Biologics (Live Webinar)	18 Participants from different Labs	NIB & USP Hyderabad / Dr. Krishna Menon, Senior Scientific & Standards Liaison, Dr. Anu Uppal, Senior Scientific Affairs Manager
2.	Refresher Training on Laboratory Quality Management System (LQMS) as per ISO/IEC 17025:2017 requirements	All Lab Staff	QMU & IT/ Ms. Rashmi Shrivastava, Scientist Grade-III





<b>S. No.</b>	<b>Title</b>	<b>Attended by</b>	<b>Organizer/ Trainer</b>
<b>3.</b>	Biosafety practices (Chemical handling, storage and spillage management)	All Lab Staff	QMU & IT/ Dr. Suresh Kumar, Scientist Grade-III
<b>4.</b>	Training & Mock Drill for Evacuation Plan in Emergency condition	All NIB Staff	QMU & Engg./ M/s Zeenat Techno services- Mr. RK Chaurasia- Fire Officer
<b>5.</b>	COVID - 19 testing and Biomedical waste Management related activities	All Lab Staff	QMU & IT/ Dr. Suresh Kumar, Scientist Grade-III
<b>6.</b>	Establishing a Reference Standard	All Lab Staff	QMU & IT/ Dr. Charu Mehra Kamal, Scientist Grade-II
<b>7.</b>	Method Validation	All Lab Staff	QMU & IT/ Ms. Y. Madhu, Scientist Grade-III
<b>8.</b>	Training on Laboratory Quality Management System and Internal Audit as per IS/ISO/IEC 17025:2017	23 Participants from different Labs.	NIB & NITS, BIS / Mr. Dileep Kumar Arora & Mr. Dipak Kumar Mukhopadhyay (Ex-BIS)
<b>9.</b>	Measurement Uncertainty	All Lab Staff	QMU & IT /Mr. Subhash Chand, Scientist Grade-III
<b>10.</b>	SOP preparation (SOP Review & Amendments) and Document Control	All Lab Staff	QMU & IT/ Ms. Rashmi Shrivastava, Scientist Grade-III
<b>11.</b>	External Quality Assurance Assessment Scheme (EQAAS)	All Lab Staff	QMU & IT /Mr. N. Nanda Gopal, Scientist Grade-III

## NIB'S RESPONSE TO COVID-19 PANDEMIC

The COVID-19 pandemic marked the year 2020. During this difficult time, NIB, besides operating on the front line of public health protection, continued with all its activities to fulfil its mandates following necessary COVID appropriate behaviour and guidelines issued from time to time by the Ministry of Health & Family Welfare. With a vital role to play, NIB once again proved its relevance for the country's health systems.

NIB played its role at the forefront in the nation's response to COVID-19. NIB established India's First High throughput COVID-19 sample testing facility in emergency time.

Ever since its inception in April 2020, the COVID- 19 sample testing at NIB has tested more than 2.5 lakh of COVID-19 suspected clinical samples till then. NIB's dedicated team worked 24x7 in the difficult times of COVID-19.

NIB has also been carrying out the quality evaluation of COVID-19 RT- PCR kits, RT-LAMP kits, RNA extraction kits and VTMs. In addition to this, NIB has established a facility for undertaking the Quality Control testing of COVID Vaccines- Covaxin, Covishield & ZyCoV-D





## COLLABORATION

1. Networking with blood banks/ hospitals of Delhi/ NCR for collection of plasma bags: The 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 that are reactive for HIV, HCV, HBsAg & Syphilis and which are non-reactive.
2. 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 the Institutional Human Ethics Committee and letter of authorization from DCG (I) to various blood banks/ hospitals to provide non-infective and non-clotted leftover blood samples for carrying out quality control of Blood Grouping reagents.
3. The Biochemical Kit Laboratory has collaborated with Department of Endocrinology, AIIMS, New Delhi from 29.03.2019 to July 2021 for Validation studies for Ion Exchange Chromatography Principle-based 'Laboratory Reference Method for estimation of HbA1c' and 'International Guideline' based protocols for various quality control tests/ parameters for evaluating rapid HbA1c assay kits. The laboratory has successfully completed its commitments in the said collaborative project by computing the statistical analysis of the data together with related graphical projections. The outcome of the study is about to be published as a scientific journal article.
4. Blood Products Laboratory has extended its technical expertise to an Indigenous Manufacturer, on request, in establishing the test for vWF as per I.P. Monograph in a new product *i.e.* Dried Antihaemophilic factor VIII –vWF, intended for use in treating vWF deficient patients. This is in line with the support & strengthening of Indian industries for plasma-derived products. As of date, there is no Indigenous manufacturer for the said product.
5. Therapeutic Antibody Laboratory (TAL) participated in World Health Organization (WHO)-National Institute for Biological Standards and Control (NIBSC) International Collaborative Study for preparation of the following.
  - a. 1st WHO International Standard for the biological activities of Cetuximab - study completed and data of candidate material evaluation sent to NIBSC for further analysis.
  - b. 2nd WHO International Standard for human Interleukin-6 (IL-6) - study completed and data of candidate material evaluation sent to NIBSC for further analysis.
  - c. 1st WHO International Standard for VEGF165 - study completed and data of candidate material evaluation sent to NIBSC for further analysis.
6. Vaccine & Antisera Laboratory 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 the department of Biological standardization, OMCL Network & Healthcare, EDQM, Council of Europe. Final testing has been completed and data of the same has been submitted to EDQM
7. Blood Products Laboratory submitted results for WHO International collaborative study (CS 666) for developing the 3rd WHO International Standard for Rabies Immunoglobulin organized by NIBSC, UK.





8. Animal Facility has collaboration with Indian Institute of Technology (IIT), Delhi for projects titled
  - a. "Corneal delivery of antifungal-peptide conjugate encapsulated nanoparticle formulation in an experimental animal model of *Fusarium solani*"
  - b. "Nanoformulation-Cell penetrating peptide mediated delivery of Riboflavin to ocular cells"
9. Animal Facility has collaboration with Jaypee Institute of Information Technology (JIIT), Noida for project titled "Identification and Characterization of miRNAs relevant to cardiac diseases"
10. Animal Facility has collaboration with Director, ICMR-National Institute of Pathology for project titled "In vitro and in vivo anticancer efficacy of combination therapy with alpha linolenic acid, lignans and BCG against urinary bladder cancer"
11. Animal Facility has collaboration with SGT University, Gurgaon for project titled "Evaluation of the effect of IRAK 1/4 dual kinase inhibitor and one herbal compound in imiquimod induced Psoriasis model in mice"
12. NIB has collaboration with Indian Pharmacopoeia Commission- Ghaziabad for contribution to the development of new pharmacopoeia monographs and revision of existing pharmacopoeia monographs in the area of biologicals.

## PARTICIPATION IN PT / ILC / EQAAS-NATIONAL / INTERNATIONAL

- A. Enrolled and successfully participated quarterly in EQAS- 2021-22 for HIV, HBV, HCV and Syphilis Serology 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. NIB results were concordant with reference results.
- B. Successfully participated in all three rounds of External Quality Assurance Scheme-2021 for Nucleic Acid Testing of HBV DNA Viral Load, HCV RNA Viral Load, HIV-1 RNA Viral Load and Multimarker Blood Screening NAT with NRL, Australia.
- C. NIB as a National Reference Laboratory of NACO has regularly participated in EQAS program organized by Apex Lab (National AIDS Research Institute), Pune and scored 100% matching results.
- D. Participated in external proficiency program for Anti-A, Anti-B and Anti-D (IgM) blood grouping reagents conducted by Indian Red Cross Society, Delhi on 05th August 2021. The performance of the staff was found to be 100% satisfactory.
- E. Enrolled in the Association of Clinical Biochemists of India (ACBI)/ Christian Medical College (CMC) in External Quality Assessment Scheme (EQAS) – 2021 & 2022 for Chemistry II (Glucose, Cholesterol and Triglyceride), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore.
- F. Participated in proficiency testing of SARS-CoV-2 panel with ICMR-NIV, Pune on 27/08/2021 and results found 100% concordant.
- G. Results submitted for PTS 224 on the determination of total protein in Immunoglobulins, an international PT Study organized by the European Directorate for Quality of Medicines (EDQM), France.
- H. Participated in proficiency testing PTS 223: Human anti-D immunoglobulin assay (Flow Cytometry) with Z score < 2 organized by the European Directorate for Quality of Medicines (EDQM), France





## EXPERT COMMITTEE MEETINGS

1. Dr. Meena Kumari, Scientist Grade-II & Head Blood Products Laboratory has attended Meeting of the Expert Working Group- Blood and Blood Related Products' organized by IPC Ghaziabad on 20th May 2021.
2. Dr Harish Chander- Scientist Grade-I, Dr Charu M Kamal, Scientist Grade-II & Head, Dr Ratnesh K Sharma- Scientist Grade-II & Head, Ms. Sudha V. Gopinath Scientist Grade-III, Ms Gurminder Bindra, Scientist Grade-III and Mr. Subhash Chand- Scientist Grade-III participated in the Meeting of the Expert Working Group – Biotechnology-Derived Therapeutic Products through Video conferencing on 30.06.2021 to discuss the "Proposed amendments in IP 2018" with IPC and subject experts.
3. Dr. J. P Prasad- Deputy Director Quality Control, Ms. Kanchan Ahuja, Scientist Grade-III- Blood Reagent Laboratory and Dr Charu M Kamal, Scientist Grade-II & Head, Ms. Sudha V. Gopinath Scientist Grade-III and Mr. N. Nandagopal, Scientist Grade-III of Enzyme & Hormones Laboratory, as experts attended the meeting of the Expert Working Group- Blood and Blood-Related Products through video conferencing on 8th October 2021 organized by Indian Pharmacopoeia, Ghaziabad to discuss on proposed amendments in the IP 2018.
4. Dr Harish Chander- Scientist Grade-I, Mr. Harit Kasana- Scientist Grade-II & Head and Mr. Jaipal Meena Scientist Grade-III of Vaccine and Antisera Lab attended the Meeting of Expert Working Group – Vaccine & Immunoserum for Human Use through video conferencing on 14th March 2022 organized by Indian Pharmacopoeia Commission (IPC), Ghaziabad.
5. Dr. Ratnesh K. Sharma, Scientist Grade-II & Head
  - a. attended the Assessment Committee Meeting as External Expert for Assessment Promotion Scheme for Technical Staff (APS) held on 23.03.2022 at NICPR, Noida
  - b. participated as External Expert for Probation Clearance Committee Meeting held on 22.11.2021 at NICPR, Noida.
  - c. participated as an External Expert in the Virtual NABL Accreditation Committee Meeting held on 24.11.2021 and 20.12.2021 at Gurugram, Haryana.
  - d. with other TAL scientists participated in the
    - i. 1st meeting of the advisory committee regarding setting up the BSL-3 facility, identification of proposed building and proposed area at NIB held on 14.09.2021.
    - ii. 2nd meeting of the advisory committee regarding the finalization of EOI and layout presentation by selected vendors for setting up the BSL-3 facility at NIB was held on 08.02.2022.
6. Mr. Subhash Chand, Scientist-III, participated in a virtual meeting on 'Malaria Monoclonal Antibodies for Malaria Prevention: Preferred Product Characteristics and Clinical Development' held on 03.11.2021 and 11.11.2021.
7. Dr Harish Chander- Scientist Grade-I, Dr Ratnesh K Sharma- Scientist Grade-II, and Mr. Subhash Chand- Scientist Grade-III attended the Meeting on Discussion of Draft Monographs - Rituximab Drug substance (DS) and Drug product (DP) through video conferencing on 27th August 2021 at Indian Pharmacopoeia Commission, Ghaziabad.
8. The 08th Meeting of Technical Expert Committee was held on 02nd June 2021 via video conferencing for strengthening of Quality Control



Testing of Immunodiagnostic Kit Laboratory under the Chairmanship of Prof S. P. Thyagarajan, Chairman for Viral Diagnosis and Research Labs ERTL Programme of DHR, ICMR, Prof of Emeritus & Dean Research, Sh. Ramachandra University of Chennai, Tamilnadu and former Vice Chancellor of University of Madras.

9. Dr Charu M Kamal, Scientist Grade-II & internal expert and Ms Gurminder Bindra, Scientist Grade-III & internal expert attended the 1st Institutional Biosafety Committee (IBSC) along with DBT Nominee on 22.03.2022 to discuss the IBSC Guidelines applicable for NIB and IBSC applications if any (R&D projects -both Intramural and Extramural), action plan for the next year 2022-23 on IBSC related activities of the institute.
10. Ms. Ajanta Sircar, Scientist Grade-II & Lab Head with other scientists from Biochemical Kit Lab had attended the meeting of
  - a. the expert group committee members to finalize the technical specifications of the Type II Water Purification System under the Chairmanship of Dr. R. S. Sharma on 14.06.2021 at NIB, Noida.
  - b. the expert group committee members to finalize the technical specifications of fully automated clinical chemistry analyzer through video conferencing under the Chairmanship of Dr. R. S. Sharma on 15.07.2021 at NIB, Noida.
  - c. the 'Equipment Specifications Expert Group Committee meeting' for finalizing the Technical Specifications of 'Fully Automated Clinical Chemistry Analyzer' under the Chairmanship of Dr. R. S. Sharma on 23.12.2021 at NIB, Noida.
11. Dr Shikha Yadav, Scientist Grade II (Vet) & Head, Animal Facility
  - a. nominated by CPCSEA, Minister of Fisheries, Animal Husbandry and Dairying as CPCSEA Main Nominee in the Institutional Animal Ethics Committee of Galgotias University, Greater Noida, Uttar Pradesh. She attended their IAEC meeting for review of the scientific

protocols of the institute for ethical approval on 16th April 2021.

- b. nominated as a member of the Institutional Animal Ethics Committee (IAEC) of Sardar Vallabhbhai Patel University of Agriculture and Technology (SVPUAT), Meerut and she attended their meeting on 29.6.21 to review and approve their research protocols for ethical approval.
  - c. nominated as a member of the Institutional Animal Ethics Committee (IAEC) of the National Brain Research Centre (Under DBT, Ministry of Science & Technology), Manesar, Haryana and she attended their 32nd meeting on 7th July 2021 to review and approve their research proposals for ethical approval and perform the annual inspection of their Animal Facility.
  - d. nominated as the main CPCSEA Nominee in the Institutional Animal Ethics Committee (IAEC) of IIMT College of Pharmacy, Greater Noida by CPCSEA, Ministry of Fisheries, Animal Husbandry and Dairying and she attended their meeting on 11.8.21 for review of research protocols.
  - e. invited as an Expert Member in the Departmental Promotion Committee (DPC) meeting under Dynamic Assured Career Progression Scheme for Medical Officers /Doctors/Veterinary Officer of North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Ministry of Health & Family Welfare, Shillong, Meghalaya on 23.2.22 via online mode under the Chairpersonship of Director General (ICMR).
  - f. nominated as a member of Institutional Animal Ethics Committee (IAEC) of Biomed (P) Ltd, Ghaziabad by CPCSEA, Ministry of Fisheries, Animal Husbandry & Dairying and she attended their meeting on 31.3.22 for review of their research protocols for ethical approval.
12. Dr Suresh Kumar, Scientist Grade III (Vet), Animal Facility

- a. attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA Main nominee on 10th April 2021 at All India Institute of Medical Science (AIIMS), New Delhi, India.
  - b. attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA Main nominee on 26th June 2021 at All India Institute of Medical Science (AIIMS), New Delhi, India.
  - c. attended the interview board on 20th July 2021 as an expert member for the selection of RA for Animal House in Dr. D.P. Rastogi Central Research Institute for Homoeopathy CCRH, Ministry of AYUSH, Govt. of India, Noida, UP, India.
  - d. attended the Institutional Animal Ethics Committee (IAEC) meeting as a Scientist from Outside Institute on 17th January 2022 at National Research Centre on Equines, Sirsa Road, Hisar- 125001, Haryana, India.
  - e. attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA- Main nominee to review the research protocols on 11th February 2022 at the University of Delhi South Campus, New Delhi, Delhi 110021, India.
  - f. attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA- Main nominee to review the research protocols on 11th February 2022 at the University of Delhi South Campus, New Delhi, Delhi 110021, India.
13. For ethical compliance for testing products the necessary approvals of the proposals/ study protocols were accorded in the following ethical committee meetings:
- a. Twelfth Institutional Human Ethics Committee (IHEC) meeting was held on 14th January 2022 via Video Conferencing.







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- b. 57th, 58th and 59th Institutional Animal Ethics Committee (IAEC) meeting- 17th June 2021, 21st October 2021 and 27th January 2022 respectively
14. Institutional Biosafety Committee (IBSC) has been restructured with DBT representative and external experts in line with RCGM Guidelines and the 1st Meeting of this committee was held under the

chairmanship of Dr. Harish Chander, Scientist Grade-I & i/c Deputy Director (Quality Control), NIB on 22nd March 2022 to review the routine and R&D activities related to biosafety. IBSC team took a laboratory round for biomedical waste management related activities in various laboratories.



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

1. Immunodiagnostic Kits & Molecular diagnostic Laboratory is WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and syphilis in-vitro diagnostic assays. Senior Staff of the WHO CC contributed as a resource person in various workshops/ conferences/ forums of WHO Country office & WHO SEARO. Dr. Akanksha Bisht, Scientist Grade-II
  - a) is one of the resource person to facilitate the preparation of post content of E-training program on medical Devices (In-vitro-diagnostics), mode of online delivery of training contents including pre and post self-assessments and feedback for the online training programme being organized by WHO in collaboration with JSS AHER (Initiated from July 2021)
  - b) was one of the expert speaker for WHO Web Training Series on Blood Separation and Plasma Fractionation for the WHO-South East Asian Region Countries.
2. NIB as a National Reference Laboratory of NACO has organized two workshops during this financial year 2021-22 for distribution of HIV EQAS panel, Randomization of PT panel from the field training on NACO Prayogshala to nine State Reference Laboratories of Uttar Pradesh & Uttarakhand by inviting the Technical officers of all SRLs, SHARE INDIA representative and Assistant Director UPSACS Lab Services on 22nd October 2021 (offline) and 08th February 2022 (virtual) at NIB. Distributed the HIV proficiency panel to all ten State Reference Laboratories of Uttar Pradesh. Dr. R. K. Sharma, Scientist Grade – III attended
  - a. Apex lab meetings of NACO virtually on 29th July 2021 at NIB.
  - b. webinar on Promotion of Voluntary Blood Donation and Felicitation of Voluntary Blood Donation, Supporting Organization & Blood Centers on 01st October 2021 at NIB.
3. Dr. Gauri Misra, Scientist Grade-II delivered Lectures on
  - a. "Regulatory aspect on Medical Diagnostic Kits/ Therapeutics at Kalinga Institute of Industrial Technology Bhubaneswar, Odisha held on 29.11.2021.
  - b. "Structure-Based Approaches for Drug-Discovery" in Genomics4Health- Session 4 "Genomics in Drug Discovery" on virtual platform (23-10-2021).
4. Dr. Gauri Misra Scientist Grade-II participated in Scientific Interaction with the faculty of GIMS, Noida for developing research linkages (Virtual intellectual meeting) held on 21st June 2021.
5. Dr. Gauri Misra participated as an external expert in First hub experts meeting to discuss the queries of the innovators on 4th March 2022 by BIRAC.
6. Scientists of Quality Management Unit participated in Pharma Investigation & CAPA Online Workshop - 24th-25th Feb, 2022
7. Training was imparted to 01 blood bank official, Mr. Satish Dubey from Indian Red Cross Society (IRCS), New Delhi on "Cryopreservation and thawing of Red blood cells" at Blood Reagent Laboratory, NIB from 14th to 16th March 2022.
8. Scientists of Blood Products laboratory have attended a webinar titled "Role of pharmacopoeia in ensuring availability of quality medicines" on 25th February 2022, organized by the National Institute of Pharmaceutical Education And Research (NIPER), Mohali, Punjab
9. Dr. Paras Jain, Junior Scientist attended following webinars:
  - a. "Analysis of peptide and impurities using capillary electrophoresis" on 18 Feb 2022 organized by Sciex India Pvt Ltd.
  - b. "Amino acid analysis: Key challenge and practical approach to application-based



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solution" on 4 June 2021 organized by Waters India Pvt Ltd

10. Training has been successfully imparted to the

scientists of the National Institute of Animal Biotechnology (NIAB), Hyderabad from 14-17th March 2022 on quality control testing of Covishield and Covaxin vaccine products.



11. Dr Shikha Yadav was invited as guest faculty in the 3rd Workshop on Basic Training in Animal Handling & Experimentation organized by the Center for Comparative Medicine, Institute of Liver and Biliary Sciences (ILBS), New Delhi to deliver a talk on "Pain Assessment and Management in Rodents" on 29th July 2021

12. Dr. Shikha Yadav attended conference on 3R's Research & Progress "Advances in Animal Models and Cutting-Edge Research in Alternatives" on 18-19th November 2021 that was organized at the University of Hyderabad, Hyderabad

13. Paper titled - Shankar S, Shah S.G, Yadav S, and Chugh A (2021) Novel Corneal Targeting Cell Penetrating Peptide for Management of Corneal Diseases and Disorders, in which Dr Shikha Yadav is co-author was presented in the 27th Annual

Meeting of the Indian Eye Research Group (IERG or ARVO, India Chapter), 7-10 Oct.2021 and was awarded the Best Oral Presentation Award.

14. Dr Shikha Yadav delivered a talk on "Ethics and Regulations for Humane Care and Use of Animals in India" on 23rd December in a 3-day HYBRID Workshop on "In vivo Preclinical Imaging and Drug Discovery" organized from 21-23rd December 2021 by Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), Tata Memorial Center, Mumbai.

15. Dr Shikha Yadav was invited as a guest speaker in the Regional Workshop on "Role of Laboratory Animals in Bio-medical Research" organized by North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Ministry of Health & Family Welfare, Shillong in Hybrid





Mode to deliver a talk on "Occupational Hazard for Laboratory Animal Workers" on 22nd March 2022.

16. Dr. Suresh Kumar, Scientist Grade- III invited as a speaker on 29th June 2021 for delivering a lecture on "CPCSEA guidelines for laboratory animal facility and health indicators of laboratory animals" in the international webinar organized by the School of Pharmacy, Sharda University, Greater Noida (UP)- 201306.
17. Dr. Suresh Kumar virtually participated as a delegate in the 12th India Probiotic Symposium on 5th & 6th March 2022 organized by the Gut Microbiota and Probiotic Science Foundation, India.
18. Dr Akanksha Bisht, Head- HvPI invited as a speaker for the following:-
  - a. CME on Haemovigilance organized by Department of Pathology, Government Institute of Medical Sciences, Greater Noida, Uttar Pradesh on 06.04.2021
  - b. An online educational event on the occasion of World Blood Donor Day 2021 organized by The Department of Transfusion Medicine at Super Speciality Paediatric Hospital and Post Graduate Teaching Institute (SSPH PGTI), Noida, Uttar Pradesh with National Health Mission (NHM) Blood Cell Uttar Pradesh on 12th June 2021
  - c. Webinar on the eve of World Blood Donor Day (WBDD) 2021 organized by a member organization of the Federation of Indian Blood Donors Organizations (FIBDO) on 13th June 2021.
  - d. National Webinar on VBDS, Haemovigilance Programme on 24th July 2021 organized by Federation of Blood Donor Organizations of India (FBDOI), West Bengal in association with NIB supported by Mani Trust Kalimpong.
- e. Virtual National Workshop on Clinical Pharmacology and Therapeutics (NWCPT) organized by the Department of Pharmacology, Postgraduate Institute of Medical Education & Research, Chandigarh held from 09th August 2021 to 14th August 2021
- f. World Health Organization, South-East Asia Region Training Series Towards 100 per cent Voluntary Blood Donation - Understanding Challenges and Barriers in South-East Asia organized on a virtual platform by the Department of Transfusion Medicine, PGIMER, Chandigarh, on 08th October 2021.
19. Dr Akanksha Bisht, Head- HvPI being Secretary of International Haemovigilance Network (IHN) attended the following:-
  - a. GAPP (facilitating the Authorisation of Preparation Process for blood, tissues and cells), final Dissemination Conference online with the host location Thessaloniki, Greece on 20th & 21st January 2022.
  - b. International Haemovigilance Network (IHN) virtual mini-seminar 2021 organized by IHN on Tuesday, 28th September 2021.
  - c. 2022 Virtual mini-seminar of the International Hemovigilance Network on plasma vigilance" organized by IHN on 29 March 2022.
20. NIB under the Haemovigilance Programme of India (HvPI) has organized 04 virtual CMEs/ Workshops/ Conferences across the country & trained about 4283 participants which include Blood centre officials, clinicians, nurses & blood centre technical staff so as to create awareness about the programme.



## CONTRIBUTION TO DEVELOPMENT OF PHARMACOPOEIA MONOGRAPH

The institute contributes from time to time towards the development of new monographs as well as

up-gradation of existing monographs in Indian Pharmacopoeia monographs in the field of Biologicals.

Revision	New
<ol style="list-style-type: none"><li>1. Anti-A Blood Grouping Reagent</li><li>2. Anti-B Blood Grouping Reagent</li><li>3. Anti-AB Blood Grouping Reagent</li><li>4. Anti-D (IgM) Monoclonal Blood Grouping Reagent</li><li>5. Human Anti D Immunoglobulin (Intramuscular)</li><li>6. Human Anti D Immunoglobulin (Intravenous)</li><li>7. Dried Human Anti-hemophilic Fraction</li><li>8. Human coagulation factor VIII (rDNA)</li><li>9. Human Albumin</li><li>10. Human Prothrombin Complex</li><li>11. Human Coagulation Factor IX</li><li>12. Insulin Aspart</li><li>13. Pegfilgrastim</li><li>14. Teriparatide Concentrated Solution</li><li>15. Interferon Alpha 2 b injection</li><li>16. Insulin Glargine injection</li><li>17. rFSH</li><li>18. Heparin</li><li>19. Streptokinase</li><li>20. Menotropin for injection</li><li>21. Heparin sodium injection</li><li>22. Haemophilus Influenzae type b vaccine</li><li>23. Rituximab Drug substance (DS)</li><li>24. Rituximab Drug product (DP)</li></ol>	<ol style="list-style-type: none"><li>1. Anti-D Blend (IgM + IgG) Monoclonal Reagent</li><li>2. Anti-D (IgG) Monoclonal Reagent</li><li>3. Anti-Human Globulin (AHG) reagent</li></ol>



## PREPARATION AND SUPPLY OF NATIONAL REFERENCE STANDARDS/ SERA PERFORMANCE PANELS

The institute is the nodal organization in the development and also the sole repository for National Reference Standards for Human Insulin and Insulin Lispro and performance panels for HIV, HBsAg, HCV and syphilis.

2021-2022, a total number of 840 plasma bags were collected by the Laboratory out of which 281 were reactive for HIV, HCV, HBsAg & Syphilis and 559 were non-reactive. The list of blood bank / Hospitals and details of plasma bags collected are elaborated in the Table below:

### A. Collection of plasma bags: During the year

S. No.	Name of Hospital/Blood Bank	S. No.	Name of Hospital/ Blood Bank
1.	Indian Red Cross Society, Delhi	11	Lady Hardinge hospital, Delhi
2.	Sir Ganga Ram Hospital, Delhi	12	ESIC Model Hosppital, NOIDA, UP
3.	Fortis Healthcare, Gurugram	13	BLK Superspecility Hospital, Delhi
4.	Apollo Hospital, Indraprastha, Delhi	14	RML, Hospital, New Delhi
5.	Guru Teg Bahadur Hospital, Delhi	15	LIONS Blood Bank, Delhi
6.	Medanta Hospital, Gurugram	16	Deen Dayal Upadhyay Hospital, Delhi
7.	Lok Nayak Hospital, Delhi	17	Kailash Hospital, NOIDA, UP
8.	Fortis Escort Okhla, Delhi	18	Rajiv Gandhi Cancer Hospital, Delhi
9	Shri Balaji Action Hospital, Delhi	19	MMG Hospital, Ghaziabad
10	Max Super Speciality Hospital, Patpargang, 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 2021-22, the laboratory supplied 22 Performance Panel to 18 indigenous manufacturers to strengthen the Quality of products during manufacturing of the products.



**D. Two National Reference Standards** were developed namely Indian Pharmacopoeia Reference Standard (IPRS) for Human Insulin (2010) and IPRS for Insulin Lispro (2014). These are being characterized against EDQM CRS and at par in quality with the internationally available CRS and economic at the same time. These are being purchased by the various indigenous manufacturers to get reliable data for quality control purposes. It also helps many new manufacturers to set up the facility for the preparation of the drug product. The link to IPRS is also available on the IPC website so as to facilitate its purchase. During the year 2021-22 lab provided 03 No. of IPRS to two indigenous manufacturers





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## RESEARCH & DEVELOPMENT

### MoU between NIB and AcSIR

As a step towards higher excellence, a Memorandum of Understanding MoU was signed between Dr. Anup

Anvikar (Director NIB) and Dr. Rajender Singh Sangwan, (Director-AcSIR) at NIB on 28th February 2022.



### Scientific Research:

The scientists of NIB are undertaking scientific research as per their laboratory work in the field of biologicals. There are N=14 intramural research projects ongoing with NIB funding and the scientists also secured extramural funding and in the current reporting year, there are N=4 extramural projects. NIB also welcome collaborative research or studies from various organizations like NIBSC, EDQM, etc.

National Institute of Biologicals (NIB) also aims to identify potential candidates interested in pursuing Postdoctoral fellowship / Research Associateship /SRF at NIB, NOIDA. The area of research will be as per the mandate of NIB with the main focus in the field of mechanistic studies in quality evaluation of biologicals for in-depth understanding of diagnostics, prophylactics and therapeutics. There is one RA and 2 SRF currently working at NIB.

**INTRAMURAL PROJECTS**

S. No.	Title
1.	Development of National Reference Standard Program for Insulin Glargine
2.	An Alternative method to animal testing for Quality Control testing of Erythropoietin
3.	Development and Validation of Cell line based Assays to determine the Biological Activity of Recombinant Follicle Stimulating Hormone (rFSH)
4.	Estimation of the potency of Urokinase assay by Chromogenic method for replacement of existing bioassay.
5.	Development of an alternate kit-based method for Potency Assay in Human Rabies Immunoglobulin(IM)
6.	Development of an alternate kit based method for "Anti- complementary activity" (ACA) test for Human Normal/Specific Immunoglobulin for intravenous use.
7.	To replace Barbitol Buffer with an alternate suitable buffer in the test for "Protein Composition" in Human Albumin and Human normal/specific Immunoglobulins.
8.	Analytical and functional characterization of Anti- CD20 monoclonal antibody biosimilars marketed in India
9.	Spectrophotometric evaluation of the biological activity of Vedolizumab as an alternative to FACS
10.	Analytical profiling of Anti- HER2 monoclonal antibody biosimilars marketed in India.
11.	Development of National Reference Standard (NRS) for Biological Activity of Trastuzumab
12.	Development of National Reference Standard (NRS) for Biological Activity of Rituximab
13.	Detection of Spike Protein Expression of SARS COV-2 by immune-fluorescence and immune-blotting for quality testing of viral vector-based vaccines
14.	BCG (BACILLE CALMETTE-GUERIN) vaccine National Reference Standard (NRS)

**EXTRAMURAL PROJECTS**

S. No.	Title	Funding Agency
1.	Quercetin induced reactivation of Mutant p53	DST-SERB
2.	Evaluating the potential of new chromone derivatives against human Great wall kinase for cancer therapy using comparative cell based and proteomics investigations	ICMR
3.	Harmonization of COVID-19 RT-PCR kits efficiency data towards enhancing their specificity and sensitivity for different strains of SARS-CoV-2.	ICMR
4.	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



## 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 Organization (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). On request, Institute also provides technical expertise for assessment as per ISO 17025: 2017 for overseas laboratories.

**GMP inspections:** Participation of 07 NIB scientists as Experts in Joint Inspection of 04 Biotherapeutic manufacturing units in India (Ahmedabad and Uttarakhand) along with CDSCO and state drug control officer:

**CPCSEA inspection:**

01 NIB scientist from Animal Facility has performed joint annual inspections of 02 Animal Facilities in Greater Noida, Uttar Pradesh to ensure compliance with the CPCSEA regulations.

### NIB scientists involved in Joint inspections

S. No.	Name	Designation
1.	Dr. Charu M. Kamal	Scientist Grade-II
2.	Dr. Ratnesh K. Sharma	Scientist Grade-II
3.	Ms. Sudha V Gopinath	Scientist Grade- III
4.	Ms. Gurminder Bindra	Scientist Grade- III
5.	Mr. N. Nandagopal	Scientist Grade- III
6.	Mr. Subhash Chand	Scientist Grade- III
7.	Dr. Sanjay Mendiratta	Junior Scientist
8.	Dr. Shikha Yadav	Scientist Grade II



## TRAINING UNIT

### 1. Aim & Scope:

The training unit functions with the objective, which is in line with NIB mandate 3.3 as laid down in the Memorandum of Association. 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 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 is organizing 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 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.

### 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.

Institute in collaboration with Blood Cell, National Health Mission, organized two Hands-on Residential Training Programmes on "Training of Trainers for Strengthening of Blood Services and e-Rakt Kosh" with total 78 participants. Due to current COVID-19 pandemic, these training programmes, one for Blood Bank Officials from the State of Haryana state from: (18th March to 04th August 2021) and other for Chhattisgarh state from: (21st October to 17th November 2021), were conducted as combination of Two-days Online live lectures sessions for all participants of one training & 3-days batch wise Hands-on Residential Training at NIB.

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



**NHM Haryana**



**NHM Chandigarh**

**Table 1:** 02 Days online and 03 days Hands-on Residential Training Programme for “Training of Trainers for Strengthening of Blood Services” in collaboration with Blood Cell, National Health Mission (NHM), Ministry of Health & Family Welfare, and Government of India.

Trainings	Duration		No. of Participants	Total
Hands-on Training for four Batches of Blood Bank participants of <b>Haryana state</b>	2 <sup>nd</sup> Batch 05-04-2021	07-04-2021	9	42
	3 <sup>rd</sup> Batch 05-07-2021	07-07-2021	10	
	4 <sup>th</sup> Batch 12-07-2021	14-07-2021	6	
	5 <sup>th</sup> Batch 26-07-2021	28-07-2021	8	
	6 <sup>th</sup> Batch 02-08-2021	04-08-2021	9	
<b>02-days Online</b> Live lectures and	All participants: 21-10-2021	17-11-2021	40	40
Hands-on Training for two Batches of Blood Bank participants of <b>Chhattisgarh state</b>	Batch-I: 25-10-21	27-10-2021	20	
	Batch-II: 15-11-2021	17-11-2021	16	
			<b>Total</b>	<b>82</b>

## 2.2 Training of Post Graduate Students from various Universities at NIB under “National Skill Development & Hands-on Training on Quality Control of Biologicals” programme:

Institute in line with National Skill Development programme provided 2-weeks Hands-on Training on “Quality Control of Biologicals” to M.Sc. Biotechnology Students and a Faculty from Vinoba Bhawe University, Hazaribagh (Jharkhand),



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

The training covers techniques used in quality evaluation like HPLC, Electrophoresis, ELISA,

Bacterial Endotoxin testing, Transfusion Transmitted Infection testing, Blood Serology, Cell culture aseptic handling, sub culturing and maintenance, cell line based potency assays, animal handling, use of laboratory animals etc. in

Quality Control testing of Biologicals performed in various labs of NIB and to create awareness about Global scenario of biological testing. The training programme conducted this year is given in Table 2:

**Table 2:** National Skill Development & Hands on-Training on Quality Control of Biologicals programme

Trainings	Duration	No. of Participants
National Skill Development and Hands on Training in Quality control of Biologicals for Post Graduate students (M.Sc. Biotechnology) of Vinoba Bhave University, Hazaribagh (Jharkhand),	22-11-2021 to 03-12-2021	15
		

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

The institute provides 6 weeks training programme and also 4 -6 months' project work in Quality Control of Biologicals in various NIB laboratories to

Graduate/ Post Graduate Students of various Universities and Institutes. The training on various analytical platform makes them proficient, help in their future research endeavours and enable them to get good job opportunities.

S. No.	Trainings	Duration	No. of Participants
01	Summer Training and Project work of Post Graduate/ Under Graduate students from subject Biotechnology, Biochemistry, Microbiology, Pharmacy etc.	April, 2021 to March, 2022	21

**2.4** Institute has initiated **Structured training courses** in a variety of techniques and method validation, internal QC involved in the QC testing of biologicals initiated for Students / Industry Professionals/ Regulatory Officials/ Medical Professionals/ Clinical laboratory personnel/ Researchers/ Personnel of the testing and manufacturing Unit

### 2.5 NIB-DPSRU Scientific Collaboration

- On invitation, a team of NIB-Scientists visited and interacted with the Faculty and Senior Officials of Delhi Pharmaceutical Sciences and Research University (DPSRU) on 13th August 2021. The representative members of the two institutes



deliberated on various aspects to materialize the modalities of collaboration through a formal Memorandum of Understanding MoU between NIB and DPSRU, including a "Certificate programme on Quality Assurance of Biopharmaceuticals".



- b. Meeting on brain storming for NIB-DPSRU Joint Certificate Course- Training unit facilitated the meeting on brain storming for NIB-DPSRU collaborative certificate course on Quality Control of Biopharmaceutical & Biologicals, held here at NIB on 29th December, 2021 under the Chairmanship of Dr J P Prasad, Deputy Director (QC-NIB). Different modalities were discussed and deliberated for establishing and launching this joint training course.



## **2.6 Visit of pharmacy students from Kerala 17th March 2022-**

NIB hosted the Lab visit of B. Pharm students along with faculty members from the College of Pharmaceutical Sciences, (Govt. Medical College

Calicut, Kerala) on 17th March 2022. The students were given a basic overview of NIB and also discussed about Quality control of Biologicals and related technological platforms. The students visited various Laboratories, and interacted with concerned scientists



## HAEMOVIGILANCE PROGRAMME OF INDIA (HvPI)

### 1. Scientific Activities Undertaken:

- a. Implementation and coordination of activities of the 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. **110** new blood centres have been enrolled under this programme during the said financial year taking a total of **1240** blood centres under this programme. National Institute of Biologicals has a web-based reporting system for adverse transfusion reactions and donor reactions via indigenously developed software(s) Haemo-Vigil and Donor-Vigil. A total number of **13,314** Adverse Reaction Reports have been reported via Haemovigilance Software(s) during this financial year out of which **4,715** reports pertain to adverse blood transfusion reactions and **8,599** reports are attributed to reactions during blood donation.
- c. **WHO Project**  
Regional desk review (situational analysis) of regulations overseeing quality and safety of blood and blood products in WHO member states of South-East Asia Region (SEAR):- Head HvPI was one of the key contributors in

the said project. The document of regional desk review (situational analysis) has been submitted to WHO in the month of May 2021

- d. Multi-centre Cross-sectional Questionnaire Survey on the effectiveness of the Haemovigilance Programme of India for the enrolled reporting centres under HvPI was initiated on 14th January 2022.
- e. **First National Conference on Haemovigilance organized by NIB from 09th – 11th December 2021 (Online Mode)**

HvPI entered into 10th year on 10th December 2021 & on this occasion, the First National Conference on Haemovigilance via online mode was organized by NIB for 3 days from 9th-11th December 2021.

**Inaugural Ceremony:** Dr Mansukh Mandaviya, Union Health Minister, Ministry of Health & Family Welfare, Government of India was the chief guest for the conference.

The other guests who were the part of the inaugural ceremony were Shri Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare, Government of India; Dr Mandeep Kumar Bhandari, Joint Secretary (R), Ministry of Health & Family Welfare, Government of India; Dr V. G. Somani, Drugs Controller General (I), CDSCO, New Delhi and Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC, Ghaziabad.





### **Salient Features of the First National Conference on Haemovigilance**

A total of 47 experts participated for the said conference from all across the country.

An overwhelming response to this conference is evident from fact that about 2763 number of

registrations were done for the conference & about 70 abstracts were submitted for the conference. Apart from online platform many participants participated the conference through the live streaming on YouTube channel of the First National Conference on Haemovigilance.





## INFORMATION TECHNOLOGY DIVISION

IT-related infrastructure is well maintained by the independent IT division across the campus including Laboratory & Animal House building, Administration building, Hostel and Guest House.

### 1. Laboratory Information Management Software (LIMS):

The IT division is currently maintaining the in-house developed LIMS software. During the year, the IT Division also developed and merged the SRRD Portal with respective laboratories in LIMS Software.

### 2. Sample Tracking Invoice Generation Software:

The IT division is currently maintaining the in-house developed software for Invoice Generation against testing fees received for Quality Control Evaluation of all indigenously produced and imported biological products submitted by the manufacturers.

### 3. Other Invoice Generation Software:

The IT division is currently maintaining and updating the in-house developed software for generation of Invoices against payment received other than testing fees of samples such as Sale of Laboratory

Animals to CPCSEA Registered Institutes and Reference Standards – Biotech Products, Old Newspapers & Magazines and e-Waste etc. Presently, the Invoice Generation Software's are being used by the Sample Receipt & Report Dispatch Unit and Finance & Account Division of the Institute.

4. IT Division 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. IT Division has also initiated the Security Audit of New Dynamic Website of the Institute in November, 2021 and correction is under progress.
6. IT Division has also upgraded the 200 mbps BSNL Internet Leased Line Connectivity for strengthening the network facility at NIB, Noida.
7. DHCP Server and Wi-fi access points installed to strengthen the IT related services at NIB, Noida.



## ENGINEERING DIVISION

The NIB campus specifically Laboratory & Animal House Building is complemented by various engineering services/ facilities/ installations to facilitate the day-to-day scientific activities.

### **Proposal/Works have been initiated for the following:**

- (i) "Repairing & overhauling of 08MVA, 33/11kV, HT Power Transformer No.2 of M/s. Crompton Greaves make {bearing S.No.6058/2}.
- (ii) Supply, Installation, Testing & Commissioning of electrical items for fire Alarm/ detection system installed at Lab & Animal House.
- (iii) Renovation of walk-in-cold rooms installed in Basement of Administrative Building.
- (iv) Repair of Centrifugal chiller, 750 Tr, M/s Carrier, USA make for HVAC system installed for Laboratory & Animal House building.
- (v) Conversion of Boilers from HSD to Natural Gas (NG) basis.
- (vi) 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 the Institute.
- (vii) Renovation of Firefighting System underground pipelines with CPWD.
- (viii) Procurement of SS pipelines, fitting, M.S. pipelines etc. for maintenance of various supply line system of NIB, Noida.
- (ix) Tendering process & Award the contract 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.
- (x) Tendering process is going on for Supply, Installation, Testing, Commissioning (SITC) of:
  - a. 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.
  - b. Centrifugal Chiller (Water cooled) with allied accessories & complete job and also the buyback with dismantling of existing chiller No.-3(Out of order) in Laboratory & Animal House Building by M/s HITES, Noida.
- (xi) Supply, Installation of 24 Nos. Fire House Boxes and 48 Nos. Fire Hose pipes.

Services contracts for annual operation and maintenance contract, and AMCs/ CMCs of the following Services/ facilities and fixed scientific equipment:

  - (i) Operation & Comprehensive Contract for
    - a. 20 Nos. Walk-in-cold Rooms, Environmental Rooms, Incubators which are installed in Lab. & Animal house Building.
    - b. firefighting system, water supply system, water softening plant system, neutralization system including centralized water softening plant of the Institute.
    - c. 3 x 2.8T/Hr at 10.5kg/sqcm steam generating boiler including Economizers and allied accessories etc.
    - d. centralized R.O. Plant system installed in the Laboratory & Animal House Building.
  - (ii) Operation and maintenance contract for
    - a. HVAC plant System including Window/ Split Cassette and package type AC units installed in various buildings of the Institute.

- b. Steam Sterilizers, Glassware Washers, Glassware Dryers, Tunnel Washers and Case & Rack Washers of M/s Steris USA make installed in the Animal House Facility of the Institute.
  - c. 3 x 2.6MW, 11KV Emergency Captive power plant system
- (iii) Operation and Non Maintenance contract for External & Internal services (Electrical) installed at NIB Noida.
- (iv) Operation and Non-comprehensive Maintenance for Fire Alarm/ Detection system & PA System, installed in the Laboratory & Animal House Building” at NIB Noida.
- (v) AMC of 17 Nos. Fume Hoods (M/s Kewaunee) installed in Lab. & Animal House Building.
- (vi) Repair and maintenance of the 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 viz: 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.
- (vii) To make provision for supply, installation, testing and commissioning separate Air conditioning Unit to control the Humidity and temperature in Existing Sterility Clean Room”.
- (viii) Validation of Sterility Testing Clean Room twice in a year as per WHO guidelines in Laboratory”.
- (ix) Relaying of Polyurethane flooring in Sterility Lab
- (x) Award of contract for “Operation & Comprehensive Maintenance of ETP & STP”.
- (xi) 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.
- (xii) Complete management of annual service contracts viz. maintenance of Horticulture, Pest & Rodent Control and Housekeeping, etc.
- (xiii) Providing bilingual signages on all buildings and Roads in the campus
- (xiv) Setting up of Meeting Rooms at:
- a. Administrative Building, Room No. A-212.
  - b. 2nd floor of Laboratory Building, Room No. L-2002.





## REPORT OF THE ADMINISTRATIVE WORK

**Head of the Administration:** Shri J. P. Pant, Administrative Officer

### 1. General Body of the Institute

#### Composition of the General Body:

<b>Secretary Health &amp; Family Welfare</b> Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi- 110011	<b>Chairman</b>
<b>Secretary</b> Department of Biotechnology, New Delhi	<b>Member</b>
<b>Secretary, DHR &amp; DG, ICMR</b> Ansari Nagar, New Delhi – 110029	<b>Member</b>
<b>Director General of Health Services,</b> Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi – 110011	<b>Member</b>
<b>Additional Secretary (Health)</b> Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi – 110011	<b>Member</b>
<b>Additional Secretary &amp; F.A.</b> Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi – 110011	<b>Member</b>
<b>Joint Secretary</b> Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi – 110011	<b>Member</b>
<b>Drugs Controller General (India),</b> Directorate General of Health Services, F.D.A. Bhawan, Kotla Road New Delhi – 110002	<b>Member</b>
<b>Secretary</b> Health & Family Welfare, H. Block Secretariat, Govt. of Andhra Pradesh, Hyderabad, Andhra Pradesh	<b>Member</b>
<b>Secretary</b> Health & Family Welfare Department, Government of West Bengal, Writers Building, Kolkata	<b>Member</b>

**Chairman**

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

**Member****Director**

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

**Member****The Chairman-cum-Managing Director**

National Dairy Development Board,  
Anand, Gujrat

**Member****Managing Director**

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

**Member****Director,**

NIB, NOIDA

**Member Secretary****Meetings of the General Body:**

13th Meeting of the General Body was held on 01-02-2022

**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

**Chairman****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,**

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**



## NATIONAL INSTITUTE OF BIOLOGICALS

**Drugs Controller General (India),**  
Directorate General of Health Services,  
F.D.A. Bhawan, Kotla Road  
New Delhi – 110002

**Member**

**Director,**  
NIB, NOIDA

**Member Secretary**

### Meetings of the Governing Body:

30th Meeting of the Governing Body was held on 12-07-2021

31st Meeting of the Governing Body was held on 01-02-2022

### 3. Standing Finance Committees.

#### Composition of the Standing Finance Committee:

**Additional Secretary**  
Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi– 110 011

**Chairman**

**Additional DG, ICMR**  
or his nominee  
Ansari Nagar, New Delhi – 110029

**Member**

**Joint Secretary**  
Ministry of Health & Family Welfare,  
Nirman Bhawan, New Delhi – 110011

**Member**

**Drugs Controller General (India) or his nominee**  
(Not below the rank of Asstt. Drugs Controller (I)),  
F.D.A. 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 33rd Meeting of the Standing Finance Committee was held on 27.10.2021



#### 4. Promotions, Appointments/ Superannuation/ Quit Services during the year 2021-22 in the Institute: -

##### Appointments

S. No.	Name of Employee	Designation
1	Ms. Sanchi Goel	Junior Scientist on 24-08-2021
2	Dr. Saurabh Sharma	Scientist Grade-III on 07-03-2022
3	Dr. Sanjay Mendiratta	Scientist Grade-III on 07-03-2022
4	Dr. Varun Singh	Scientist Grade-III on 07-03-2022
5	Dr. Hemant Kumar Verma	Scientist Grade-II on 09-03-2022

##### Superannuation/Quit services

S. No.	Name of Employee	Designation
1	Dr. J.P. Prasad	Deputy Director (QC) superannuated on 31-12-2021
2	Sh. Kallol Saha	Junior Scientist Expired on 27-11-2021

#### 5. Staff in position

##### PERSONNEL

##### A. Scientific

S.No.	Name	Designation
1	Dr. Anup Kumar Anvikar	Director NIB
2	Dr. Harish Chander	Scientist Grade-I
3	Sh. Neeraj Malik	Scientist Grade-II
4	Dr. Charu M. Kamal	Scientist Grade-II
5	Dr. Akanksha Bisht	Scientist Grade-II
6	Dr. Meena Kumari	Scientist Grade-II
7	Sh. Harit Kasana	Scientist Grade-II
8	Dr. Gauri Misra	Scientist Grade-II
9	Dr. Ratnesh K. Sharma	Scientist Grade-II
10	Ms. Ajanta Sircar	Scientist Grade-II
11	Dr. Hemant Kumar Verma	Scientist Grade-II
12	Dr. Shikha Yadav	Scientist Grade-II (Vet)
13	Ms. Sudha V. Gopinath	Scientist Grade-III
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	Sh. Subhash Chand	Scientist Grade-III
22	Dr. Manoj Kumar	Scientist Grade-III
23	Sh. Jaipal Meena	Scientist Grade-III
24	Sh. Tara Chand	Scientist Grade-III
25	Dr. Pankaj K. Sharma	Scientist Grade-III
26	Sh. N. Nanda Gopal	Scientist Grade-III
27	Dr. Ashwini Kumar Dubey	Scientist Grade-III
28	Dr. Saurabh Sharma	Scientist Grade-III
29	Dr. Sanjay Mendiratta	Scientist Grade-III
30	Dr. Varun Singh	Scientist Grade-III
31	Dr. Suresh Kumar	Scientist Grade-III (Jr. Vet)
32	Dr. Manjula Kiran	Junior Scientist



<b>S.No.</b>	<b>Name</b>	<b>Designation</b>
33	Ms. Vandana Tandasi	Junior Scientist
34	Dr. Birendra Kumar	Junior Scientist
35	Sh. Ajay Kumar Ade	Junior Scientist
36	Sh. Anirban Mukherjee	Junior Scientist
37	Dr. Anoop Kumar	Junior Scientist
38	Ms. Archana Sayal	Junior Scientist
39	Sh. Rajeev Kumar	Junior Scientist
40	Md. Daud Ali	Junior Scientist
41	Dr. Swati Shalini	Junior Scientist
42	Ms. Apoorva Anand	Junior Scientist
43	Dr. Paras Jain	Junior Scientist
44	Sh. Brij Bhushan	Junior Scientist
45	Sh. Subhash Kumar	Junior Scientist
46	Dr. Supriya	Junior Scientist
47	Sh. Anup Kumar	Junior Scientist
48	Ms. Sanchi Goel	Junior Scientist
49	Ms. Girija L.V.	Laboratory Technician
50	Sh. Brij Bahadur	Laboratory Technician
51	Sh. Sukhen Majhi	Laboratory Technician
52	Dr. Mohammed Imran	Laboratory Technician
53	Sh. Reetesh Kumar	Laboratory Technician
54	Sh. Mohit Lal	Laboratory Technician
55	Ms. Poonam	Laboratory Technician
56	Sh. Lakhan	Laboratory Technician
57	Sh. Prem Prasad	Laboratory Technician
58	Sh. Sinto M.V.	Laboratory Technician
59	Sh. Mohit Sharma	Laboratory Assistant
60	Ms. Priya Bhatt	Laboratory Assistant
61	Sh. Rajeev Kumar Srivastava	Laboratory Assistant
62	Sh. Prdeep	Laboratory Assistant
63	Sh. Narender Kumar	Laboratory Assistant
64	Sh. Parminder Kumar	Junior Animal Caretaker

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

S.No.	Name	Designation
65	Sh. Q. W. Zaheeruddin	Senior Administrative Officer (P)
66	Sh. J.P. Pant	Administrative Officer
67	Sh. P.K. Mohapatra	Administrative Officer (F)
68	Sh. Manmeet Singh Bhatia	Section Officer
69	Sh. Sanjeev Kumar	Section Officer (Deputation)
70	Sh. U.N. Sharma	Section Officer
71	Sh. Deepak Mahajan	Jr. Programme Officer
72	Sh. Praveen Kumar Pant	Administrative Assistant
73	Sh. Pradeep Kumar	Administrative Assistant
74	Sh. Dhirender Singh	Administrative Assistant
75	Sh. Partho Mandal	Administrative Assistant
76	Sh. Varun Pandey	Administrative Assistant
77	Sh. R.K. Arora	Stenographer Grade-B
78	Sh. Pradeep Kumar Mehta	Administrative Assistant
79	Sh. Pawan Kumar Sharma	Administrative Assistant
80	Sh. Prem Chand Gupta	Assistant-I
81	Ms. Savita Rani	Assistant-I
82	Sh. Govind Singh Rawat	Driver
83	Sh. Harinder Singh	Driver
84	Sh. Leela Kishan	Driver
85	Sh. Bijender Singh	M.T.S
86	Sh. Subhash Chand	M.T.S
87	Sh. Suraj Pal	M.T.S
88	Sh. Rakesh	M.T.S
89	Sh. Prem Chand Diwan	M.T.S
90	Smt. Shoba	M.T.S
91	Smt. Rajendri Devi	M.T.S
92	Sh. Mukesh Kumar	Assistant Engineer (Electrical)
93	Sh. R.P. Joshi	Assistant Engineer (Civil)
94	Sh. Subhash Chand	Jr. Engineer (Electrical)
95	Sh. Chander Pal	Jr. Engineer (Mechanical)
96	Sh. Amarjit Singh	Jr. Engineer (Mechanical)
97	Sh. Krishna Kumar	Jr. Engineer (Civil)
98	Sh. H.P. Vashisth	Electrician

## RAJBHASHA (HINDI)

In pursuance of the Official Language Policy of the Government of India, a Rajbhasha Cell has been set up in NIB. During the year 2021-22, this Cell took various steps/ initiatives to increase the progressive use of Hindi in day-to-day official work such as Hindi Workshops were organised in every quarter, Celebration of Hindi Pakhwada from 1-15 September, 2021 and various competitions were conducted during this period. The winners of the competitions were given away the cash prizes. Besides this, with the advice of Director, NIB another Hindi Competition titled "Shabdarth and Hindi Essay Writing" was conducted on 25th February, 2022. The winners officials of this competition were given away the cash prizes by the Director of Institute. It is pertinent to mention here that the words/phrases included in the Question paper were taken from the list of words which were already displayed in display board installed in the Institute Premises. This initiative was well received by the employees of the Institute.

### Quarterly meetings of Official Language Implementation Committee

Quarterly meetings of the Official Language

Implementation Committee were 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 action were suggested to rectify the shortcomings found in the implementation of Hindi.

### 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. Also the Institute attended the meeting held by the Town Official Language Implementation Committee, NOIDA.

### Award

The Institute was honoured with an award by Bhartiya Bhasha Avam Sanskriti Kendra for outstanding implementation of Rajbhasha during the year 2019-20. This award was received by Shri J.P. Pant, Administrative Officer in a Seminar held at Nainital from 18-20 Nov 2021.



**Other Activities**

- The website of the Institute is bilingual and updated in Hindi also from time to time.
- All the standard forms are bilingual and are uploaded in website of the Institute.
- All the computers being used are having facility to work in Hindi. Mangal Unicode is uploaded in all these computers.

- Hindi/bilingual standard drafts of routine letters have been made available to the concerned units with a view to increase the use of Hindi in correspondence.

The Institute is taking all steps to achieve the targets set in the Annual Programme for the implementation of Official Language issued by the Department of Official Language, Ministry of Home Affairs, Government of India.



## EVENTS

### Chintan Shivir

National Health Authority (Ministry of Health and Family Welfare) and the National Institute of Biologicals, organized a two-day "Chintan Shivir – Heal in India" at the National Institute of Biologicals, NOIDA on 4-5 March 2022 in order to have a discussion on bringing policy promoting medical tourism to promote India as a destination for wellness travel, Indian

traditional medicine and wellness systems, the potential of health insurance, and digital health. Further discussions over strengthening medical infrastructure and improving primary and tertiary healthcare were also held in the workshop. Hon'ble Union Health Minister Dr. Mansukh Mandaviya, Minister of State for Health Dr. Bharati Pravin Pawar, senior officials from the Centre and States, and industry experts, participated in the 'Chintan Shivir.'





**Hon'ble Union Health Minister Dr. Mansukh Mandaviya visited various laboratories of the Institute and interacted with the scientists.**



### **International Women's day**

With great zeal and enthusiasm, NIB celebrated International Women's day on 8 March 2022 with the theme "Gender equality today for a sustainable tomorrow". Dr. (Mrs.) Shashi Khare, former Deputy Director (Quality Control) – NIB was the Chief Guest for this year's International Women's day celebration.

She emphasised that the purpose of the day is not only to honour a woman's accomplishments but also to raise awareness about bias. She shared her experiences of her scientific journey during her interaction with the women staff and motivated them to continue to contribute to the nation's growth.





## EMPOWERING CONSUMERS: RIGHT TO INFORMATION ACT, 2005

In terms of Section 4(1) (b) and 4(2) of the Right to Information Act, 2005, the Institute has nominated the

following officers as PIO and Appellate Authority under the RTI Act, 2005:

Sh. W. Z. Quazi, Senior Administrative Officer	Appellate Authority
Dr. Ratnesh K Sharma, Scientist Grade-II	Public Information Officer (PIO)
Sh. P. K. Mohapatra, Administrative Officer	

Status of RTI Applications Received during the Financial Year 2021-22 (upto 31st March, 2022)

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/s7(1)
Request	13	6	32	0	0	40	120
First Appeals	0	-	8	0	0	8	0



# AUDITOR'S REPORT



**Chandiwala Virmani & Associates**

Chartered Accountants

SF-3A, 11th Floor, 43, Daryaganj, Near Valmiki Mandir, Delhi 110002

Ph: 011-43587399, Email: chandiwala@virmani.com



**INDEPENDENT AUDITOR'S REPORT**

To  
**National Institute of Biologicals**  
A-32, Institutional Area, Sector-62  
Noida (Uttar Pradesh)-201309.

**Opinion**

We have audited the financial statements of **National Institute of Biologicals** (herein after called "NIB"), which comprise Balance Sheet as at 31st March, 2022, the Income & Expenditure Account and Receipt and Payment Account for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Subject to Emphasis of matters Para below, in our opinion, the accompanying financial statements give a true and fair view of the financial position of the **NIB** as at 31st March, 2022, and of its financial performance for the year then ended in accordance with the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI).

**Basis for Opinion**

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

**Emphasis of Matters**

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

**Other Matters**

Attention is also invited to the following:

- Note No. 1 Reconciliation of Property, Plant & Equipment and its physical verification.

Contd..2

-2-

- Note No. 5 regarding GST on advances received.
- 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 includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

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

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

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

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

**Chandiwala Virmani and Associates**

**Chartered Accountants**

Reg. No. 000082N

**CA Yuganshu Gaur**

**Partner**

(M. No.: 438595)

UDIN: 22438595AORTRO4254

Place: Noida

Date: 10/08/2022



## NATIONAL INSTITUTE OF BIOLOGICALS

### NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health & Family Welfare

DETAILS OF GRANT UTILISATION FOR THE  
FINANCIAL YEAR 2021-22

PARTICULARS	Amount in ₹				
	GIA - SALARY	GIA - GENERAL	GIA - ASSETS	GIA - SAP	TOTAL
<b>RECEIPTS</b>					
Grant unutilized b/f from the Previous Year	24,07,083.00	1,12,67,379.97	5,11,015.63	6,897.00	1,42,94,064.60
Grant In Aid Received From Ministry	14,75,93,000.00	23,72,55,330.00	2,54,89,000.00	9,52,330.00	47,47,05,000.00
<b>TOTAL RECEIPTS (A)</b>	<b>15,00,00,083.00</b>	<b>24,85,22,710.97</b>	<b>2,60,00,015.63</b>	<b>9,59,227.00</b>	<b>48,55,00,036.60</b>
<b>LESS:- EXPENDITURE INCURRED &amp; PROVISION</b>					
Establishment Expenses	15,52,31,443.00	-	-	-	15,52,31,443.00
Administrative Expenses	-	11,56,35,723.05	-	3,24,854.00	11,60,30,577.05
Lab Services-Operation & Maintenance Exp	-	18,75,48,014.70	-	-	18,75,48,014.70
Increase in Stock of P/L for Boilers & D.G Set	-	-17,71,429.00	-	-	-17,71,429.00
Grant utilised for Security Deposits - Electricity	-	43,27,322.00	-	-	43,27,322.00
Payment made for Fixed Assets during the year:					
Additions in Fixed Assets	-	-	2,07,24,523.00	-	2,07,24,523.00
Less: Advance of Previous year - Utilized against Fixed Assets	-	-	-76,09,312.99	-	-76,09,312.99
Less: Adjustment for amount of fixed asset excess charged in P.Y	-	-	-18,88,531.00	-	-18,88,531.00
Advance against Fixed Assets, Goods & Services (Net)	-	37,56,501.00	1,75,87,563.00	-	1,58,44,106.00
Less: Advance of Prev. Year Utilized/Refunded against Goods & Services	-	-2,02,834.00	-	-	-2,02,834.00
Add: Grant Utilised for Provisional Expenses increase/decrease	-	-10,20,109.00	-	-	-10,20,109.00
<b>TOTAL CURRENT YEAR EXPENDITURE / UTILISATION (B)</b>	<b>15,52,31,443.00</b>	<b>20,83,70,228.75</b>	<b>2,33,14,344.07</b>	<b>3,94,854.00</b>	<b>48,73,10,869.82</b>
<b>GRANT RECEIVABLE / PAYABLE TO GOV (A) - (B)</b>	<b>-52,31,360.00</b>	<b>2,79,850.22</b>	<b>66,85,671.56</b>	<b>5,643.00</b>	<b>16,89,194.78</b>



*[Signature]*







# **NATIONAL INSTITUTE OF BIOLOGICALS**

(Ministry of Health and Family Welfare, Government of India)

Plot No. A-32, Sector-62, NOIDA-201 309 (UP) INDIA

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