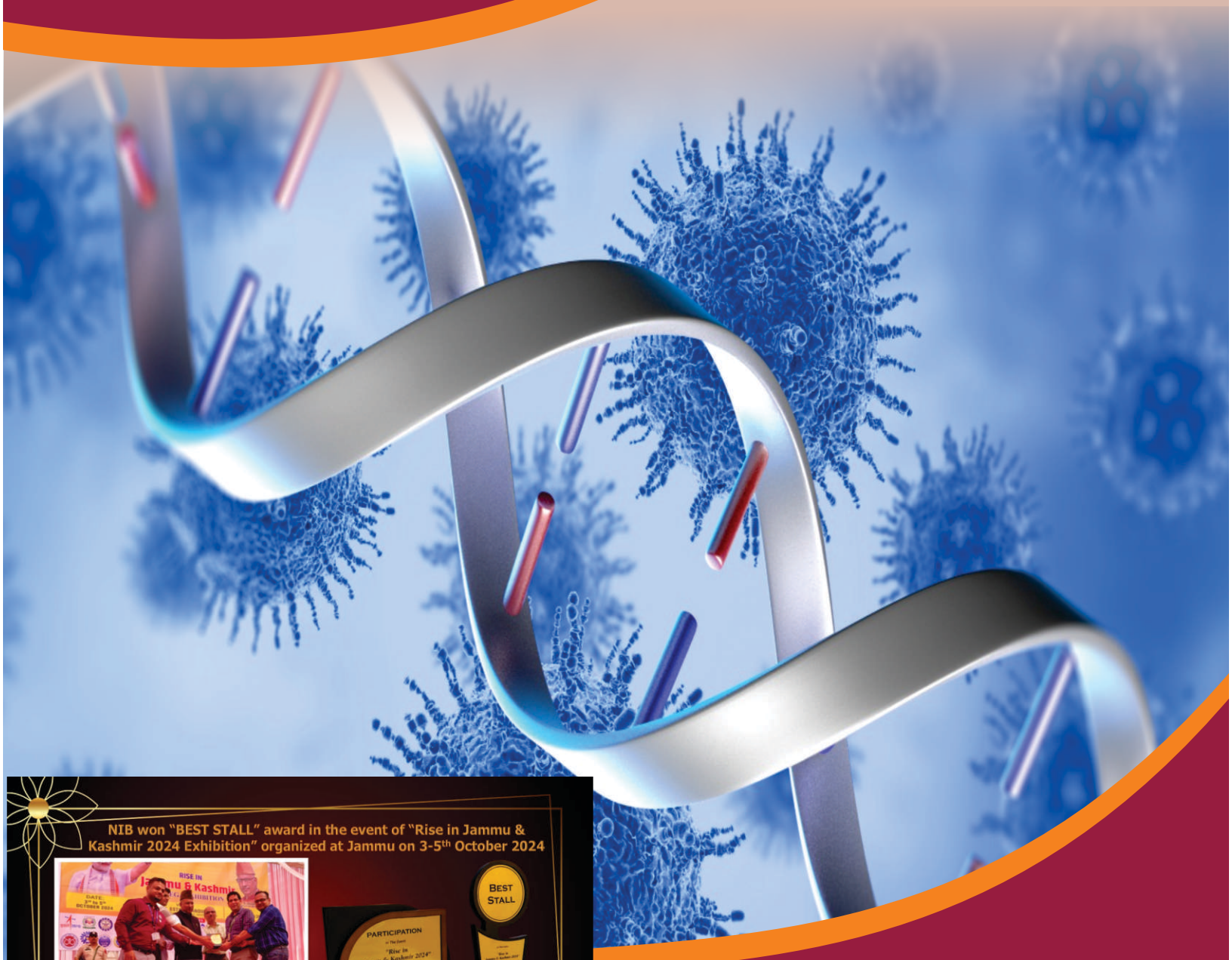




ANNUAL REPORT

2024 - 2025



NIB won "BEST STALL" award in the event of "Rise in Jammu & Kashmir 2024 Exhibition" organized at Jammu on 3-5th October 2024



Facilitation of award by Er. GULAM ALI,
MP (Rajya Sabha) - J&K to NIB



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,
भारत सरकार

National Institute of Biologicals
Ministry of Health & Family Welfare,
Government of India



Shri J.P. Nadda

Hon'ble Union Minister
Health and Family Welfare & Chemicals and Fertilizers
Government of India



Shri. Prataprao Jadhav

Hon'ble Minister of State (Independent
Charge) of Ministry of Ayush and
Minister of State Ministry of Health and
Family Welfare,
Government of India



Smt Anupriya Patel

Hon'ble Minister of State Health
and Family Welfare & Chemicals
and Fertilizers
Government of India

INTRODUCTION

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

The Institute is performing primary statutory function of Quality Control of Biologicals e.g. Insulin, erythropoietin, blood products, diagnostic kits e.g. HIV, HBV, HCV, therapeutic monoclonal antibodies like Trastuzumab and Rituximab used in cancer treatment etc. in accordance with provisions of Drugs & Cosmetics Act 1940 and Rule 1945 amended from time to time. The biological products are tested as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms, in the NIB laboratories. The Institute is also accredited by NABL as per ISO/ IEC 17025:2017 for the scope defined.

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

- i) to ensure quality of Biological and Biotherapeutic products, both imported and manufactured indigenously moving in the Indian market.
- ii) to contribute in finalizing the specifications for biological products to be incorporated in Indian Pharmacopoeia,
- iii) to prepare National Reference Standards for biological products,
- iv) to train technical personnel in the public and private sectors in the field of Quality

Control of Biological products and Haemovigilance programme,

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

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

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

The Laboratory and Animal House facility of the Institute, constructed in February, 2006, have 42 Biosafety Level (BSL)-2 laboratories equipped with modern scientific equipment for testing of Biological and Biotherapeutic products. There are 20 walk-in-cold rooms and 03 walk-in-deep freezers (-20°C), and 64 bio-safety cabinets. All equipment are under Annual Maintenance Contract (AMC) or Comprehensive Maintenance Contract (CMC) and are regularly calibrated by a ISO/IEC 17025:2017 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, Government of India. The revenue generated from testing of biologicals is deposited in the Consolidated Fund of India with Ministry of Health & Family Welfare, Government of India.

REPORT FROM THE DESK OF DIRECTOR



It gives me immense pleasure to present the Annual Report of National Institute of Biologicals (NIB) for the year 2024-25 that illustrates the significant work carried out at the Institute

Being the premier institute for assuring quality of biologicals in India, NIB is actively involved in the systematic examination of the quality of biologicals and immunobiological products, with a view to enable the release of indigenous & imported products after test and analysis as per the national requirements.

NIB continued to play a crucial role in ensuring the quality of biological products through rigorous analytical evaluation. The Institute received a total of 2,120 samples across various product categories, including government-supplied, service, and standardization samples. Notably, 246 of these samples were submitted by different State Medical Procurement Agencies, reflecting growing reliance on NIB's quality assurance services. A total of 2,007 test reports were issued during the year, including three samples evaluated for parallel testing and reported to CDSCO

alongside CDL, Kasauli. Of these, 101 samples (5.03%) were declared "Not of Standard Quality" (NSQ), underscoring the Institute's proactive role in identifying substandard products and its unwavering commitment to public health and regulatory excellence in line with the national goal of a "Healthy India."

In the last decade, the capacity of NIB to test different types of biologicals has increased substantially from 141 in year 2013-14 to 312 in year 2024-25. The institute has enhanced its capacity to test newer biologicals and is sharing its domain expertise with other countries for strengthening the quality of biologicals in other parts of the world

NIB has successfully completed the desktop surveillance audit in accordance with ISO/IEC 17025:2017 in the discipline of Chemical and Biological testing.

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

The Scientists have also been invited for sharing their knowledge through expert committee meetings of BIRAC Start Ups, CCSEA, BIS technical committee etc. and as invited speaker for Haemovigilance Programme of India. The nomination of NIB scientists as faculties for international conferences, meetings and workshops have

reinforced the global presence of the institute & its role in strengthening the regulations, testing and manufacturing of biologicals

The institute is the nodal organization in development & also the sole repository for National Reference Standards for Human Insulin, Insulin Lispro and Performance Panels for HIV, HBsAg, HCV and Syphilis. The collaboration with WHO Collaborating centers like NIBSC for development of International Reference standards for Biotherapeutics specifically Monoclonal antibodies and plasma derived has reiterated the international stature of the institute in the field of quality control of biologicals.

The first quarter of the FY 2024, is highlighted with the participation of scientists in WHO SEAR Regional Hybrid workshop on improving access and building capacity on the optimal use of reference standards held on 14-15.05.2024, and subsequent by the new initiatives of the institute for improving the access to Biological Reference Standards. The one-day interactive program organized by NIB involving WHO, CDSCO, IPC, industry/academia as well as experts in this field has paved way to flag certain important factors affecting Development of Biological Standards. We acknowledge and appreciate all the participants of the meet for their active participation and valuable inputs for strengthening such activities of the Institute.

The institute has also contributed in developing as well as upgradation of Indian Pharmacopoeia monographs in the field of Biologicals.

NIB actively participated in the CDSCO-NABL-ICMR Joint Program for *in-vitro* Diagnostic Testing Laboratories held at

ICMR Headquarters, New Delhi on 28.05.2024, and at ICMR-NIE, Chennai on 07.06.2024, contributing to discussions on quality and regulatory frameworks for IVDs. NIB also showcased its institutional capabilities and quality assurance initiatives at the 19th International Conference of Drug Regulatory Authorities (ICDRA), held from 14-15.10.2024 at Yashobhoomi Convention and Expo Centre, New Delhi, through an exhibition stall. This year has also been notable for awards and recognitions, with the National Institute of Biologicals receiving the Best Stall Award at “Rise in Jammu & Kashmir 2024,” in recognition of its impactful display and outreach efforts highlighting the Institute’s role in ensuring the quality and safety of biological products. Additionally, in recognition of its efforts toward official language promotion, NIB received accolades when a staff member secured the first prize in a poetry competition organized by the Nagar Rajbhasha Karyanvayan Samiti, Rajbhasha Vibhag, Ministry of Home Affairs, Government of India.

Continuing its advancement in research and academic pursuits, the institute adopted a multi-pronged strategy to strengthen scientific capabilities. Under the Ph.D. programme in collaboration with AcSIR, 18 scholars are currently enrolled, conducting research under the mentorship of senior scientists. The launch of the first batch of Post-Doctoral Fellows marked another milestone, with two researchers focusing on quality control and emerging biologicals. A total of 22 intramural research projects are being led by scientists, addressing key areas such as biological standardization, development of reference materials, assay validation, and alternative testing methodologies. These initiatives reaffirm the institute’s commitment to

scientific excellence, regulatory innovation, and public health advancement.

Under the Haemovigilance Programme of India (HvPI), NIB has made significant strides in strengthening blood safety surveillance and awareness. A total of 201 new blood centres were enrolled, expanding the network to 1,649 centres, with continued use of indigenously developed Haemo-Vigil and Donor-Vigil software for adverse transfusion event reporting. Notably, NIB organized and participated in multiple national and international training events, including the National Workshop on Haemovigilance and Donor Vigilance at NIB, BLODCON-2024, and TRANSCON-2024 in Ahmedabad. The programme marked its international presence at the International Haemovigilance Symposium in Athens, Greece. World Blood Donor Day was celebrated with a campus walk and public engagement at NIB. A landmark article highlighting a decade of HvPI's progress was published in *Vox Sanguinis*, an international peer-reviewed journal. Through consistent outreach, Continuous Medical Education and global engagement, HvPI continues to reinforce its position as a pivotal initiative for transfusion safety in India.

NIB continued its pivotal role in capacity building and technical skill enhancement in the domain of quality control of biologicals. Through its institutional initiatives, NIB conducted two-week residential National Skill Development Training (NSDT) programs for 162 postgraduate students from universities across tribal and remote regions of India. Additionally, the Institute organized structured laboratory-based courses for 39 participants, covering advanced topics such as cell culture

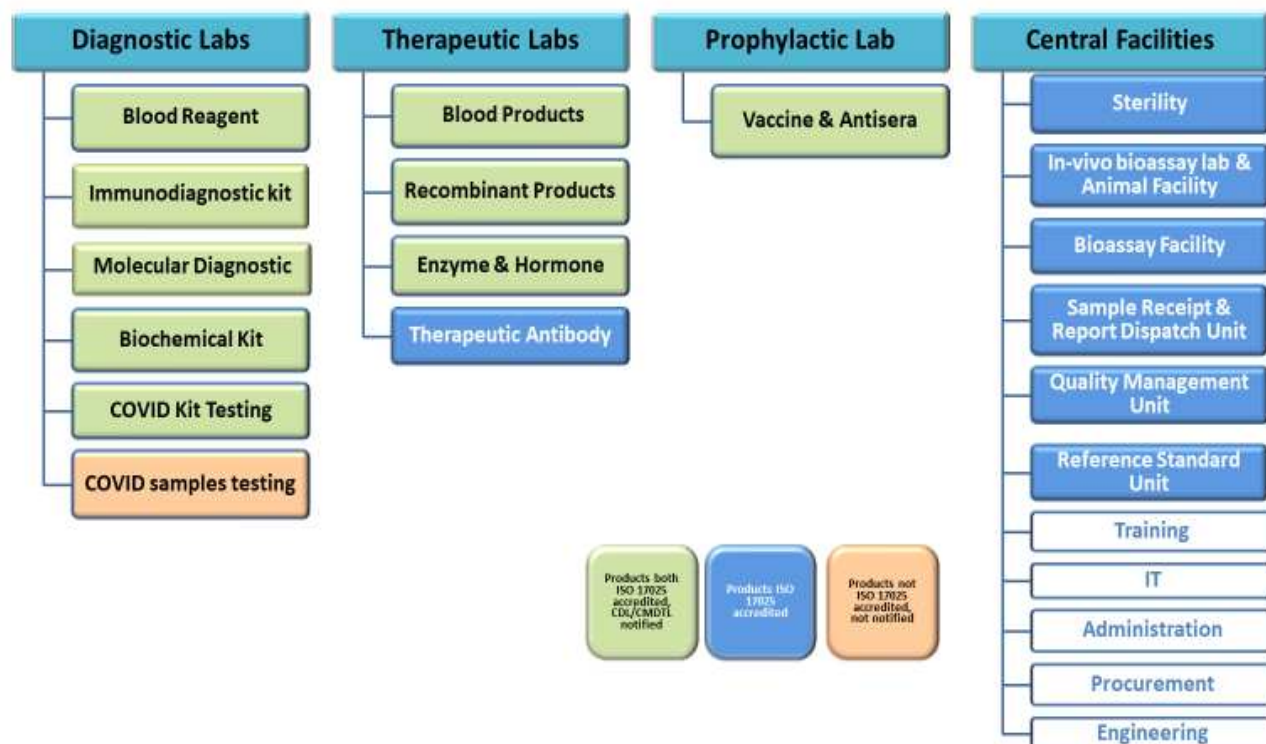
techniques, RT-PCR, HPLC, animal handling ethics, and ISO 17025:2017 quality standards. More than 40 graduate and postgraduate students also benefited from hands-on summer and project training programs in various NIB laboratories. The institute also organized in-house expert-led seminars for its scientific, administrative staff on subjects including IPR, GLP

diagnostics, laboratory data integrity and in other functional and behavioral aspects.

The Institute has been recognized as one of the top-performing institutions during the Karmayogi Saptah – National Learning Week by the Ministry of Health and Family Welfare, with over 81% of staff completing learning targets on the IGOT platform. Furthermore, academic visits were facilitated for students from premier institutions, further cementing NIB's leadership in developing a skilled and informed workforce for the biological sector.

With the unwavering support and guidance from Ministry of Health & Family Welfare, Government of India, Central Drugs standards and Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC) and Indian Council of medical Research (ICMR), we plan to move forward with a strong commitment for quality of Biologicals, public health and academic excellence.

OVERVIEW OF QUALITY CONTROL TESTING AT NIB



April 2024 to March 2025

S. No.	Category	Types of Biologicals
1	Blood Grouping Reagents	98
2	Immunodiagnostic & Molecular Diagnostic Kits	64
3	Biochemical Kits	3
4	Blood Products	26
5	Recombinant Products	36
6	Therapeutic Monoclonal Antibodies	36
7	Enzymes & Hormones	21
8	Vaccines	16
9	COVID-19 Kit Testing Laboratory	8
Total		308

Samples Received

The institute received a total of 2120 samples for testing purposes under various product categories (including Government samples, Survey samples, Service samples, and samples for Standardization). Of this total, 246 samples were specifically received from different State Medical Procurement Agencies. (Refer to Fig. 1 for detailed product category distribution).

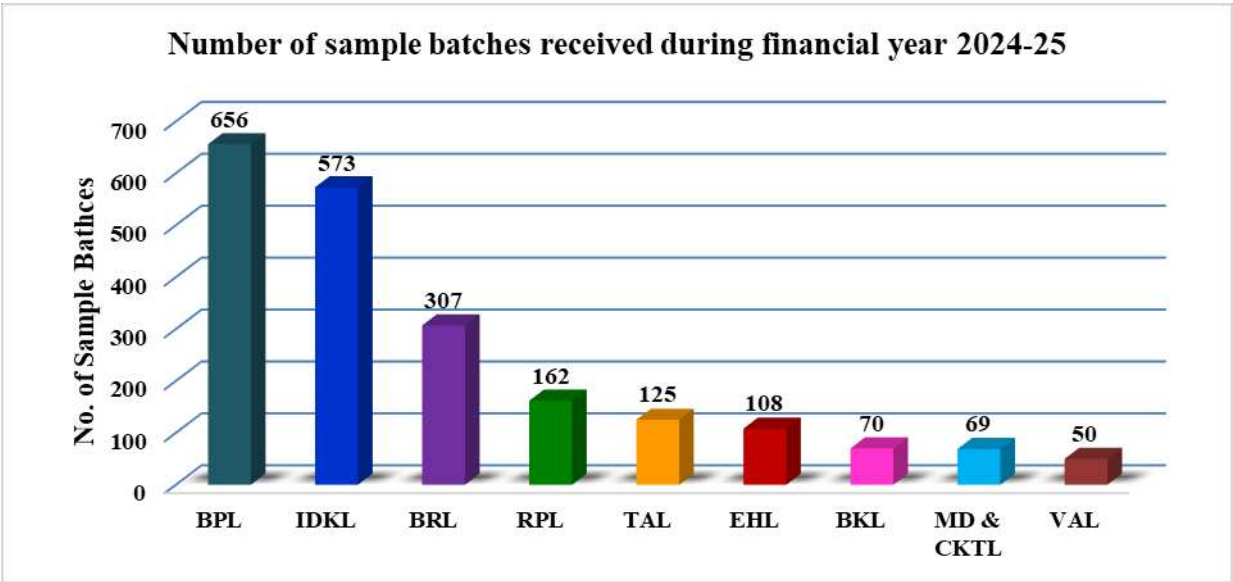


Fig. 1: Total number of samples received at NIB and their distribution in various categories/ laboratories (BPL, Blood Products Laboratory; IDKL, Immunodiagnostic Kit Laboratory; BRL, Blood Reagent Laboratory; RPL, Recombinant Products Laboratory; TAL, Therapeutic Antibodies Laboratory; MD & CKTL, Molecular Diagnostics & COVID-19 Kit Testing Laboratory; EHL, Enzymes and Hormones Laboratory; BKL, Biochemical Kit Laboratory; VAL, Vaccine and Antisera Laboratory).

Release of Test Reports

A total of 2007 test reports were released (Refer to Fig. 2). This includes 3 samples reported to CDSCO for parallel testing in addition to CDL, Kasauli. Of the total reports released, 101 samples (5.03%) were found to be "Not of Standard Quality" (NSQ) (Refer to Fig. 3). This represents an increase from the previous year's 4.12% (2023-24). The reporting of "Not of Standard Quality" samples depicts the Institute's unwavering dedication to protecting and promoting public health, directly supporting the government's aim of a "Healthy India."

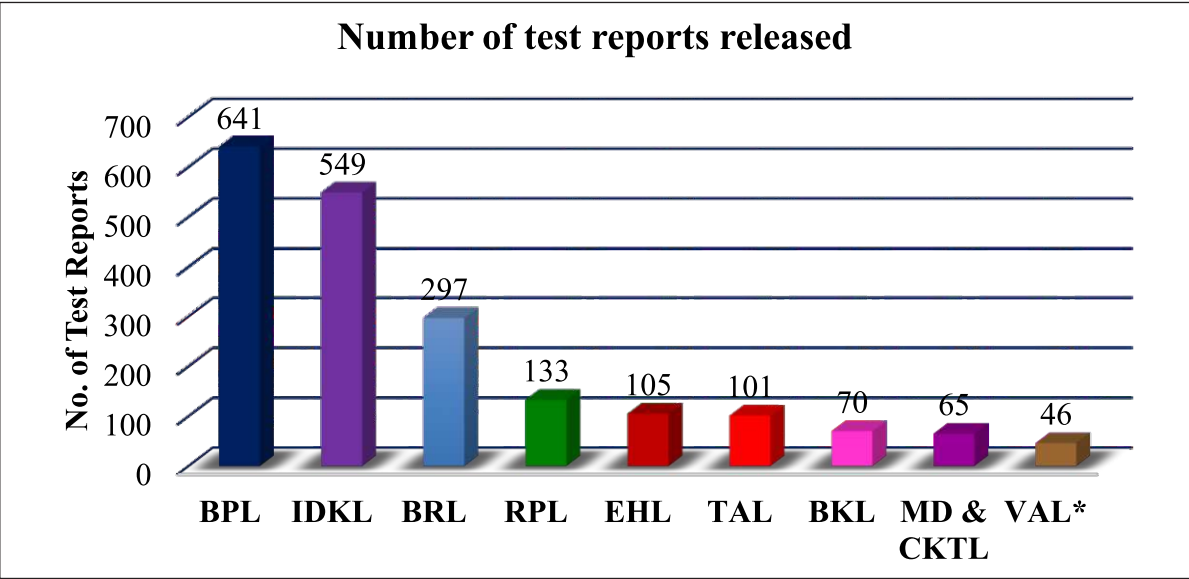


Fig. 2: Lab-wise distribution of the reports released from NIB (BPL, Blood Products Laboratory; IDKL, Immunodiagnostic Kit Laboratory; BRL, Blood Reagent Laboratory; RPL, Recombinant Products Laboratory; TAL, Therapeutic Antibodies Laboratory; MD & CKTL, Molecular Diagnostics & COVID-19 Kit Testing Laboratory; EHL, Enzymes and Hormones Laboratory; BKL, Biochemical Kit Laboratory; VAL, Vaccine and Antisera Laboratory).

***VAL (including 03 samples for parallel testing in addition to CDL, Kasauli reported to CDSCO)**

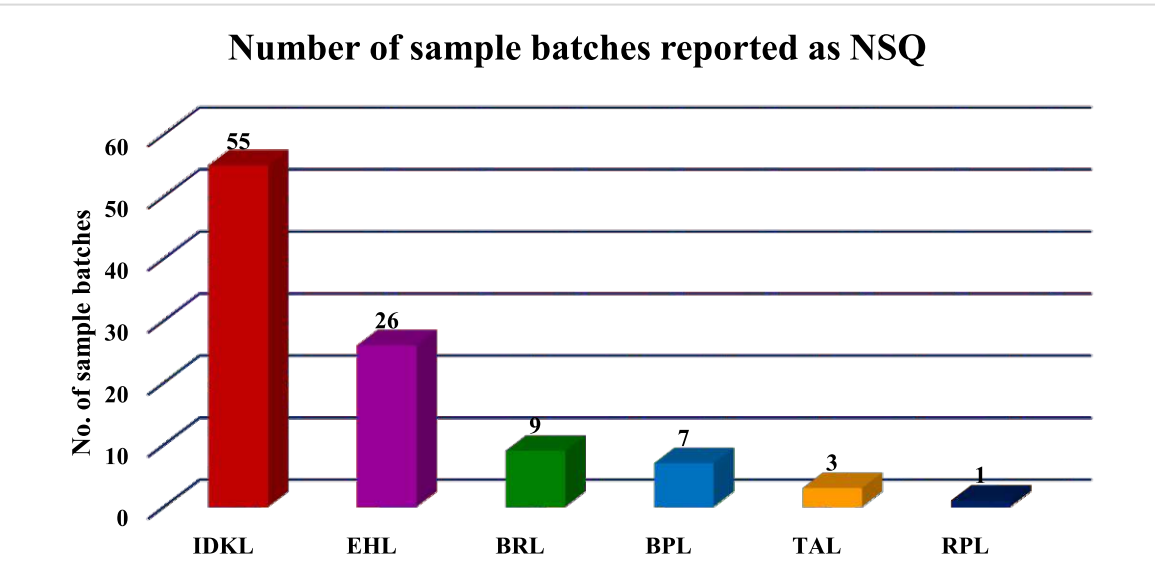
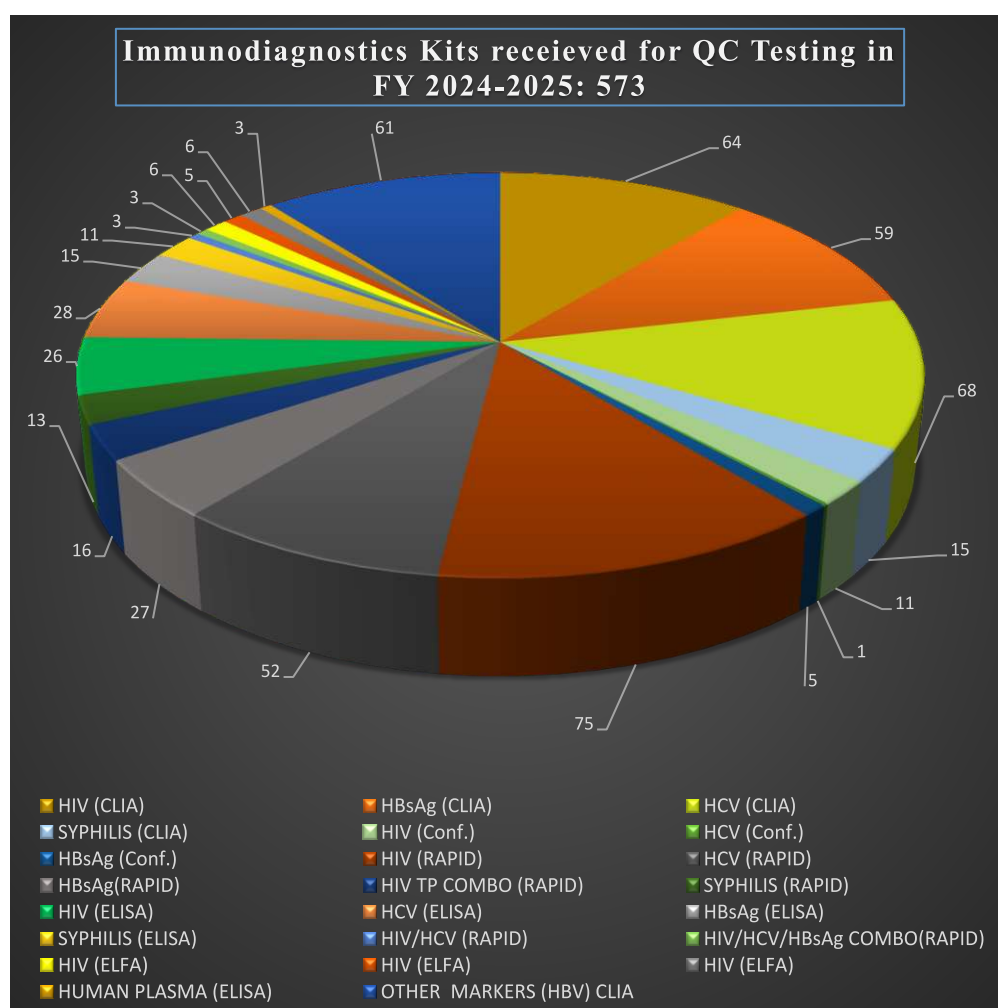


Fig. 3: Lab-wise number of NSQ reports released (IDKL, Immunodiagnostic Kit Laboratory; EHL, Enzymes and Hormones Laboratory; BRL, Blood Reagent Laboratory; BPL, Blood Products Laboratory; TAL Therapeutic Antibodies Laboratory; RPL Recombinant Products Laboratory).

NIB LABORATORIES

Immunodiagnostic Kit Laboratory (IDKL)

The National Institute of Biologicals, NOIDA is notified Central Medical Device Testing Laboratory (CMDTL) by Government of India vide Gazette No. S.O. 2237 (E), dated 01st June, 2018 for *in-vitro* diagnostics for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C virus. Immunodiagnostic Kit Laboratory has been conducting Quality Control testing of 57 types of indigenously manufactured and imported kits viz. Rapid, ELISA, Confirmatory, CLIA & ELFA Kits for HIV, HCV, HBsAg & syphilis intended to be used for blood donor screening for Human Immunodeficiency virus (HIV), Hepatitis-B virus and Hepatitis-C virus. These kits are forwarded by Central Drugs Standard Control Organization (CDSCO) and its offices, procurement division of NACO and different Government agencies. It regularly supplies plasma panels of HIV-Ab, HCV-Ab, HBsAg and Syphilis to indigenous manufacturers for strengthening the quality of indigenously manufactured kits.

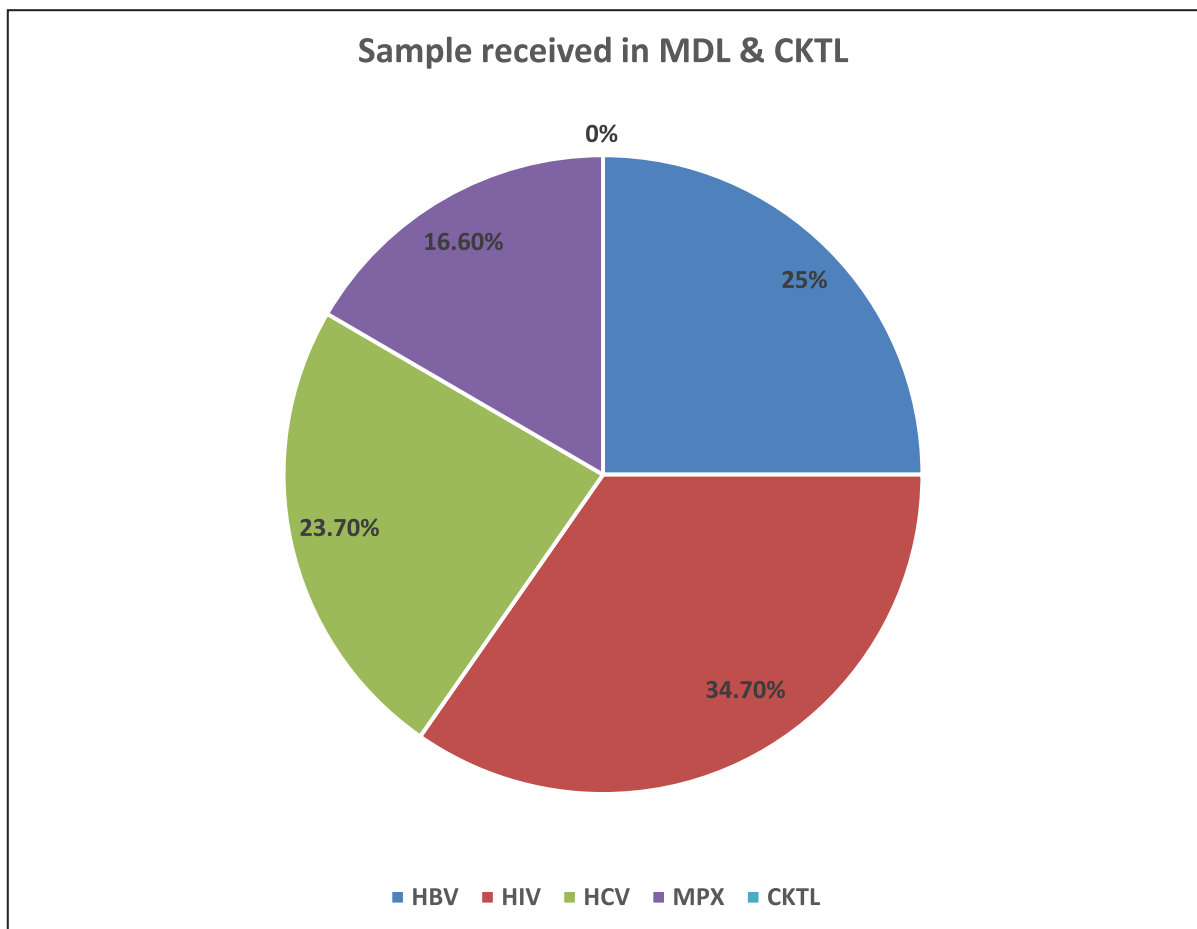


Molecular Diagnostics Laboratory (MDL)

MDL has been conducting Quality Control testing of indigenously manufactured and imported molecular diagnostic test kits intended to be used for blood donor screening and viral load monitoring of Human Immunodeficiency Virus (HIV), Hepatitis-B Virus (HBV) and Hepatitis-C Virus (HCV).

COVID-19 Kit Testing Laboratory (CKTL)

Institute is one of the 24 centers in the country identified in the ICMR-DCGI guidelines for validation and batch testing of COVID-19 Diagnostic Kits dated 04.06.2020 at ICMR’s website. In view of this NIB established a COVID-19 Kit Testing Laboratory (CKTL) for QC evaluation of SARS CoV-2 diagnostic kits to promote and safeguard public health in 2020. The laboratory is responsible for QC evaluation of RT-PCR Kits, COVID-19 RT-LAMP (Loop-mediated isothermal amplification) Kits, Viral RNA Extraction Kits, VTM (Viral Transport Medium) & Swabs directed from ICMR’s online portal. The performance of these kits is satisfactory or non-satisfactory based on the sensitivity and specificity as defined by ICMR.

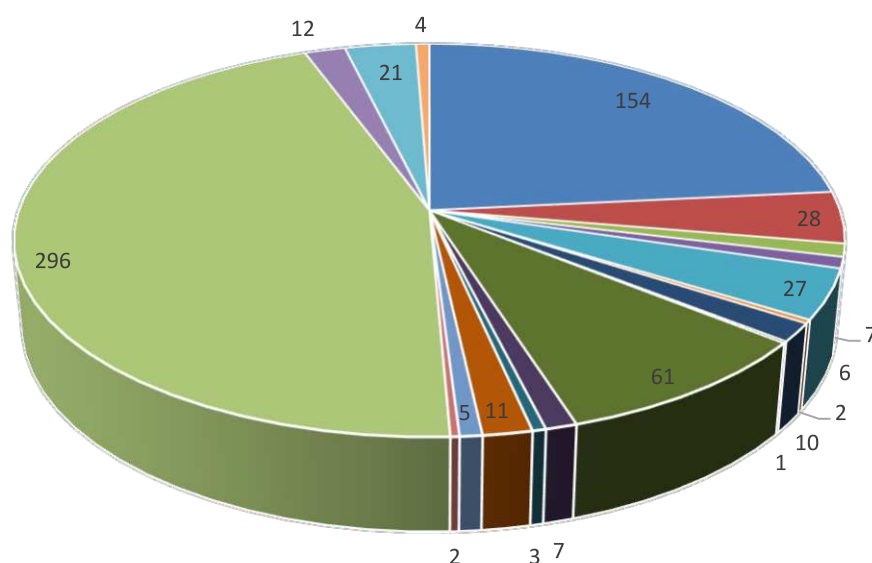


Blood Products Laboratory (BPL)

BPL was set up with the aim assuring the quality of plasma derived products marketed in India. Since these biological therapeutics are inherently complex and variable, vigilant monitoring is required to ensure the quality as well as safety of such products. Presently, Blood Products Laboratory is testing twenty-seven different blood products as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or international norms. Blood Products Laboratory has established complete testing of a new product Human Coagulation Factor-X as per manufacturer’s protocol during this period.

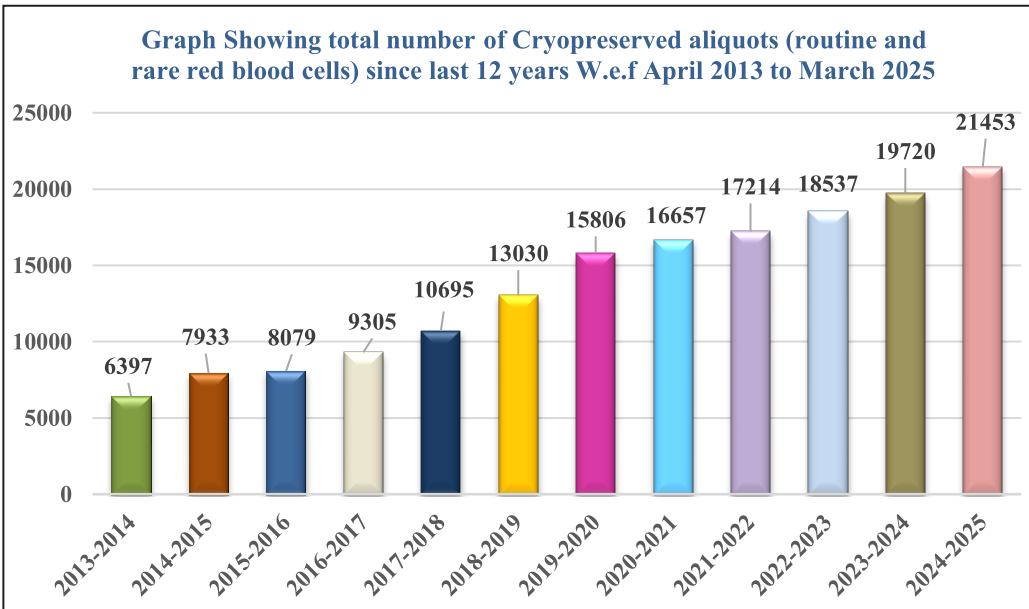
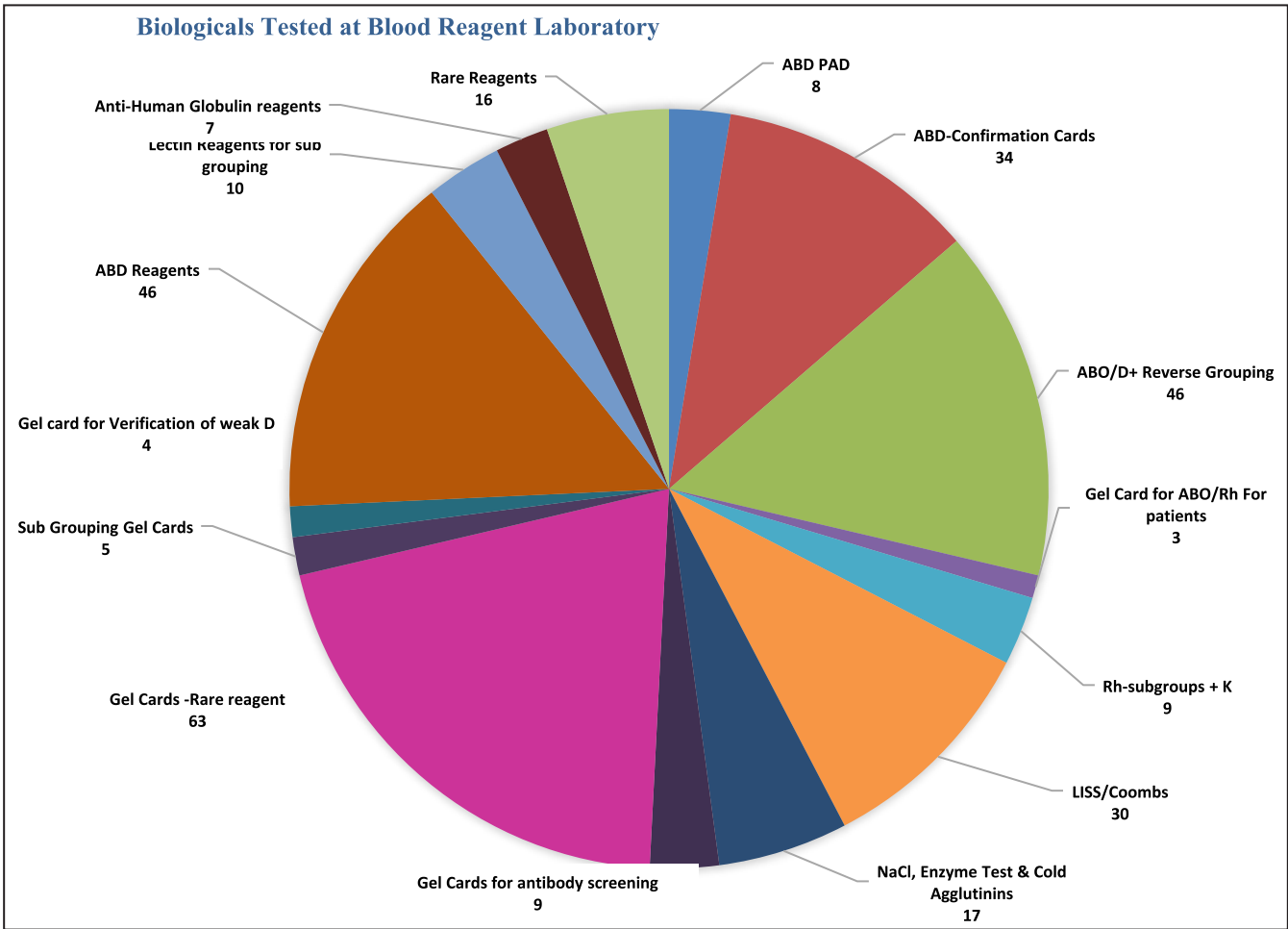
Biologicals Tested at Blood Products Laboratory

- Human Coagulation Factor - VIII
- Recombinant Human Coagulation Factor - VIII rDNA
- Recombinant Human Coagulation Factor - VIII rDNA, Glycopegylated
- Recombinant Human Coagulation Factor - VIII rDNA, Glycopegylated
- Human Coagulation Factor IX
- Recombinant Human Coagulation Factor - IX rDNA
- Recombinant Human Coagulation Factor - IX rDNA Pegylated
- Human Coagulation Factor X (Coagadex)
- Human Normal Immunoglobulin (IV)
- Tetanus Immunoglobulin (IM)
- Human Normal Immunoglobulin (IM)
- Rabies Immunoglobulin
- Hepatitis B Immunoglobulin (IM)
- Hepatitis B Immunoglobulin (SC)
- Human Albumin
- Anti-Inhibitor Coagulant complex (Feiba)
- Fibrin Sealant



Blood Reagent Laboratory (BRL)

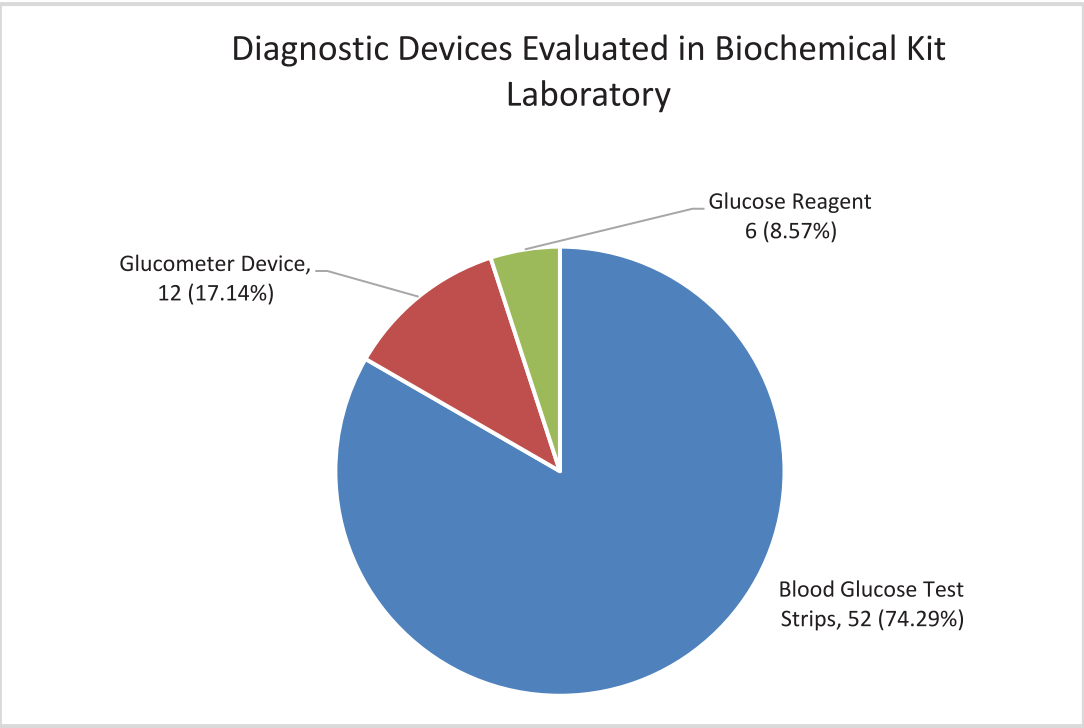
BRL carries out quality control evaluation of Blood Grouping Reagents. The laboratory has the infrastructure and expertise for testing 98 different types of Blood Grouping Reagents and Gel cards for safe blood transfusion. DCG (I) has directed to various blood banks/ hospitals to provide non-infective and non-clotted left-over blood samples from blood banks for carrying out quality control of Blood Grouping reagents, Gel Cards and Microplates. The laboratory maintains and strengthens the repository for cryopreserved panel cells for routine and rare red blood cells from the left-over samples collected from various blood banks. The laboratory has taken up Anti-Jk^b reagent for NABL scope in 2024. Further, the laboratory has taken up the standardization for IgA, IgM and IgG sensitized cells.



Biochemical Kit Laboratory (BKL)

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

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



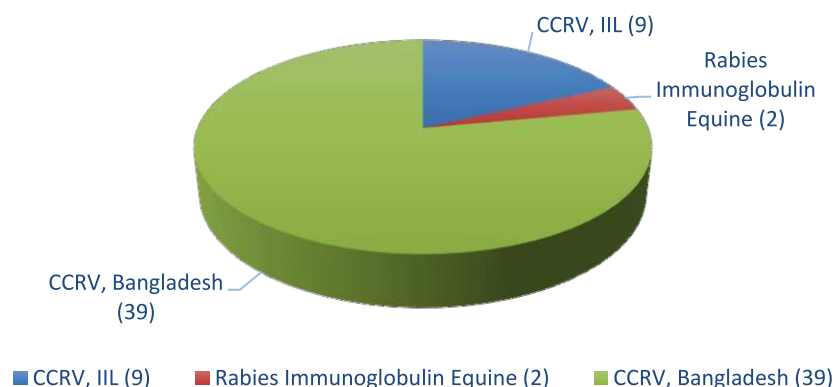
Vaccine & Antisera Laboratory (VAL)

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

A series of meetings and an audit by CDSCO officials was carried over to verify and ensure the preparedness for Quality control testing of Oral Polio vaccine and Rabies Vaccine at NIB. The facility in total was appreciated. Further in meetings it was decided that (a) a percentage of the Rabies vaccines manufactured indigenously (received for lab testing by CDL, Kasauli for domestic market) will be sent for testing at NIB, Noida, (b) and that NIB, Noida will initiate the procedures of qualification & validation for the testing of the newer vaccines Haemophilus influenzae type b vaccine and Meningococcal vaccine.

In March 2025, NIB and CDSCO officials discussed the preparedness of testing of various vaccines at NIB i.e. Measles vaccine, Measles & Rubella vaccine (MR), Oral Polio vaccine (OPV) and BCG vaccine. Further, CDSCO also advised NIB to have a meeting with the CDL Kasauli to finalize the testing of various vaccine and come up with number of batches along with the timeline to take up the testing of above-mentioned vaccines. So far, Vaccine and Antisera lab has tested and released 09 batches of CCRV vaccine manufactured indigenously. Lab has also tested and released 39 batches of CCRV vaccine & 02 batches of Rabies Immunoglobulin (Equine) received from Bangladesh. NIB has also received the pentavalent (Vaxtar-5 DTPHH) & Tetravalent (Easyfour DTPHib) Hib vaccine for standardization of Hib component using High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection (HPAEC-PAD).

Total no. of vaccine batches received at VAL



Recombinant Product Laboratory (RPL)

RPL is involved in the Quality Control testing of batches of Insulin, Insulin analogues, Growth factors, Cytokines, Erythropoiesis stimulating agents (Darbepoietin and Erythropoietin), Osteoporotic agent (Teriparatide), peptides, Glucagon like peptides -1 agonist (GLP-1 agonist), and anti-obesity oral tablets and injections.

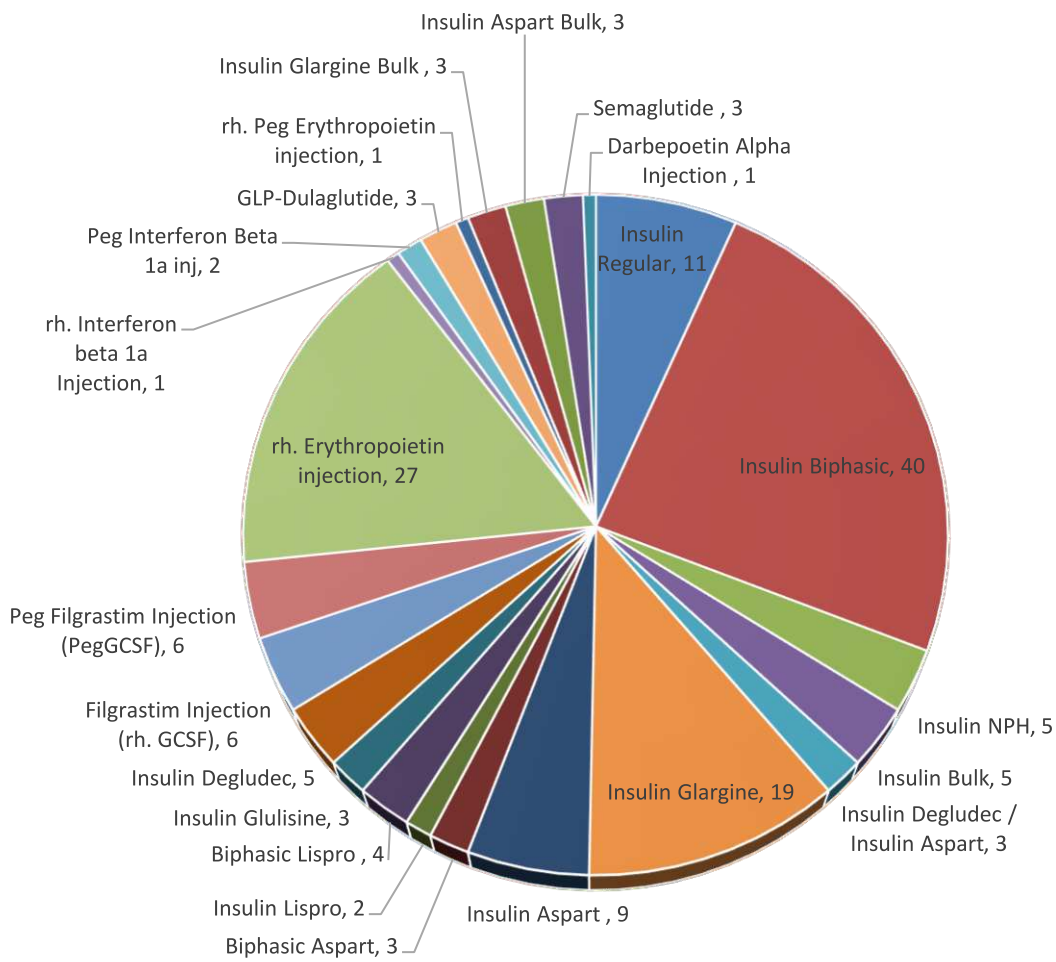
Over the years laboratory has expanded its scientific activities utilizing the infrastructure and scientific expertise of the laboratory, complying with the standards of ISO and NABL in assuring the quality of test results and measurement of traceability. Laboratory is testing about 36 types of Recombinant Products. Laboratory has developed two National Reference Standards for Human Insulin and Insulin Lispro which are being purchased by various indigenous stakeholders and pharmacopoeial bodies on a routine basis. These National Reference Standards have been developed through inter collaborative study involving manufacturers and regulatory bodies. Laboratory has also contributed towards 23 no. of Monographs development in Indian Pharmacopoeia and routinely verifies the upcoming monographs or any amendments proposed by Indian Pharmacopoeia Commission (IPC).

Laboratory also imparts structured training on analytical techniques like HPLC to students from academia and industry. Post graduate students also undergo dissertation programme in the area of biotherapeutics. RPL has been providing handholding to indigenous manufacturers for upcoming techniques and any troubleshooting during testing.

Laboratory actively participates in Proficiency Testing programmes with various National and International organizations.

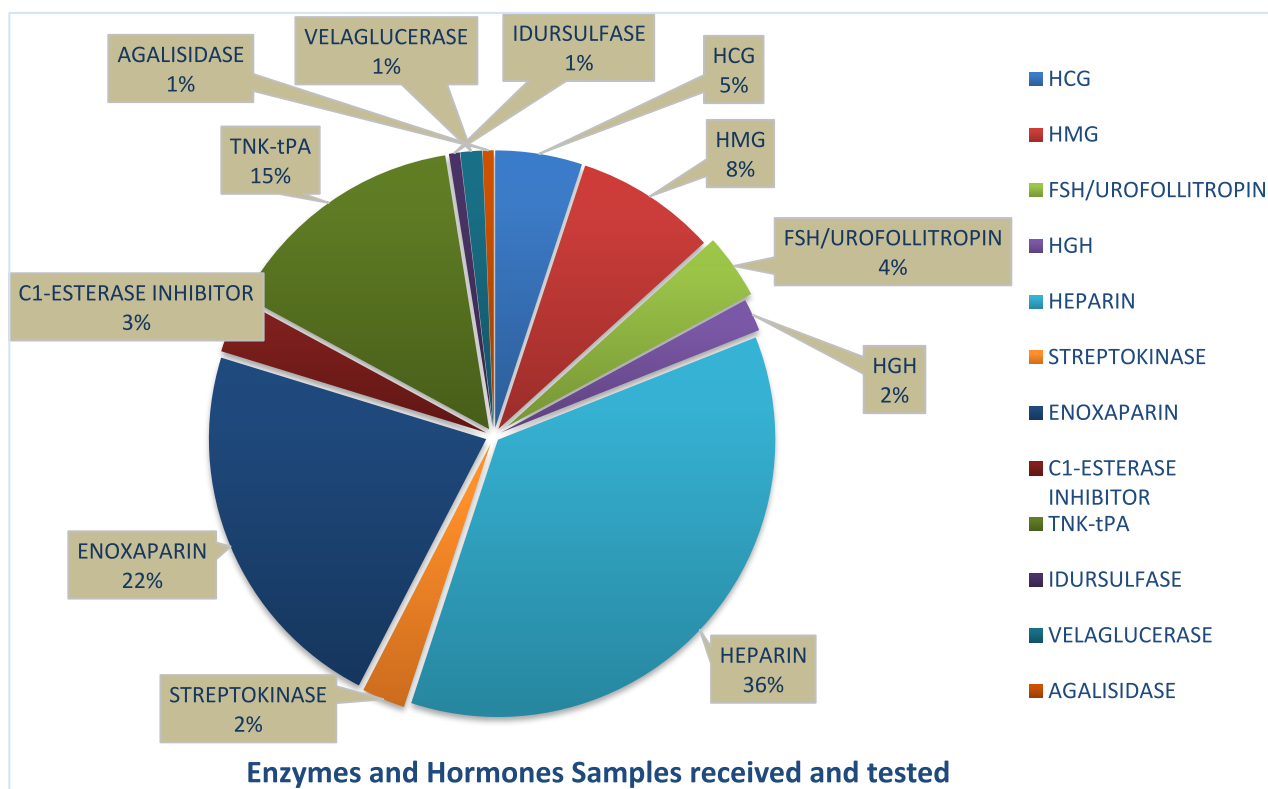
Laboratory is also carrying out Inter-laboratory testing for various QC test Parameters such as Osmolality, Bacterial Endotoxin Test by Kinetic Chromogenic assay (KCA) and HPLC based tests so as to facilitate release of Certificate of Analysis.

Number and Types of samples received in RPL



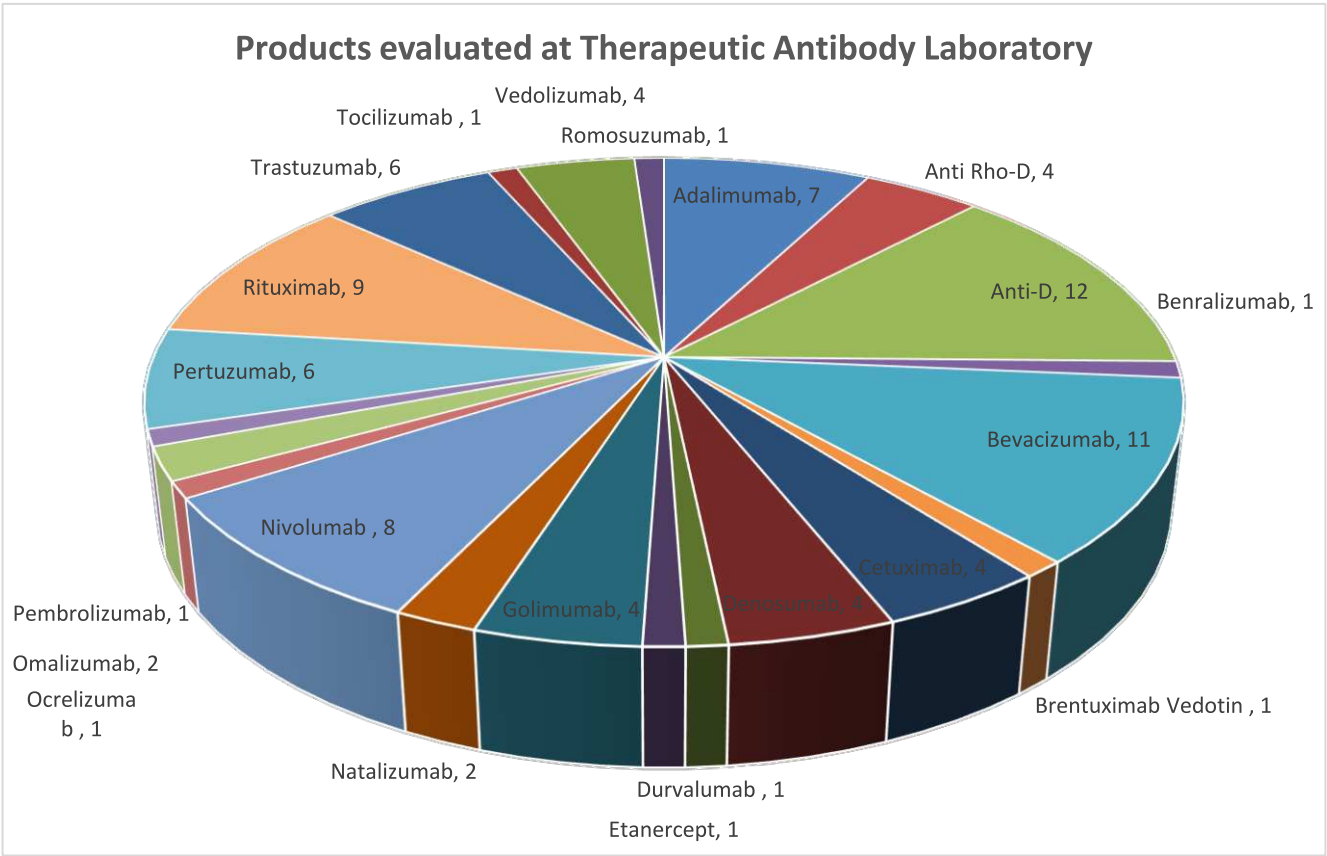
Enzymes & Hormones Laboratory (EHL)

EHL has been set up for Quality Control testing of various biotherapeutic enzymes and hormones for their identity, potency, safety and other tests as applicable to the product. The laboratory also functions towards the development of monograph for incorporation in Indian Pharmacopoeia, monograph test method verification, test method standardizations for new biologicals such as rare disease therapeutics. The laboratory participates in Proficiency Testing (PT), Inter-Laboratory Collaborative (ILC) Studies with national and international organizations.



Therapeutic Antibodies laboratory (TAL)

TAL is the first apex laboratory for QC testing of Therapeutic Monoclonal Antibodies in India. TAL currently has a testing capability of 36 different Therapeutic Antibody molecules and Antibody-Drug conjugates. Laboratory is also actively involved in Monograph verification along with Indian Pharmacopoeia Commission (IPC) for Therapeutic Monoclonal Antibodies, Proficiency Testing studies and is also imparting training to Master’s students for their dissertation projects. In addition, Laboratory is also now receiving Under-the-act samples of Therapeutic Antibody molecules from various parts of India for quality evaluation.



CENTRAL FACILITIES

***In-vivo* Bioassay Laboratory & Animal Facility (IVBL & AF)** is a central support unit for all laboratories of the Institute. The laboratory is engaged in performing *in-vivo* tests (i.e., Abnormal Toxicity Test, Pyrogen Test, Identity & Potency Assays and other miscellaneous tests) as per Indian or other Pharmacopoeia for quality control evaluation of biologicals received in the institute. The laboratory also ensures timely availability of small laboratory animals viz. Mice (Swiss Mice, BALB/c Mice); Rats (Sprague Dawley Rats, Wistar Rats); Guinea pigs and Rabbits of specific age, sex and weight for various *in-vivo* tests by a planned breeding program and the staff of the laboratory ensures high quality animal husbandry and care that meets the requirements of animal welfare regulations and guidelines provided by the Committee for Control and Supervision of Experiments on Animals (CCSEA). The laboratory also provides good quality laboratory animals to educational and research institutes and industries in Delhi-NCR and neighboring states and generates additional revenue for the Institute. Besides using small laboratory animals for performing QC tests on different biologicals, they are also used for research purposes. All the test protocols for use of animals in QC testing and research are approved by the Institutional Animal Ethics Committee (IAEC) of NIB.

In-vivo Bioassay Laboratory & Animal Facility has performed *in-vivo* QC evaluation tests on a total of 1273 samples of different biologicals forwarded by the laboratories of NIB. A total of 508 samples were tested for Abnormal Toxicity, 613 samples for Pyrogen, 114 samples for Identity and Potency Assay, 38 samples for miscellaneous tests. A total of 13,622 animals were provided during the year 2024-25 by the Animal Facility, of which 10,782 animals were used to conduct the *in-vivo* QC tests, 6 were used for research and 2834 were sold to other institutes, details of which are provided in figures 1, 2 & 3. A revenue of Rs. 3,33,20,690/- was generated in the year 2024-25 by *In Vivo* Bioassay Laboratory & Animal Facility through QC testing and sale of laboratory animals to outside institutes.

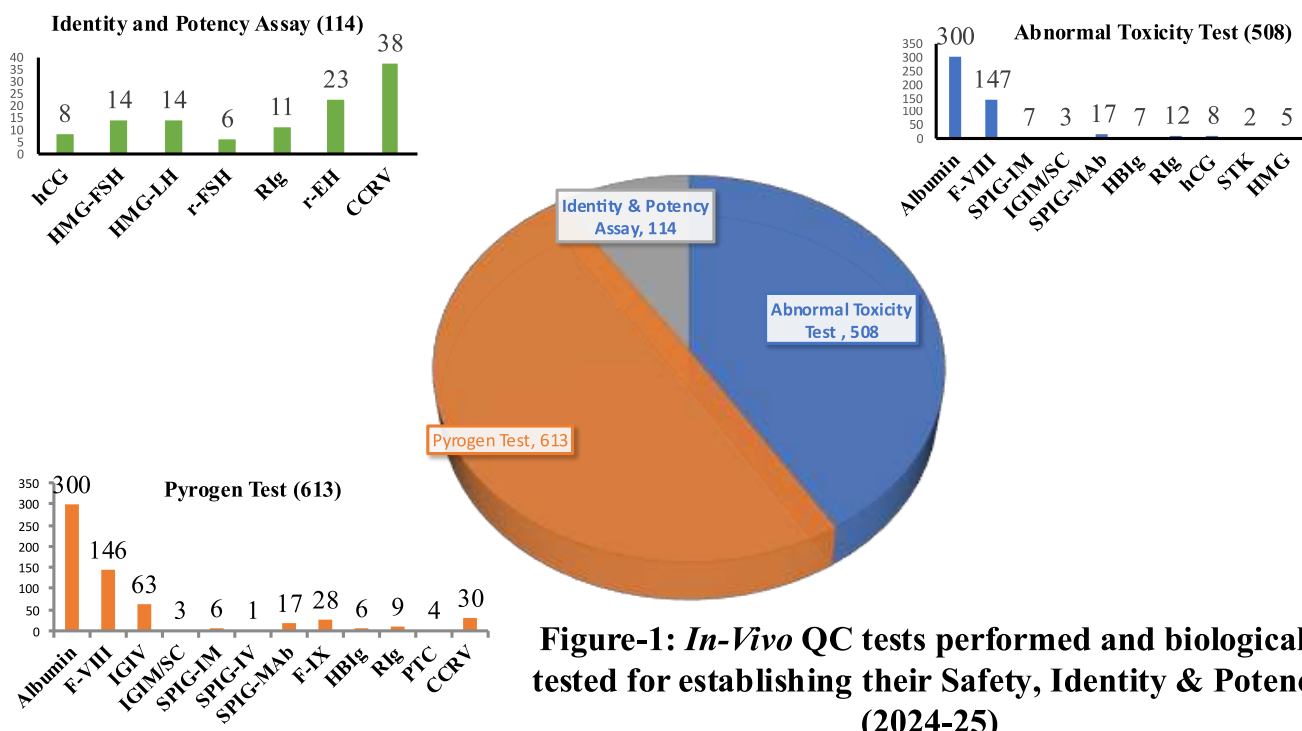


Figure-1: *In-Vivo* QC tests performed and biologicals tested for establishing their Safety, Identity & Potency (2024-25)

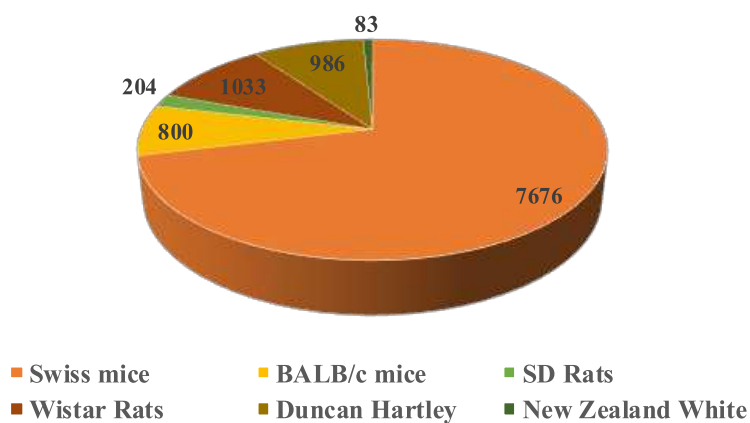


Figure-2: Animals used in QC testing (2024-25)

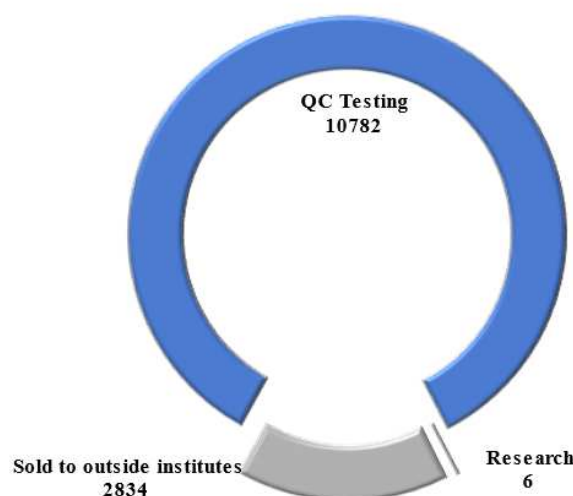


Figure -3: Animals used in QC, Research & Sold outside (2024 -25)

As a commitment to the 3R's, the scientists of the *In Vivo* Bioassay Laboratory & Animal Facility and laboratories worked in close coordination to reduce the number of animals used in the quality control testing by testing more than one batch of the same product at the same time with a common reference or control group. This enabled us to save 2729 laboratory animals in the year 2024-25, the details of which are provided below:

S. No.	Details of QC Test	Number of Animals Saved
1.	Potency Assay for r-FSH & Urofollitropin, hCG, hMG-LH, hMG-FSH	207 rats
2.	NIH Potency assay for Rabies Immunoglobulin (RIg)	500 mice
3.	Potency assay for Recombinant Erythropoietin (r-EH)	350 mice
4.	Potency assay for Cell Culture Rabies Vaccine (CCRV)	1672 mice
Total		2729

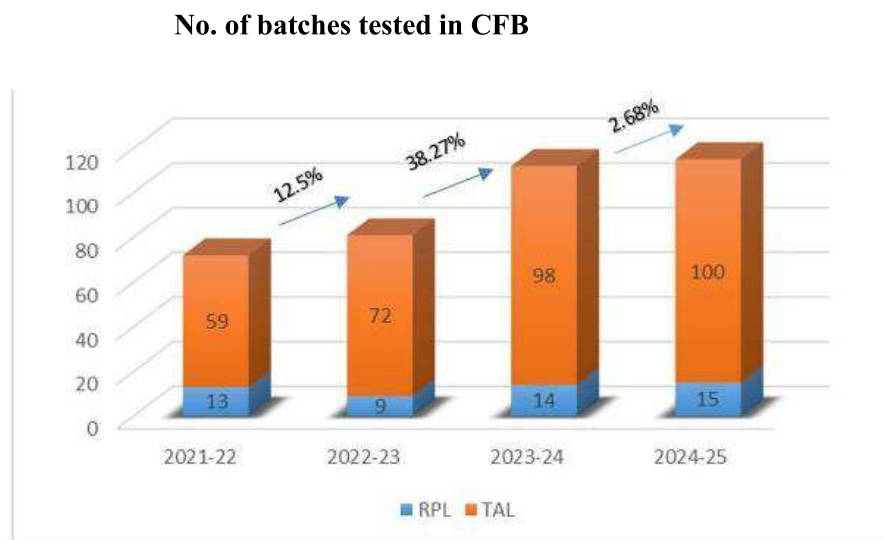
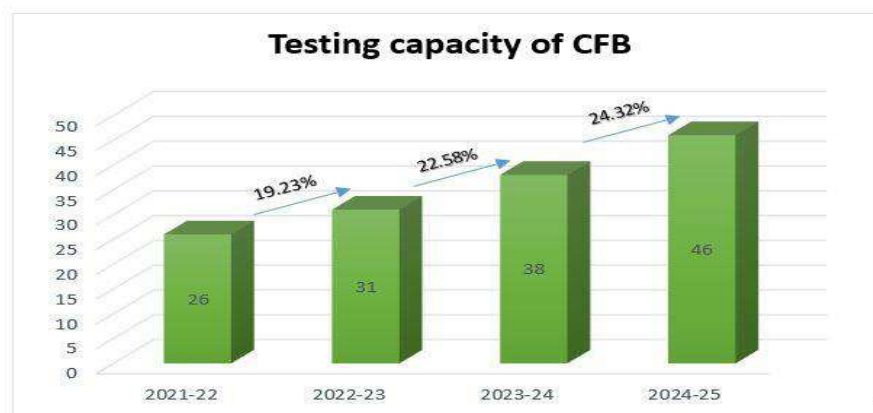
Centralized Facility for Bioassays (CFB)

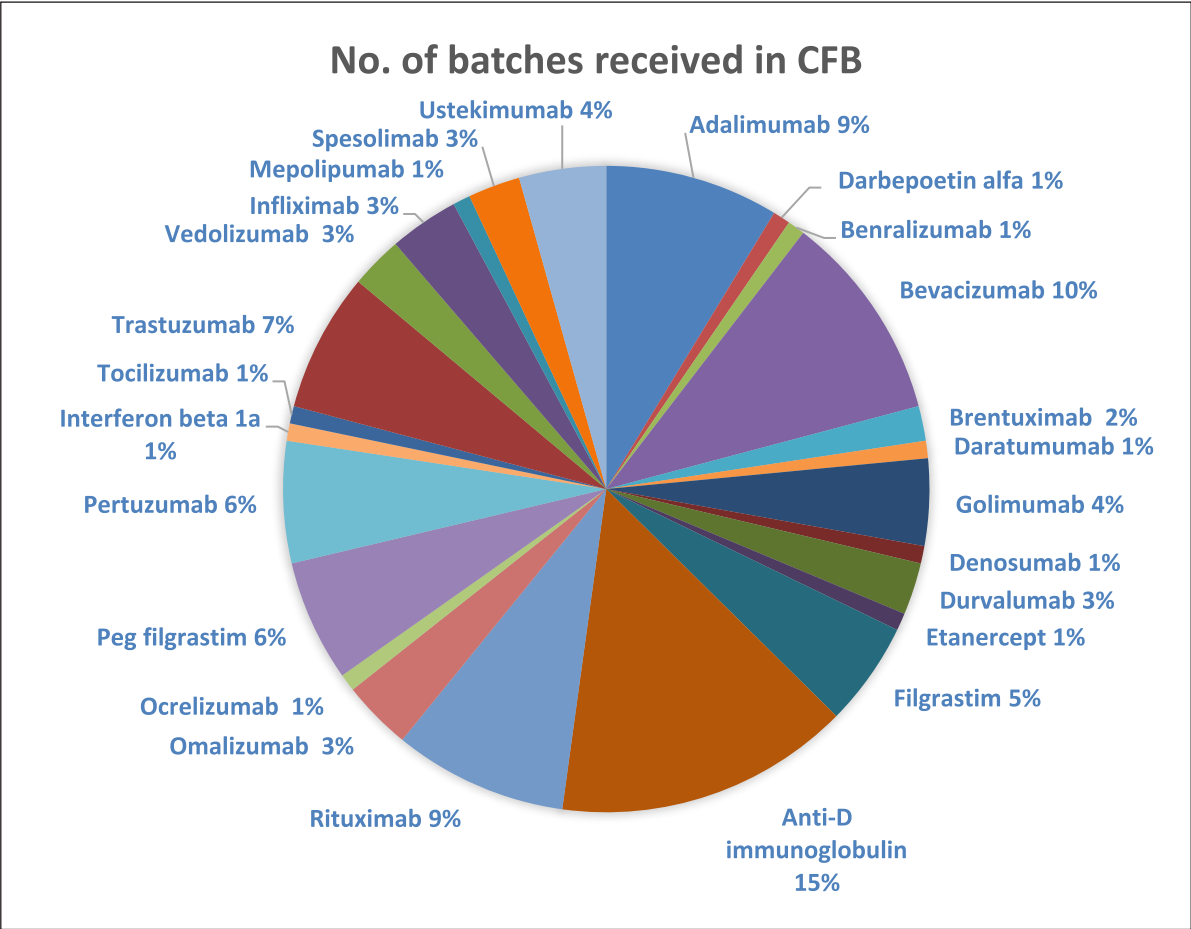
CFB is equipped to carry out cell-based bioassays, one of the critical quality attributes of biotherapeutics quality evaluation. The laboratory currently maintains a cell repository of around 42 cell lines to carry out bioassays for different biotherapeutics. CFB contributed to developing the Monograph for Indian Pharmacopoeia: Rituximab DS and Rituximab DP in IP2022. Additionally, the monograph verification for Trastuzumab DS and Trastuzumab DP has been completed for the next edition of the Indian Pharmacopoeia.

CFB, which includes four biosafety modules, was established to handle cell-based bioassays as part of quality control evaluation for various recombinant products such as peg-erythropoietin, Filgrastim, Interferon, Therapeutic Antibodies, Immunoglobulin, and other therapeutic proteins referred to by various product testing laboratories at NIB. It is equipped with workstations, Class II type B2 Biosafety cabinets, Centrifuges, CO2 incubators, Refrigerators, Deep Freezers, Microscopes, and Cell counters. Cryopreservation equipment, Fluorescence-Activated Cell Sorting (FACS), 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), Antibody-dependent cell-mediated Cytotoxicity (ADCC) assays, apoptosis assays, reporter gene assays, and neutralization assays.

CFB conducts a structured training course on 'Basics of Cell Culture & Bioassays' and actively participates in various NIBSC collaborative studies for the preparation of the WHO International Standard for Bioassays, organized by NIBSC, UK. The laboratory is undertaking scientific research activities in the field of laboratory work, especially in the development of alternative in vitro bioassays for bioanalytical characterization of biologicals.





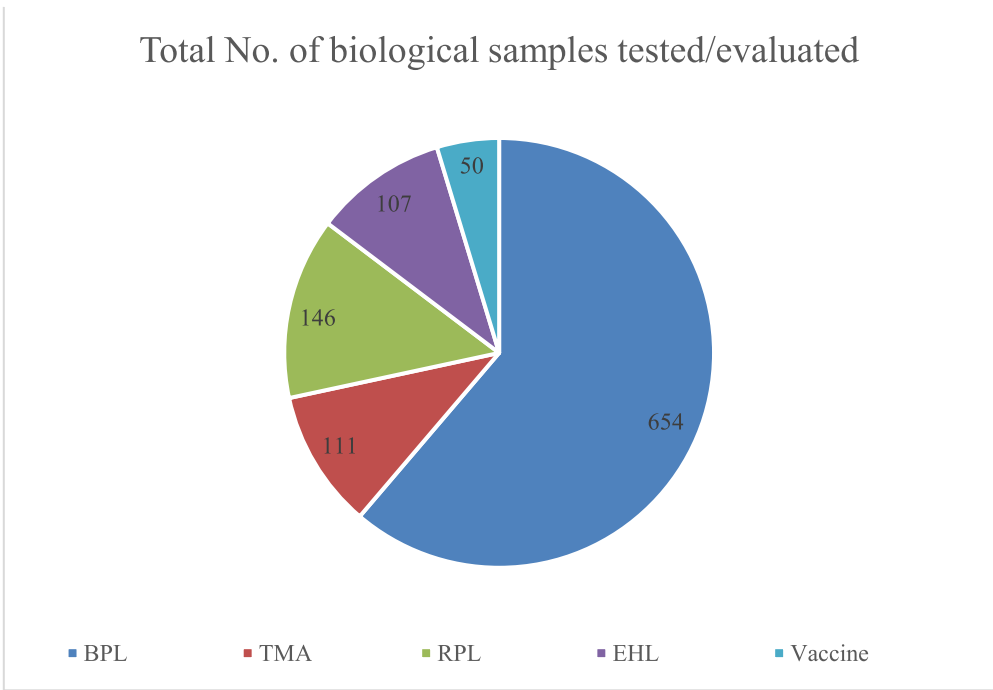
Sterility Testing Laboratory (STL)

STL is a Central Facility well equipped with required equipment viz laminar air flow cabinet in cleanroom, dedicated walk-in incubators at temperatures specified by the pharmacopoeial method for each test media, autoclaves etc. to test the various biological products referred to it for sterility testing by either of the two Sterility Testing Techniques Viz. Direct-Inoculation or Membrane Method (Closed Sterility Test Method) in accordance with the pharmacopoeial method. It also has Environmental microbiology laboratory for isolation & biochemical characterization of clean room environmental isolates and handling & maintenance of reference strains of bacterial & fungal strain

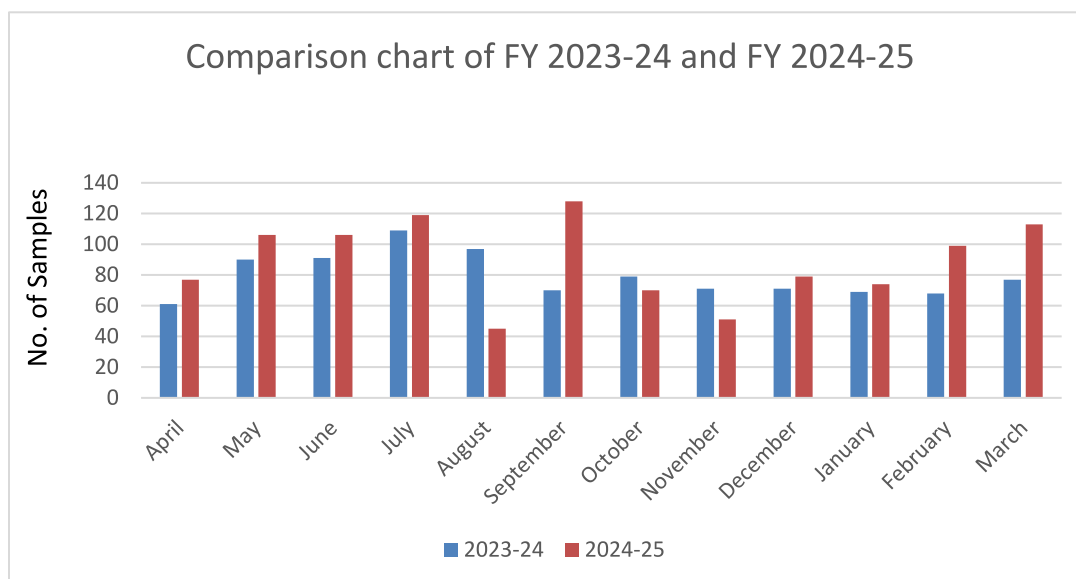
1. Total No. of biological samples tested/ evaluated: Illustrated in table given below:

Type of Biological tested	No. of batches received and evaluated	No. of batches not found to be of standard
Blood Products	654	3
Therapeutic Antibody	111	2
Recombinant Products	146	0
Enzymes & Hormones	107	5
Vaccine and antisera	50	0
Total No. of Biological Samples received	1068	10

2. Total No. of biological samples tested/evaluated: Illustrated graphically given below:



3. Total No. of biological samples tested/ evaluated in FY 2023-24 & 2024-25:



Sample Receipt and Report Dispatch Unit (SRRDU)

SRRDU has been an integral and independent functional unit of the institute since 2008. Serving as the primary interface between NIB and its stakeholders, the SRRD Unit manages the receipt of all incoming products and the dispatch of all Certificates of Analysis (CoA). The SRRD Unit's operations are meticulously managed to ensure efficiency, accuracy, and security. The unit receives biologicals, including biotherapeutics, diagnostics, and vaccines, from the National Drug Regulatory Authorities (CDSCO) and various State Government Medical Procurement Agencies. Additionally, samples are accepted from Drug Inspectors (both survey and samples forwarded under the Drugs & Cosmetics Act, 1940) and other critical stakeholders.

Sample Verification & Storage

Upon arrival, samples and their accompanying documents are physically verified. Any discrepancies are promptly communicated to the forwarding authority via email. To ensure sample integrity for future reference, requisite quantities are retained for up to three months post-expiry at their recommended storage temperatures (frozen, refrigerated, or room temperature). The unit maintains two dedicated walk-in cold rooms (2-8°C and -20°C) for optimal sample preservation. For enhanced security, the entire unit is under CCTV surveillance, and all samples and documents are securely stored under lock and key.

LIMS Entry & File Management

The unit's robust digital and physical processes include, (i) detailed entry of every received sample into both a Physical Receipt Register and our online LIMS portal, (ii) registration and verification of samples, followed by the generation of a sample acknowledgment receipt via the LIMS portal for stakeholders, with a copy secured in the batch file (iii) creation of a file/forwarding number and the seamless forwarding of samples to respective NIB laboratories for QC testing followed by CoA generation through our LIMS-based SRRD portal & (iv)

preparation of physical files for each product batch, which are then forwarded to the relevant NIB laboratory.

Reference Standard Unit (RSU)

During the reporting year, NIB made significant strides in the development of Biological reference standards. Key strategies and modalities were developed for creating National Biological Reference Standards for Rituximab, Trastuzumab, and Bevacizumab, and possibility of sourcing candidate Reference material was explored with stakeholders. A proposal for collaborative study was also initiated for the development of *in-vitro* diagnostic (IVD) Reference panels related to blood safety.

NIB has also engaged internationally by virtually participating in the WHO SEAR Regional Hybrid Workshop on 'Improving Access and Building Capacity on the Optimal Use of Reference Standards,' held in Bangkok, Thailand, from 14-15.05.2024. Additionally, NIB hosted discussions with delegates from the United States Pharmacopeia (USP) on biosimilar standards to strengthen collaboration and alignment with global best practices.

To foster stakeholder engagement and gather expert inputs, the Institute organized one-day interactive program with regulators, industry experts, standard-setting bodies, and policymakers. This program, held on 24.07.2024, identified key challenges such as candidate material availability, lyophilization infrastructure, funding requirements, and the need for capacity-building. Furthermore, the First meeting of the Expert Committee for National Biological Reference Standards was convened on 25.07.2024, focusing on NIB's ongoing initiatives and discussing the guidance document on in-house reference standard development.

Continued emphasis was placed on institutional capacity-building through participation in workshop on Inter-laboratory Comparison (ILC) organized by National Institute for Training on Testing and Standardization (NITS) and also attended the joint EDQM-USP webinar on "Overcoming obstacles in establishing pharmacopoeial reference standards: insights from case studies" held on 10.10.2024.



WHO-SEAR REGIONAL HYBRID WORKSHOP ON IMPROVING ACCESS AND BUILDING CAPACITY ON THE OPTIMAL USE OF REFERENCE STANDARDS, BANGKOK, THAILAND, 14-15.05.2024



ONE-DAY INTERACTIVE PROGRAMME ON MAKING OF BIOLOGICAL REFERENCE STANDARDS: INDIAN PERSPECTIVE HELD ON 24.07.2024



FIRST MEETING OF THE EXPERT COMMITTEE FOR BIOLOGICAL REFERENCE STANDARDS ON 25.07.2024

GOVERNMENT GAZETTE NOTIFICATIONS

CENTRAL DRUGS LABORATORY: The Institute is notified Central Drugs Laboratory vide the following details:

Notification details	Kits/ Class of drug
G.S.R 249 (E) 4 th Apr 2002	Oral Polio Vaccine, Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus
G.S.R 908 (E) 22 nd Dec 2014	Blood grouping reagents, Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis Virus, Blood products (Human Albumin, Human Normal Immunoglobulin (intramuscular and intravenous), Human Coagulation Factor VIII, Human Coagulation Factor IX, Plasma Protein Fractionation, Fibrin Sealant Kit, Anti-Inhibitor Coagulation Complex), Recombinant Products- (Recombinant Insulin and Insulin analogues, r-Erythropoietin (EPO), r-Granulocyte Colony Stimulating Factor (G-CSF)), Biochemical kits (Glucose Test Strips, Fully automated analyser-based glucose reagents
G.S.R 250 (E) 15 th Mar, 2017	Enzyme and Hormones such as- Streptokinase (Natural and Recombinant), Human Chorionic Gonadotropin (hCG), Human Menopausal Gonadotropin (hMG); Bacterial vaccine such as-Bacillus Calmette-Guerin (BCG) vaccine; Viral vaccines such as- Live attenuated Measles vaccine, Live attenuated Rubella vaccine, Cell culture Rabies vaccine

CENTRAL MEDICAL DEVICE TESTING LABORATORY: The Institute is notified Central Medical Device Testing Laboratory vide the following details:

Notification details	Category of medical device
S.O. 2237 (E) 1 st Jun 2018	<i>In-vitro</i> 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
S.O. 1928 (E) 25 th Apr 2023	<i>In-vitro</i> Diagnostics Medical Devices for Human Immuno-deficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus, Syphilis, Blood Grouping, RT-PCR Kits for Diagnosis of COVID-19, Ribonucleic acid (RNA) Extraction Kits for Diagnosis of Covid-19, Viral Transport Medium (VTM) for diagnosis of COVID-19, RT-LAMP Kit for diagnosis of COVID-19, Glucose Test strip, Fully Automated Analyser-based Glucose Reagent and Glucometer.

GOVERNMENT ANALYST(S):

NIB scientists are notified Government Analysts vide the following details:

Notification details	Name of Government Analyst and classes of drugs
S.O. 2393(E) 2 nd Sep 2015	Ms. Kanchan Ahuja- Blood Grouping Reagents Ms. Ajanta Sircar- Glucose Test Strips, Fully automated analyser-based glucose reagents
S.O. 4271(E) 26 th Nov 2019	Dr. Rajesh Kumar Sharma- Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus Ms. Kanchan Ahuja- Blood Grouping Reagents Ms. Ajanta Sircar- Glucose Test Strips, Fully automated analyser-based glucose reagents Dr. Meena Kumari, Ms. Madhu Erramilli- Human Albumin, Human Normal Immunoglobulin (intramuscular and intravenous), Human Coagulation Factor VIII, Human Coagulation Factor IX, Plasma Protein Fractionation, Fibrin Sealant Kit, Anti-Inhibitor Coagulation Complex Dr. Charu. M. Kamal, Ms. Gurminder Bindra- Recombinant Products-Recombinant Insulin and Insulin analogues, r-Erythropoietin (EPO), r-Granulocyte Colony Stimulating Factor (G-CSF) Sh. Subhash Chand- Therapeutic Monoclonal Antibody Products- Rituximab, Trastuzumab, Adalimumab, Bevacizumab Sh. Harit Kasana, Sh. Jaipal Meena- Vaccine Products- Bacillus Calmette-Guerin (BCG) vaccine, Live Attenuated Measles vaccine, Live Attenuated Rubella vaccine, Cell Culture Rabies vaccine, Oral Polio vaccine

Notification details	Name of Government Analyst and classes of drugs
S.O. 2191(E) 15 th / 17 th May, 2023	Dr. Rajesh Kumar Sharma, Dr. Richa Baranwal - <i>In-vitro</i> Diagnostics Medical Device for Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus and Syphilis. Ms. Kanchan Ahuja, Dr. Pankaj Kumar Sharma - <i>In-vitro</i> Diagnostics Medical Device for Blood Grouping. Ms. Ajanta Sircar, Dr. Varun Singh - Glucose Test Strips, Fully automated analyser-based Glucose Reagent and Glucometer. Dr. Gauri Misra, Dr. Ashwini Kumar Dubey - RT-PCR Kits for Diagnosis of COVID-19, Ribonucleic acid (RNA) Extraction Kits for Diagnosis of COVID -19, Viral Transport Medium (VTM) for Diagnosis of COVID -19 and RT-Lamp Kit for diagnosis of COVID -19.
G.S.R 91 (E), 2 nd Feb 2024	Dr. Ratnesh Kumar Sharma, Dr. Saurabh Sharma - Nivolumab, Denosumab, Ranibizumab Dr. Manoj Kumar, Sh. Tara Chand - Human Albumin, Human Normal Immunoglobulin (intramuscular and intravenous), Human Coagulation Factor VIII, Human Coagulation Factor IX, Plasma Protein Fractionation, Fibrin Sealant Kit, Anti-Inhibitor Coagulation Complex, Rabies Immunoglobulin
S.O. 203(E) 27 th Mar 2025	Dr. Akanksha Bisht, Dr. Rajesh Kumar Sharma, Dr. Richa Baranwal - <i>In-vitro</i> Diagnostics Medical Devices Dr. Varun Singh - Biochemical Kits Dr. Gauri Misra, Dr. Ashwini Kumar Dubey - Molecular Diagnostic Kits Ms. Kanchan Ahuja, Dr. Pankaj Kumar Sharma - Blood Grouping Reagents Dr. Meena Kumari, Ms. Y. Madhu, Dr. Manoj Kumar, Mr. Tara Chand, Ms. Sudha V Gopinath - Blood Products, including recombinant origin Dr. Charu. M. Kamal, Ms. Gurminder Bindra, Dr. Sanjay Mendiratta, Ms. Shalini Tewari - Recombinant products Dr. Subhash Chand, Dr. Ratnesh Kumar Sharma, Dr. Saurabh Sharma, Dr. Harish Chander, Dr. Jyoti Sharma - Monoclonal Antibodies Dr. Hemant Kumar Verma, Mr. N. Nanda Gopal, Ms. Rashmi Shrivastava -Enzymes and Hormones, including recombinant origin Mr. Harit Kasana, Mr. Jaipal Meena, Dr. Manjula Kiran, Mr. Neeraj Malik -Vaccine and Antisera

NIB scientists are notified Government Analysts vide the following details by and for the indicated State/ UT

Notification details	Name of Government Analyst and classes of drugs
SRO. 193 21 st Apr 2017 Govt of Jammu & Kashmir	Ms. Kanchan Ahuja - Blood Grouping Reagents Ms. Ajanta Sircar - Glucose Test Strips, Fully automated analyser-based glucose reagents
SO. 28 3 rd Mar 2022 (UT of Ladakh)	Dr. Rajesh Kumar Sharma, Dr. Meena Kumari, Ms. Madhu Erramilli, Ms. Kanchan Ahuja, Ms. Ajanta Sircar, Dr. Charu M. Kamal, Ms. Gurminder Bindra, Sh. Subash Chand, Sh. Harit Kasana, Sh. Jaipal Meena

MEDICAL DEVICE TESTING OFFICER(S): NIB scientists are notified Medical Device Testing Officer(s) vide the following details:

Notification details	Name of MDTO for medical device
S.O. 5330 (E) 10 th Dec 2024	Dr. Rajesh Kumar Sharma, Dr. Richa Baranwal, Ms. Kanchan Ahuja, Dr. Pankaj Kumar Sharma, Ms. Ajanta Sircar, Dr. Varun Singh, Dr. Gauri Misra, Dr. Ashwini Kumar Dubey - <i>In-vitro</i> Diagnostic Medical Devices

NIB scientists are notified Medical Device Testing Officer(s) vide the following details by and for the State of Jharkhand

State Notification details	
Letter No. 22/ निदे./ औषधि/ Testing- 18-02/2016-297(D) 15 th Mar 2024 (Jharkhand Govt.)	Dr. Rajesh Kumar Sharma - <i>In-vitro</i> Diagnostics kits for HIV, HBsAg, HCV. Ms. Kanchan Ahuja - Blood Grouping Reagents. Ms. Ajanta Sircar - Glucose Test Strips, Fully automated analyzer-based Glucose Reagent

QUALITY MANAGEMENT UNIT

The Quality Management System of NIB is deeply integrated into its operations, ensuring the highest standards in testing biological products. Accredited to ISO/IEC 17025:2017 since 2011, NIB demonstrates its competence in biological and chemical testing, reinforcing stakeholders' confidence in its services. The scope of testing has increased gradually over a period of time in the disciplines of biological testing and chemical testing.

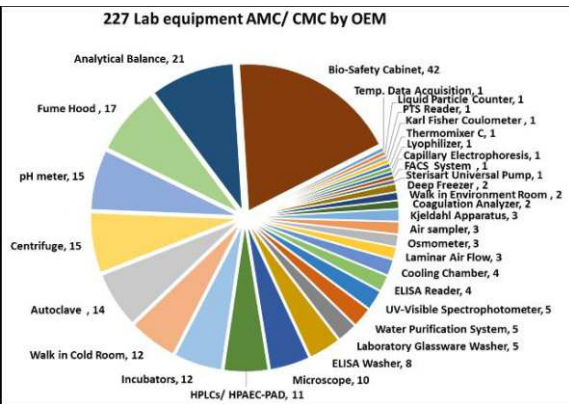
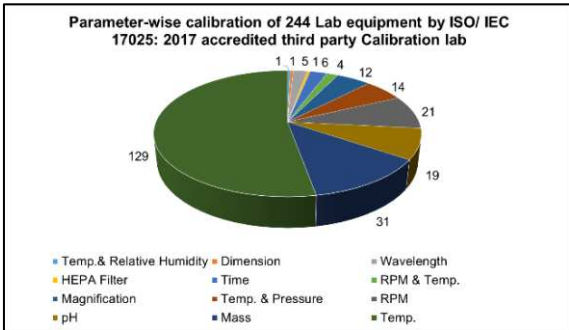
As part of the NIB's commitment, the QMU spearheads the continuous enhancement of NIB's LQMS through managing a range of accreditation activities and quality assurance measures. This includes accreditation related activities viz, ensuring timely updates and reviews of Standard Operating Procedures (SOPs), Scope of Accreditation, Intermediate check of Volumetric Glassware, and Operation & Maintenance of Micropipettes. Internal quality audits and Management Review Meetings are meticulously planned and coordinated by QMU.

QMU also manages Alert Calendars and/or e-mails to ensure timely revision and review of critical documents and processes. It manages essential records including Temperature & Humidity Sheets, IQC & trend charts, blind sample testing, and repeat testing results. It maintains the master lists of SOPs, equipment, logbooks, Method Validation/ Verification data, PT/ EQAS/ ILC records, registers, files, CRM/ RS, critical reagents, and authorized personnel. QMU provides essential items to labs/units viz; calibrated standard weight box, UV-calibration kit, thermometers, and pharmacopoeias, pipette leak test unit and other miscellaneous items- health card, log books, immunization cards, logo sheets, lab coats, sheets for reporting of NSQ samples.

QMU coordinates with procurement, finance, laboratory, IT departments and SRRDU to ensure seamless operations with respect to equipment (about 400) service,

calibration (onsite and off-site) and payment release for seamless focus on testing by respective laboratories/ units; inclusion of new products, quantity and fee in the Testing fee document on the institute's website to reflect new products and fees, facilitating stakeholder access and actively assessing customers' feedback received from the SRRDU, underscoring NIB's commitment to continuous improvement and customer satisfaction respectively.

The integrity and reliability of equipment are upheld through regular updates of authorized usage lists, preventive maintenance by Original Equipment Manufacturers (OEMs) through AMC/CMC, and calibration by ISO/IEC 17025:2017 accredited Calibration Labs.



Risk Assessment training imparted by QMU to equip lab/unit personnel with the necessary skills to discern potential risks associated with newly acquired products or the verification/ validation process of test parameters and empower lab/unit staff to identify risks promptly and implement

appropriate control measures to mitigate them effectively.

A manuscript titled “Measurement uncertainty in testing of biologicals in national control laboratories for ISO/IEC 17025: practical approaches” was published on 14 April 2024 in the journal “Accreditation and Quality Assurance” by Springer.

NIB has successfully completed the desktop surveillance audit in accordance with ISO/IEC 17025:2017 in the discipline of Chemical and Biological testing, and the decision letter for the same has been received from NABL on 16.07.2024 with validity till 15.08.2025.

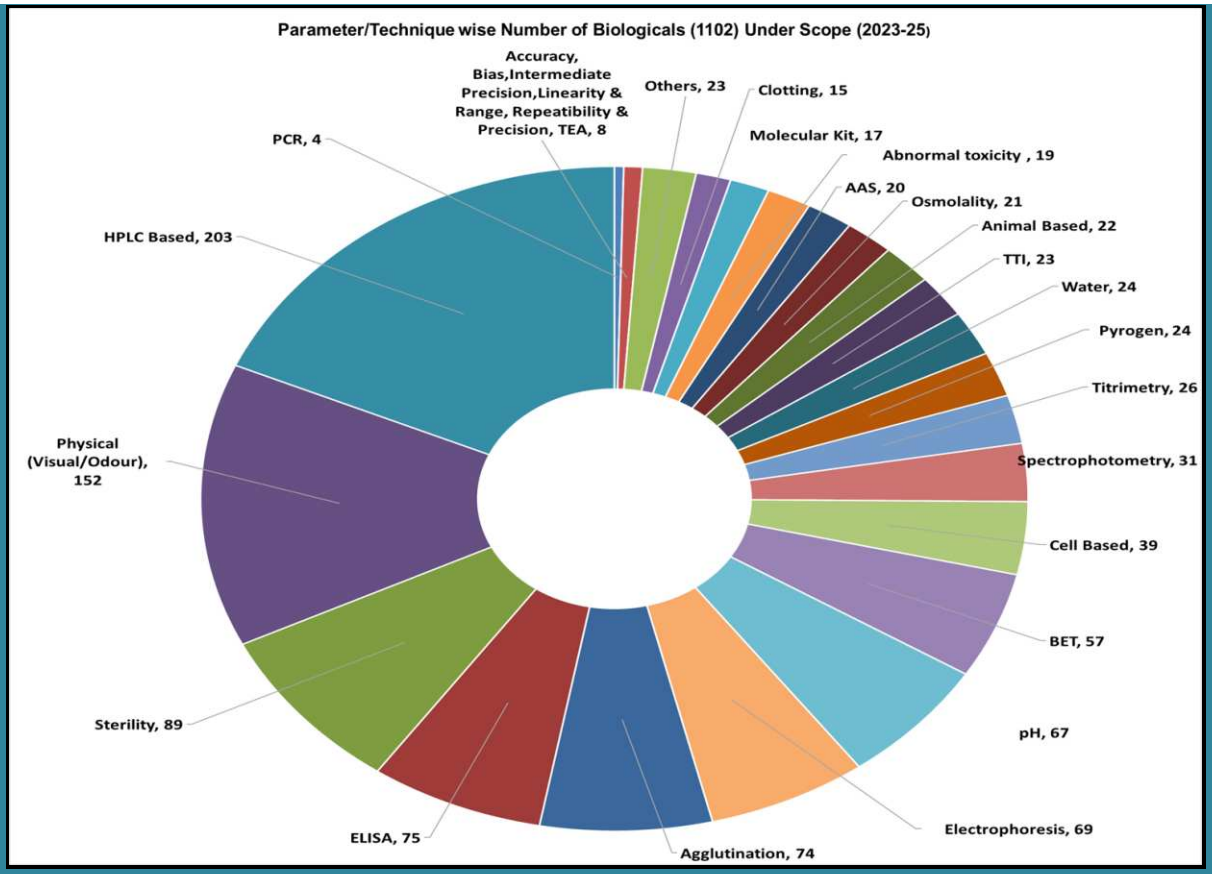
QMU successfully conducted the annual Internal Audit of NIB Laboratories/ Units as per the requirements of ISO / IEC 17025:2017 from 12-14.11.2024 and

Management Review Meeting on 20.12.2024 for the renewal of accreditation.

The process for filling the application on the NABL portal for renewal of accreditation has been initiated in the month of December, 2024 and application successfully submitted in the month of January, 2025

QMU plays a vital role in facilitating visits to various laboratories and units of NIB in coordination with the Training Unit. These visits offer guests/participants a firsthand experience of our facilities and operations, enriching their understanding and fostering collaboration within the scientific community.

The QMU remains dedicated to upholding and advancing NIB’s standards of excellence in biological and chemical testing.



COLLABORATIONS

1. **Blood Grouping Reagents Laboratory:** The laboratory collaborated with various blood banks and hospitals across Delhi/NCR for the collection of non-infective and non-clotted leftover blood samples. This initiative was undertaken with the approval of the Institutional Human Ethics Committee and with authorization from the Drugs Controller General of India DCG (I). The collected samples were utilized for quality control testing of blood grouping reagents. Additionally, the laboratory collaborated with the Indian Pharmacopoeia Commission, Ghaziabad, to contribute to the development of new pharmacopoeia's monographs and the revision of existing ones related to blood grouping reagents.
2. **Immunodiagnostic Kit Laboratory:** The Immunodiagnostic Kit Laboratory has established network with blood banks and hospitals across Delhi/NCR for the collection of plasma bags. These are essential for the preparation of plasma panels used in the quality control testing of both indigenous and imported immunodiagnostic kits received at NIB from the offices of the Central Drugs Standard Control Organization (CDSCO). The laboratory specifically requires infectious plasma bags reactive for HIV, HBV, HCV, and Syphilis. In this regard, the Drug Controller General of India (DCG(I)) has issued directions to various blood banks and hospitals to support NIB by providing such plasma bags. The laboratory routinely collects both reactive (HIV, HCV, HBsAg, and Syphilis) and non-reactive plasma bags.

The laboratory collected a total of 276 plasma bags, of which 49 were reactive (47 for HIV and 2 co-reactive for HIV and Syphilis) while the remaining 227 were non-reactive. The details of the contributing blood banks and hospitals are provided in the table below.

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

3. The Centralized Facility for Bioassay has been actively participating in various collaborative studies organized by the National Institute for Biological Standards and Control (NIBSC), UK, for the development of WHO International Standards for bioassays. Additionally, the facility contributes to the Indian Pharmacopoeia Commission (IPC) by supporting the verification of monographs for inclusion in the Indian Pharmacopoeia (IP).
4. Dr. Shikha Yadav collaborated with Dr Archana Chugh, Professor, School of Biological Sciences, IIT Delhi for a project titled “Investigating the anticancer potential of Ltc2a peptide in *in-vivo* model system” and *in-vivo* experiments under the project were completed during this period.

PARTICIPATION IN PT/ IL/ EQAS- NATIONAL/INTERNATIONAL

1. The Biochemical Kit Laboratory participated in EQAS with CMC, Vellore for the analytes: Glucose, Creatinine, Albumin, Uric Acid, Cholesterol, and Triglyceride on monthly basis and scored 100% results.
2. Blood Reagent Laboratory participated in external proficiency program for Anti-A (02), Anti-B (02), Anti-AB, Anti-D-IgM (03), Anti-A₁ Lectin and Anti-H Lectin blood grouping reagents (a total of 10 reagents) conducted by Indian Red Cross Society, New Delhi. The performances were found to be satisfactory.
3. Enzymes and Hormones Laboratory participated in the Proficiency testing program (PT/IPL/01/04/24) for the calendar year 2024-25 on Chromatographic purity by HPLC & Test for pH conducted by Indian Pharmacopoeia Commission (IPC) Ghaziabad and completed successfully with compliance remarks
4. The Immunodiagnostic Kit Laboratory has been regularly participating in External Quality Assessment Scheme (EQAS) since 1999. Laboratory has enrolled and participated in Multimarker Blood screening EQA Program (MMBS4310) with National Serology Reference Laboratory, (NSRL) Australia, a NATA-accredited proficiency testing provider, complying with ILACG13:08/2007 and fully accredited Proficiency Testing provider under ISO 17043: 2010. This program meets the highest international quality standards. Laboratory successfully participated thrice in this duration with NRL, Australia EQAS-2024-25. The results were concordant with reference results.
5. The Molecular Diagnostic Laboratory has successfully participated in External Quality Assessment Scheme (EQAS) Programme conducted by NRL, Australia for Viral Load Monitoring of HBV, HCV, HIV and NAT Proficiency Testing. The laboratory has put-up the tests for viral load monitoring of HBV, HCV, HIV and Qualitative Multimarker blood donor screening and the generated results were uploaded on the NRL-EQAS website.
6. The COVID Kit Testing Laboratory has participated in the virology external quality assessment scheme (VIROEQAS) Programme conducted by Christian Medical College, Vellore for the SARS-CoV-2. The performance of the laboratory is of excellent category.
7. Recombinant Products Laboratory participated in the following Proficiency Testing programme/ILC with Indian Pharmacopoeia Commission [Round 01 (PT/IPL/01/04/24) during 2nd quarter of 2024 (11.06.2024)] for two parameters:
 - a) Chromatographic purity by HPLC
 - b) pH

Lab has received certificate of Participation with SATISFACTORY PERFORMANCE.

- Lab has participated in PT study with IPC, Ghaziabad for Chromatographic Purity by HPLC (PT/IPL/03/11/24) on 20.01.2025. Lab has received certificate of Participation with SATISFACTORY PERFORMANCE.
- Lab participated in Interlaboratory comparison (ILC) study for Teriparatide on 20.02.2025 for Assay Parameter conducted by Indian Pharmacopoeia Commission, Ghaziabad. The results were SATISFACTORY

8. Therapeutic Antibodies Laboratory has participated in proficiency testing programme (PT/IPL/01/04/24) to determine the pH and Chromatographic purity by HPLC method with Indian Pharmacopoeia Commission (IPC) and scored a SATISFACTORY performance.
9. Vaccine and Antisera Lab has participated in EDQM Collaborative study (BSP-148) for the Standardization of an *in-vitro* assay for the potency control of Human Rabies Vaccine by ELISA, conducted by Department of Biological Standardization, OMCL Network & Healthcare, EDQM, Council of Europe. Phase 3 study has completed by the ELISA test of 24 batches of Rabies Vaccine as per BSP protocol shared by EDQM. The results were communicated to EDQM on 15.05.2024 for final result analysis & report.

EXPERT COMMITTEE MEETINGS

1. Institutional Animal Ethics Committee (IAEC)

Three IAEC meetings were organized during the preview period for timely ethical approvals so that all *in-vivo* QC tests could be performed for the biologicals received at NIB in the designated turnaround time periods. A total of 48 protocols were reviewed and approved by the committee during this period.

- a) 68th Institutional Animal Ethics Committee (IAEC) meeting- 10.06.2024.
- b) 69th Institutional Animal Ethics Committee (IAEC) meeting- 17.10.2024.
- c) 70th Institutional Animal Ethics Committee (IAEC) meeting- 11.03.2025.

The annual inspection of In Vivo Bioassay Laboratory & Animal Facility was also conducted by IAEC on 10.06.2024 and the inspection report had been submitted to the Committee for Control and Supervision of Experiments on Animals (CCSEA), Ministry of Fisheries, Animal Husbandry & Dairying by the main CCSEA nominee in the Committee.

2. Institutional Ethics Committee (IEC)

The Institutional Ethics Committee (IEC) at NIB ensures the ethical conduct of research involving human subjects. It primarily reviews proposals from NIB laboratories that use human samples for quality control testing of biological products or for other research purposes. The committee is committed to protecting the dignity, rights, safety, and well-being of all participants by adhering to the fundamental ethical principles of autonomy, beneficence, non-maleficence, and justice. These principles guide the process of obtaining informed consent where applicable, ensuring potential benefits outweigh risks, avoiding harm, and promoting fairness. The IEC reviews all research proposals before commencement and monitors the progress of ongoing studies on an annual basis. The 15th Institutional Ethics Committee meeting was held on 22.04.2024 at NIB, NOIDA. During the meeting, the committee reviewed and provided expert input on the progress of 15 ongoing quality control and research proposals involving human-derived materials.

3. Institutional Biosafety Committee (IBSC)

The 4th Institutional Biosafety Committee (IBSC) meeting was held on 22.07.2024 on hybrid mode to review the routine and R&D activities related to biosafety. The committee reviewed two ongoing R&D projects progress report presented by Principal Investigators/ Co- Principal Investigators.

IBSC team along with the engineering and biomedical waste management took a laboratory round for biomedical waste management related activities covering various Biotherapeutic, Diagnostic, Vaccine laboratories, STP and ETP waste management area. The visit also covered biomedical waste disposal route from collection points up to final vendor pick up area.

Other Expert Committee Meetings:

4. Scientists from Central Facility for Bioassay, Recombinant Products Lab, Therapeutic Antibodies Lab and Enzymes & Hormones Lab virtually attended 15th Meeting of the Expert Working Group-Biologicals and rDNA Products held at IPC on 13.02.2025.
5. Scientists from Centralized Facility for Bioassay attended the Meeting for discussion on Trastuzumab Concentrated Solution and Trastuzumab Injection draft Monographs for IP on 28.02.2025.
6. Scientists from the Enzymes and Hormones Laboratory participated in an expert committee meeting convened by CDSCO, New Delhi, to finalize technical matters related to the Recombinant Human Follicle Stimulating Hormone (r-hFSH) Drug Substance and Drug Product.
7. Dr. Harish Chander Deputy Director (QC), Dr. Charu Mehra Kamal, Scientist Grade-I, Ms. Sudha V. Gopinath, Scientist Grade-II and Dr. Subhash Chand, Scientist Grade-III virtually attended WHO Regional hybrid workshop on improving access and building capacity on the optimal use of reference standards, Bangkok, Thailand on 15.05.2024.
8. Dr. Harish Chander Deputy Director (QC), Dr. Charu Mehra Kamal, Scientist Grade-I, Ms. Sudha V. Gopinath, Scientist Grade-II and Dr. Subhash Chand, Scientist Grade-III participated in Expert committee meeting for National Biological Reference Standards on 25.07.2024.
9. Dr. Harish Chander Deputy Director (QC), Dr. Charu Mehra Kamal, Scientist Grade-I, Ms. Sudha V. Gopinath, Scientist Grade-II and Dr. Subhash Chand, Scientist Grade-III participated in the meeting for Discussion on Biotherapeutics Products Applications including Biosimilar Standards with USP delegates on 25.07.2024.
10. Dr. Shikha Yadav, Scientist Grade-I, attended the Institutional Animal Ethics Committee (IAEC) meeting of Bio-Med Pvt. Ltd., Ghaziabad as the main Nominee of CCSEA to review their research protocols for ethical approval on 26.06.2024.
11. Dr. Shikha Yadav, Scientist Grade-I, had been nominated as the main CCSEA Nominee in the IAEC of Galgotias University, Greater NOIDA by CCSEA and she attended their IAEC meeting for review and approval of their research protocols and also performed annual inspection of their Animal House on 13.11.2024.
12. Dr. Shikha Yadav, Scientist Grade-I, had been nominated as a member of IAEC Committee of MAX PETZ Hospital Pvt Ltd by CCSEA, Ministry of Fisheries, Animal Husbandry and Dairying and she attended their IAEC meeting for review and approval of their research proposals on 11.12.2024.
13. Dr. Shikha Yadav, Scientist Grade-I, had been nominated as CCSEA nominee in the IAEC of Bio- Med Private Limited, Ghaziabad, UP and attended their IAEC meeting to review and approve their research proposals on 20.01.2025.
14. Dr. Charu M. Kamal, Scientist Grade-I participated in One-Day Workshop-cum-Brainstorming Session for Technical Committee Members as member of MSD 20 Reference Material Sectional Committee on 29.07.2024 at NITS, NOIDA.



15. Dr. Charu M. Kamal, Scientist Grade-I attended virtually Stakeholder's meeting for discussion of 1) Trastuzumab Concentrated Solution 2) Trastuzumab Injection draft monograph organized by IPC Ghaziabad on 19.09.2024.
16. Dr. Charu M. Kamal, Scientist Grade-I attended virtually BIS Sectional Committee Meeting MSD20-REMCO-NMC on 23.09.2024.
17. Dr. Charu M. Kamal, Scientist Grade-I, Ms. Gurminder Bindra, Scientist Grade-III and Dr. Birendra Kumar, Junior Scientist attended 15th Meeting of the Expert Working Group - Biologicals and rDNA Products Hosted by Indian Pharmacopoeia Commission on 13.02.2025.
18. Dr. Charu Mehra Kamal, Scientist Grade-I attended an expert committee meeting convened by the CDSCO, New Delhi on 07.02.2025 to examine the sameness of Enoxaparin API and formulation manufactured from an ovine source with respect to a porcine source through video conferencing.
19. Dr. Gauri Misra, Scientist Grade-I has attended various 'Technical Advisory Committee (TAC)' meetings of MedTech Mitra for providing handholding support to MedTech innovators on 08.04.2024, 09.04.2024, 10.04.2024, 15.04.2024, 02.05.2024, 04.06.2024, 05.07.2024, 06.08.2024, 06.09.2024, 23.10.2024, 11.11.2024 11.03.2025 at ICMR Headquarters, New Delhi.
20. Dr. Gauri Misra, Scientist Grade-I has virtually attended the FIRST HUB meeting (special session) of DBT-BIRAC on 05.04.2024, 08.11.2024, 06.12.2024, 07.03.2025 for addressing queries of innovators.
21. Dr. Gauri Misra, Scientist Grade-I as chairperson, has virtually attended the 'Technical cum Purchase Committee' meeting of NIMR, New Delhi on 05.04.2024, 25.09.2024 & 14.10.2024 & 18.02.2025.
22. Dr. Gauri Misra, Scientist Grade-I, as an external expert, has virtually attended the NIMR-Negotiation committee meeting on 15.04.2024 & 16.04.2024, 28.03.2025.
23. Dr. Gauri Misra, Scientist Grade-I has been appointed as an Interview Board member for the post of Examiner of Patents and Design by National Testing Agency (NTA) from 19.04.2024 - 25.04.2024.
24. Dr. Gauri Misra, Scientist Grade-I, as an expert, has virtually attended the national level malaria working group meeting for revised protocol organized by ICMR headquarters on 15.05.2024 & 16.05.2024.
25. Dr. Gauri Misra, Scientist Grade-I, as an external expert, has virtually attended the meeting with respect to online application in form MD-28 for granting permission to Import or Manufacturing License for sale or distribution of new in vitro diagnostics medical device for the detection of COVID-19 on 08.05.2024 organized by CDSCO, New Delhi.
26. Dr. Gauri Misra, Scientist Grade-I virtually attended the MHD 20- Medical Biotechnology and Medical Nanotechnology organized by Bureau of Indian Standards Headquarters held on 06.06.2024, 12.09.2024, 04.12.2024 & 10.03.2025.
27. Dr. Gauri Misra, Scientist Grade-I attended 6th Vigyan Bharti Adhiveshan on 22.06.2024 & 23.06.2024 at Pune, Maharashtra.
28. Dr. Gauri Misra, Scientist Grade-I been nominated as an external member of the Technical Evaluation Committee of NICHDR. (National Institute of Child Health and Development Research) & ICMR-CCP (Centre for Cancer Pathology) and attended a virtual meeting held on 03.07.2024.

29. Dr. Gauri Misra, Scientist Grade-I, as a chairperson, virtually attended the negotiation committee regarding AMC/CMC repairing of equipment of ICMR-NIMR on 09.07.2024 06.08.2024.
30. Dr. Gauri Misra, Scientist Grade-I virtually attended Technical-cum-Purchase Committee meeting on 26.07.2024 organized at ICMR-NIMR, New Delhi.
31. Dr. Gauri Misra, Scientist Grade-I as an external expert, reviewed the ‘ad-hoc and fellowship program under ITR Division’ on 29.08.2024 & 30.08.2024 at ICMR (HQ), New Delhi.
32. Dr. Gauri Misra, Scientist Grade-I virtually attended workshop on ‘Handling support to MedTech Innovation: Essentials of Regulation complaint Clinical Investigation’ under the MedTech Mitra: A Niti Ayog-ICMR-CDSCO Initiation on 07.08.2024.
33. Dr. Gauri Misra, Scientist Grade -I virtually attended 40th NRL Workshop held from 07.10.2024-09.10.2024 organized at Melbourne, Australia.
34. Dr. Gauri Misra, Scientist Grade-I as an expert, has attended ‘Life Sciences Start-up Summit’ in the panel on Novel Innovations addressing Healthcare Demands: “The Significance of Health Research and Quality Control Regulation” from 04-05.10.2024 at ILS (DBT), Bhuvneshwar supported by BIRAC, DST GOO.
35. Dr. Gauri Misra, Scientist Grade-I as an external expert, has attended the Project Review Group (PRG) Committee meeting at ICMR (HQ) on 18.10.2024 & 12.12.2024.
36. Dr. Gauri Misra, Scientist Grade – I, as an expert, virtually attended “The malaria IVD Performance Evaluation protocol review meeting” of the ICMR appointed Working Group organized by ICMR Headquarters on 05.11.2024.
37. Mr. Harit Kasana, Scientist Grade-II, Mr. Jaipal Meena, Scientist Grade-III and Dr. Manjula Kiran Scientist Grade-III, virtually attended the 13th and 14th Meeting of “Expert Working Group (EWG)-Vaccine & Immunoserum for Human Use” regarding discussion on monograph and general chapter updation held at IPC 01.04.2024 and 07.01.2025 respectively.
38. Dr. Gauri Misra, Scientist Grade-I as an expert, has virtually attended “The technical working group meeting to conduct a landscape review of diagnostic kits for priority emerging infectious disease” organized by National One Health Programme for prevention and control of Zoonosis, National Center for Disease Control, New Delhi on 14.11.2024.
39. Dr. Gauri Misra, Scientist Grade-I as an external expert, has virtually attended a meeting with respect to Clarification of the point raised by Hemogenomics Pvt. Ltd., on the tender notice for implementation of NAT Technology in IRCS Blood Center on 19.11.2024.
40. Dr. Neelima Mishra, Director NIB and Dr. Gauri Misra, Scientist Grade-I has attended 8th Convocation of AcSIR at Bharat Mandapam Convention Center, New Delhi on 23.11.2024.



41. Dr. Gauri Misra, Scientist Grade-I, invited as speaker by IIT Delhi, Department of Biomedical Engineering at Pre-Market Compliance Workshop organized by mPragati on 05.12.2024 and delivered a lecture on “Fundamental of *In-vitro* Diagnostics Testing Methodology for Developing Regulation-Complaints IVDS” at IIT, Delhi.
42. Dr. Gauri Misra, Scientist Grade-I, has received a certificate of excellence from Director-General ICMR, for showcasing Innovation titled “Allele-Specific primer probe sets for the rapid and Accurate Diagnosis & Differentiation of Omicron & Delta Variant of SARS-CoV-2” at DHR-ICMR Health Research excellence Summit 2024 on 14.11.2024.
43. Dr. Gauri Misra, Scientist Grade-I as member secretary has organized the ‘7th Technical Expert Committee meeting on Diagnostics’ under the chairmanship of Dr. V.M Katoch (Former Secretary, DHR & DG-ICMR, New Delhi) on 29.01.2025 at NIB, NOIDA for strengthening the scientific activities in Molecular Diagnostics Laboratory.
44. Dr. Gauri Misra, Scientist Grade-I & AcSIR Coordinator has virtually attended the coordinator’s meet with the Director, AcSIR on 02.02.2025.
45. Dr. Gauri Misra, Scientist Grade-I virtually attended technical cum purchase committee meeting held at NIMR-ICMR on 18.02.2025.
46. Dr. Gauri Misra, Scientist Grade-I has virtually attended the meeting of committee on contracts regarding implementation of NAT Technology in IRCS, NHQ Blood Centre New Delhi held on 28.02.2025.
47. Dr. Meena Kumari, Scientist Grade-II, Ms. Kanchan Ahuja, Scientist Grade-II, Ms. Y. Madhu, Scientist Grade-III & Mr. Tara Chand, Scientist Grade-III attended 9th meeting of Expert Working Group-Blood and Blood Related Products at Indian Pharmacopoeia Commission, Ghaziabad on 12.04.2024.
48. Dr. Meena Kumari, Scientist Grade-II was invited as an expert member for the Virtual meeting of the UG/PG Board of Studies held on 15.10.2024 at Department of Biotechnology, UIET, KUK, Kurukshetra
49. Dr. Meena Kumari, Scientist Grade-II & Mrs. Y. Madhu, Scientist Grade-III were invited for Subject Expert Committee (SEC) meeting by Blood Products Division, CDSCO (HQ), New Delhi to be held on 25.10.2024 at CDSCO (HQ), New Delhi.
50. Dr. Meena Kumari, Scientist Grade-II and Ms. Kanchan Ahuja, Scientist Grade-II attended meeting of 10th Expert Working Group-Blood and Blood Related Products at Indian Pharmacopoeia Commission, Ghaziabad on 20.03.2025.
51. Dr. Hemant Kumar Verma, Scientist Grade-II attended the virtual Meeting that was chaired by Joint Secretary, Department of Pharmaceuticals on 21.01.2025 to review the Guidelines issued by Department of Pharmaceuticals for implementing the provisions of Public Procurement (Preference to Make in India).
52. Ms. Rashmi Shrivastava, Scientist Grade-III nominated from NIB, attended a meeting on 19.04.2024 at ICMR Hq. to demonstrate the cost recovery model followed by NIB NOIDA for performance evaluation of *in-vitro* diagnostics.
53. Rashmi Shrivastava, Scientist Grade-III, attended a negotiation meeting at ICMR-NICPR as Chairperson on 01.05.2024.
54. Rashmi Shrivastava, Scientist Grade-III attended an Expert Committee meeting of ICMR for IVD evaluation charges at ICMR HQ with ICMAI representatives on 13.05.2024 (in person) and for reviewing the IVD Evaluation Charges on 01.10.2024 (virtually) and 07.11.2025 at ICMR HQ.

55. Ms. Rashmi Shrivastava, Scientist Grade-III, attended the price fixation (condemnation) committee meeting on 31.12. 2024 at ICMR-NICPR, as an external expert.
56. Mr. N. NandaGopal, Scientist Grade-III nominated as Member, Board of Studies-Botany under Alumni Category at S.G.S. Arts College (an autonomous college under UGC), Tirumala Tirupati Devasthanams, Tirupati. Andhra Pradesh.
57. Dr. Suresh Kumar, Scientist Grade-III, attended the Institutional Animal Ethics Committee (IAEC) meeting as a CCSEA nominee “Link Nominee” to review the research protocols at Dhiti Life Sciences, New Delhi on 01.06.2024.
58. Dr. Suresh Kumar, Scientist Grade-III, attended the Institutional Animal Ethics Committee (IAEC) meeting as a CCSEA nominee “Scientist from outside Institute” to review the research protocols at National Institute of Immunology, New Delhi on 11.07.2024 and 06.03.2025.



NIB stall to showcase NIB activities at 2-day Exhibition in 19th International Conference of Drug Regulatory Authorities (ICDRA) held at Yashobhoomi convention and expo center, New Delhi on 14-15.10.2024

59. National Institute of Biologicals (NIB) organized a one-day meeting of domain experts on 6th March 2025, focused on strengthening quality control testing and capacity building programmes at NIB. The meeting brought together experts from academia, healthcare professionals, industry experts, and representatives from CDSCO and IPC. Sessions covered the institute’s ongoing quality control activities, centralized facilities, key challenges, and training programmes. The event concluded with actionable recommendations and felicitation of the experts for their valuable contributions.



60. An online Meeting was held on 27.03.2025 regarding collaboration with NCVBDC, Delhi for establishing QC testing of Malaria and Dengue IVD test kits at NIB, NOIDA and research proposals in the area of Quality Control of Malaria/Dengue IVD test kits.

ORGANIZATION/PARTICIPATION IN CONFERENCE/ WORKSHOP/ SYMPOSIA

1. NIB participated in the event of "Rise in Jammu & Kashmir 2024" held at Jammu, Jammu & Kashmir on 03-05.10.2024. The event highlighted the exhibitions of government functioning in different aspects of the country's building economy. Apart from industry participation, a huge interest of youth from local schools and colleges was also registered at the event. The event concluded on 05.10.2024 with NIB winning the "BEST STALL" award. The award was facilitated by Er. Gulam Ali, Member of Parliament (Rajya Sabha).
2. Dr. Harish Chander, DD(QC), invited as a panelist for Panel Discussion at CME on bridging Science & Technology: Advancing Multidisciplinary Research in Healthcare” on National Science Day at Government Institute of Medical Sciences, NOIDA on 28.02.2025.
3. One day workshop under EQAS (External Quality Assessment Scheme) for distribution of HIV proficiency test panel for HIV serology (Round 1, 2024-25) to state Reference Laboratories of Uttar Pradesh and Uttarakhand by NACO-NRL, NIB was held on 25.10.2024. Technical Officers of 10 SRLs participated in the program which was presided by Head- IDKL and NRL In-charge and joined by Dr. Rakesh Rai, Deputy Director UPSACS.
4. One day workshop under EQAS (External Quality Assessment Scheme) for distribution of HIV proficiency test panel for HIV serology (Round 2, 2024-25) to state Reference Laboratories of Uttar Pradesh and Uttarakhand by NACO-NRL, NIB was held on 20.02.2025. Laboratory Technicians and a Technical Officer of SRLs participated in the program which was presided by Head-IDKL and NRL In-charge.
5. Recombinant Products Laboratory Organized one day workshop on "Latest strategies adopted by Global Pharmacopoeias and Industry perspectives and practices for Biologicals" at NIB on 22.10.2024. The representatives from IPC and stakeholder attended the same.
6. NIB, NOIDA & Federation of Blood Donor Organizations of India (FBDOI) have jointly organized the National Workshop on Haemovigilance, Donor vigilance & Voluntary Blood Donation from 14-16.06.2024 at NIB NOIDA. Dr. Akanksha Bisht, Scientist Grade-I gave the presentations on “Role of NIB in Haemovigilance and Donor Vigilance Programme in India” in the said Workshop.
7. Reference Standard Unit organized one-day interactive program with regulators, industry experts, standard-setting bodies, and policymakers on Making of Biological reference Standards: Indian perspective on 24.07.2024 to foster stakeholder engagement and gather expert inputs. Dr. Harish Chander, DD(QC), delivered a lecture on “Role of NIB in development of National Biologicals Reference Standards” and Dr. Charu M Kamal, Scientist Grade-I, delivered a talk on “Establishment of National Biological Reference Standards (NBRS)- NIB Experience”. Ms. Sudha V Gopinath, Scientist Grade-II delivered a talk on “Challenges in Development of Biological Reference Standards and Way Forward” and Dr. Subhash Chand, Scientist Grade-III delivered a lecture on “International Collaborative Studies for Development of International Standards (IS)-Case Report”.
8. Dr. Manjula Kiran, Scientist Grade-III, invited to deliver a talk at the 50th Conference of Association of Clinical Biochemists of India (ACBICON) 2024 organized by Department of Biochemistry, PGIMER, Chandigarh from 04-07.12.2024. She presented a talk on “Quality

Control Testing of Biologicals: An Important Step for a Molecule from Laboratory (API) to Life (Finished Product)”.

9. Dr. Suresh Kumar, Scientist Grade-III, delivered a talk on “Biosafety Practices in Biomedical Laboratories and Disposal of Biomedical Waste Management” at the Department of Microbiology and Biotechnology, SRM University, Haryana, on 21.09.2024.
10. Mr. Jaipal Meena, Scientist Grade-III, attended a National Conference on advanced materials for sensor under the series “Sensor for Society” on 19.12.2024 at Jawaharlal Nehru University, New Delhi. He presented a poster entitled “Indigenous Development of an Immunoassay for precise detection of Total Immunoglobulin against Rabies in Post-Vaccination serum”.
11. Scientists from NIB attended 19th International Conference of Drug Regulatory Authorities (ICDRA 2024) in New Delhi organized by CDSCO, MOHFW, Government of India in collaboration with the World Health Organization (WHO), held from 14-18.10.2024.
12. Scientists from NIB attended “Genomics Data Conclave” held on 09.01.2025 at Vigyan Bhavan, New Delhi, organized by DBT, Ministry of Science & Technology



13. Dr. Harish Chander, DD(QC) delivered a talk as a Keynote Speaker by ETPharma’s Biomolecule Workshop & Connect - Mumbai Chapter on 27.04.2024.
14. Dr. Harish Chander, DD(QC), delivered a talk on cancer in "Translational Trends in Natural and Health Sciences (TTNHS-2024)" from 04-06.12.2024.
15. Dr. Harish Chander, DD(QC), delivered a talk on the analysis of online cancer databases “Harmonizing Informatics Tools with Pharmaceutical Research for Accelerated Translation in Healthcare: Academia and Industrial Perspectives (HITPATH-2025)” during 14-16.02.2025.
16. Dr. Shikha Yadav, Scientist Grade-I, delivered talk on “Post-Operative Care” in the Rodent Surgery Workshop organized by the Centre for Comparative Medicine (CCM) and Liver Physiology Lab of the Institute of Liver and Biliary Sciences (ILBS), New Delhi, on 26.04.2024.
17. Dr. Shikha Yadav, Scientist Grade-I, delivered lecture on “Ethical Evaluation– An International Perspective; Severity Classification” and organized Group work on same in FELASA (Federation of European Laboratory Animal Scientists Association) Accredited training program on “Certificate Course in Laboratory Animal Science” at Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Chennai, on 24.06.2024.
18. Dr. Shikha Yadav, Scientist Grade- I, had been invited as resource person for workshop on Handling and care of laboratory animals at Jawaharlal Nehru University (JNU), Delhi where she delivered talk on “Perioperative Care, Anesthesia, Surgical Techniques and Analgesia and

- Pain: Its Causes, Category Monitoring and Distress in Laboratory Animals” and organized hands-on training on basic bi methodologies for participants from 13-17.07.2024.
19. Dr. Shikha Yadav, Scientist Grade-I, delivered talk on “Ethical evaluation: International Perspective and Severity Assessment in the FELASA Accredited course on Laboratory Animals” at TANUVAS, Chennai, on 26.07.2024.
 20. Dr. Shikha Yadav, Scientist Grade-I, delivered lecture on “Pre-Surgery/pre-operative Preparations for Mouse Survival Procedures, Survival Surgery Standards- Postoperative Care” in the workshop titled “NeuroTechLab: Applied Techniques in Neuroscience Research” organized by National Brain Research Centre (DBT), Ministry of Science & Technology, Manesar, Haryana, on 06.08.2024.
 21. Dr. Shikha Yadav, Scientist Grade-I, delivered expert lecture as resource person on “Points for consideration during Inspection of Animal House Facility and Importance of Record Keeping of various forms of CCSEA” in the Nominee Training organized by Joint Commissioner (AH) & Member Secretary (CCSEA), Ministry of Fisheries, Animal Husbandry and Dairying, at Amity University, Sector-125, NOIDA, Uttar Pradesh from 05-06.02.2025.
 22. Dr. Shikha Yadav, Scientist Grade-I, was invited as Resource Person in “Course on Laboratory Animal Science” at CSIR-Institute of Genomics and Integrated Biology (IGIB), Delhi to deliver lecture on “Perioperative care and Analgesia” on 19.01.2025
 23. Dr. Shikha Yadav, Scientist Grade-I, participated as a jury member in the World Congress on Translational Cancer Research & Immunotherapy (WTCRI) 2025, jointly organized by the Mahatma Gandhi University of Medical Sciences and Technology (MGUMST) Jaipur, Ichan School of Medicine at Mount Sinai, New York, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore and The Hormol Institute, Austin, at MGUMST, Jaipur, India from 10-12.02.2025.
 24. Dr. Shikha Yadav, Scientist Grade-I, had been invited to deliver talk on “Minimizing pain and distress in laboratory animals” in online mode in DHR-ICMR funded 4-weeks Comprehensive training program on Animal Research and Experimentation & Good Laboratory Practices (CARE-GLP) being organized by CSIR-North East Institute of Science & Technology (CSIR-NEIST) Jorhat, Assam on 27.02.2025.
 25. Dr. Charu Mehra Kamal, Scientist Grade-I gave an expert talk on “Assessment of Quality of Biotherapeutics” at Current Global Industry Trends, Innovation and Opportunities for Pharmacy Professionals on 11.02.2025 at Delhi Pharmaceutical Sciences and Research University (DPSRU).
 26. Dr. Gauri Misra, Scientist Grade-I was invited as a special guest and expert speaker to deliver a talk, share insight and experience in GBRC (Gujarat Biotechnology Research Centre) Gandhinagar, Gujarat on account of their monthly event “PRABODU” (Promoting Research Awareness in Biotechnology for the Development of Human Resources) on 18.01.2025.
 27. Dr. Gauri Misra, Scientist Grade-I was invited for an expert talk on “Advancing Molecular Diagnostics: Regulatory insight and research perspectives” at School of applied Science and Technological, Gujarat Technology University, Ahmedabad on 23.01.2025.
 28. Dr. Gauri Misra, Scientist Grade-I was invited as a keynote speaker for the Council of Science & Technology (CST-UP) entitled ‘Fostering Indian Pharmaceutical Industries and Challenges in Sustainable Environment Development’ held from 27.04.2024 to 28.04.2024 at Galgotias University, Greater NOIDA, UP.

29. Dr. Gauri Misra, Scientist Grade-I, has delivered a keynote lecture the workshop “Gel to gene mastering PCR prime design and Electrophoresis” on the topic “PCR as a frontline method for Molecular Diagnostics” organized by Gautam Buddha University, Greater NOIDA, UP on 20.11.2024.
30. Dr. Ratnesh Kumar Sharma, Scientist Grade-II & Ms. Rashmi Shrivastava-Scientist Gr III nominated by NIB, attended राष्ट्रीय वैज्ञानिक संगोष्ठी तथा स्थापना दिवस “निबार्ध मौसम पूर्वानुमान प्रणाली तथा अनुप्रयोग” (National Scientific Seminar and Foundation Day on “Intermediate Weather Forecasting Systems and Applications) on 24.03.2025 at National Centre for Medium Range Weather Forecasting, Ministry of Earth Sciences, Sector 62, NOIDA
31. Dr. Ratnesh Kumar Sharma, Scientist Grade-II was nominated to attend ‘Capacity Building Programme on Preventive Vigilance’ in Ministry of Health and Family Welfare, Nirman Vihar, New Delhi on 28.10.2024.
32. Dr. Neelima Mishra, Director NIB, Mr. Harit Kasana, Scientist Grade-II, Ms. Shalini Tewari, Scientist Grade-III and Dr. Subhash Chand, Scientist Grade-III visited M/s Indian Immunologicals Ltd., Hyderabad on 18-19.02.2025 for discussion of vaccine batch testing at NIB.



33. Ms. Sudha V Gopinath, Scientist Grade-II, Ms. Kanchan Ahuja Scientist Grade-II & Dr. Pankaj K. Sharma, Scientist Grade III participated in the 1st National CME of the Indian Society of Transfusion Medicine (ISTM) organized by the Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology from 11-12.07.2024 at Thiruvananthapuram, Kerala.
34. Ms. Sudha V Gopinath Scientist Grade-II, Ms. Shalini Tewari Scientist Grade- III and Dr. Subhash Chand, Scientist Grade III attended joint EDQM-USP webinar on “Overcoming obstacles in establishing pharmacopoeial reference standards: insights from case studies” held on 10.10.2024.
35. Ms. Sudha V Gopinath Scientist Grade-II, and Ms. Kanchan Ahuja, Scientist Grade-II, participated in 15th International meeting of World Pharmacopoeia (IMWP) on 05.02.2025 at Dr. Ambedkar International Centre, Delhi Organized by Indian Pharmacopoeia Commission (IPC).
36. Ms. Kanchan Ahuja, Scientist Grade-II attended a CME cum workshop on “Advanced ABO blood grouping and Rh phenotyping” on 09-10.04.2024 at Institute of Liver and Biliary Sciences (ILBS), New Delhi.
37. Ms. Kanchan Ahuja, Scientist Grade-II & Dr. Pankaj Kumar Sharma Scientist Grade-II participated ASSOCHAM Conference on Diagnostics organised by The Associated Chambers of Commerce & Industry of India at Hotel Lalit, New Delhi on 01.10.2024.
38. Ms. Kanchan Ahuja, Scientist Grade-II participated in one day “Genomics Data Conclave” organized by Department of Biotechnology (DBT) on 09.01.2025 at Vigyan Bhawan, New Delhi.

39. Ms. Kanchan Ahuja, Scientist Grade-II attended Bureau of Indian Standards (BIS) webinar on “Strengthening Healthcare Ecosystem through Standards” on 16.01.2025.
40. Dr. Neelima Mishra, Director NIB, Ms. Kanchan Ahuja, Scientist Grade-II and Dr. Richa Baranwal, Scientist Grade-III attended an annual convention for Deans/HODs of academic institution & research organization in health sector held on 31.01.2025 at NITS NOIDA.



41. Dr. Akanksha Bisht, Scientist Grade-I, attended 32nd GB meeting of National Blood Transfusion Council (NBTC) under the Chairmanship of (Prof.) Dr. Atul Goel, DGHS on 29.05.2024 at Nirman Bhawan, New Delhi.
42. Ms. Shalini Tewari, Scientist Grade- III and Ms. Rashmi Shrivastava, Scientist Grade III conducted the Internal Audit of *in-vitro* Diagnostic testing laboratory of ICMR-NIMR as per ISO/IEC 17025:2017 for NABL preparation on 05.08.2024 as internal auditor.
43. Ms. Kanchan Ahuja, Scientist Grade-II and Dr. Richa Baranwal, Scientist Grade III, virtually attended the 17th meeting of the MHD 19-*in-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices held on 27.09.2024.
44. Dr. Richa Baranwal, Scientist III, delivered a talk on “Quality Control Testing of *in-vitro* Diagnostic Kits” during two days Awareness Workshop held from 03-04.02.2025 on 'Navigating the Regulatory Landscape in Medtech Sector' at IIT-Kanpur, NOIDA campus, Uttar Pradesh.
45. Rashmi Shrivastava, Scientist Grade III, was nominated as speaker, attended CDSCO-NABL-ICMR Joint Program for *in-vitro* Diagnostic Testing Laboratories at ICMR HQ Delhi on 28.05.2024 and at ICMR-NIE Chennai on 07.06.2024 for delivering a talk on Assuring Quality in setting up CMDTL: Practical Approaches.



CDSCO-NABL-ICMR Joint Program for *in-vitro* Diagnostic Testing Laboratories at ICMR HQ Delhi on 28.05.2024 and at ICMR-NIE Chennai on 07.06.2024

46. Ms. Rashmi Shrivastava, Scientist Grade-III, invited as a panelist for Session VI entitled "Revolutionizing Healthcare: Exploring the Future of Healthcare Innovation in Transforming Lives" attended Kashmir Science Summit (Two-day Inter-University Academic Brainstorming), held in Srinagar from 23-24.08.2024.
47. Ms. Rashmi Shrivastava- Scientist Grade-III attended Genome India Data during Genomics Data Conclave on 24.01.2025 held at Vigyan Bhawan, New Delhi.
48. Ms. Rashmi Shrivastava- Scientist Grade-III, along with Dr. Hemant Kumar Verma, Scientist Grade II were nominated to showcase NIB activities at a 2-day Exhibition in 19th International Conference of Drug Regulatory Authorities (ICDRA) held at Yashobhoomi Convention and Expo Center, New Delhi on 14.10.2024 to 15.10.2024.
49. Dr. Subhash Chand, Scientist Grade-III participated in session "Future of Pharma QC: Rapid Microbiological Methods" to deliver regulatory perspective on Rapid Microbiological Methods and Panel discussion in conference BioMLuminescence India 2025 held on 20.02.2025 at Ahmedabad, India
50. Mr. Jaipal Meena, Scientist-III, attended a National Conference on advanced materials for sensor under the series "Sensor for Society" on 19.12.2024 at Jawaharlal Nehru University, New Delhi. He presented a poster entitled "Indigenous Development of an Immunoassay for precise detection of Total Immunoglobulin against Rabies in Post-Vaccination serum".
51. Mr. N. Nanda Gopal, Scientist Grade-III attended a training at DBT Center of Excellence for Biopharmaceutical Technology (COE-CBT), IIT Delhi on "CBT Course Series 2024" from 10-12.12.2024.
52. Mr. Tara Chand, Scientist Grade-III, Mr. Anoop Kumar, Junior scientist, Dr. Imran, Lab Technician and Mr. Rajeev Srivastav, Lab Assistant have attended a lecture titled "Control of Data and Records - Quality management Aspects" on 24.05.2024.
53. Mr. Tara Chand, Scientist-III and Ms. Archana Sayal, Junior Scientist attended training for Anti-Complementary Activity test in Immunoglobulins at M/s PlasmaGen BioSciences Pvt. Ltd. Bengaluru from 18-20.12.24.
54. Dr. Saurabh Sharma, Scientist Grade-III participated in 2-day workshop on "Scientific Writing, Research Integrity and Publication Ethics" on 20-21.03.2025 at ICMR-NIMR New Delhi Campus.
55. Dr. Jyoti Sharma, Scientist Grade-III, Dr. Priya Sharma, Junior Scientist, Dr. Mohammad Imran, Lab Technician, Mr. Mohitlal, Lab Technician attended 4-day training programme on 'Laboratory Quality Management System and Internal Audit as per IS/ISO/IEC 17025:2017 from 06-09.08.2024 at NITS, NOIDA.
56. Dr. Jyoti Sharma, Scientist Grade-III attended 9th Annual CBT Course Series 2024 hosted by DBT Centre of Excellence for Biopharmaceutical Technology (COE-CBT) from 10-12.12.2024 at IIT Delhi, Hauz Khas, New Delhi.
57. Mr. Anoop Kumar, Junior Scientist, Mr. Brij Bahadur, Junior Scientist and Mr. Reetesh Kumar Prajapati, Laboratory Technician attended a seminar titled "Advanced Analytical Solutions Day: Discover the Future of Ion Chromatography" organized by M/s Thermo Fisher Scientific at New Delhi on 22.05.2024.
58. Md. Daud Ali, Junior Scientist, Mr. Subhash Kumar, Junior Scientist attended 2-day capsule course on "Medical Device Quality and Risk Management" held during 21-22.10.2024 at National Institute of Training for Standardization, NOIDA conducted by Bureau of Indian Standards.

59. Dr. Gauri Misra, Scientist Grade-I, has attended the 20th Technical Advisory Committee (TAC) meeting of MedTechMitra hosted by Atal Innovation Mission (AIM)-Niti Aayog in New Delhi on 09.09.2024.



60. Mr. Subhash Kumar, Junior Scientist participated in preparing for Pharma industry expectations-Orientation Session for Aspiring Pharma Graduates webinar on 24.02.2025.
61. Ms. Suchitra, Junior Scientist attended 04-day training programme on "Laboratory Quality Management System and Internal Audit as per IS/ISO/IEC 17025:2017", held from 09-12.09.2024 at NITS, NOIDA.
62. Mr. Rajeev Kumar, Junior Scientist, presented a poster titled "NIB-INSTITUTE FOR SAFEGUARDING OF PUBLIC" at XV Annual Conference of Indian Society for Malaria and other Communicable Disease (ISMOCD) held from 31.01.2025-02.02.2025 at NIMR, ICMR-NIMR, Delhi.
63. Ms. Sanchi Goel, Junior Scientist, virtually attended a seminar on "An Opportunity to Explore the Technicalities of Calibration Weights & Their Types Based on Usage" by technical expert from M/s Mass Praizise on 18.07.2024.
64. Ms. Sanchi Goel, Junior Scientist, virtually attended the National Seminar on "Metrology and Conformity Assessment" organized by Legal Metrology, Ministry of Consumer Affairs, Food & Public Distribution, Department of Consumer Affairs, Government of India on 27.07.2024.
65. Ms. Sanchi Goel, Junior Scientist, attended seminar on " Overview of Quality Management System and its Implementation" organized by Bureau of Indian Standards-CRO on 04.09.2024 at Hotel Royal Plaza, Cannaught Place, New Delhi.
66. Ms. Sanchi Goel, Junior Scientist, virtually attended a One-day Webinar on "British Pharmacopoeia 2025" organized by British Pharmacopoeia -Medicine & Healthcare Products Regulatory Agency on 16.09.2024.
67. Dr. Priya Sharma, Junior Scientist, participated and successfully completed the hands-on-training programme entitled "Genetic and Microbial Monitoring of Animals" under CSIR Integrated Skill Initiative at CSIR-Centre for Cellular and molecular Biology (CCMB), Hyderabad, India, from 26-31.08.2024.
68. Dr. Farha Deebea, Post Doctoral Fellow delivered talk on "Gene Targeting Precision: CRISPR/Cas9 and Cell Line Knockout" on National Science Day, CME on "Bridging Science and Technology: Advancing Multidisciplinary Research in Healthcare" organized by Multi-Disciplinary Research Unit (MRU), Department of Research; Development (R&D) on 28.02.2025 at Government Institute of Medical Sciences (GIMS), Greater NOIDA.
69. Dr. Farha Deebea, Post Doctoral Fellow attended 32nd Skill Development Programme on Pharmacovigilance (Virtual mode), National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), 03-07.03.2025, Indian Pharmacopoeia Commission (IPC), Ghaziabad, UP.
70. Ms. Kavita, Mr. Krishnakant Dalai, Mr. Sohikul Islam (PhD scholars) and Pooja Bharali (Research Assistant) attended hands-on-training on Flow cytometer: Detection of molecular markers (DNA and Protein) in cancer research at National Institute of Cancer Prevention and Research, NOIDA held on 23-24.04.2024.

71. Mr. Sohidul Islam (PhD scholar) attended a webinar on “multi-omics data analysis in Bioinformatics” held on 15.05.2024.
72. Mr. Sohidul Islam (PhD scholar) attended a webinar on “Next Generation Sequencing-Optimizing Techniques” held on 25.07.2024.
73. Mr. Sohidul Islam (PhD scholar) has attended an ‘Information Session” on the Fellowship Opportunities in German Universities, offered by DAAD Regional Office, for AcSIR Ph.D. students and AcSIR Faculty virtually held on 05.07. 2024.
74. Mr. Sohidul Islam (PhD scholar) attended an Online Seminar on Art of Scientific writing on 08.09.2024 and a “Cancer Biology Certification course” on 18-27.10.2024, organized by CATR.
75. Ms. Pooja Bharali (Research Assistant) has given an oral presentation on “Assessing the Comparative Bioactivity of Trastuzumab Biosimilars Using a Cell-Based Inhibition of Proliferation Assay” at 20th National Research Scholars Meet held at ACTREC, TMC Mumbai held on 11-12.12.2024.
76. Mr. Sohidul Islam (PhD scholar) presented a poster Entitled “Expression of Endophilin-A in Breast Cancer correlates with Metastasis and Prognosis-Evidence from Database Analysis” at 1st International Computational Biology Conference 2025, held on 19-21.02.2025 at IBDC, RCB, Faridabad, Haryana, India.
77. Ms. Kavita (PhD scholar) presented a poster on “Expression of CHAC2 in Breast Cancer: Functional and Prognostic Insights” on National Science Day at Government Institute of Medical Sciences, NOIDA on 28.02.2025.
78. Mr. Krishnakant Dalai (PhD scholar) presented a poster on “Expression of KIBRA in Breast Cancer: Bioinformatics and Experimental Perspectives” on National Science Day at Government Institute of Medical Sciences, NOIDA on 28.02.2025.
79. Mr. Sohidul Islam (PhD scholar) presented a poster on “Database Analysis of Endophilin an Expression In-Breast Cancer: Correlation with Metastasis and Prognosis” on National Science Day at Government Institute of Medical Sciences, NOIDA on 28.02.2025.
80. Ms. Pooja Bharali (Research Assistant) presented a poster on “Evaluation of the comparative bioactivity of trastuzumab biosimilars based on binding and cell-based potency assay” on National Science Day at Government Institute of Medical Sciences, NOIDA on 28.02.2025.
81. Ms. Rashmi (PhD Scholar) presented a poster on “Investigation the CBX Family in Breast Cancer: Prognostics Implication of CBX3” in a Workshop on Computational Oncology: Integrating experiments and computational models (WOCON-24) organized by IIT-BHU, Varanasi in collaboration with the Param Hansa Centre for Computational oncology, IISc Bangalore during 17-18.12.2024 and published the following scientific abstracts in the Young Scientist Conference (YSC), in the India International Science Festival (IISF) 2024 on 20.12.2024
 - I. Investigating the CBX Family in Breast Cancer: Prognostic Implications of CBX3”
 - II. “Silencing Serine/Threonine Kinases to Disrupt Breast Cancer Signaling Pathways”.
82. Ms. Rashmi (PhD Scholar) presented a poster on “Development of a Microfluidic CRISPR-CAS 9/12 based Lateral Flow Assay for rapid and Economical identification of Dengue Virus Serotypes” at the XV Annual Conference of Indian Society of Malaria and Other Communicable Diseases (ISMCD) in collaboration with NIMR-ICMR and MCD on the theme ‘Climate change and growing threat of vector borne diseases’ at ICMR-NIMR, Delhi from 31.01.2025 to 02.02.2025.
83. Mr. Praveen Kumar, Project Technical Support-III (PTS=III) attended a 5 day training on Malaria Microscopy organised by NCVBDC, Delhi, from 17.03.2025 to 21.03.2025 at NCVBDC, Delhi. He successfully completed the training and achieved A- grade.



CONTRIBUTION IN DEVELOPMENT OF INDIAN PHARMACOPEIA MONOGRAPH

Blood Reagent Laboratory published a total number of 09 monographs in the Indian Pharmacopoeia.

A total of 06 amendments to below mentioned monographs have been proposed in the year 2024-2025.

1. Anti-D (IgM) Blood Grouping Reagent
2. Anti-D (IgM + IgG) Blood Grouping Reagent
3. Anti-D (IgG) Blood Grouping Reagent
4. Anti-Human Globulin (AHG) reagent

Recombinant Products Laboratory submitted a proposal to harmonize the system suitability criteria and specification limit for test on “Dimers and related substances of higher molecular mass. Determine by Size Exclusion Chromatography (2.4.16) in Erythropoietin concentrated Solution monograph IP 2022”. NIB gave expert opinion to IPC, Ghaziabad on the justification for the proposed change received from stakeholder as requested by IPC.

Therapeutic Antibodies Laboratory is involved in verification of Trastuzumab monograph in collaboration with Indian Pharmacopoeia Commission (IPC).

Vaccine and Antisera Laboratory contributed through Expert Working Group of IPC in the development and amendments of the monographs from time to time as desired.

Blood Products Laboratory submitted the proposals for amendment in:

1. Albumin Monograph for addition of alternative method i.e. Method-III under “Assay” for Total Protein in Indian Pharmacopoeia on 19.02.2025.
2. Human Prothrombin Complex Monograph for Addition of Solubility Test parameter under “Tests” in Indian Pharmacopoeia on 14.02.2025.
3. Human Coagulation Factor (rDNA) for solubility test on 25.02.2025.

Centralized Facility for Bioassays verified the Inhibition of proliferation assay for the biological activity of trastuzumab and submitted it for further deliberation and discussion with IPC for incorporation in the draft IP monograph. A discussion on the inclusion of the Trastuzumab Concentrated Solution monograph and the Trastuzumab injection draft monograph in the Indian Pharmacopoeia was held on 28.02.2025.

Enzyme and Hormone Laboratory submitted the expert opinion for proposed amendment in Somatropin for Injection monograph IP 2022. The lab was also involved in finalizing the nomenclature for the Alfa and Beta forms of Recombinant Human Follicle Stimulating Hormone (rFSH) Drug Substance and Drug Product in the IP 2022 monograph.

PREPARATION AND SUPPLY OF NATIONAL REFERENCE STANDARDS/ SERA PERFORMANCE PANELS

IMMUNODIAGNOSTIC KIT LABORATORY

1. 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.
2. Immunodiagnostic Kit laboratory has supplied 08 nos. of performance panels of various markers to indigenous manufacturers for strengthening their quality during manufacturing process of Immunodiagnostic kits.

BLOOD REAGENT LABORATORY

1. The laboratory collected 405 blood samples, grouped, sub-grouped, and phenotyped for the Rh factor in the year of 2024-2025, which will be used for the quality control evaluation of blood grouping reagents.
2. The laboratory maintains and strengthens the repository for cryopreserved red blood cell panels (routine and rare blood group), using leftover samples collected from various blood banks. The laboratory cryopreserved 1,733 aliquots of red blood cells. As a result, the total number of aliquots increased from 19,720 to 21453.

RECOMBINANT PRODUCT LABORATORY

1. **Development of National Reference Standard for Insulin Glargine:** In continuation to the meeting held for development of First National Reference Standard (NRS) for Insulin Glargine, NIB has received confirmation from the innovator for the supply of candidate material.
2. **Supply of reference standard** supplied a total of 11 vials of Human Insulin IPRS and 07 vials of Human Insulin Lispro to indigenous manufacturers.

CENTRAL FACILITY FOR BIOASSAY

Central Facility for Bioassay initiated for preparation of National Reference Standards for biological activity for 3 mAbs in collaboration with Reference Standard Unit of NIB.

PUBLICATIONS

1. Rajput MK, Singh MP, Singh A, Chand T, Kumar A, Kumari M. Effect of amino acid addition as stabilizers on total protein content of intravenous therapeutic human normal Immunoglobulin. *Asian J Pharm Clin Res.* 2024 July 7; 148-152.
2. Kumar A, Maheriya T, Madhu Y, Neetu K, Chander H, Kumari M. Validation of GF-AAS Method for the Determination of Aluminium Content in Human Albumin Finished Product. 2024 Sept 4; 20(8): 792-799.
3. Raghuwanshi B, Ahuja K, Sharma G, Sharma K, Singh M, Yadav A, et al. The Distribution Patterns of Rhesus (Rh) Antigens. *Cureus.* 2024 June; 16(6): e62476.
4. Bharali P, Chand S, Chander H. A Cost-Effective and Robust Cell-Based Bioassay Method for Evaluating the Bioactivity of Trastuzumab-like Antibodies. *Biomedicines.* 2025 Jan; 13(1): 23.
5. Meena J, Shiekh F, Bindra G, Yadav S, Kasana H, Chander H, et al. Challenges in Ensuring the Safety of Aluminum Adjuvanted Vaccine: A Case Study of Inactivated Rabies Vaccines by National Control Laboratory. 2024.
6. Kasana H, Ade AK, Meena J, Sayal A, Sheikh F, Anvikar AR, et al. SARS-CoV-2 spike protein expression as an identification in quality control testing for Adenovector based COVID-19 vaccine. *J Immunol Methods.* 2024 June 1; 529: 113680.
7. Kumar A, Misra G, Mohandas S, Yadav PD. Multi-epitope vaccine design using in silico analysis of glycoprotein and nucleocapsid of NIPAH virus. *PLOS ONE.* 2024 May 10; 19(5): e0300507.
8. Sharma MP, Shukla S, Misra G. Recent advances in breast cancer cell line research. *Int J Cancer.* 2024 May 15; 154(10): 1683-1693.
9. Roy M, Mathur S, Gupta PP, Kaushik S, Misra G, Kothari SL, et al. Elucidation of EhSec1 and Interaction with EhSyntaxin1A /1B of Entamoeba Histolytica via Docking and Molecular Simulations. 2025 Aug 20
10. Kumar A, Saini S, Anvikar A, Mishra N, Misra G. Evolving Landscape of Emerging Virus Diagnosis: Challenges and Innovations. *Mol Biotechnol.* 2025 Mar 5;
11. Chand T, Dubey AK, Misra G. Unraveling HPV-associated cancer complexity: From molecular insights to innovative therapies. *Heliyon.* 2025 Feb 15; 11(3): e42437.
12. Garg N, Kamal CM. Advancements on Substitution of *in-vivo* Method(s) with *in-vitro* Method(s) for Recombinant Human Erythropoietin Potency Assays. *Int J Pept Res Ther.* 2025 Jan 28; 31(2): 28.
13. Garg N, Mendiratta S, Bindra G, Gehlot S, Goswami K, Kamal CM. Estimation of protein aggregates in Darbepoetin alfa formulations by developing a single validated analytical method. *J Chromatogr B.* 2025 Mar 15; 1254: 124518.

14. Karpe SC, Kiran M, Majhi S, Meena J, Kumar R, Chander H, et al. Clotrimazole as a new frontier: Drug repurposing and its efficacy in cancer therapy. *Cancer Pathog.* 2025 Mar 26
15. Rohira H, Shankar S, Yadav S, Srivastava PP, Minocha S, Vaddavalli PK, et al. RiTe conjugate mediated corneal collagen crosslinking, a novel therapeutic intervention for keratoconus - in vitro and in vivo study. *Int J Pharm.* 2024 May 10; 656: 124092.
16. Sood J, Shankar S, Shah SG, Yadav S, Chugh A. Application of membrane-active peptide-based therapeutics in the management of stromal melts associated with microbial keratitis (Conference Paper).
17. Kumar S, Raj VS, Pandey RP. Immunotherapy by modulating the gut microbiome and related pathophysiology in mice. *ImmuneCONNECT (2024)-The Official Newsletter of the Indian Immunology Society (IIS).* 2024 Oct; (Issue II).
18. Kumar S, Deeba F, Sharma P, Kumar L, Kumari R, Chaudhary M, et al. Analysis of historical data to accelerate deletion of Abnormal Toxicity Test requirement for biologicals and vaccines. *Toxicol Rep.* 2024 Dec 1; 13: 101815.
19. Kumar S, Mukherjee R, Gaur P, Leal É, Lyu X, Ahmad S, et al. Unveiling roles of beneficial gut bacteria and optimal diets for health. *Front Microbiol.* 2025 Feb 18;16.
20. Mendiratta S, Bindra G, Sukhwinder S, Katoch P, Pandey K, Chander H, Anvikar AR, Kamal CM. Less is more: Validating a single method for comprehensive rh-insulin analysis. *Journal of Pharmaceutical & Biomedical Analysis.* 2024 July; 244.
21. Shalini Tewari, Niharika Trivedi, Sanchi Goel, Rashmi Shrivastava, Sudha. V. Gopinath, Ayushi Khurana, Anupkumar R. Anvikar, Measurement uncertainty in testing of biologicals in national control laboratories for ISO/IEC 17025: practical approaches, (Published online: 14th April 2024) in *Accreditation and Quality Assurance Journal*, Springer., <https://link.springer.com/article/10.1007/s00769-024-01589-8>

Patent (s):

1. Dr. Gauri Misra, Scientist Grade-I, has filed the following Patent on 15.05.2024: “Allele-specific primer probe sets for the rapid and accurate diagnosis and differentiation of Omicron and Delta variant of SARS Cov-2” in the name of National Institute of Biologicals, Patent Application No. 202411038068.
2. A patent titled “A novel formulation for breast cancer and process thereof” has been filed by Lovely Professional University, Jalandhar along with Mr. Harit Kasana, Scientist Grade-II and Dr. Manjula Kiran, Scientist Grade-III as external co-inventors. The work submitted for the patent is part of one-year dissertation work conducted in Vaccine and Antisera Lab under their supervision.

Books(s)

Misra, G. (Ed.). (2024). *Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices* (1st ed.). CRC Press.

Book Chapter(s):

1. Kiran M. “Accreditation for Biologicals” in *Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices*. In: *Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices*. CRC Press; 2024.

2. Kumar S, Atul PK. Animal Models for Gut Microbiome Research. In: Animal Models in Research: Principles and Practice. 2024. p. 255-81.
3. Kumar A. Animal-Based Testing Methods and Their Alternatives in Quality Control Evaluation of Biologicals. In: Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices. CRC Press; 2024.
4. Sharma B, Singh P, Shukla S, Misra G. Good Manufacturing Practices in Quality Control. In: Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices. CRC Press; 2024.
5. Dubey AK, Gupta M. Importance of Quality Control in Biologicals. In: Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices. CRC Press; 2024.
6. Chand T, Dubey AK. Quality control considerations specific to the development and production of gene and cell therapies. In: Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices. CRC Press; 2024.
7. Singh S, Sharma MP, Misra G. Regulatory Bodies: European Medicines Agency (EMA) and Pharmaceutical Inspection Co-operation Scheme (PIC/S). In: Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices. CRC Press; 2024.
8. Kumar A, Dubey A, Misra G. Role of cytokines in Chikungunya infections, in Cytokine Response Against Major Human Viral Infections. In: Cytokine Response Against Major Human Viral Infections. 2024.

RESEARCH AND DEVELOPMENT

1. Ph.D. Programme:

As a step towards higher excellence, NIB signed an MOU with AcSIR on 28.02.2022, for conducting Ph.D. Program at NIB with special emphasis on Quality evaluation of Biologicals. Following students have been enrolled in this programme:

S.N.	Name of Ph.D. Scholar	Enrolment/Registration No.	Session	Fellowship/Internal	Ph.D. Guide/Supervisor
1	Krishnakant Dalai	10BB22A72011	August (2022)	CSIR-UGC NET JRF	Dr. Meena Kumari
2	Kavita	10BB22A72010	August (2022)	CSIR-UGC NET JRF	Dr. Harish Chander
3	Rashmi	10BB22A72005	August (2022)	CSIR-UGC NET JRF	Dr. Gauri Misra
4	Jaipal Meena	10BB22A72008	August (2022)	INTERNAL	Dr. Shikha Yadav
5	Rashmi Shrivastava	10BB22A72007	August (2022)	INTERNAL	Dr. Harish Chander
6	Gurminder Bindra	10BB22A72006	August (2022)	INTERNAL	Dr. Charu Mehra Kamal
7	N. Nanda Gopal	10BB22A72009	August (2022)	INTERNAL	Dr. Charu Mehra Kamal
8	Sohidul Islam	10BB23J72004	January (2023)	UGC- NFOBC	Dr. Harish Chander
9	Supriya Shukla	10BB23J72002	January (2023)	DBT-JRF	Dr. Gauri Misra
10	Manika P Sharma	10BB23J72003	January (2023)	DST-INSPIRE	Dr. Gauri Misra
11	Tara Chand	10BB23J72005	January (2023)	INTERNAL	Dr. Gauri Misra
12	Anirban Mukharjee	10BB24A72005	August (2024)	INTERNAL	Dr. Ashwani K. Dubey
13	Ajay Ade	10BB24A72006	August (2024)	INTERNAL	Dr. Harish Chander
14	Md. Daud Ali	10BB25J72008	January (2025)	INTERNAL	Dr. Richa Baranwal
15	Rajiv Kumar	10BB25J72006	January (2025)	INTERNAL	Dr. Richa Baranwal
16	Archana Sayal	10BB25J72005	January (2025)	INTERNAL	Dr. Manoj Kumar
17	Anup Kumar	10BB25J72007	January (2025)	INTERNAL	Dr. Manoj Kumar
18	Garima	10BB25J72004	January (2025)	UGC-JRF	Dr. Ratnesh K. Sharma

2. NIB Sponsored Post-Doctoral Fellowship (PDF) Programme:

NIB has started the institute sponsored Postdoctoral fellowships (PDFs) at NIB with the aim is to develop professional skills in the field of quality control and development of new biologicals such as diagnostic kits, vaccines, recombinants products, monoclonal antibodies, etc. The trained postdoctoral fellows would improve on quality control methods of testing the biologicals and would contribute towards the development of new biologicals. In a long-term this programme would help NIB and MoHFW in safeguarding the public health.

In pursuance, NIB had its first batch of 02 PDFs in FY 2024-25 and details are as below:

S.No.	Name of PDF	Date of Joining at NIB	Supervisor
1	Dr. Farah Deebea	01.08.2023	Dr. Shikha Yadav
2	Dr. Nupur	12.07.2023	Dr. Charu M. Kamal

3. Intramural Research Projects:

The scientists of NIB are undertaking scientific research as per their laboratory work in the field of biologicals. There are following intramural research projects are ongoing with NIB funding:

S. No.	Name of Project	Name of Investigator & Co-investigator	Status/ Remark
1)	Estimation of potency of Urokinase assay by Chromogenic method for replacement of existing bioassay	Dr. Hemant Kumar Verma Mr. N. Nanda Gopal	Ongoing
2)	Comparative study to check the viability of cryopreserved Red blood cells (A ₁ , A ₂ and A ₂ B cells) when thawed and re-suspended in Alsever's solution for a period of 3 months	Ms. Kanchan Ahuja Dr. Pankaj K. Sharma, Mr. Subhash Kumar	Ongoing
3)	Comparative study to check the viability of cryopreserved red blood cells sensitized with Anti- D (IgM) with thawed Anti-D (IgM) sensitized cryopreserved red blood cells re-suspended in Alsever's solution for a period of 2 years	Ms. Kanchan Ahuja Dr. Pankaj K. Sharma, Mr. Subhash Kumar	Ongoing
4)	Formulation and <i>in-vitro</i> evaluation of clotrimazole-loaded polymeric nanoparticles for drug repurposing in breast cancer treatment	Mr. Harit Kasana Dr. Manjula Kiran	Ongoing
5)	Rapid microbiological Method for Sterility testing of Biotherapeutics.	Dr. Subhash Chand Mr. Neeraj Malik, Mr. Anirban Mukherjee	Ongoing
6)	Development of National Reference Standard (NRS) for Biological Activity of Rituximab, Trastuzumab, Bevacizumab.	Dr. Harish Chander Dr. Charu M. Kamal, Ms. Sudha V. Gopinath, Dr. Subhash Chand	Ongoing
7)	Validation of method for estimating Identity and Purity of Darbepoetin alfa by SDS-PAGE method	Dr. Charu Mehra Kamal Dr. Sanjay Mendiratta Ms. Gurminder Bindra	New
8)	Development of National Reference Standard (NRS) for Insulin Glargine	Dr. Charu Mehra Kamal Ms. Gurminder Bindra Dr. Sanjay Mendiratta	Ongoing
9)	Harmonization of cell-based potency estimation assay of Darbepoetin alfa formulations	Dr. Charu Mehra Kamal	New
10)	Development and validation of Darbepoetin RP-HPLC method for estimation of purity, identity and related proteins	Dr. Charu Mehra Kamal Dr. Sanjay Mendiratta Ms. Gurminder Bindra	New
11)	<i>In vitro</i> method development for recombinant human erythropoietin (rHuEPO) potency estimation	Dr. Charu Mehra Kamal Ms. Gurminder Bindra Dr. Sanjay Mendiratta Dr. Birendra Kumar	Ongoing
12)	Analytical Method Development on Ultra High-Performance Liquid Chromatography	Dr. Charu Mehra Kamal Dr. Gaurav Pratap Singh Jadaun	New

S. No.	Name of Project	Name of Investigator & Co-investigator	Status/ Remark
	(UHPLC) for determining Identification, Potency and Purity of Anti Diabetics		
13)	To study the neurotoxicity of rabies vaccine excipients by intracerebral route in mice	Dr. Subhash Chand Dr. Shikha Yadav	New
14)	Standardization and optimization of the inhibition of proliferation assay for anti-TNF monoclonal antibodies	Dr. Subhash Chand Mr. Ajay Kumar Ade	Ongoing
15)	Standardization and Validation of Monocyte Activation Test (MAT) for biologics	Dr. Subhash Chand Mr. Ajay Kumar Ade	New
16)	Development and validation of Homogeneous Time Resolved Fluorescence (HTRF) as a high-throughput platform for assessing Identity of Therapeutic Monoclonal Antibody samples received on Form-18	Dr. Ratnesh Kumar Sharma	New
17)	A combination therapy of Nivolumab and Bacillus Calmette-Guerin for management of urinary bladder cancer: An exploratory study	Dr. Ratnesh Kumar Sharma	New
18)	Establishment of Bacterial Endotoxin Test in Blood Products as an Alternate Method for the Rabbit Pyrogen Test	Dr. Shikha Yadav	Ongoing
19)	Evaluation of an alternate kit-based method (ELISA) for potency assay in human rabies immunoglobulin (IM)	Dr. Meena Kumari Ms. Y.Madhu	Ongoing
20)	An alternate kit-based method for “Anti complementary activity” (ACA) test for Human Normal Immunoglobulin for intravenous use.	Dr. Meena Kumari Dr. Manoj Kumar	Ongoing
21)	Establishment of Quality Control Malaria Testing Laboratory at NIB	Ms. Y. Madhu Dr. Supriya Sharma	New

Biotherapeutic Research Laboratory (BTRL)

BTRL was established in 2024 with the vision of advancing the frontiers of biotherapeutic innovation. Dedicated to research in the field of biotherapeutics, the laboratory concentrates on the design and development of next-generation therapeutic strategies with a central focus of the laboratory is the development of monoclonal antibodies (mAbs), with particular emphasis on antibody-drug conjugates (ADCs). Through the integration of advanced molecular biology techniques, the lab aims to develop novel methods for the testing of biotherapeutics such as mAbs and ADCs. Additionally, the laboratory is actively engaged in the discovery and validation of cancer biomarkers, with a special focus on breast cancer therapeutics. Through interdisciplinary collaboration and a commitment to translational research, the Biotherapeutic Research Laboratory endeavors to bridge the gap between scientific discovery and clinical application, ultimately aiming to improve patient outcomes in oncology and other therapeutic areas. Furthermore, the laboratory is designated with various scientific equipment for carrying out experiments in the field of cancer biotherapeutics.

The PhD research program at the laboratory operates under the umbrella of the Academy of Scientific and Innovative Research (AcSIR), encompassing both internal and external scholars. Currently, five PhD candidates are actively engaged in research within the laboratory—two of whom are internal scholars from NIB, while the remaining three are external fellows selected through AcSIR. In addition to the doctoral researchers, the laboratory hosts a research assistant working under an ICMR-funded project. The lab has also successfully supervised the dissertation of a postgraduate student and currently has a trainee involved in ongoing research activities, reflecting its commitment to fostering academic growth and hands-on scientific training

Research Projects Extramural and Intramural

S. No	TITLE	PROGRESS MADE	EXPECTED OUTCOMES
Extramural Projects			
1.	Development of <i>in-vitro</i> bioassay for biological activity of anti-HER2 therapeutic monoclonal antibodies based on the variability in the expression of HER2 in breast cancer cell lines	Optimization and validation of Trastuzumab biosimilars on HER2 positive breast cancer cell lines and tissues	One single method is developed to assess the functional potency of trastuzumab biosimilars on HER2 positive cell line of SKBR3.
Ongoing PhD Projects			
1.	Expression and regulation of FNBP4 in breast cancer		
2.	Expression and regulation of CHAC2 in breast cancer		
3.	Expression and regulation of KIBRA in breast cancer		
4.	Role of i-motif in the regulation of p53 mediated transcription		

Molecular Research Lab (MRL)

MRL has established strong collaborative networks with leading academic and clinical research institutions to enhance interdisciplinary research capacity. As part of the ICMR-funded Advanced Center for Clinical Evaluation of Diagnostics of National Importance (Project ID: ICMRCARE-2023-0000517), MRL is engaged in multicentric diagnostic evaluation studies in collaboration with IIT, Kanpur, IIT Delhi, AIIMS, New Delhi and Vardhman Mahavir Safdarjung Hospital, New Delhi.

Research Projects

S. No.	Project Title	Name of Investigator and Co-Investigators	Status/Remarks
1.	Advanced Centre for Clinical Evaluation of Diagnostics of National Importance (Project ID: ICMRCAREP-2023-0000517)-funded by ICMR Budget: Rs. 15 Crores (funded by ICMR, New Delhi), Tenure: 2024-2029	Site Principal Investigator from NIB-Dr. Gauri Misra Co-investigators from IIT Kanpur, IIT Delhi, AIIMS, New Delhi, Vardhman Mahavir Safdarjung Hospital, New Delhi and various institutions of ICMR	Ongoing
2.	Identification and validation of new “potential protein biomarker panel” for head and neck squamous cell carcinoma using translational proteomics. (Project ID: IIRPIG-2024-01-00541)-funded by ICMR Budget: 3 Crores, Tenure: 2025-2027	Site Principal Investigator from NIB-Dr. Gauri Misra Project Coordinator: Dr. Ashok Verma, Scientific Officer-H, ACTREC, Mumbai	Ongoing
3.	Design, Development and Validation of a Microfluidic CRISPR-CAS 9/12 based Lateral Flow Assay (POC) for rapid and economical identification of Dengue Virus Serotypes (DENV1, DENV2, DENV3 and DENV4)-funded by ICMR Budget: 18 Lakhs	PI: Dr. Archana U Kadam Mentor: Dr. Gauri Misra	Completed (01 patent filed)
4.	Harmonization of COVID-19 RT-PCR Kits efficiency data towards enhancing their specificity and sensitivity for different strains of SARS-Cov-2-funded by ICMR Budget: 26.62 Lakhs	PI: Dr. Gauri Misra Co-PI: Mr. Brij Bhushan	Completed (01 patent filed) 03 International publications

RENDERING TECHNICAL EXPERTISE THROUGH JOINT INSPECTIONS

The Institute provides technical expertise for the enforcement of implementing standards in India through joint inspections of (i) manufacturing premises in coordination with the Central Drugs Standards and Control Organizations (CDSCO), (ii) Animal Facilities conducted by Committee for the Control and Supervision of Experiments on Animals (CCSEA) and (iii) Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and as NABL assessor for testing laboratories in India.

- i) Dr. Ratnesh Kumar Sharma, Scientist Grade-II, participated virtually in a meeting held on 09.01.2025 along with CDSCO officials as subject expert in 'Joint inspection to grant permission in Form CT-11 to manufacture r-DNA derived drugs for the purpose of Examination, Test and Analysis at M/s Zydus Research Center, Zydus Life Science Limited, Ahmedabad, Gujarat, India.
- ii) Dr. Meena Kumari, Scientist Grade-II and Mr. Tara Chand, Scientist Grade-III participated in joint inspection with CDSCO for the grant of permission in Form CT-11 to manufacture Recombinant Human Albumin-20% Drug Substance and Recombinant Human Albumin 5%, 10% and 20% albumin in 50mL/100mL fill volumes-Drug Product at manufacturing facility M/s Shilpa Biocare Private Limited, Yadgir, Karnataka, India for the purpose of examination, test and analysis from 28.11.24 to 29.11.24
- iii) Mr. N. Nanda Gopal, Scientist Grade-III nominated as NABL Assessor for ISO/IEC 17025:2017 Assessment at M/s Zydus Life sciences Ltd, Ahmedabad from 28-29.09.2024.
- iv) Dr. Subhash Chand, Scientist Grade-III had been appointed as Observer by National Accreditation Board for Testing and Calibration Laboratories (NABL) for the assessment of a CAB as per ISO/IEC 17025:2017 at New Delhi on 04-05.05.2024.

TRAININGS AT NIB

Aim & Scope:

Focusing on Skill Development in “Quality Control of Biologicals”, NIB imparts Two-weeks residential Hands-on Training to Post-Graduate students of Biotechnology, Microbiology, Biochemistry from Universities of Himachal Pradesh, Jammu & Kashmir, North Eastern States and students from universities of Tribal Regions of the country i.e., Chhattisgarh, Jharkhand, Assam. The institute also provides Six weeks summer training and Four-Six months Project Work training in Quality Control of Biologicals in various NIB laboratories to Graduate and Post Graduate Students of various universities/ institutions, to enhance their technical capabilities, that would help in their future research endeavors. With an aim to disseminate knowledge in the field of Biologicals, NIB has launched different training programmes including lab specific structured training courses of One-Two weeks tenure. The Training Unit plays a major role in organizing these training programmes and also developing new programmes as well as strengthening the training activities of the Institute, under approved Annual Capacity Building Plan.

Training Activities Undertaken:

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

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

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. The five training batches conducted under this programme, are given in Table 1.

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

Name of Institute	Duration		No. of Participants
M.Sc. Biotechnology Students of Guru Ghasidas Vishwavidyalaya, Bilaspur, (Chhattisgarh)	22-04-2024	03-05-2024	31
M.Sc. Biotechnology Students of Vinoba Bhave University Hazaribagh, (Jharkhand)	03-06-2024	14-06-2024	30
M.Sc. Biotechnology Students of Bodoland University, Kokrajhar, (Assam)	27-08-2024	06-09-2024	31
Shaheed Mahendra Karma Vishwavidyalaya, Bastar, Chhattisgarh and Himachal Pradesh University, Shimla, Himachal Pradesh	18-11-2024	29-11-2024	38
Mizoram University, Mizoram and Nagaland University, Nagaland	06-01-2025	17-01-2025	32
Total			162



Two weeks residential NSDT programme on “Quality Control of Biologicals” with total 36 participants (35 M.Sc. Biotechnology Students + 01 Faculty member) from Guru Ghasidas Vishwavidyalaya, Bilaspur, Chhattisgarh) conducted from 22.04.2024-03.05.2024.



Two weeks residential NSDT programme on “Quality Control of Biologicals” involving total 30 participants (29 M.Sc. Biotechnology Students + 01 Faculty member) from Vinoba Bhave University Hazaribagh, (Jharkhand) conducted from 03-14.06.2024, at NIB-NOIDA



Two weeks residential NSDT programme on “Quality Control of Biologicals” involving total 31 participants (30 M.Sc. Biotechnology Students + 01 Faculty member) from Bodoland University, Kokrajhar, (Assam) conducted from 27.08.2024-06.09.2024, at NIB-NOIDA



Two weeks residential NSDT program on “Quality Control of Biologicals” involving total 38 participants (M.Sc. Biotechnology Students & Faculty from two universities; Shaheed Mahendra Karma Vishwavidyalaya, Bastar, (Chhattisgarh) and Himachal Pradesh University, Shimla, (Himachal Pradesh)) conducted from 18-29.11.2024 at NIB-NOIDA

Training of International delegates: Two delegates from Indonesia visited the Immunodiagnostic Kit Laboratory on 29.04.2024. Hands-on training on quality control testing of *In-vitro* diagnostic kits was provided to the delegates.



2.	Short -term Training Course on RT-PCR including RNA extraction	08-07-2024 to 12-07-2024	2
3.	Quality Control of Blood Products using Atomic Absorption Spectrometry (AAA)”	05-08-2024 to 09-08-2024	2
4.	Five-days training titled “Ethical use & care of laboratory animals in research and regulatory testing” (Batch-I)	02-09-2024 to 06-09-2024	12
	Five-days training titled “Ethical use & care of laboratory animals in research and regulatory testing” (Batch-II)	02-12-2024 to 06-12-2024	13
5.	Two-days training titled “Fundamentals of laboratory quality management system (ISO/IEC 17025: 2017)”	24-09-2024 to 25-09-2024	2
6.	Five-days training on “Application of Reverse Phase High Performance Liquid Chromatography (HPLC) for Identification and Potency Testing of Human Insulin”	13-01-2025 to 17-01-2025	01
7.	Five-days training course on “Quality Control Testing of Immunodiagnostic Kits”	20-01-2025 to 24-01-2025	01
8.	Five-days training course on “Quality Control of Blood Products using Coagulation Analyser (CA) special reference to Human coagulation factor VIII potency assay”	17-03-2025 to 21-03-2025	01
Total			39



Five-days training course entitled as “Cell Culture based Techniques for Evaluation of Biologicals and Vaccines” conducted from 24-28.06.2024 in Vaccine and Antisera Laboratory, NIB.



Two-days training titled” Fundamentals of Laboratory Quality Management Systems (ISO/IEC 17025: 2017)” held at QMU scheduled from 24-25.09.2024, as a part of structured Training course.

Training Programmes for other Institutes facilitated by NIB			
S. No	Event	Facilitator	Date
1.	ICMR Funded two-days training workshop on “Public Procurement of Goods and Services through Government e-Marketplace (GeM) portal” for Officers of Administration and Accounts of ICMR Institutes / Centers,	ICMR Delhi and NIB- NOIDA	24-01-2025 to 25-01-2025
2.	DHR Funded two-days training workshop on “Public Procurement of Goods and Services through Government e-Marketplace (GeM) portal” for Scientists, officers of Administration and Accounts of MRU, MRHRU & DHR	DHR Delhi and NIB- NOIDA	20-02-2025 to 21-02-2025



ICMR Funded Two-days training workshop On “Public Procurement of Goods and Services through Government e-Marketplace (GeM) portal” for Officers of Administration and Accounts of ICMR Institutes / Centers, held on 24-25.01.2025 at NIB-NOIDA.



DHR Funded two-days training program on “Public Procurement of Goods and Services through Government e-Marketplace (GeM) portal” for Scientists, officers of Administration and Accounts of MRU, MRHRU & DHR, held on 20-21.02.2025 at NIB-NOIDA.

Trainings/ Events under Annual Capacity Building plan-2024-25

In order to ensure the highest quality standard and effectiveness of work culture, NIB customized Annual Capacity Building plan 2024-25 (involving internal, external trainings, Online, Offline workshops and special lectures) for the NIB Scientific faculty and other Officials. Most of the events proposed under this programme are held at NIB while few trainings through ISTM- Delhi, & NITS-NOIDA.

Onsite Lectures/ Events for NIB staff			
S. No.	Date	Title	Facilitator/ Trainer
1.	29-04-2024	Orientation Training Programme on “Building Effective Team	Dr. Nidhi Phutela (Director- Symbiosis Management Studies)
2.	30-04-2024	Lecture Session on “Biomedical waste management Regulations and Best practices”	Dr. Suresh Kumar (Scientist Grade-III, NIB)
3.	24-05-2024	Lecture Session on “Control of Data and Records- Quality Management Aspects”	Ms. Rashmi Srivastava (Scientist Grade-III, NIB)
4.	20-06-2024	Lecture Session on “Investigation of OOS results and repeat testing: NIB Policy”	Ms. Y. Madhu (Scientist Grade-III, NIB)
5.	02-07-2024	Lecture Session on “Intellectual Property Rights IPR”	Dr. Vivek Kashyap Lead (Associate Director)- Patents, Roche Products (India) Pvt. Ltd.
6.	30-07-2024	Lecture “Biosafety Regulations and best practices Laboratory Biosafety Management”	Sh. N. Nanda Gopal (Scientist Grade-III, NIB)
7.	15-10-2024	Lecture on “SciFlow- an innovative writing and publishing platform for scientific publishing”	Balani Infotech Pvt Ltd. Sector 67, NOIDA, UP
8.	21-10-2024	Lecture session on Basics & principle of volumetric analysis	Dr. J. P. Prasad (Ex. DD-QC, NIB-NOIDA)

9.	22-10-2024	Scientific Seminar on Application of Statistical Tools in Biomedical Research	Dr. D. K. Yadav (Faculty, Head Dept. of Statistics & Demography) NIHFW New Delhi.
10.	23-10-2024	Lecture cum-interaction session on topic; Stress Management	Dr. Vinay Sharma Professional (Corporate Trainer & Senior Adviser)
11.	23-10-2024	Training and felicitation of Sanitary Workers Swacchta Hi Sewa Campaign	Training unit, Engineering & Admin. NIB, NOIDA
12.	24-10-2024	Seminar on Leadership and team management	Dr. Nidhi Phutela (Director-Symbiosis Centre for Management Studies, NOIDA)
13.	25-10-2024	Scientific session on Artificial Intelligence in Medical Diagnostics	Dr. Sanjay Singh and Dr. Adarsh Srivastava (Roche Diagnostics India Pvt. Ltd.)
14.	26-11-2024	Lecture on “Smart Sensing platforms for SARS-COV-2”	Dr. Sonu Gandhi (Scientist-E, National Institute of Animal Biotechnology NIAB, Department of Biotechnology,
15.	29-11-2024	Lecture cum Interaction Session on “Procurement in Scientific Research”	Ms. Rekha Saxena Scientist-G, National Institute of Cancer Prevention and Research, NOIDA Indian Council of Medical Research (ICMR)
16.	27-12-2024	One-Day Training workshop on “Procurement process through GeM”	Ms. Rekha Saxena Scientist-G, National Institute of Cancer Prevention and Research, NOIDA Indian Council of Medical Research (ICMR)
17.	28-01-2025	Lecture Session on “Good Laboratory Practices– NGCMA Guidelines and Requirements”	Dr. Ekta Kapoor Scientist 'F' & Head National GLP Compliance Monitoring Authority, DST.
18.	07-03-2025	Seminars on “Basics of Statistics and its Applications”	Dr. R. J. Yadav (Ex. Sr. Scientist ICMR Delhi, Consultant Statistics-NIB).
19.	18-03-2025	Lecture Session on “Drugs and Cosmetic Act and Rules”	Dr. Arvind Kukrety Deputy Drugs Controller (I), CDSCO, Delhi
20.	26-03-2025	Lecture Session on “HPLC Data Analysis, Integrity Ensuring Control of Chromatographs, and Results”	Sh. Amod Yadav (Waters Corporation, Delhi, INDIA).

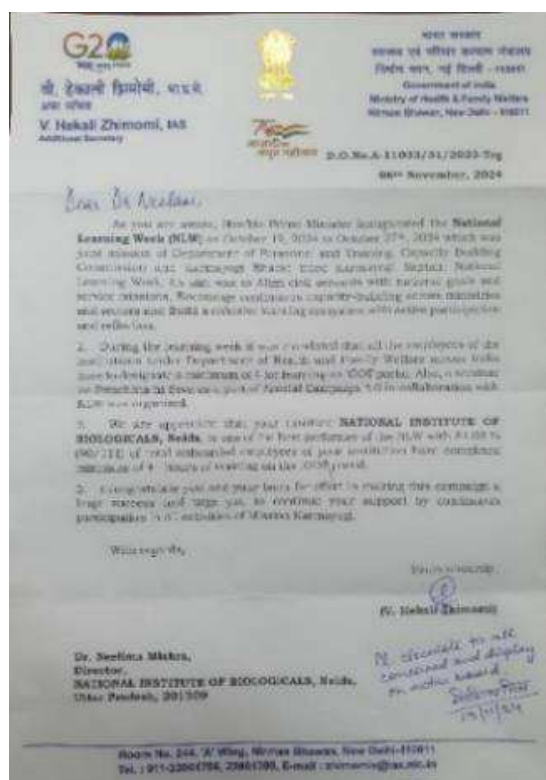
Off-site Trainings / Lectures and other events for NIB staff				
S. No.	Date	Title	Facilitator/ Trainer	Participants
21.	13-05-2024 to 14-05-2024	Two-Days Online workshop on Income tax	ISTM, New Delhi	01 NIB Finance official

22.	24-06-2024 to 25-06-2024	Two-Days Online workshop on ILC-PT	BIS, NITS-NOIDA	01 NIB Sr. Scientist
23.	06-08-2024 to 09-08-2024	Four days training on “LQMS and Internal Audit as per IS/ISO/IEC 17025:2017”	BIS, NITS-NOIDA	06 NIB Lab staff
24.	13-08-2024	One Day Workshop on Content Creation for IGOT platform	NIHFW, New Delhi	02 NIB Sr. Scientists
25.	09-09-2024 to 12-09-2024	Four days training on “LQMS and Internal Audit as per IS/ISO/IEC 17025:2017”	BIS, NITS-NOIDA	04 NIB Lab staff
26.	21-10-2024 to 22-10-2024	Two-day Capsule Course on Medical Device Quality and Risk Management	BIS, NITS-NOIDA	03 NIB Lab staff
27.	06-12-2024	One-day workshop on Content Creation and Monitoring MoHFW Courses on IGOT Platform under Mission Karmayogi	NIHFW, Delhi	02 NIB IT Officials
28.	20-12-2024	Online CERT-In's training program on "Cyber Crisis Management Plan (CCMP)"	CERT, New Delhi	02 NIB IT Officials

Appreciation for Karmayogi Saptah National Learning Week at NIB

NIB-NOIDA organized special lectures / events at the Institute during the Karmayogi Saptah-National Learning Week held from 19-25.10.2024. In this regard, NIB got prompt support from various guest speakers/ resource person with their expertise lecture cum interaction sessions during this NLW program. In addition to this, 81% of the employees of institute completed the minimum 4 + plus hours of learning on the IGOT portal

NIB declared as One of the Best Performers of National Learning Week by MoHFW, Government of India.



Glimpse of various events organized under Karmayogi Saptah- National Learning Week celebrated from 19-25.10.2024.



VISITS TO NIB LABORATORIES

- **Lab visit of Clinical Research students from DBT-THSTI Faridabad**

Training unit facilitated and coordinated all arrangements to manage Half-day Lab visit of M.Sc. Clinical Research students from DBT-Translational Health Science and Technology Institute (THSTI) Faridabad Haryana, to NIB-NOIDA, scheduled to be held on 30.08.2024. The visit is proposed to involve total 26 THSTI personal (23 M.Sc. Clinical Research students and 3 staff members).

- **One-day Lab visit of IIIT-NOIDA students to NIB**

Training unit facilitated and coordinated in organising One-day Laboratory visit of students including M. Tech. Biotechnology, M.Sc. Microbiology & PhD scholars from Jaypee Institute of Information Technology (IIIT) NOIDA, held on 06.11.2024. **Total 31 Students** accompanied by 03 Faculty staff were part of this one-day lab visit.



One-day Laboratory visit of students from Jaypee Institute of Information Technology (IIIT) NOIDA, held on 06.11.2024.

HAEMOVIGILANCE PROGRAMME OF INDIA

1. Scientific Activities Undertaken:

- a. Implementation and coordination of activities of Haemovigilance Programme of India (HvPI) is one of the mandates of NIB as per its bye-laws 3.4.1 as approved in the 24th Governing Body meeting of NIB held under the Chairmanship of Secretary (Health & F.W.)/ Chairman, Governing Body of NIB on 12.12.2014.
- b. **201** new blood centres have been enrolled under this programme during said financial year taking a total **1649** 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.
- c. **Publication:** Bisht A, Patidar GK, Arora S, Marwaha N. Evaluation of the progress of a decade-long haemovigilance programme in India. Vox Sang. 2024 Dec;119(12):1278-1284.

2. Training/ Workshop/ Conference Organized:

- a. NIB under Haemovigilance Programme of India (HvPI) organized **05** CMEs/ Workshops/ Conferences across the country so as to create awareness about the programme & trained about **790** participants which includes Blood centre officials, clinicians, nurses, blood donor motivators, blood centre technical staff.
- b. Federation of Blood Donor Organizations of India (FBDOI) & NIB have jointly organized the National Workshop on Haemovigilance, Donor Vigilance & Voluntary Blood Donation at NIB, NOIDA from 14-16.06.2024. The National Workshop was inaugurated by the Chief Guest Srimat Swami Sarvalokanandaji Maharaj, Secretary, Ramakrishna Mission, New Delhi and Dr. Anup Anvikar, Director NIB presided the Inauguration Programme. Dr. Akanksha Bisht, Scientist Grade-I, NIB welcomed the gathering and enlightened the audience on “Role of NIB in Haemovigilance and Donor Vigilance Programme in India” in the Workshop. NIB also organized the 2.0 km walk around the campus of NIB, NOIDA & candle lighting event as part of the celebration of World Blood Donor Day on 14.06.2024 at NIB, NOIDA wherein Dr. Akanksha Bisht, Scientist Grade-I & Dr. R.K.Sharma, Scientist Grade-III participated.
- c. A two-day Continuing Medical Education (CME) program on Haemovigilance were organized by the National Institute of Biologicals (NIB), NOIDA & All India Institute of Medical Sciences (AIIMS), Vijaypur Jammu, from 09-10.08.2024 at AIIMS Jammu. The CME focused on the knowledge that can improve their exiting understanding of transfusion-related risks, promote adherence to best practices, and foster a culture of safety and continuous improvement. Day one was dedicated for the Faculty and the Senior Residents & Day two was dedicated for the Nursing Officers.
- d. BLODCON-2024, Federation of Indian Blood Donors Organizations (FIBDO'S) National Conference & Workshop on 17-19.10.2024 at NIB, NOIDA. The National Conference and Workshop was inaugurated by Dr. Neelima Mishra, Director, NIB, and Ms. Aparna Mishra, Judge of the District Consumer Commission, Jharkhand, were the Guests of Honour.
- e. In partnership with the Indian Society of Blood Transfusion and Immunohaematology (ISBTI), NIB played a key role in the success of **TRANSCON-2024**, the 49th Annual National Conference, held from 21-23.11.2024, in Ahmedabad, Gujarat. NIB in collaboration with ISBTI organized a dedicated session on Haemovigilance.

- f. A Continuing Medical Education (CME) on Haemovigilance Programme of India organised by Sindhu Hospitals Hyderabad in collaboration with National Institute of Biologicals (NIB), NOIDA held on 07.03.2025 at Sindhu Hospitals, HITEC city Hyderabad. Dr. Akanksha Bisht, Scientist Grade-I gave the presentation on “Haemovigilance Programme of India- An Overview & Update” & also participated in panel discussion along with Dr. Rajesh Sharma, Scientist Grade-III.



3. Participation in Training/ Workshop/ Conference:

National:-

- a. Dr. Akanksha Bisht, Scientist Grade-I, invited as a faculty in the 12th Annual Conference of ISTM-TRANSMEDCON 2024, the annual conference of the Indian Society of Transfusion Medicine (ISTM) organized at Tamil Nadu held from 26-29.09.2024 at Chennai. Wherein she participated as one of the panelists in the Session of Small steps lead to big journeys - Licensing haemovigilance on 29.09.2024.
- b. Dr. Akanksha Bisht, Scientist Grade-I, invited as a Guest Speaker in the National Voluntary Blood Donation Day Programme organized by Federation of Blood Donor Organisations of India (FBDIO) on 01.10.2024 at Constitution Club of India, New Delhi. Shri Hansraj Gangaram Ahir, Chairperson of the National Commission for Backward Classes, and former Honourable Minister of State for Home Affairs, Government of India was the Chief Guest of the programme. She gave a presentation on the topic “Voluntary Blood Donation, Haemovigilance”.
- c. Dr. Akanksha Bisht, Scientist Grade-I, invited to delivered a talk on “Role of NIB in Haemovigilance and Donorvigilance Programme in India” on 12.01.2025 in the National Workshop on Voluntary Blood Donation organized by Federation of Blood Donor Organizations of India, Indian Red Cross Society, Gujarat State Branch along with Ahmedabad Red Cross Blood Centre Gujarat on 12-13.01.2025 at Red Cross Shatabdi Bhavan, Ahmedabad, Gujarat. Dr. Rajesh Kumar Sharma, Scientist Grade-III, NIB also participated as panelist in the said National Workshop.
- d. Dr. Akanksha Bisht, Scientist Grade-I invited as a resource person for 24th Residential Training Programme on “Good Clinical Practices and Pharmacovigilance” and she gave presentation on “Overview of the Haemovigilance” on 21.02.2025 for officials of CDSCO, IPC and States Drugs Control Departments at NIHFV, New Delhi.

- e. Dr. Akanksha Bisht, Scientist Grade-I invited and delivered a lecture on “Hemovigilance Program of India: Journey so far” on 27.02.2025 at Post Graduate Institute of Child Health, NOIDA.

International:-

- a. Dr. Akanksha Bisht, Scientist Grade-I invited as speaker in International Haemovigilance symposium 2024 organized by International Haemovigilance Network (IHN) on 11-12.04.2024 in Athens Greece wherein she gave the presentation on “A Decade of Dedication: The Growth and Development of the Haemovigilance Programme in India” during the symposium which provided an overview of Blood Regulatory Mechanism in India, inception & implementation of Haemovigilance Programme of India (HvPI).



INFORMATION TECHNOLOGY DIVISION

1. **eOffice Portal:** IT Cell has implemented & Go-Live the eOffice Portal since January 2024 in the Institute. During the period, eFile (ver. 7.3.11) and PIMS (ver. 3.3.8.1) versions has been upgraded for the smooth functioning of eOffice Portal and implemented the SSL Certificate (https). eOffice Data report are tabulated below for information

eFiles Created	eFiles (Moved)	eFiles (Active)	eReceipts Created	eReceipts Moved	Active Users	DSC	eFile Adoption (%)	Data Last Updated on
2762	123704	2739	17394	823852	104	2491	100	31-03-2025

2. **SPARROW Portal:** IT Cell is in the process to implement the Sparrow Portal in the Institute. Live demo for the same has been given to Admin team for User Acceptance Test during the month of January, 2025.
3. **AEBAS Portal:** IT Cell has implemented the face-based biometric attendance functionality and successfully running in the Institute within the GPS parameters longitude & latitudes set in the portal having entry point locations such as Laboratory Block Point, Admin Block Entry, IT and Library Entry Point, SRRD Unit Entry (Back Side) and Director Office. There are approximately 85 number total registered devices (faced-based) shown in the AEBAS Portal.
4. **NIB's Website:** IT Cell has cleared the vulnerabilities and deployed the updated patches from time to time received from NIC. Installed and implemented the Wild Card SSL Certificate (https) in the website.
5. **Laboratory Information Management Software (LIMS):** IT Cell is currently maintaining and updating in-house developed LIMS

software. During the year, IT Cell has updated Sample Tracking Invoice Generation Software and Other Invoice Generation Software. This software facilitates for generation of invoices pertaining to testing fee received from manufacturers and for other services such as Sale of Animals, Biotech Products, eWaste, and Old Newspapers etc. In addition, IT Cell has also updated the CoAs, deletion and shifting of testing parameters, changes in database along with the testing fees, for various laboratories in LIMS Portal.

6. IT Cell has updated the LAN Intranet Portal using dot net technology and deployed in IIS Server. IT Cell has also updated the information received from Quality Management Unit such as SOPs, Monographs, AMC records, Committees etc. on LAN Portal.
7. DHCP Server configured in Network Security Sophos Firewall, implementation of web and application policy for securing the network to strengthen the IT related services.
8. IT Cell has received the new Delegated Admin access from NIC for management of email accounts. This will help to update the personal information and create new email ids as and when required by the Institute. In additions, IT Cell has also provided support to migrate to new email server of NIC.
9. NIB is hosting Meetings, Conferences, Workshops, Trainings and Academic activities for the past few years. IT Cell has provided IT related support in Conference Room, Meeting Room, Class Room and Bioinformatics Centre for various online as well offline training programmes and meetings held in the Institute. Beside this, IT Cell has also provided the technical support for arrangements of virtual meetings held during the year.

ENGINEERING DIVISION

The NIB campus specifically Laboratory & Animal House building is complemented by various engineering services/facilities/installation to facilitate the day-to-day scientific activities. Details information about the various engineering works/services/facilities and installations undertaken during the Financial Year 2024-2025.

➤ Electro Mechanical Engineering works Undertaken:

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

1. Renovation work of walk-in-cold rooms installed in Basement of Administrative Building.
2. Ongoing process to repair works of Centrifugal chiller, 200 Tr, M/s TRANE, USA make for HVAC system installed for Administrative & Cafeteria Building.
3. Conversion of Boilers from HSD to Natural Gas (NG) basis.
4. Administration of various electro-mechanical engineering services/ facilities installation of day-to-day operation and maintenance & repairing, which are provided/ installed in the various buildings/ areas of NIB Campus.
5. Renovation work Fire-fighting System underground pipelines with CPWD.
6. Tendering process is going on for Supply, Installation, Testing & Commissioning of Centrifugal Chiller (Water cooled) with allied accessories & complete job in respectively and also the buyback with dismantling of existing chiller No.-3 (Out of order) in Laboratory & Animal House Building at NIB, NOIDA by M/s HIETES, NOIDA.
7. Tendering for Operation and Non-comprehensive Maintenance for Fire Alarm/ Detection system & PA System, installed in the Laboratory & Animal House Building” at NIB NOIDA.
8. Tendering for “Operation & Comprehensive Maintenance of ETP &STP”.
9. Liason with the CPWD for Expansion of Laboratory & Animal House Building.
10. Solarized of NIB Buildings under PM Surya Ghar Muft Bijli Yojna.
11. Tendering for SITC of IP Based EPABX system.
12. Tendering process for repair & maintenance of Capacitor banks.

Apart from the above, the Institute has finalized/ongoing the services contracts for annual operation and maintenance contract and AMCs/CMCs of the following engineering services/facilities and fixed scientific equipment during the Financial Year 2024-2025.

1. Operation & Comprehensive Contract of 20 Nos. Walk-in-cold Rooms, Environmental Rooms, Incubators installed in Lab. & Animal house Building, NIB, NOIDA.
2. Operation and comprehensive maintenance contract for fire-fighting system, water supply system, water softening plant system, neutralization system including centralized water softening plant of the Institute.
3. Operation and maintenance contract for 3 x 2.8T/Hr at 10.5kg/sqcm steam generating boiler including Economizers and allied accessories etc.
4. Operation and maintenance contract for centralized R.O. Plant system installed in the Laboratory & Animal House Building.
5. AMC of 17 Nos. Fume Hoods (M/s Kewaunee) installed in Lab. & Animal House Building, NIB, NOIDA.
6. Operation and maintenance contract for External & Internal services (Electrical).
7. Operation and maintenance contract for HVAC plant System including Window/ Split Cassette and package type AC units installed in various buildings of the Institute.

8. Operation and maintenance contract for Sterilizers, Glass Washers, Glassware Dryers, Tunnel Washers and Case & Rack Washers installed in the Animal House facility of the Institute.
9. Repair and maintenance of the following engineering installation/ facilities/ fixed scientific equipment under AMC/ CMC contract with OEM or their authorized service agency in India, which are installed in various buildings/ areas of the Institute namely are: Elevators/ Lifts, Centralized UPS system, Electrical appliances, LED Signage, Telecommunication/ EPABX system/ PRI lines services, Bio-Safety Cabinets & Laminar Air Flow Stations, Air Compressor (Atlas Copco Make), Refrigerators and Bio-waste Disposal.
10. Operation and maintenance of Steam Sterilizers, Washers and other equipment of Steris, USA make installed in laboratory and animal house.
11. Operation and Non-comprehensive Maintenance for Fire Alarm/ Detection system & PA System, installed in the Laboratory & Animal House Building” at NIB NOIDA.
12. To make provision for supply, installation, testing and commissioning separate Air conditioning Unit to control the Humidity and temperature in Existing Sterility Clean Room” in NIB Campus, NOIDA.
13. Validation of Sterility Testing Clean Room twice in a year as per WHO guidelines in Laboratory” at NIB, NOIDA.
14. Contract for “Operation & Comprehensive Maintenance of ETP & STP”.
15. Work assigned to CPWD, for renovation/ replacement of Stainless Steel (SS) and other piping network of Lab & Animal House.
16. Environmental monitoring of Stacks (ETP, STP, Chimney flues, Noise, Soil etc.) through NABL accredited agency for obtaining Air & Water consent orders from UP, Pollution Control Board.
17. Logistic support during various programmes such as National Health Mission Trainings, Skill Development Trainings, Seminars, Meetings, visits of dignitaries etc. to the Institute from time to time.
18. Process of Planning, Designing & Execution of Seating Plan in Finance Section at first floor of Admn. Building.
19. GeM tendering process is going on for SITC of 07 Nos. UPS system.
20. GeM tendering process is going on for SITC of Relay.
21. GeM tendering process is going on Integration & renovation of fire alarm
22. GEM tendering process is going on for SITC of 05 Nos ductable Air-conditioners (11 Tr each) in Library, IT cell & Training unit.
23. Tendering for replacement of damaged shells of Boiler Chimney.

Brief of Civil works under taken during the year:

1. Annual Maintenance contract for lawn & garden in NIB, campus NOIDA.
2. Annual maintenance contract for pest control, Rodent control & Anti-termite treatment in NIB, campus NOIDA.
3. Operation & comprehensive maintenance of ETP & STP plant in NIB, campus NOIDA.
4. Cleaning of Recharge pits & its silt chamber networks in NIB, NOIDA.
5. PVC flooring in office area & epoxy flooring & glass partitions etc. in Lab. At Admn. Building.
6. Painting of Staff Quarters (Type-III & Type-I) in NIB, NOIDA.
7. Renovation of wash Room (Male & Female) at ground floor of Admn. Building.
8. Miscellaneous civil works (display of tree plantation plaque card, purchase of artificial grass carpet for tree plantation by Hon'ble Health Secretary, MoHFW, on the occasion

of NIB's Foundation Day i.e. 27.01.2025 & retrofitting work of Director's Glass Almirah etc.) in NIB, NOIDA.

9. Annual Rate contract for providing & fixing banners in NIB, NOIDA.
10. Environmental monitoring of Stacks (ETP, STP, Chimney flues, Noise, Soil etc.) through NABL accredited agency for obtaining Air & Water consent orders from UP, Pollution Control Board.
11. Complete management of repairs & maintenance works and troubleshooting related to maintenance complaints in 19 buildings (area of buildings more than 35000 Sqm.), services and Institute campus to ensure uninterrupted services in the Labs, Animal Facility, Guest House, Hostel, Cafeteria, Offices etc.

REPORT OF ADMINISTRATIVE WORK

Head of the Administration: Sh. Q. W. Zaheeruddin, Deputy Director (Admin.)

1. General Body of the Institute

Composition of the General Body:

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

Chairman Serum Institute of India Ltd., 212/2 Hadapsar, Pune - 411 028	Member
Director Pasteur Institute of India, Coonoor – 643 103 (The Neelgiris)	Member
The Chairman-cum-Managing Director National Dairy Development Board, Anand, Gujrat.	Member
Managing Director Haffkine Bio-Pharmaceutical Corpn. Ltd., Acharya Donde Marg, Parel, Mumbai.	Member
Director, NIB, NOIDA	Member Secretary

2. Governing Body of the Institute

Composition of the Governing Body:

Secretary (Health & Family Welfare) Ministry of Health & Family Welfare Nirman Bhawan, New Delhi-110011	Chairperson
Secretary Department of Biotechnology, New Delhi	Member
Secretary, DHR & DG, ICMR Ansari Nagar, New Delhi – 110029	Member
Director General of Health Services Directorate General of Health Services, Nirman Bhawan, New Delhi- 110011.	Member
Additional Secretary (Health) Ministry of Health & Family Welfare Nirman Bhawan, New Delhi – 110011.	Member
Additional Secretary & F.A. Ministry of Health & Family Welfare Nirman Bhawan, New Delhi – 110011	Member
Joint Secretary Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi - 110011.	Member

Drugs Controller General of India
Directorate General of Health Services,
Nirman Bhawan, New Delhi- 110011.

Member

Director,
NIB, NOIDA

Member Secretary

Meetings of the Governing Body:

35th Meeting of Governing Body was held on 28.03.2025

3. Standing Finance Committees.

Composition of the Standing Finance Committee:

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

Chairman

Addl. DG, ICMR or his nominee
Indian Council of Medical Research,
Ansari Nagar, New Delhi - 110029.

Member

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

Member

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

Member

Director (IFD)
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi - 110011.

Member

Director,
NIB, NOIDA

Member Secretary

Meetings of the Standing finance Committee:

The 37th Meeting of Standing Finance Committee was held on 06.11.2024

4. Promotions, Appointments/ Superannuation/ VRS granted by the Institute during the year 2024-25:-

Appointments

S. No.	Name of Employee	Designation
1.	Dr. Neelima Mishra	Director on 11.10.2024

Promotions

S. No.	Name of Employee	Designation
1.	Dr. Akanksha Bisht	Scientist Grade-I on 08.05.2024
2.	Dr. Gauri Misra	Scientist Grade-I on 08.05.2024
3.	Sh. Q.W. Zaheeruddin	Deputy Director (Admin.) on 09.04.2024
4.	Ms. Poonam	Junior Scientist on 07.05.2024

Superannuation/VRS

S. No.	Name of Employee	Designation
1.	Sh. Dhirender Singh	Administrative Assistant (VRS on 03.03.2025)
2.	Ms. Girija L.V.	Lab Technician (VRS on 10.11.2024)
3.	Sh. Leela Kishan	Driver (Retired on 30.09.2024)

5.Staff in position

PERSONNEL

A.Scientific

S. No.	Name	Designation
1.	Dr. Neelima Mishra	Director
2.	Dr. Harish Chander	Deputy Director (Quality Control)
3.	Dr. Shikha Yadav	Scientist Grade-I (Vet)
4.	Dr. Charu M. Kamal	Scientist Grade-I
5.	Dr. Akanksha Bisht	Scientist Grade-I
6.	Dr. Gauri Misra	Scientist Grade-I
7.	Sh. Neeraj Malik	Scientist Grade-II
8.	Dr. Ratnesh K. Sharma	Scientist Grade-II
9.	Dr. Meena Kumari	Scientist Grade-II
10.	Sh. Harit Kasana	Scientist Grade-II
11.	Ms. Ajanta Sircar	Scientist Grade-II
12.	Dr. Hemant Kumar Verma	Scientist Grade-II
13.	Ms. Sudha V. Gopinath	Scientist Grade-II
14.	Ms. Kanchan Ahuja	Scientist Grade-II
15.	Dr. Rajesh K. Sharma	Scientist Grade-III
16.	Ms. Gurminder Bindra	Scientist Grade-III
17.	Ms. Shalini Tewari	Scientist Grade-III

18.	Dr. Richa Baranwal	Scientist Grade-III
19.	Ms. Rashmi Srivastava	Scientist Grade-III
20.	Ms. Y. Madhu	Scientist Grade-III
21.	Dr. Suresh Kumar (Jr. Vet)	Scientist Grade-III
22.	Dr. Pankaj K. Sharma	Scientist Grade-III
23.	Dr. Manoj Kumar	Scientist Grade-III
24.	Sh. N. Nanda Gopal	Scientist Grade-III
25.	Sh. Tara Chand	Scientist Grade-III
26.	Sh. Subhash Chand	Scientist Grade-III
27.	Sh. Jaipal Meena	Scientist Grade-III
28.	Dr. Ashwini Kumar Dubey	Scientist Grade-III
29.	Dr. Sanjay Mendiratta	Scientist Grade-III
30.	Dr. Saurabh Sharma	Scientist Grade-III
31.	Dr. Varun Singh	Scientist Grade-III
32.	Dr. Manjula Kiran	Scientist Grade-III
33.	Dr. Jyoti Sharma	Scientist Grade-III
34.	Ms. Vandana Tandasi	Junior Scientist
35.	Dr. Birendra Kumar	Junior Scientist
36.	Sh. Anirban Mukherjee	Junior Scientist
37.	Sh. Rajeev Kumar	Junior Scientist
38.	Ms. Archana Sayal	Junior Scientist
39.	Dr. Anoop Kumar	Junior Scientist
40.	Sh. Ajay Kumar Ade	Junior Scientist
41.	Md. Daud Ali	Junior Scientist
42.	Sh. Subhash Kumar	Junior Scientist
43.	Ms. Apoorva Anand	Junior Scientist
44.	Dr. Paras Jain	Junior Scientist
45.	Dr. Swati Shalini	Junior Scientist
46.	Sh. Brij Bhushan	Junior Scientist
47.	Dr. Supriya Saini	Junior Scientist
48.	Sh. Anoop Kumar	Junior Scientist
49.	Ms. Sanchi Goel	Junior Scientist
50.	Sh. Brij Bahadur	Junior Scientist
51.	Ms. Suchitra	Junior Scientist
52.	Dr. Priya Sharma	Junior Scientist
53.	Ms. Poonam	Junior Scientist
54.	Sh. Sukhen Majhi	Lab Technician
55.	Dr. Mohammed Imran	Lab Technician
56.	Sh. Reetesh Kumar	Lab Technician
57.	Sh. Mohit Lal	Lab Technician
58.	Sh. Prem Kumar Prasad	Lab Technician

59.	Sh. Sinto M.V.	Lab Technician
60.	Sh. Lakhan	Lab Technician
61.	Sh. Himanshu Shukla	Lab Technician
62.	Sh. Mohit Sharma	Lab Assistant
63.	Ms. Priya Bhatt	Lab Assistant
64.	Sh. Rajeev Kumar Srivastava	Lab Assistant
65.	Sh. Prdeep	Lab Assistant
66.	Sh. Narender Kumar	Lab Assistant
67.	Sh. Parminder Kumar	Jr. Animal Caretaker

B. Administration, Finance, Procurement & Engineering

S. No.	Name	Designation
1.	Sh. Q.W.Zaheeruddin	Deputy Director (Admin.)
2.	Sh. P.K. Mohapatra	Administrative Officer
3.	Sh. Deepak Mahajan	Jr. Programme Officer
4.	Sh. Manmeet Singh Bhatia	Section Officer
5.	Sh. U.N. Sharma	Section Officer
6.	Sh. Sanjeev	Section Officer
7.	Sh. R.K.Arora	Stenographer Grade B
8.	Sh. Praveen Kumar Pant	Administrative Assistant
9.	Sh. Varun Pandey	Administrative Assistant
10.	Sh. Partho Mandal	Administrative Assistant
11.	Sh. Pradeep Kumar Mehta	Administrative Assistant
12.	Sh. Pawan Kumar Sharma	Administrative Assistant
13.	Sh. Vishnu	Administrative Assistant
14.	Sh. Mukesh Kumar	Assistant Engineer (Electrical)
15.	Sh. R.P. Joshi	Assistant Engineer (Civil)
16.	Sh. Subhash Chand	Jr. Engineer (Electrical)
17.	Sh. Chander Pal	Jr. Engineer (Mechanical)
18.	Sh. Amarjit Singh	Jr. Engineer (Mechanical)
19.	Sh. Krishna Kumar	Jr. Engineer (Civil)
20.	Sh. H.P. Vashisth	Electrician
21.	Sh. Prem Chand Gupta	Assistant-I
22.	Ms. Savita Rai	Assistant-I
23.	Sh. Akshat Sabherwal	Assistant-I
24.	Ms. Nisha Dhillon	Assistant-I
25.	Sh. Nitesh Kumar	Assistant-I
26.	Ms. Saroj Verma	Assistant-I
27.	Sh. Praveen Kumar	Assistant-I
28.	Sh. Alok Verma	Assistant-II
29.	Sh. Nikhil Pratap Singh	Assistant-II

30.	Ms. Komal Parkash	Assistant-II
31.	Sh. Arun Saini	Assistant-II
32.	Sh. Govind Singh Rawat	Driver
33.	Sh. Harinder Singh	Driver
34.	Sh. Bijender Singh	M.T.S.
35.	Sh. Subhash Chand	M.T.S.
36.	Sh. Suraj Pal	M.T.S.
37.	Sh. Rakesh	M.T.S.
38.	Sh. Prem Chand Diwan	M.T.S.
39.	Smt. Shoba	M.T.S.
40.	Smt. Rajendri Devi	M.T.S.

RAJBHASHA CELL

For the implementation of Official Language Policy of the Government of India, a Rajbhasha Cell has been set up in NIB. To ensure the progressive use of Hindi in day-to-day official work, various measures and initiatives were taken by the Institute during the year 2024-25. These include translation of material from English to Hindi and vice versa, making available standard drafts in Hindi/bilingual form, conducting of Hindi Workshops on regular basis etc. During the year under review, Hindi Pakhwada was organised in the Institute from 14-30.09.2024 and various Hindi competitions were conducted during this period. During the year 2024-25, in collaboration of the Department of Official Language, Ministry of Home Affairs, Government of India, Hindi Parangat Class Training Course was conducted in the premises of the Institute. Under this Hindi training course 14 officials of NIB were trained and brought under the category of proficient in Hindi.

The Town Official Language Implementation Committee honoured NIB with the Consolation Prize for doing outstanding Hindi work during the year 2023-24. Also, during the year under review, one official of the Institute Mrs. Rashmi Shrivastava, Scientist Grade-III received First Prize in Hindi Competition “Swarachit Kavya Path” held under the aegis of Town Official Language Implementation Committee, NOIDA for the employees of its Member Offices.



Quarterly meetings of Official Language Implementation Committee

Quarterly meetings of the Official Language Implementation Committee were held for each quarter under the Chairmanship of Director/Director Incharge, NIB. In these meetings progress of use of Hindi in official work was reviewed and necessary actions were suggested to rectify the shortcomings found in the implementation of Hindi.

Participation in other meetings/workshops/seminars

The nominated officials of the Institute attended/participated in the review meetings and workshops held by the Ministry of Health and Family Welfare, Government of India. Also, the Institute attended the meetings held by the Town Official Language Implementation Committee, NOIDA. Four Officials of the Institute had attended the Fourth All India Hindi

Diwas Sammelan held in New Delhi on 14-15.09.2024 by the Department of Official Language, Ministry of Home Affairs, Government of India.

Other activities

- The website of the Institute is bilingual and updated in Hindi also from time to time.
- All the computers being used in NIB, have the facility to work in Hindi. Mangal Unicode is uploaded in all these computers.
- Help literature with regard to the disposal of biological waste of Labs has been made available in bilingual form.

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

EVENTS

INTERNATIONAL YOGA DAY CELEBRATIONS

NIB celebrated International Yoga Day on 21.06.2024



HINDI PAKHWADA 2024

NIB celebrated Hindi Diwas and Hindi Pakhwada from 16.09.2024 to 30.09.2024 with high spirit and enthusiasm. Several competitions have been organized to encourage the use of Hindi language in regular office work among staff.



WOMEN'S DAY CELEBRATIONS

NIB celebrated International Women's Day with a great enthusiasm and spirit by organizing various competitions and cultural activities on 08.03.2024.



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:

A. Appellate Authority

Dr. Gauri Misra, Scientist Grade-I

Link Officer

Dr. Ratnesh Kumar Sharma, Scientist Grade-II

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

B. Public Information Officer

Sh. P.K. Mohapatra, Administrative Officer

Sh. Harit Kasana, Scientist Grade-II (Scientific Activities)

Link Officer

Sh. U. N. Sharma, Section Officer

Sh. Manmeet Singh, Section Officer

During the year (2024-25), the Institute received the following numbers of applications as detailed below to obtain various types of information under the RTI Act: -

Status of RTI Applications Received during the Financial Year 2024-25 (up to 31.03.2025)

Particulars	Opening Balance	No. of Applications Received as transfer from other PA u/s 6(3)	Revived (Including cases transferred to other PAs)	No of cases transferred to other PAs u/s 6(3)	Decision where request/ appeal Rejected	Decision where request/ appeal Accepted	Registration Fee Collected (in Rs.) u/s 7(1)
Request	0	29	14	0	0	43	140
First Appeals		8	0	0	0	0	0

POSH Act, 2013 (Prevention, Prohibition, and Redressal of Sexual Harassment of Women at the Workplace)

The Institute complies with the POSH Act, 2013 on prevention, prohibition, and redressal of sexual harassment of women at the workplace. It has an Internal Complaints Committee (IC) in compliance with the Act. The members of the IC are responsible for conducting inquiries pertaining to such complaints and organising the training for the awareness of the staff. During the year 2024-25, one complaint was received and a process of addressing was initiated by the IC. The Annual Report of IC for the year 2024 has been duly submitted to the District Officer.

Independent Auditor's Report

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

Report on the Audit of the Financial Statements

Qualified Opinion

We have audited the accompanying Financial Statements of M/s National Institute of Biologicals ("the NIB"), which comprise the **Balance Sheet as of March 31, 2025 and the Income & Expenditure Account and Receipt & Payment Account for the year then ended**, and notes to the financial statements, including a summary of the significant accounting policies and other explanatory information.

In our opinion and to the best of our information and according to the explanations given to us, except for the possible effects of the matter described in the "**Basis for Qualified Opinion**" paragraph below, the financial statements give the information required by the applicable laws and regulations in the manner so required and give a true and fair view of the financial position of the **NIB** as at March 31st, 2025 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 Qualified Opinion

We have conducted our audit of the Financial Statements in accordance with the Standards on Auditing (SA's) issued by ICAI. Our responsibilities under those Standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the **NIB** in accordance with the Code of Ethics issued by the Institute of Chartered Accountants of India and we have fulfilled our other ethical responsibilities in accordance with the Code of Ethics.

Balance confirmation for sundry creditors amounting to ₹1,55,17,621/-, including long-pending opening balances of ₹1,25,28,447/-, have not been made available to us. Consequently, we were unable to verify the correctness, existence, and completeness of these balances and related transactions.

H.O.: Plot No. 73, Jagriti Enclave, Phase 3, Delhi-110092

2nd Office: Plot No. 1/583, 1st and 2nd Floor, Near Max Specialty Hospital, Sector-1, Vaishali, Ghaziabad (UP)-201010

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

B.O.: Jhansi, Sonipat, Guwahati



In the absence of sufficient and appropriate audit evidence regarding these payables, the accuracy of the reported liabilities and the corresponding effect on income, expenditure, and net assets could not be ascertained.

Emphasis of Matter

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

- a. **Note No. 2** of these financial statements indicates that NIB is procuring certain Fixed Assets through its procurement consultant M/s. HLL Lifecare Ltd. The reconciliation/settlement with M/s HLL Lifecare Ltd. is under process as on the date of Balance Sheet, hence, the Overstatement/Understatement of Capital Assets cannot be quantified.
- b. **Note No. 8:** GST is not being deposited in the month of advance received against supply of services of testing and sale of reference standards which are contrary to subsection (2) of Section 13 of CGST Act, 2017 and which attract interest liability on delay payment of GST.

Our opinion is not modified in respect of these matters.

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

Management is responsible for the preparation of these financial statements that give a true and fair view of the state of affairs, results of operations and cash flows of the NIB in accordance with the accounting principles generally accepted in India.

This responsibility also includes maintenance of adequate accounting records for safeguarding the assets of the NIB and for preventing and detecting frauds and other irregularities; selection and application of appropriate accounting policies; making judgments and estimates that are reasonable and prudent; and design, implementation and maintenance of adequate internal financial controls, that were operating effectively for ensuring the accuracy and completeness of the accounting records, relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

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

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



Auditor's Responsibilities for the Audit of the Financial Statements .

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



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

Report on Other Legal and Regulatory Requirements

We report that during the year ended 31st March 2025:

- a) We report that we have obtained all the information and explanations which to the best of our knowledge and belief were necessary for the purposes of our audit.
- b) In our opinion, proper books of account as required by law have been kept by the NIB so far as appears from our examination of those books.
- c) The Balance Sheet, Income and Expenditure Account, and Receipts and Payments Account dealt with by this Report are in agreement with the books of account.

For A G M S & Co.

Chartered Accountants

Firm Registration No.: 021141N


CA Sunil
Kumar Gupta

Partner

M. No. 096342

UDIN: 25096342 BM0CJM8754



Place: NOIDA

Date: 17/10/2025

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

DETAILS OF GRANT UTILISATION FOR THE FINANCIAL YEAR 2024-25					
					Amount In ₹
PARTICULARS	GIA - SALARY	GIA - GENERAL	GIA - ASSETS	GIA - SAP	TOTAL
RECEIPTS					
Grant unutilized b/f from the Previous Year	2,633,098.00	9,951,799.09	65,571.88	3,620.00	12,654,088.97
Grant in Aid Received From Ministry	197,367,000.00	356,049,000.00	65,434,000.00	496,000.00	619,346,000.00
TOTAL RECEIPTS (A)	200,000,098.00	366,000,799.09	65,499,571.88	499,620.00	632,000,088.97
LESS:- EXPENDITURE INCURRED & PROVISION					
Establishment Expenses	191,386,907.00	-	-	-	191,386,907.00
Administrative Expenses	-	129,831,646.84	-	484,018.00	130,315,664.84
Lab Services-Operation & Maintainance Expenses	-	195,270,983.02	-	-	195,270,983.02
Increase in Stock of Fuel for Boilers & D.G Set	-	2,659,418.00	-	-	2,659,418.00
Grant Utilised for Security Deposits - Electricity	-	-	-	-	-
Payment made for Fixed Assets during the year:					
Additions in Fixed Assets	-	-	29,422,010.00	-	29,422,010.00
Less: Advance of Previous year Utilized against Fixed Assets	-	-	-	-	-
Less: Adjustment for amount of fixed asset excess charged in P.Y.	-	-	-	-	-
Advance against Fixed Assets, Goods & Services (Net)	-	6,290,721.00	33,562,597.00	-	39,853,318.00
Less: Advance of Prev. Year Utilized/Refunded against Goods & Services	-	-1,663,432.00	-	-	-1,663,432.00
Add: Grant Utilised for Prepaid / Deferred Expenses Increase/Decrease	-	-	-	-	-
TOTAL CURRENT YEAR EXPENDITURE / UTILISATION (B)	191,386,907.00	332,389,336.86	62,984,607.00	484,018.00	587,244,868.86
GRANT RECEIVABLE / PAYABLE TO GOI (A) - (B)	8,613,191.00	33,611,462.23	2,514,964.88	15,602.00	44,755,220.11



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