Egyptian Drug Authority

هيئة الدواء المصرية

BIO INN Laboratories

# Activity REPORT

2025

https://edaegypt.gov.eg

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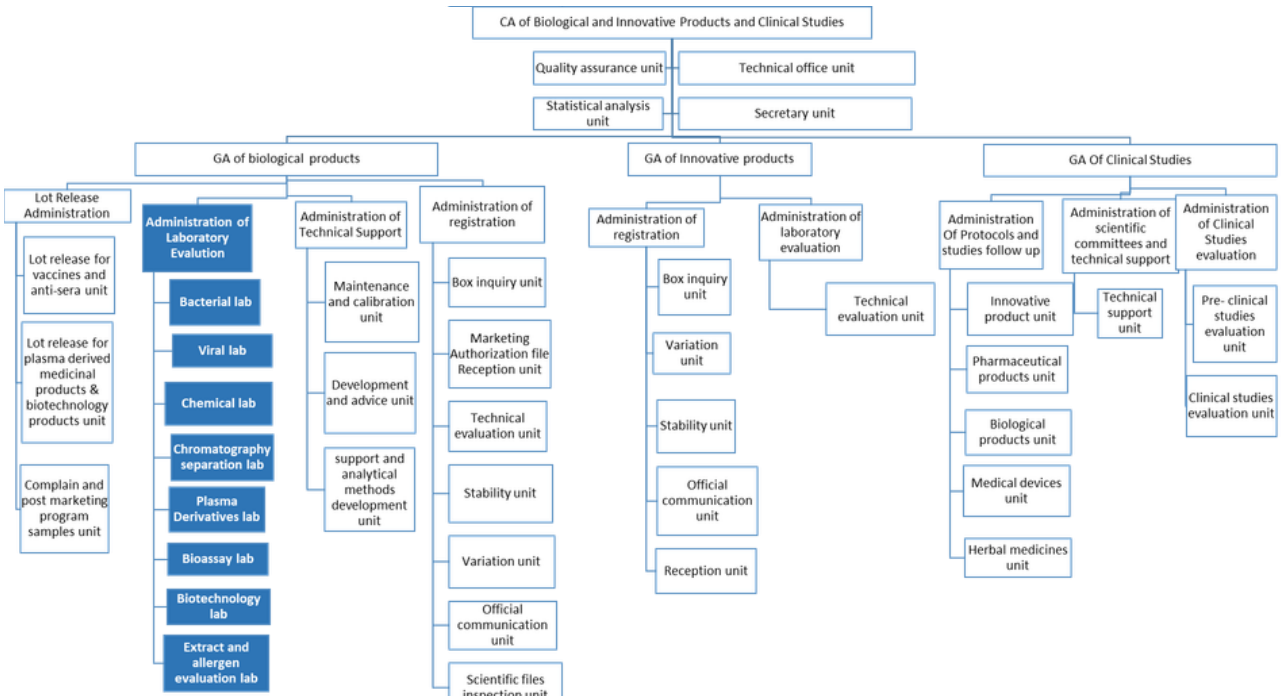
# Organizational chart

## BIOINN ORGANOGRAM



## LAB EVALUATION ADMINISTRATION – OVERVIEW

The Lab Evaluation Administration is a constituent unit of the General Administration of Biological Products, operating under the Central Administration of Biological & Innovative Products and Clinical Studies (Bio-Inn) within the Egyptian Drug Authority (EDA).

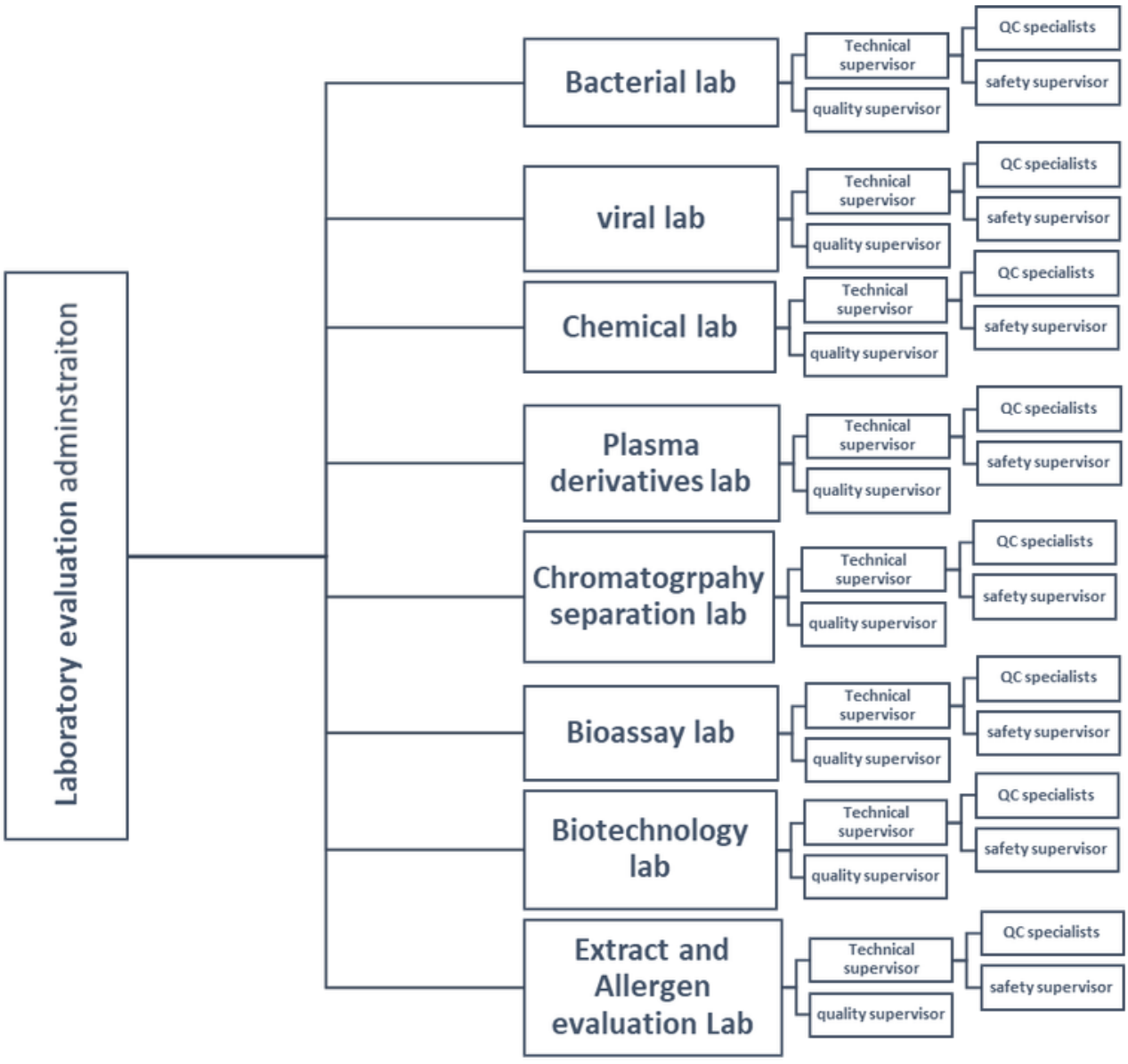
The Administration comprises eight specialized laboratories, each under the direction of an appointed Lab Manager.

The organizational structure is clearly defined and supports effective governance of laboratory activities. Overall leadership is provided by the Laboratory Evaluation Administration Manager, who is responsible for coordination, oversight, and supervise implementation of general policy and all work plans in compliance with the EDA strategic objective and plans.

Each laboratory is functionally supported by competent personnel with specific responsibilities essential to maintaining compliance with regulatory and quality requirements

This structured framework ensures that the Lab Evaluation Administration operates in a systematic, efficient, and quality-driven manner, thereby supporting the EDA’s mandate for regulatory oversight of biological products.

# LABORATORY EVALUATION ADMINISTRATION ORGANOGRAM



# Responsibilities of BioInn Labs

- Perform quality control testing on biological products to ensure compliance with regulatory and quality standards.
- Carried out validation and verification of analytical techniques used in the testing of biological substances.
- Participation in proficiency testing programs and inter-laboratory comparisons to assess testing accuracy and laboratory performance.
- Technical evaluation and assessment of documents related to the quality of product.
- Participation in GMP and licensing inspections for both domestic and international manufacturers of biological products and plasma collection facilities.
- Participating in internal quality audits to evaluate system compliance and support continuous quality improvement efforts.

## STATISTICAL DATA

Laboratory evaluation administration is intended to ensure the quality and safety of biological products. As a result, Key Performance Indicators (KPIs) are routinely monitored to ensure that laboratory testing is conducted efficiently and in accordance with defined regulatory standards.

# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

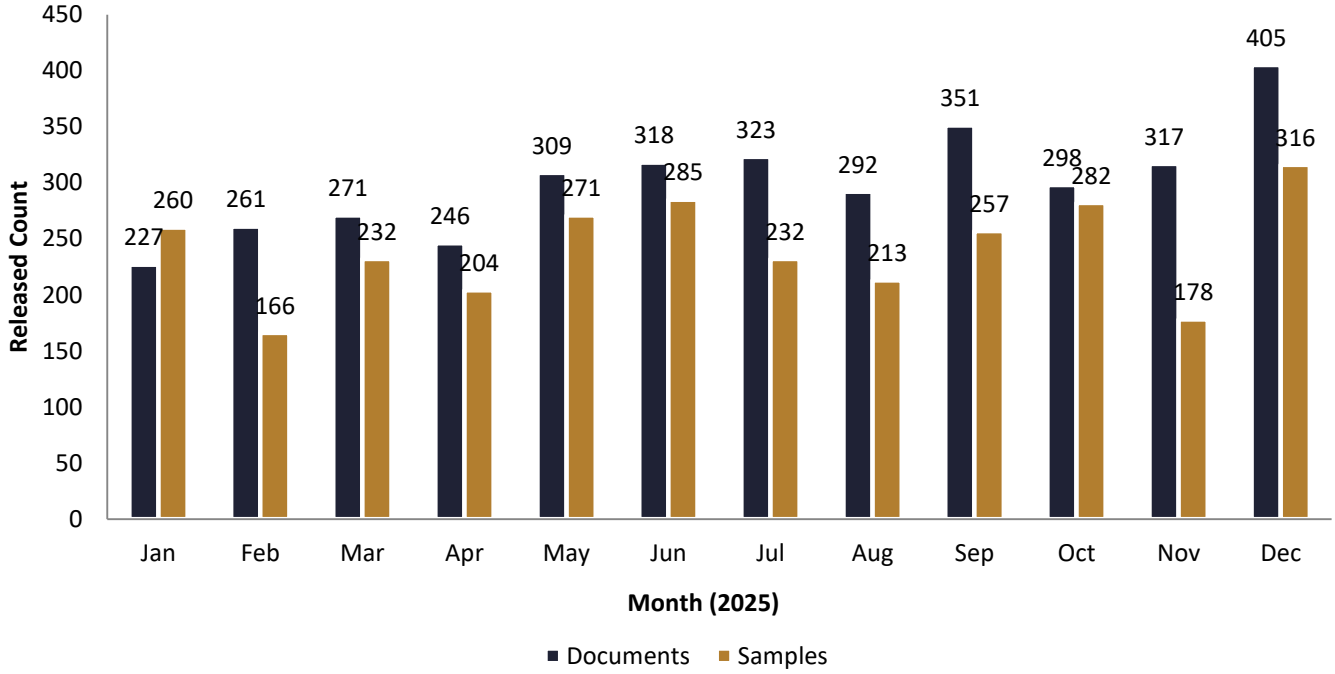
## Laboratory evaluation administration

- Sample analyses are conducted by qualified analysts in accordance with validated and standardized procedures, under the supervision of designated laboratory management at multiple levels.
- The testing covers a wide range of biological products - including vaccines, plasma-derived medicinal products, recombinant biological products, and extracted or allergenic substances - in line with applicable regulatory guidelines.
- Laboratory testing is carried out across the eight laboratories listed in the organogram provided above, with each laboratory responsible for its own specific testing procedures.
- As part of routine quality and regulatory oversight, technical assessment of quality and manufacturing data were conducted throughout the year. These reviews include:
- The technical evaluation of Summary Protocols/Certificate of analysis.
- The assessment of the Quality Module of the Marketing Authorization file for biological products including Advanced therapy medicinal Products
- The technical evaluation of quality module of Investigational medicinal products
- The technical assessment of post-approval changes.
- The following charts illustrate the total number of analyzed samples (2,896) encompassed 679 vaccine products and assessed documents (3,618), along with their distribution across laboratories throughout 2025.

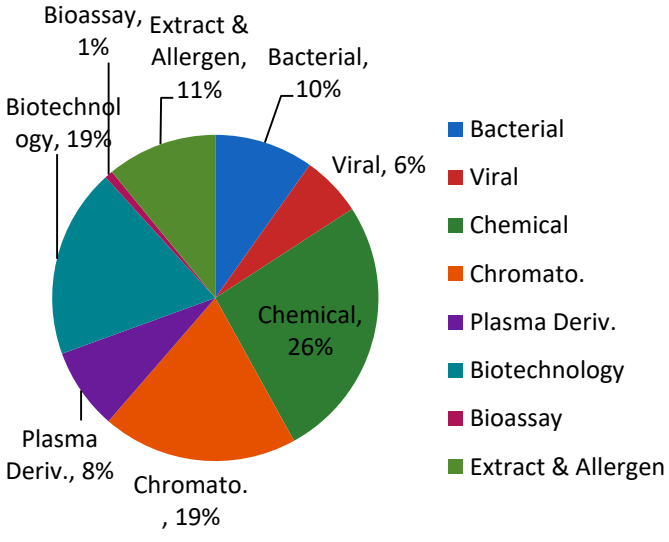
# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## Laboratory evaluation administration

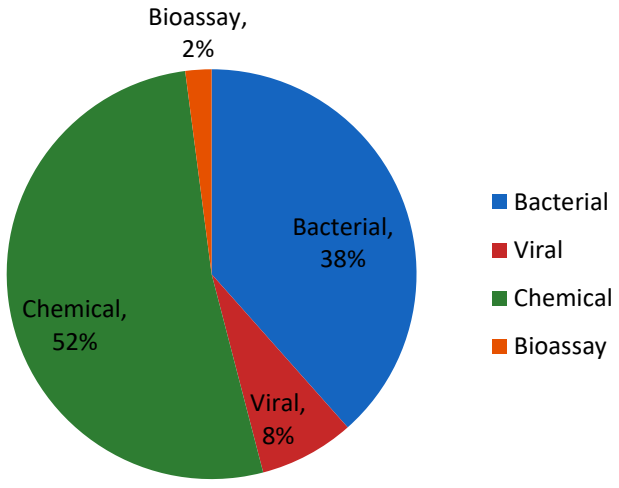
### Monthly Released: Documents & Samples Laboratory evaluation administration (All Labs) — 2025




### Annual Lab Share of Total Released — 2025



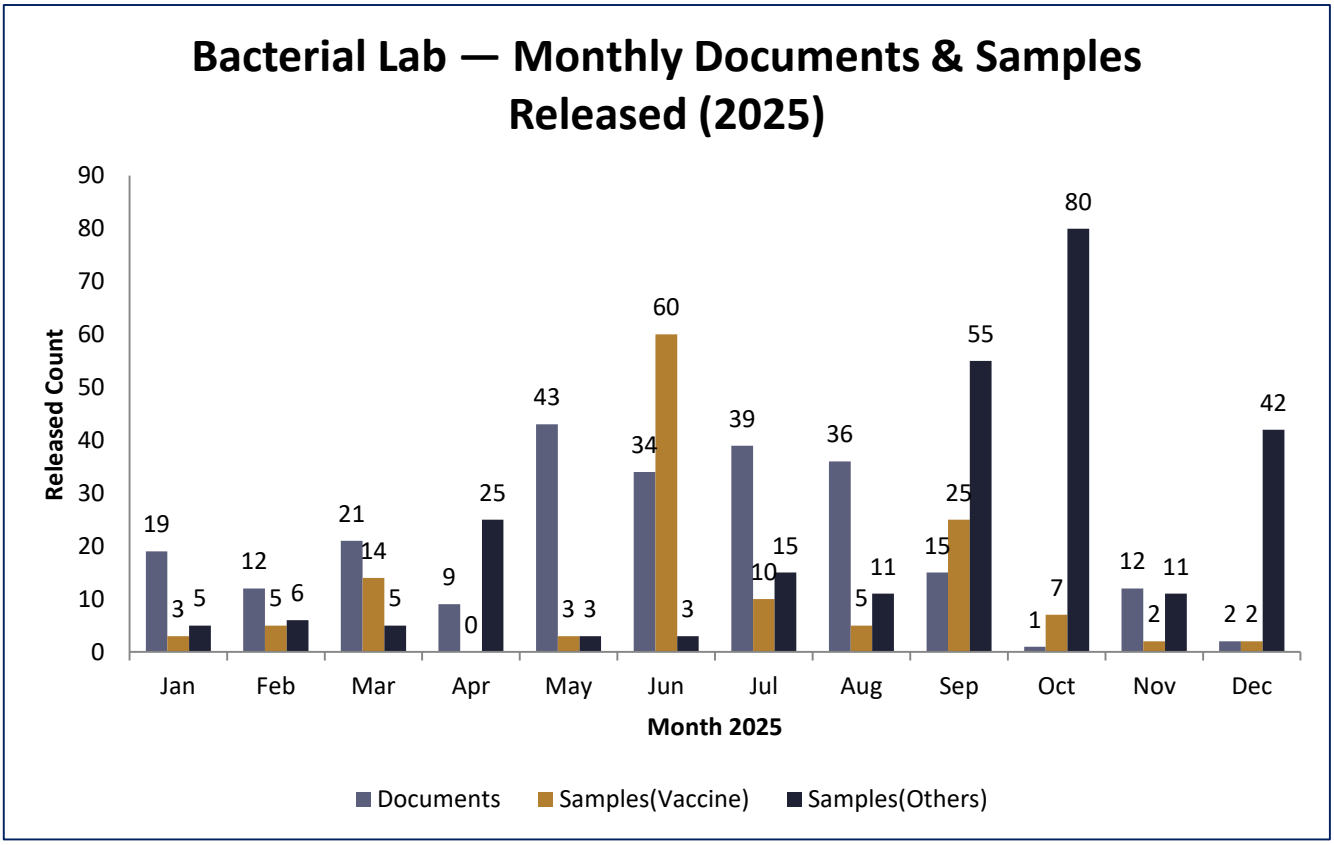

### Annual Lab Share of Total Vaccine Released — 2025



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Bacterial Laboratory

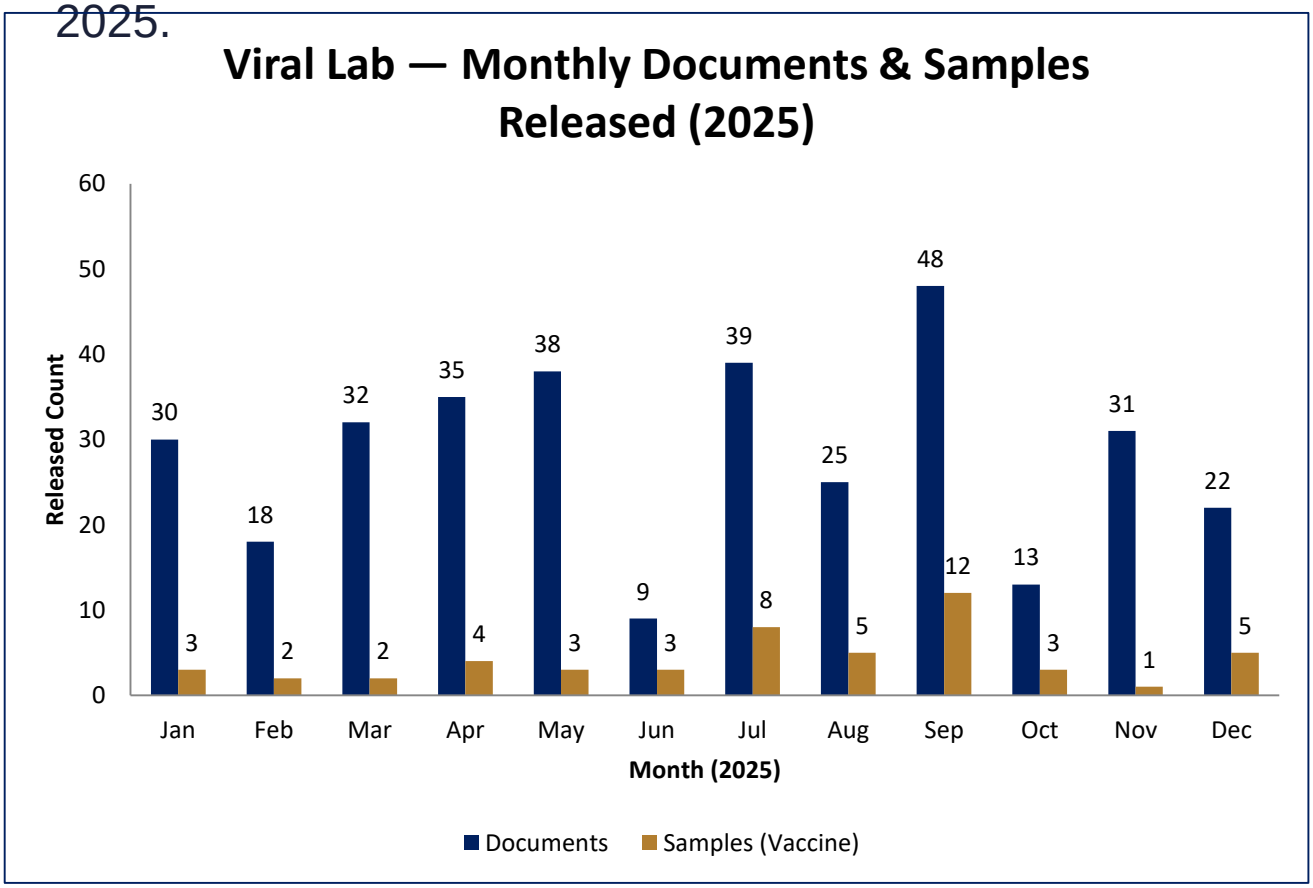
- The Bacterial Laboratory plays a central role within the Laboratory Evaluation Administration by conducting comprehensive microbiological quality control testing for all biological products.
- The laboratory specializes in performing critical assays such as endotoxin and sterility testing for biological products, in addition to conducting identification and potency testing for bacterial vaccines.
- The Bacterial Laboratory demonstrated sustained analytical capacity throughout 2025, processing a total of 397 biological product samples & and assessing 243 documents. The 397 samples encompassed 136 vaccine products and 261 other biological products, reflecting comprehensive microbial quality control oversight across the product spectrum.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Viral Laboratory

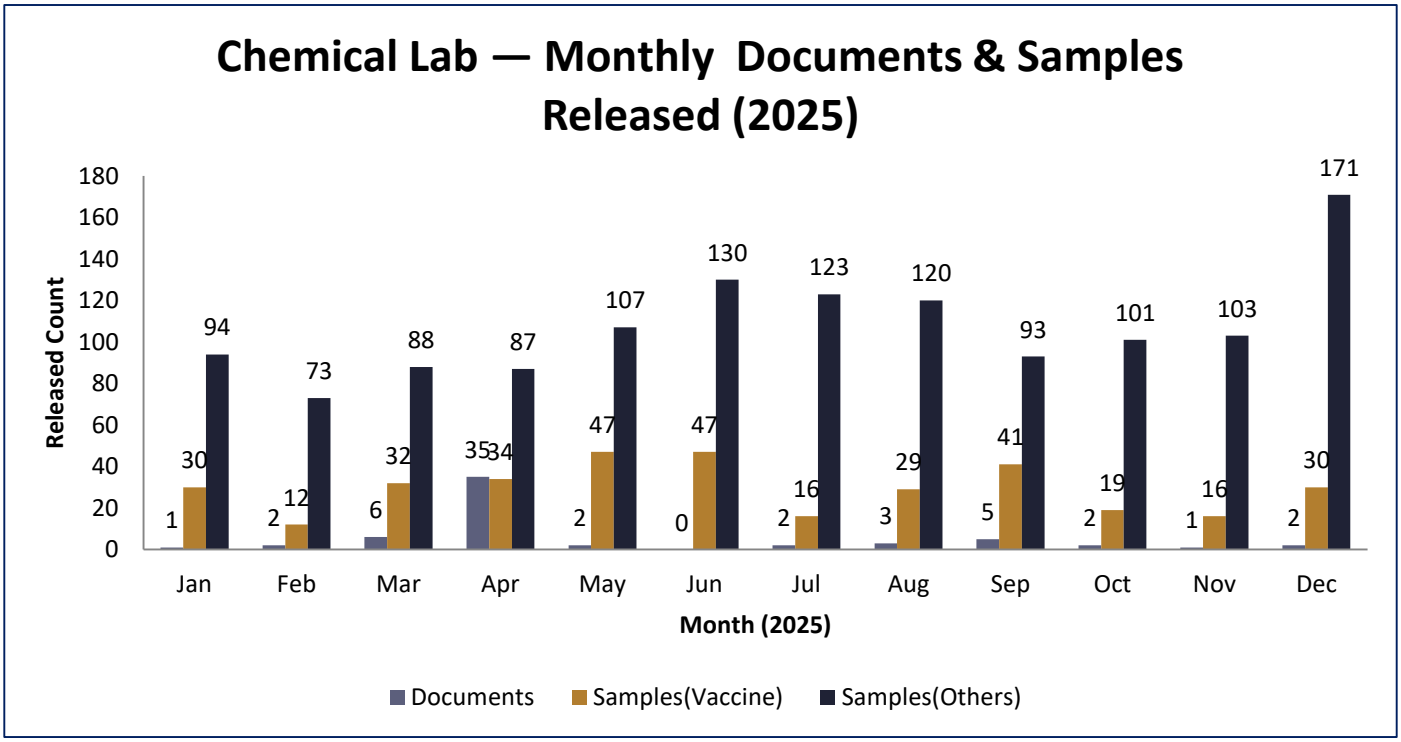
- The Viral Laboratory plays a key role within the Laboratory Evaluation Administration by conducting specialized quality control testing for viral vaccine products.
- The laboratory specializes in performing critical assays such as identification and potency testing for viral vaccines, as well as for the viral components of combined vaccines.
- Throughout 2025, the laboratory analyzed a total of 51 vaccine samples and assessed 340 documents throughout 2025.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Chemcial Laboratory

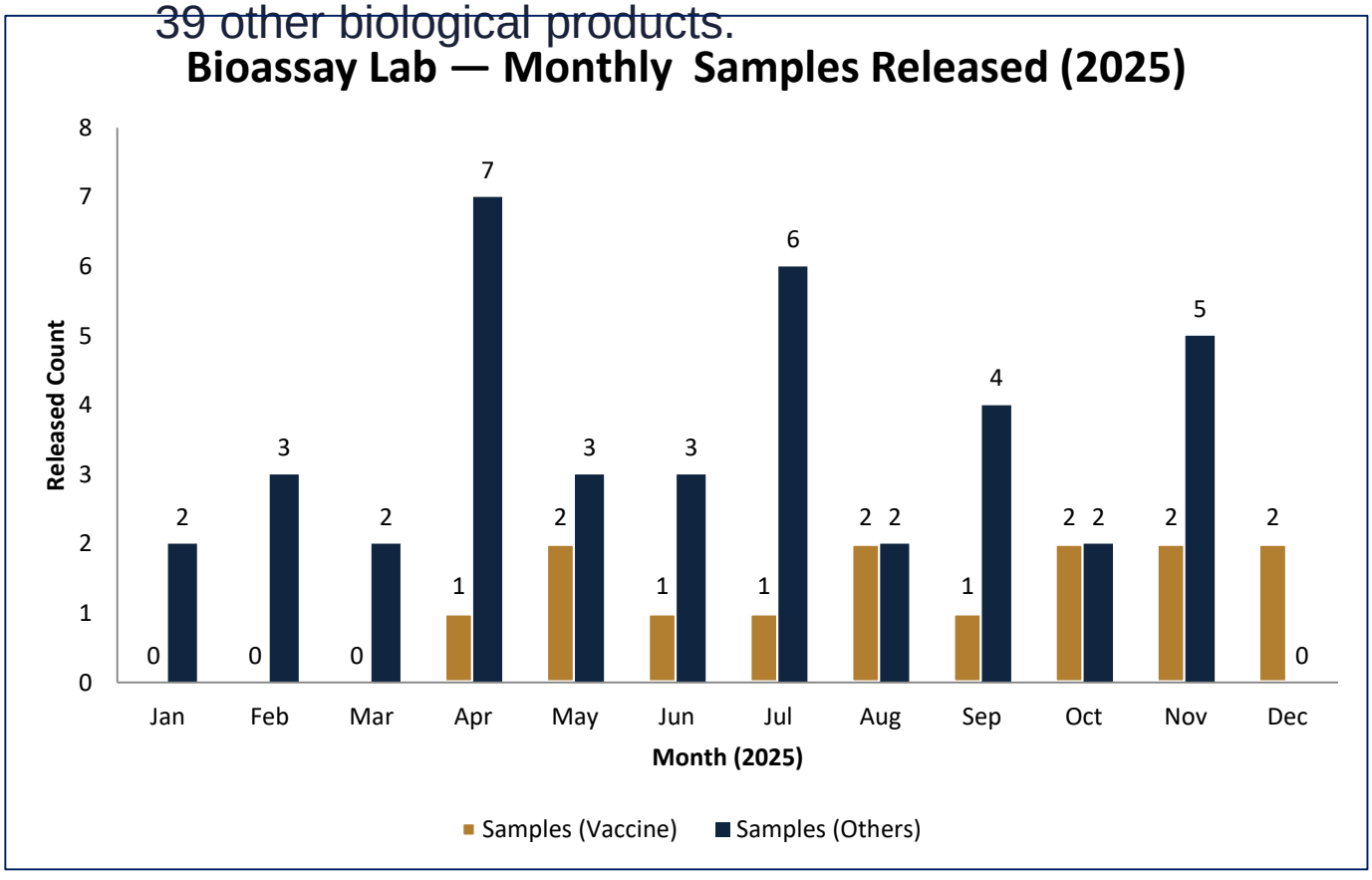
- The Chemical Laboratory plays an essential role within the Laboratory Evaluation Administration by conducting comprehensive analytical quality control testing for all biological products.
- The Chemical Laboratory demonstrated sustained analytical capacity throughout 2025, processing a total of 1,643 biological product samples & and assessing 61 documents . The 1,643 samples encompassed 353 vaccine products and 1,290 other biological products.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Bioassay Laboratory

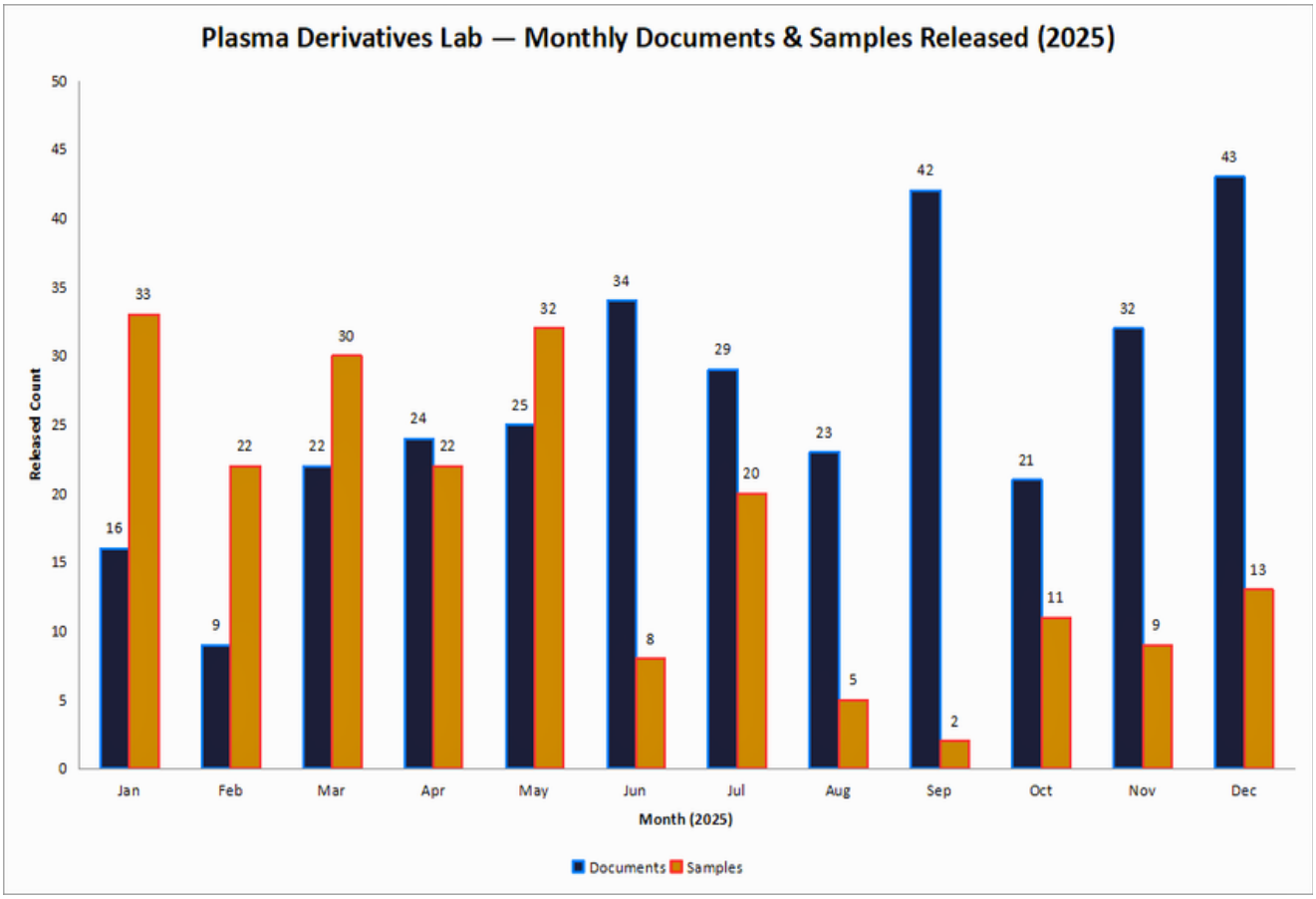
- The Bioassay Laboratory is responsible for performing safety and pyrogen tests on all biological products to ensure their  safety, and compliance with regulatory standards.
- The Bioassay Laboratory demonstrated analytical testing throughout 2025, a total of 53 biological product samples. The 53 samples encompassed 14 vaccine products and 39 other biological products.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Plasma Derivative Laboratory

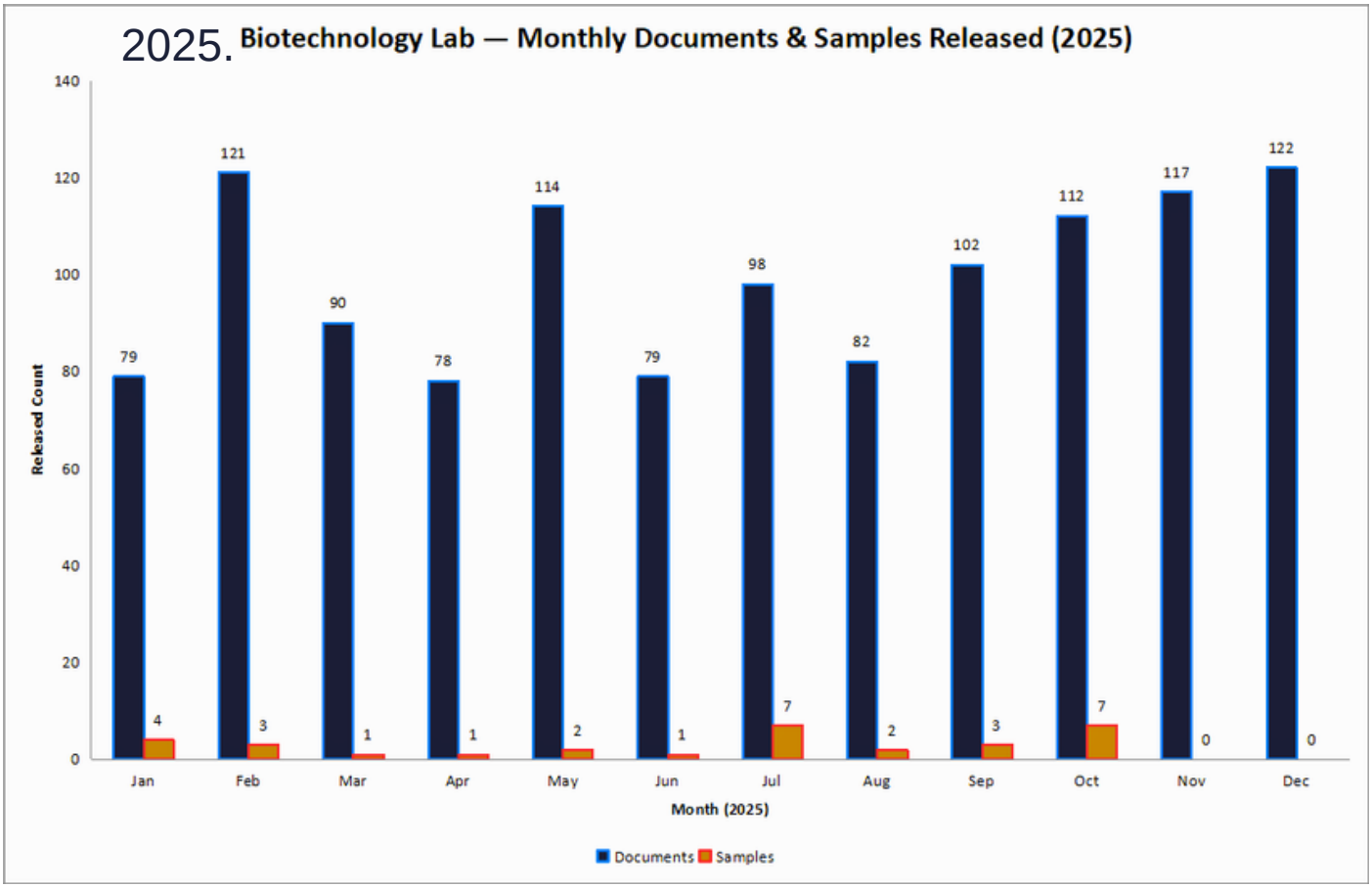
- The Plasma Derivatives Laboratory plays a key role within the Laboratory Evaluation Administration by conducting comprehensive quality control testing for plasma-derived medicinal products.
- The following chart illustrates the total number of analyzed samples (207) and assessed documents (320) throughout 2025.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

## The Biotechnology Laboratory

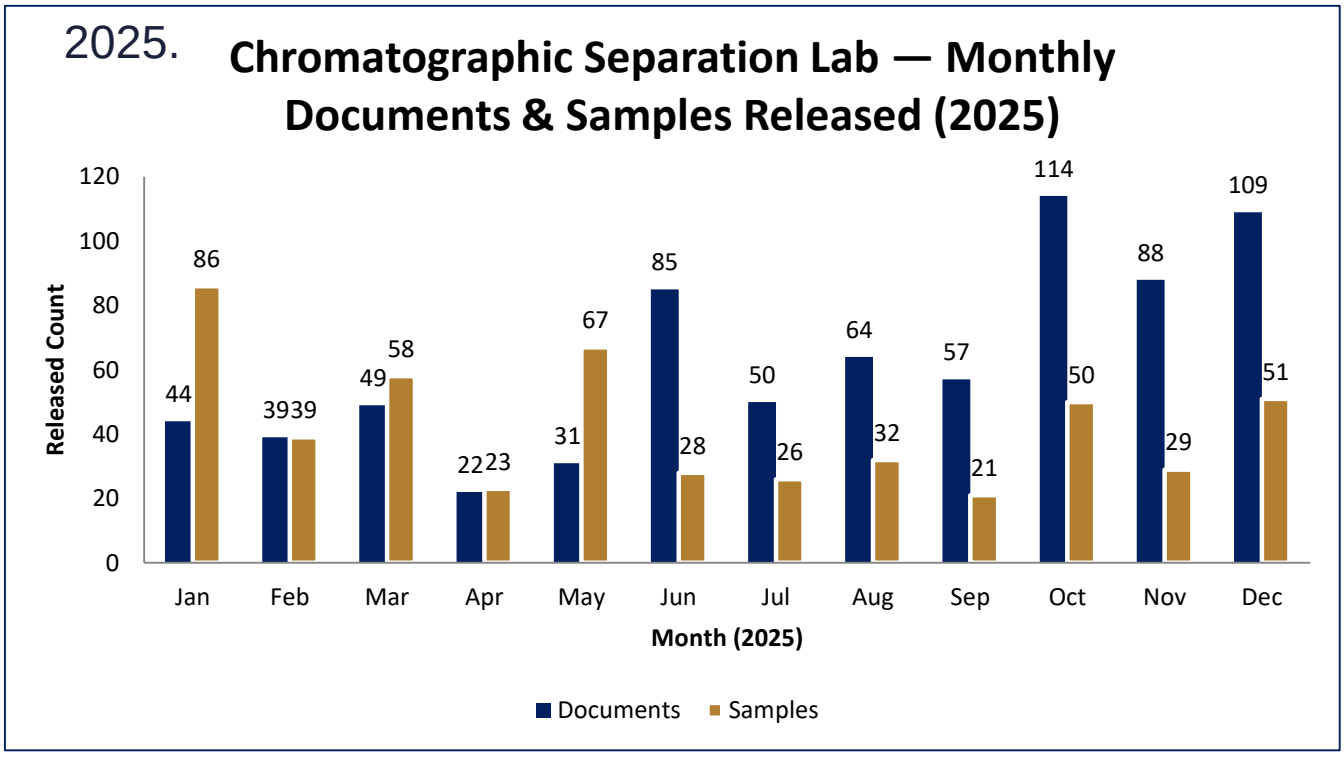
- The Biotechnology Laboratory plays a key role within the Laboratory Evaluation Administration by conducting comprehensive quality control testing for recombinant, monoclonal, and biosimilar products.
- The laboratory specializes in performing critical assays, including identification, and potency testing of these products.
- The following chart illustrates the total number of analyzed samples (31) and assessed documents (1194) throughout 2025.



## SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

### The Chromatography separation Laboratory

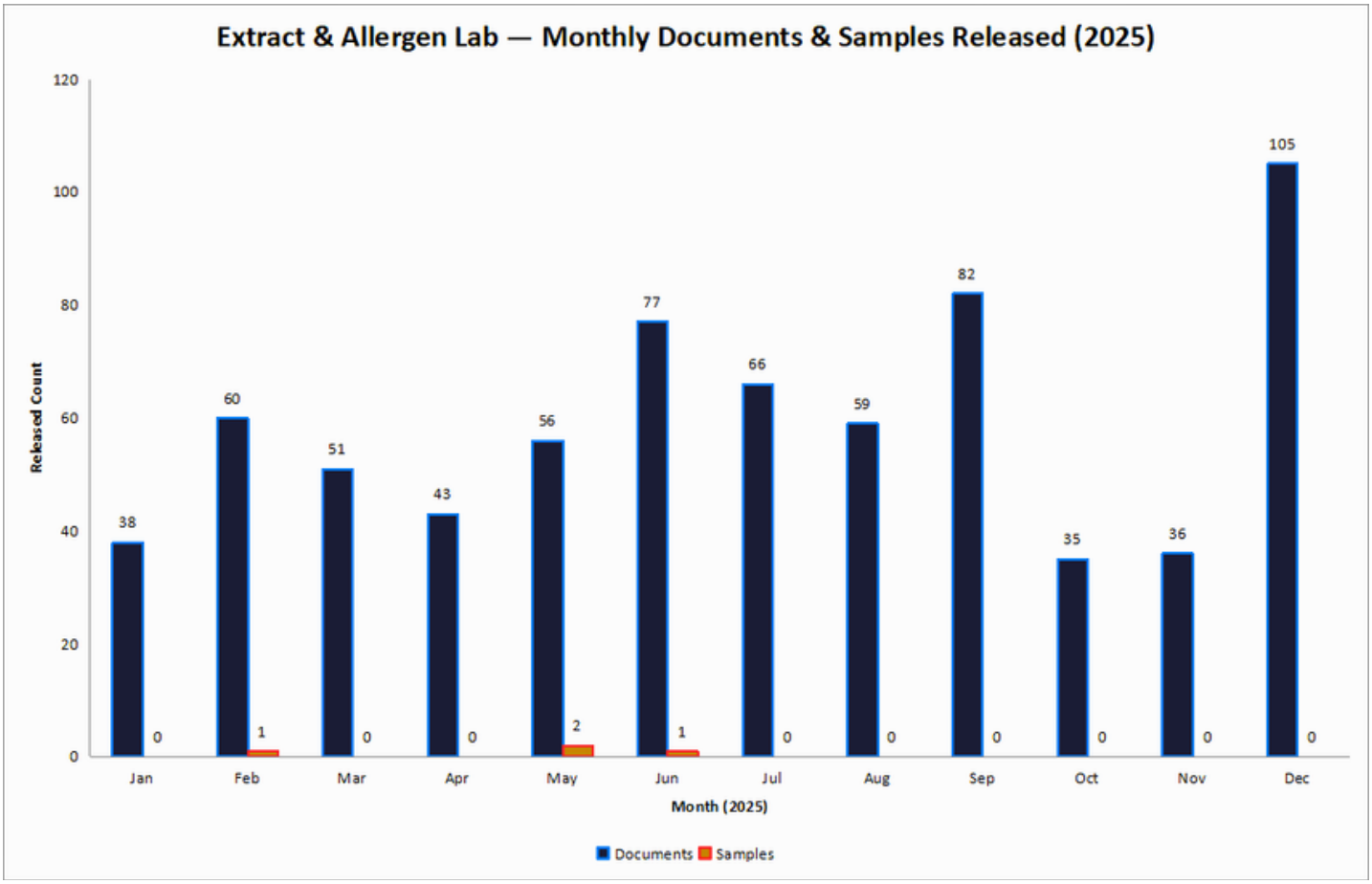
- The Chromatography Separation Laboratory plays a key role within the Laboratory Evaluation Administration by conducting quality control testing using various chromatographic separation methods for recombinant products.
- The laboratory specializes in performing critical assays and assessing the purity profiles of recombinant products.
- The following chart illustrates the total number of analyzed samples (510) and assessed documents (752) throughout 2025.



# SAMPLE ANALYSIS AND DOCUMENTS ASSESSMENT

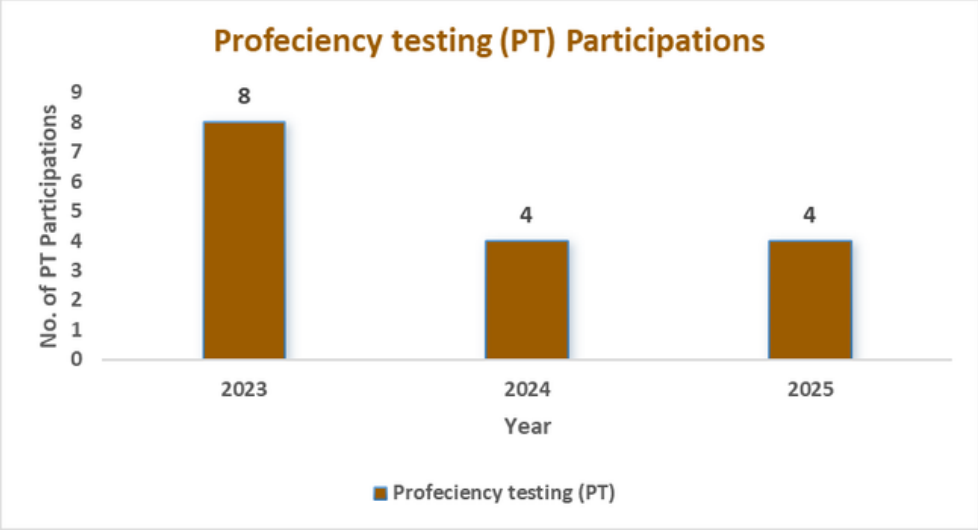
## The Extract and allergens Laboratory

- The Extracts and Allergens Laboratory plays a key role within the Laboratory Evaluation Administration through In vivo testing to ensure the quality and safety of extractable biological products.
- The following chart illustrates the total number of analyzed samples (4) and assessed documents (708) throughout 2025.



# PROFECIENCY TESTING (PT)

- The Laboratory Evaluation Administration participates in a wide range of proficiency testing (PT) schemes and inter-laboratory comparisons to verify the accuracy, consistency, and reliability of analytical results. Since the first successful PT participation in 2010, the administration has continued involvement across various test categories.
- PT Participation Areas for year 2025
    - Protein composition by Agarose electrophoresis
    - Bacterial endotoxins
    - Prekallikrein activator by Chromogenic assay
    - Liquid chromatography



# Accreditation/Recognition/ Membership

## ISO 9001/2015


- The Laboratory Evaluation Administration obtained ISO 9001 certification in 2008. Since then, all laboratory operations have been conducted in accordance with ISO 9001 and its subsequent revisions. Certification has been maintained through regular surveillance and periodic full recertification, ensuring ongoing conformity and continuous improvement of our quality management system

## ISO 17025/2017


- The Laboratory Evaluation Administration first obtained ISO/IEC 17025 accreditation in 2010 for certain test scopes. Since that time, all activities under those scopes have been carried out in full compliance with the ISO/IEC 17025 standard and its subsequent revisions. Our accreditation has been maintained each year through regular assessments, surveillance audits, and full reassessments, ensuring that technical competence and quality remain at the highest standard.
- On 16 January 2024, the Laboratory Evaluation Administration expanded its ISO/IEC 17025 accreditation to include three additional test scopes. As a result, the total number of accredited scopes now stands at nine, which are:
  - Determination of Hepatitis B Surface Antibodies using ELISA Method
  - Identification and determination of Influenza heamagglutinin content SRID assay
  - Determination of prekallikrein activator by chromogenic assay
  - Determination of Total Protein in Anti-sera & Erythropoietin (Biuret Assay)
  - Determination of bacterial endotoxin
  - Determination of Tetanus and Diphtheria toxoid content with Flocculation method procedure.
  - In vivo Pyrogen test.
  - Impurities with molecular mass greater than that of insulin.
  - Sterility testing by direct inoculation.

## WHO

- In March 2022, the Egypt Drug Authority (EDA) was accredited by the World Health Organization (WHO) for its ability to regulate and evaluate vaccines, both locally produced and imported. EDA's National Regulatory Authority reached Maturity Level 3 (ML-3)—the second-highest level in WHO's global regulatory system. Egypt became the first country in the Eastern Mediterranean Region and the ninth worldwide to achieve this level for vaccine regulation
- In April 2024, EDA also joined the WHO National Control Laboratory Network for Biologicals (WHO-NNB), reinforcing its role in ensuring the quality and safety of biological products in line with international standards.

ICH IPRP International Pharmaceutical Regulators Programme USP

- Staff members of the Laboratory Evaluation Administration actively participate in numerous international initiatives, including ICH Expert Working Groups and internal task forces focused on revising and updating ICH guidelines.
- Moreover, they involved in IPRP working groups and contribute to USP scientific programs, playing a key role in advancing global regulatory standards and scientific collaboration.

# EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES


- In July 2025, the BIO INN Laboratories of the Egyptian Drug Authority (EDA) joined the General European Official Medicines Control Laboratories Network (GEON), coordinated by the European Directorate for the Quality of Medicines & HealthCare, as an associated member. This achievement positions the EDA as the second Official Medicines Control Laboratory (OMCL) in Africa to become part of this prestigious network, marking a significant milestone in strengthening its global role in ensuring the quality of medicines and biological products.
- This accession follows the successful completion of a rigorous joint technical evaluation conducted by EDQM experts during their field visit to the Authority's biological laboratories in February 2025. It reflects the high standards of quality, compliance, and institutional excellence upheld by the EDA.
- Membership in GEON provides valuable opportunities for international collaboration, exchange of expertise, and participation in collaborative studies, while reinforcing the Authority's commitment to global regulatory standards. Furthermore, it enhances international confidence in Egypt's regulatory system and supports the EDA's strategic vision to establish itself as a recognized reference authority within the global regulatory landscape, contributing to the safety, quality, and efficacy of medicines worldwide.

# EGYPTIAN DRUG AUTHORITY JOINED THE AFRICAN NETWORK OF REGULATORY LABORATORIES (NARL)

In October 2025 , BioInn Laboratories played a key role in supporting the Egyptian Drug Authority's (EDA) successful engagement in the African regulatory landscape through joining the Network of African Reliance Laboratories (NARL) as a Reliance Laboratory.

The designation of EDA as a Reliance Laboratory reflects the growing continental confidence in its analytical and regulatory capabilities, as well as its leadership in strengthening quality control and accreditation systems. Within this context, BioInn Laboratories, as part of the National Control Laboratory (NCL) framework, contribute to advancing reliance-based practices by supporting data generation, quality evaluation, and laboratory excellence. This achievement reinforces the role of NCLs in promoting regulatory convergence, reducing duplication of testing, and enhancing the efficiency and reliability of medicines, vaccines quality assurance across Africa.

# Strengthening Regulatory Capacity in Africa

## NEPAD-AMRH

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

- EDA has officially announced in August 2023 to be one of NEPAD-AMRH Regional Centers of Regulatory Excellence (RCOREs) in the following functions: LT that focus on promoting and enhancing regulatory standards practices, strengthen the regulatory capacity and development in Africa
- As one of the NEPAD–AMRH Regional Centers of Regulatory Excellence (RCOREs), Laboratory evaluation administration submitted training programs targeted at several African countries in the East Africa region, as part of ongoing collaboration with African Union member states to strengthen regulatory capacity and harmonize practices across the continent.
- In corporation with lot release, Laboratory evaluation administration conducted specialized program (Hands-On Training Program on Vaccine and Antisera Lot Release Implementation) for the Ghana Food and Drugs Authority from 4-13 May 2025. Participants were provided with a comprehensive understanding of the manufacturing and quality control processes for selected vaccine and antisera products. It also included the evaluation of Quality Module 3 for each of the products studied, complemented by practical sessions and case studies designed to bridge theoretical knowledge with real-world application.
- Key topics covered during the training included the concepts and applications of Lot-to-Lot Consistency and the management of temperature excursions during the batch release process. Participants engaged in practical exercises on Batch Release Procedures ,as well as a dedicated workshop on the Quality Management System in Release and a session on the automation of batch release processes, highlighting EDA’s use of modern digital tools to enhance regulatory efficiency and transparency

# Strengthening Regulatory Capacity in Africa

## NEPAD-AMRH

- Laboratory evaluation administration conducted specialized program, Laboratory Tests for Snake Antivenom, Vaccine Batch Release from 17-26 August 2025 for six participants from the Food and Drugs Authority (FDA) of Ghan
- The training program explored to develop participants' skills in the evaluation and regulation of pharmaceutical and biological products, with a particular focus on improving efficiency in quality control and advanced analytical testing.
- The program included a combination of theoretical lectures and practical applications covering a range of technical and regulatory topics, including laboratory testing for snake antivenom, regulatory policies for vaccine batch release.
- Participants received in-depth training on antivenom manufacturing processes, critical quality standards, efficacy testing, data analysis and result interpretation, as well as best practices for sample handling, documentation, and integration with Quality Management Systems (QMS).

- In line with our dedication to upholding the highest global standards, BioInn Labs proudly participated in the "Comprehensive Training on Pharmacovigilance, Regulatory Documentation, and Good Clinical Practice (GCP)" from December 7-10, 2025. A primary focus of the program was to gain a deeper practical understanding of the Common Technical Document (CTD) modules, which are critical for efficient and compliant regulatory submissions. This valuable training initiative was part of a program sponsored by the Bill & Melinda Gates Foundation and organized in collaboration with the KEMRI Wellcome Trust and Biogeneric Pharma S.A.E. Our involvement underscores our commitment to continuous learning and maintaining expertise in the ever-evolving regulatory landscape.

National Achievement

# EGYPTIAN PHARMACOPEIA

- Laboratory evaluation provided Experts for participating in issuing multiple Biological Products Monographs in Egyptian pharmacopeia starting in 2021/2022
- A total of six general monographs have been issued, with active contribution from the staff of the Laboratory Evaluation Administration in their preparation.

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