# ETHIOPIAN VETERINARY ASSOCIATION



# CONTINUOUS PROFESSIONAL DEVELOPMENT MODULE ON LABORATORY INFORMATION MANAGEMENT SYSTEM

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## Course title: Laboratory information management system (LIMS)

Course code: \_\_\_\_\_

Credit point: \_\_\_\_\_

## Audience

The target audiences for this module are veterinary laboratory diagnostic service providers such as veterinarians, laboratory technologists, data encoders and IT personnel in the veterinary laboratory.

#### **Course description**

Laboratory information management system (LIMS) is a software-based system that provides an efficient way to store, manage, and track samples and associated laboratory data, automate and manage work flow, improve laboratory efficiency, generate test reports and analyze laboratory data. The module was designed to equip professionals with the skills required to manage LIMS. It covers LIMS overview, LIMS implementation, the LIMS type currently being implemented in Ethiopian veterinary laboratory and its operational guide line and administration parts. The module will enable learners to have a general concept about LIMS and its functionalities. In addition, it will assist learners to have comprehensive knowledge and skill in managing and tracking samples and sample related laboratory data through the whole laboratory process starting from the point of reception until delivery of the test report to the customer.

After the completion of this LIMS CPD module, learners should have a better understanding on LIMS in general, and on the different functional features of the LIMS in particular and how it is used. They should be familiar with the different operations and processes involved in managing sample and associated data starting from reception till creation of a test report, as well as understanding how reports and laboratory data can be generated for further analysis as well as system administration.

## **Duration:**

## **Theoretical part: 8hrs**

## **Practical part: 24hrs**

### Objective

The objective of this module is to provide laboratory diagnostic service providers with a comprehensive and efficient way to develop the knowledge and skills of their professionals on laboratory information management system and thereby to enhance their competency for efficient management of the system in sustainable manner.

# **Learning Outcomes**

Upon completing this course, the learner will be able to:

- ✓ Describe LIMS with its importance in laboratory diagnostic services
- ✓ List the core component of LIMS
- ✓ Identify functionalities and features of the LIMS
- ✓ List the criteria for implementation and evaluation of LIMS
- ✓ Describe and practically demonstrate sample and associated data processing through LIMS including data entry, generating report, data query, statistical analysis and system administration.

# Learning approach

✓ Face-to-face and virtual delivery modes will be applied to deliver the module contents in both lecture- based and practical aspects.

# **Measurement of learning**

- ✓ Throughout the module, there will be progress quiz and post test to ensure understanding of the instructional contents.
- ✓ Feedback and reflection measures will be applied.

# **Course contents**

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## Background

Laboratory Information Management System (LIMS) sometimes called Laboratory Information System (LIS) or Laboratory Management System is a software-based laboratory system designed to efficiently manage samples and associated data, automate and manage work flow, improve laboratory efficiency, generate test reports and analyze laboratory data. LIMS also facilitates transparency and compliance. All LIMS have common features that facilitate the management and analysis of laboratory data. These features include sample tracking, data analysis, reporting, automation, workflow optimization, and data integration. However, in recent times, LIMS functionality has spread even further beyond its original purpose. Assaydata management, data mining, and electronic laboratory notebook (ELN) integration have been added to many LIMS enabling the realization of translational medicine completely within a single solution. There are several different corporations that provide LIMS software but LabWarecorporationprovides LIMS for all laboratories worldwide. The primary products of LabWare are LabWare LIMS and LabWare ELN (Electronic Laboratory Notebook).

In the last 40 plus years, LIMS has evolved significantly from the early stages as simple sample management and reporting systems to sophisticated, web-based, cloud-hosted software applications that integrate and automate laboratory workflows, data management, and generate actionable insights for decision making. Until the late 1970s, the management of lab samples and associated analysis and reporting were time-consuming, manual processes often riddled with transcription errors. This gave some organizations motivation to streamline the management of laboratory data and how to be reported. The evolution of LIMS can be traced back to the early 1980s when the need arose for automated systems to manage laboratory data and workflows. Initially, LIMS were limited in functionality and mainly focused on sample registration, tracking, and test scheduling. As computer technology advanced, LIMS evolved and became more sophisticated, adding more functionalities to automate the laboratory workflows and data management processes. In the early 1990s, LIMS became more popular, and its functionality expanded to include data acquisition, data analysis and instrument calibration. The introduction of graphical user interfaces (GUIs), web-based architecture, and database management systems improved the usability of LIMS and made it more accessible to scientists and laboratory technicians.

In the late 1990s, LIMS moved towards a client-server architecture, allowing scientists to access their data from any computer on the laboratory network. In the following years, the development of cloud-based LIMS allowed users to access their data from anywhere they had an internet connection, which facilitated data sharing and collaboration between geographically separated laboratories. As of 2012, LIMS has more improved and added additional characteristics such as clinical functionality, electronic laboratory notebook (ELN) functionality as well a rise in the software as a service (SaaS) distribution model. The use of advanced technologies, such as artificial intelligence (AI), machine learning (ML), and the internet of things (IoT), is pushing LIMS into new directions, further revolutionizing the way laboratories operate. The integration of these technologies will enable laboratory operators to make better decisions and provide accurate and reliable results.<sup>1</sup>

The demands of modern laboratories are not frequently met by traditional data managing tools, and collecting, processing, and analyzing samples and sample associated data can be difficult and time-consuming. Thus, the rationale for using LIMS is to effectively manage and track laboratory samples and associated data, and workflows from reception through analysis, reporting, storage, and disposal. LIMS are designed to streamline laboratory operations, reduce the risk of errors, and improve overall efficiency in test result production and shorten turnaround time. LIMS allow for the integration of multiple laboratory functions including sample management, instrument interfacing, quality control, document management, and report generation. Features such as barcoding, electronic data capture and automated workflows can reduce the time spent on administrative tasks and increase the accuracy of results, build trust between the laboratories and the customer. In addition, LIMS can contribute to maintaining regulatory compliance by ensuring the accuracy and completeness of laboratory data, sample tracking and storage, and facilitating audit trails. The LIMS system can also assist in the compilation of data for accreditation and regulatory inspections. In general, LIMS implementation can improve laboratory productivity, data quality, and accuracy, promote regulatory compliance, and improve laboratory service which ultimately contributes to the control of livestock diseases and thereby improve production and productivity.

<sup>&</sup>lt;sup>1</sup>Laboratory information management system (2023, February 23): *Wikipedia*. Retrieved February 24, 2023 from https://en.wikipedia.org/wiki/Laboratory\_information\_management\_system.

#### **Chapter 1: LIMS overview**

#### What is Laboratory information management system (LIMS)?

LIMS is a software-based system that streamlines and automates laboratory workflows, manage laboratory samples and associated data, generate test reports, analyze data and improve laboratory efficiency. LIMS provide a centralized database that stores and manages information related to laboratory testing workflows and help laboratories to manage the entire lifecycle of laboratory samples starting from sample registration to final reporting of results. LIMS typically integrate with laboratory instruments, such PCR, ELISA reader, MALDI-TOF, spectrometers and others, and providing automated data acquisition and processing. It also ensures data quality by tracking and documenting changes to samples and tests during the entire laboratory process. LIMS is highly flexible and can be customized to meet the specific needs of a laboratory, including the compliance and regulatory requirements. Additionally, LIMS offer various reports and data visualization tools that help laboratories to monitor their operational performance and decision-making.

#### 1.1. Core Components of LIMS

A good LIMS has three core components: Sample Tracking, Protocol Execution, and Storage Organization. Imagine a laboratory in which samples are tracked differently by different researchers, using methods varying between a pen and paper and a massive spreadsheet. It would be extremely difficult to ensure your data isn't compromised by human error missing results, errors, and differences in data collected can compound any mistake. Let's go over the three components of a LIMS in more detail and explain how they work in tandem to benefit researchers and laboratory managers.

## 1.1.1. Sample Tracking

The primary function of a LIMS is to track a sample from the time it arrives in a laboratory through its testing and storage. This includes recording all data associated with the sample upon its initial accession, such as the sample's ID, source, collection date, and quantitation information (i.e. volume, and particulate amount). As the laboratory sample progresses along its workflow, additional data is captured, which is also stored in the LIMS. This includes test results, derived sample data. In addition to capturing and tracking data specific to each laboratory sample, a LIMS also tracks who has interacted with a sample and where the sample was throughout its lifecycle. For example, a sample may be placed in a batch or pooled

together with other samples the laboratory is testing. This means the laboratory sample must be tracked by an external barcode label affixed to the test tube.

#### 1.1.2. Protocol Execution

The second core component of LIMS software is to drive the standardization of a laboratory's workflows and underlying protocols, procedures, and steps. Ensuring that each laboratory tech adheres to the specific steps in a published SOP (Standard Operating Procedure) when processing a sample, regardless of who is processing the sample or running a test, is critical to obtaining an accurate and repeatable result. A LIMS supports standardization across the laboratory team by digitizing the steps in procedures and protocols. This ensures the entire laboratory staff executes the correct steps, in the correct order, when running a sample through a test.

LIMS software can manage test assignments so that when a sample arrives in a laboratory, it is immediately assigned the appropriate protocol. A LIMS can also provide a laboratory with more stringent protocol version control measures, granting visibility to research or clinical teams, depending on who is authorized to run the protocol. Laboratory test results can be recorded, sent through the appropriate approval queue, and then distributed to the necessary team members via reports.

#### 1.1.3. Storage Organization

The third core component is keeping track of where a sample is throughout its laboratory lifecycle. Starting with the individual laboratory sample, the LIMS tracks where, in a particular box, the sample tube or vial is kept. Next, the system keeps track of which drawer that box is in, and which rack the drawer is in. Furthermore, the system tracks which shelf the rack is on, and which room the freezer is in. This "storage hierarchy" (*Sample > Position > Box > Drawer > Rack > Shelf > Freezer > Room*) plays a critical role in locating samples quickly in busy laboratories. Research teams that know exactly where laboratory samples are stay productive, organized, and efficient.

#### **1.2. LIMS Functionalities**

The LIMS is an evolving system with new features and functionality being added progressively. As laboratory demands change and technological progress continues, the functionality of LIMS is also always incrementally improving and changing. Despite these changes, a LIMS tends to have a base set of

functionality that defines it. This functionality can roughly be divided into five laboratory processing phases with most LIMS software functions falling under  $each^2$ .

(1) The log in, reception and distribution of a sample and its associated data to testing laboratories for analysis.

(2) The test analysis, result validation, and compilation of the test result for reporting to the customer.

(3) The storage organization and management of the laboratory data in the database for reporting and further statistical analysis

(4) The assignment, scheduling and tracking of the sample and the associated laboratory data

(5) The processing and quality control associated with the sample and the utilized equipment and inventory systems.

There are also several pieces of core functionality associated with these laboratory processing phases that tend to appear in most LIMS which include:

**Sample management:** The core function of LIMS has traditionally been the management of samples. This typically is initiated when a sample is received in the laboratory at which point the sample will be registered in the LIMS. The registration process may involve accessioning the sample and producing barcodes to affix to the sample container. Various other parameters such as clinical or phenotypic information corresponding with the sample are also recorded. The LIMS then tracks chain of custody as well as sample location. Location tracking usually involves assigning the sample to a particular freezer location, often down to the granular level of shelf, rack, row and column. With the growing needs of laboratories, the traditional LIMS has evolved, with the system being able to do much more than just tracking samples. Modern LIMS have implemented extensive configurability as each laboratory need for tracking additional data points can vary widely.

**Equipment and application integration:** Modern LIMS offer an increasing amount of integration with laboratory instruments and applications. A LIMS may create control files that are fed into the instrument and direct its operation on some physical item such as a sample tube or sample plate. The LIMS may then import instrument results files to extract data for quality control assessment of the operation on the sample. Access to the instrument data can sometimes be regulated based on chain of custody assignments or other security features. Modern LIMS products now also allow for the import and management of raw

<sup>2</sup> kwama .L.O., ondiek ,O.C, otieno ,B.O.(2014). Laboratory information management system: a case of family aids care and educational services (faces), Journal of Business and Management.**16**, 1-14

assay data results. Integrating laboratory instruments with Laboratory Information Management Systems (LIMS) is one of the best ways to automate laboratory processes. Modern targeted assays such as quantitative polymerase chain reaction (qPCR) and deep sequencing can produce tens of thousands of data points per sample<sup>3</sup>.

**Electronic data exchange**: The exponentially growing volume of data created in laboratories coupled with increased business demands and focus on profitability, have pushed LIMS vendors to increase attention to how their LIMS handles electronic data exchanges. Attention must be paid to how an instrument's input and output data is managed, how remote sample collection data is imported and exported, and how mobile technology integrates with the LIMS. The successful transfer of data files in spreadsheets and other formats is a pivotal aspect of the modern LIMS. The transition from proprietary databases to standardized database management systems such as structured query language (SQL) has arguably had one of the biggest impacts on how data is managed and exchanged in laboratories. In addition to mobile and database electronic data exchange, many LIMS support real-time data exchange with electronic health records used in diagnostic and research laboratories.

#### Additional functionalities of LIMS

There are numerous additional **operations** that can be managed in a LIMS. These include but not limited to:

Audit management: fully track and maintain an audit trail

**Barcode handling: a**ssign one or more data points to a barcode format; read and extract information from a barcode

Chain of custody: assign roles and groups that dictate access to specific data records and who is managing them

Compliance: follow regulatory standards that have impact on the laboratory

**Customer relationship management:** handle the demographic information and communications for associated customers.

**Instrument calibration and maintenance:** Schedule important maintenance and calibration of laboratory instruments and keep detailed records of such activities.

**Manual and electronic data entry: P**rovide fast and reliable interfaces for data to be entered by a human or electronic component.

<sup>3</sup> Instrumentation: (11 February 2020) Retrieved appril 5, 2023, from https://www.scientific-computing.com/feature/instrumentation

**Personnel and workload management:** organize work schedules, workload assignments, employee demographic information, training, and financial information

**Quality assurance and control:** gauge and control sample quality, corrective and preventive action, data entry standards, and workflow.

**Reports:** create and schedule reports in a specific format; schedule and distribute reports to designated parties.

Traceability: Show audit trail and/or chain of custody of a sample

## **1.3. Features of good LIMS**

This is to mean the characteristics or qualities that are essential for a LIMS to be effective and efficient in managing laboratory operations and data. Some key features of a good LIMS include:

**Workflow Management:** This should be a feature of good LIMS which streamline and automate laboratory workflow, define and standardize workflow processes, assign tasks and tests to researchers and create essential testing points at any stage of the workflow.

**Equipment Integration:** A good LIMS should integrate easily with a wide range of laboratory instruments and automation technologies, supporting seamless data transfer and processing.

**Inventory Management:** is the process of tracking laboratory equipment, test kits, chemicals and reagents in warehouses and testing laboratories to ensure the presence of the right product in the right place at the right time. With LIMS having inventory feature, laboratory personnel must accurately keep track of laboratory equipment, test kits, chemicals and reagents that are used in laboratories. The presence of this feature avoids the unnecessary use of resources in a laboratory.

**Data management, reporting and analysis:** LIMS have features for the management of the centralized data, sufficient space to store the laboratory data, and process reports in an accurate and timely fashion to customer and stakeholders. The presence of tools for analysis is also a feature of good LIMS which helps to analyze and interpret laboratory data. The system should have features that a laboratory data can meaningfully organized in tables, graphs and charts and which is then supported with statistical analysis to generate information for decision making.

**Flexibility and Transparency:** A good LIMS should have features that allow it to be customizable and easy to use. It should be able to handle changes in data and configurations quickly and easily. It should also be able to create reports and dashboards that provide clear visibility into the data and operations. Moreover, it should be able to integrate with existing and future software systems, as well as provide flexible and dynamic search capabilities. A good LIMS should also be able to support multiple users and roles, providing user-level customization options.

**Stability Management:** Stability management is another important feature of a LIMS. A good LIMS should be able to support a wide range of operating systems and hardware configurations and be able to handle large amounts of data. It should also provide data security measures, such as encryption and backup, and be able to integrate with other software systems. Additionally, a good LIMS should also have a range of support options, such as real-time monitoring, alerting, and analytics.

**Support:** Support is an important feature of any LIMS. The presence of a vendor support for the implementation and deployment of a LIMS is helpful for the pain-free long-term adoption of the system in any laboratory. A good LIMS should provide user support in the form of documentation, tutorials, and customer service. It should also provide technical support when needed and should be able to handle any data-related issues. Additionally, a good LIMS should also have a wide range of product support options, such as a forum, online chat, phone and email support, and social media support.

**User-friendly interface and Automatic Backup**: A LIMS should have a user-friendly interface and access to the various modules and functionality based on the access privileges. Additional features which enable smooth and easy exchange of laboratory data between LIMS and other instruments via flexible integration facility are also important.

A good LIMS should be able to provide automated backup processes that allow you to recover data in the event of an outage or data corruption. It should also be able to store backups off-site and provide for secure, encrypted backups. The backup process should be automated and able to handle large datasets with minimal manual intervention. It should also be able to detect changes in data, and quickly and accurately backup the data with minimal delay.

**Improved Quality and Compliance**: Improved quality is another important feature of a LIMS. A good LIMS should be able to provide quality control measures such as data validation, consistency checks, and data integrity checks. Moreover, LIMS should be able to provide automated alerts and notifications to help you quickly detect and address any quality issues.

Compliance is another key feature of a LIMS. A good LIMS should be able to provide compliance tracking and reporting capabilities so that data remains compliant with laboratory standards. The LIMS should be able to provide tools for automating compliance processes and ensuring that all data is compliant with the relevant regulations. Moreover, LIMS should be able to provide an audit trail so that any changes in the data can tracked and ensured that the data remains compliant with the relevant regulations.

## 1.4. Who uses LIMS Software?

A LIMS can be used in various types of laboratories as described below:

- Diagnostics, Research and Clinical Laboratories specifically hematology, immunology, and microbiology could be mentioned as an example. The LIMS in those laboratories automate laboratory workflows, manage laboratory samples and associated data, maintain various test records and test results, generate reports and undertake data analysis
- Production laboratories: Include biotech and pharmaceutical laboratories. In those laboratories, LIMS increases laboratory operational efficiency, productivity, and effectiveness and assist in delivering high-quality results.
- Agriculture Testing Laboratories: Manages sample types like soil, plant tissue, seeds, insects, feed, oils, nuts, husks, flowers, and more. The laboratories maintain sample booking, tracking, testing, quality control, test report generation, facilitating growers to take decisions in the field.
- Biobanks and Biorepositories: Track biological samples and manage their storage locations for easy retrieval of the samples and their associated data.
- Food & Beverage Testing Laboratories: Manage food and beverage samples, maintain test records, generate reports, and automate testing workflows.
- Cannabis Testing Laboratories: Manages clients, test orders, cannabis samples, tests for cannabinoid and pesticide levels, terpenes, moisture, heavy metal, fungi and molds, and generates a certificate of analysis (COA) while complying with regulatory compliance.
- Oil & Gas Testing Laboratories: Manages sample batches, tests, testing schedules, sample monitoring, and review and validation of results with complete traceability for external auditing purposes.

# 1.5. Kind of LIMS by deployment type

Differences between LIMS depend on vendor offerings and organizational needs. The focus of a food and beverage lab differs from the focus of an industrial lab. There are even differences between clinical labs and research labs. The more straightforward way to differentiate LIMS is not by application type but by deployment type. LIMS can be deployed on the premises, in the cloud, or remotely.

**On-premises:** On-premises LIMS are purchased, installed, and run on services that are owned and located on the actual site of the lab facility. It is typically installed on a local server and accessed through a web browser. The downside to on-premises software is that it is time-consuming and expensive to implement and manage. Additionally, on-premise solutions put a strain on seamless data sharing or scalability potential. This kind of LIMS deployment also does not always need internet connectivity.

**Cloud SaaS:** Cloud software as a service (cloud SaaS) LIMS allow users to subscribe to the solution without having to permanently own either the system or the server in order to operate the LIMS. Cloud

SaaS LIMS simply require a secure connection to make the system's license work. A cloud-based LIMS lives and dies according to the level of customer support that the vendor provides its customers

**Remotely hosted**: This kind of LIMS lives between the on-premises and the cloud-based solutions. This is hosted in the cloud and accessed over the internet. The lab would permanently own the LIMS it bought. The software is installed and hosted at a remote data center which relieves any infrastructure or IT management needs. It also offers additional features such as scalability and access from any device with an internet connection

## 1.6. Advantage and disadvantage of LIMS

## 1.6.1. Advantage of LIMS

A LIMS offers a multitude of benefits compared to the paper based system. The main purpose of a LIMS is to improve laboratory efficiency and accuracy by reducing manual operations. Some of the key functional benefits include:

**Workflow automation:** Automating the workflow removes human errors by ensuring that all necessary tracking is completed and that all workflows defined within the LIMS promote efficiency and are adhered to a compliant manner. As the system avoids manual entry of data, it will in turn decrease the sample turnaround time, thereby test reports are timely delivered to the customer.

**Traceability:** Within the system, the whole workflow starting from reception to test report production can be monitored. It is much easier to identify who received and registered the sample, who entered and validated the result, and who produced and sent the test report to the customer. Accordingly, errors and malfunctions can be quickly identified and addressed, and followed with accountability. In addition, the system can help managers to know who performs the best based on the personnel's planned activities.

**Sample management:** Where a user can efficiently organize and track samples through the laboratory and allocate storage locations that mimic the sample storage hierarchy. LIMS can help to streamline the management of sample repositories and associated data. It also reduces the complexity of data entry and ensures accuracy, helping to save time and money.

**Maximizes efficiency:** Smooth, integrated workflows, more clearly defined and consistent processes, and connected tools with peer to peer visibility can dramatically increase sample throughput and decrease turnaround time (TAT). It increases productivity and efficiency within a laboratory by automating

workflow and record keeping. The main purpose of LIMS is to improve laboratory efficiency and accuracy by reducing manual operations.

**Minimize errors:** Manual transcriptions increase the likelihood of errors. Paper and sample data can be lost or missing creating expense and damage to the laboratory reputation. Digital workflows can significantly reduce such risks. LIMS improves compliance efforts and data integrity by reducing margin of human errors.

**Data management:** LIMS provides an efficient and organized way of managing data. It can help automate the process of data entry, storage, retrieval, and analysis. It also allows users to store and manage data in a secure environment, as well as quickly generate reports, so that decisions can be based on accurate data. The laboratory data can be remotely accessed by labortory managers and other authorized personnel.

**Laboratory compliance:** LIMS helps to ensure that all laboratory processes are compliant with regulations and organization standards, as it provides an automated solution for tracking and documenting data. This allows for accurate and timely reporting which is essential for any laboratory. Additionally, LIMS can help improve laboratory safety by providing an automated system for tracking hazardous materials and other safety measures. It is also important that LIMs is compliant with different standards including ISO/IEC 17025:2017, Good Laboratory Practice (GLP), and Good Automated Manufacturing Practice (GAMP).

**Minimize cost:**LIMS helps to achieve significant savings of time and money through consolidating and automating workflows and streamline documentation processes, thereby leading to improved laboratory efficiency.

**Maintaining confidentiality:** It is often easier to maintain confidentiality of laboratory data when using a LIMS than when dealing with a paper based system by establishing user name and password that control access to the system.

## 1. 6.2. Disadvantage of LIMS

While a LIMS can provide numerous benefits, there are also potential drawbacks to consider. Some of the drawbacks include:

**Need training:** For a LIMS implementation, training of laboratory personnel is mandatory. The training can be continuous, time consuming and expensive as the system needs continuous customization and amendments.

**Need time to adapt the system**: When starting up a new computer system, it may seem inconvenient and unwieldy to laboratory personnel. Personnel accustomed to paper based systems are challenged by such automated system and they become reluctant to adopt and proceed with the new system.

**High Cost**: Purchase and maintenance of the system are the most expensive parts of a computerized system, and the costs can be unaffordable in some settings. Moreover, some settings will not have good maintenance that is locally available. Also consider that technology changes rapidly, and the life of a computer may not be more than a few years. This might require repurchase of computer equipment periodically in order to remain updated and compatible with other systems.

**Physical-restrictions**: Adequate space and dedicated electrical requirements are necessary as well as placement of the computer away from heat, humidity, dust.

**Need for backup system:** computer information must be carefully backed up. Loss of data due to a damaged disk or system crash cannot be tolerated, and backup systems will be always critical.

**Need for IT support**: LIMS systems require significant IT support, which may require additional hiring of IT personnel or outsourcing services

**Security risks:** LIMS systems can have security risks if not managed properly. Data privacy is critical in laboratory data management, and the risk of breaches needs to be considered.

## Quiz

- 1. What is Laboratory information management system and how does it work?
- 2. Discuss the functionality of LIMS that enable to perform the laboratory operation
- 3. What are the Features evolved in good LIMS that improve the laboratory effectiveness and productiveness?
- 4. Compare your current workplace laboratory data management system with LIMS system.

## **Multiple choices**

- 1. Which of the following is the most important aspect of using laboratory information management software?
  - A. It enables the users to storage, organization, and retrieval of laboratory data
  - B. It facilitate the workflow management, as well as data collection, analysis, and reporting,
  - C. Improve data quality issues by minimize data transcription errors.
  - D. All

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- 2. Which of the following is not core component of LIMS?
  - A. Sample tracking
  - B. Protocol Execution
  - C. Storage organization
  - D. None
- 3. From the following LIMS functionality, one is the way it automates laboratory processes through the creation of control files that are fed into the instrument.
  - A. Instrument and application integration
  - B. Inventory Management
  - C. Sample management
  - D. Stability Management
- 4. Which of the following are the features of good LIMS software?
  - A. Stability Management
  - B. Automatic Backup
  - C. The presence of a vendor support
  - D. All
- 5. How LIMS improve the traceability?
  - A. Show audit trail
  - B. Maintain the chain of custody
  - C. The sample lifecycle is assessable from the sample arrival to laboratory to test report production
  - D. All
- 6. Which of the LIMS deployment type is purchased and installed at the actual site of the laboratory facilities?
  - A. Cloud SaaS
  - B. On premise
  - C. Remotely hosted
  - D. None

#### **Chapter 2: LIMS evaluation and implementation**

## 2.1. Evaluation of LIMS

Labs using paper based system might be putting their workflows and compliance costs under unnecessary stress. If your current system is costing you money and time, this presents an opportunity to find another new or an updated system that can streamline processes and track data for increased efficiencies. Before you consider changing or updating the system, here is what you need to know to conduct a need analysis of your current workflow and systems.

#### 2.1.1. Understand Laboratory Current Workflow, Systems and Needs

Discover what current processes are causing a barrier to meeting regulatory standards and where laboratory needs to create greater efficiencies that are costing time and money.

**Processing of Samples**: The central reason to implement and use a LIMS is to log, track, record, and report on samples and scientific data in a structured and consistent manner ensuring a reliable chain of custody. The processing of samples must produce accurate results every time. Any samples required to be tested need to comply with established criteria that classify the sample into fit or unfit for acceptance and carried out the intended test.

Laboratory Operations: A good lab manager should look for ways to improve quality, efficiency, and compliance. Physical space and budget spend are always under study in a lab setting the required lab operations to run efficiently and effectively. Any manual processes are at risk of human error making it difficult to scale, share, or report on results with any degree of accuracy and consistency. Any options that utilize automation give control and flexibility to deliver quality outcomes. A major benefit of using a LIMS is process automation that reduces risk of human error.

**Data Reporting:** Data reporting is equally important in understanding how efficient the workflows are and to reveal if anything is undermining the quality of products, systems and processes. It is important the system meets the challenging regulatory environment in an organization keeping the integrity of the data. LIMS improves data reporting as it makes it easy to report on all activities. Moreover, it ensures all data is stored and processed consistently through an automated process, giving greater transparency and accuracy.

#### 2.1. 2. Understand Users and Stakeholders in Implementation

Those who will be involved in the implementation depend on the type of system deployed. If the lab is implementing a SaaS system, lab personnel are needed because the lab is merely training, deploying and loading some metadata. The lab needs lab Manager and data administrator to get the information needed to be loaded to the specifications at the lab. However, if you are going down an onsite infrastructure route, you will need subject matter specialists from each area plus an overall business lead, IT leads and specialists on hardware, software and networking infrastructure which can be very costly.

## 2.1.3. Conduct Research and Vendor Demos

It's critical to look for a company with a long history of reliability and experience in implementing LIMS at specific environment. The company must be ableto have a safe data and the scalability of the system must be considered. The next step is to schedule various providers for a demo of their software. Prior to this, highlight the functions that you want to have supported and assess out of the box functionality to meet those functions. If those functions don't meet the expectations, then discuss what it needs to close the gap, which may take a second demo. It's all about cost reduction; don't immediately assume to customize it because customization increases cost, effort and risk.

#### 2.1.4. Use appropriate criteria to evaluate LIMS

The next step is to compare each provider against the criteria that lab managers should use when evaluating a LIMS. The LIMS evaluation criteria to be considered include:

- **Features**: How well does the solution fit with your workflows, or will you need additional customization?
- **Pricing:** Is the system offered on-premise or software-as-a-service? Will you be licensing or purchasing a subscription?
- **Support:** How will the vendor work with you through the design, implementation and post-launch of the LIMS?
- **Implementation Timeline:** How much customization will you need, and what timeline is expected to get the solution up and running?
- Vendor Experience: How much experience does the LIMS vendor have within your industry? Do they have any industry certifications to support their expertise
- Security: Some LIMS offer encryption to avoid data breaches.
- Data Storage: LIMS can store laboratory data on-premise or in a cloud-based server.

#### 2.2. Implementation LIMS

LIMS implementation requires an honest and comprehensive review of a laboratory needs, and vulnerabilities, followed by a prioritization in addressing the needs. In many ways, a laboratory audit helps simplify this step by flagging the most critical issues present. From there, evaluating a system will depend on selecting and purchasing the system whose out-of-the-box core functionalities best align with the laboratory needs. LIMS with less customization means a smoother for implementation. Here are the steps for implementation.

## 2.2.1. Data Population

Once a system has been selected, there are two common ways in which the laboratory data and required fields can be populated within the system. The more tedious option involves relying on the user to manually populate all of the data in the system. The alternative used by software-as-a-service (SaaS) platforms is to have users supply master data to SaaS administrators inside the platform, who then leverage preconfigured templates to easily and rapidly populate required fields.

## 3.2.2. Training

Next to the data population, every laboratory member should be trained on using the LIMS. This is generally done with the help of vendor experts or through self-training guides where individuals can go at their own pace, and reference materials that relate directly to their day to day activities.

#### 2.2.3. Validation

Validation is a critical step before the implementation of LIMS. However, aSaaS LIMS platform should come fully-validated, and therefore provides administrators with validation packages, the acceptance of which may depend on the laboratory's risk tolerance. Some LIMS also offer extensive customization options. Although customization may seem attractive at first, it means the validation must be completely redone for the final implementation.

#### 2.2.4. Implementation

Once validation is complete, implementation is ready to be resumed. Laboratories can start testing the environment, processing samples, generating result, and automatically tracking data.

## 2.3. Stakeholders in LIMS Implementation

When considering who needs to be involved in the decision to implement a LIMS, it is important to acknowledge different perspectives from all levels right across the organization. Those who will use the

system, as well as those who provide the budget, IT, and top management need to be included for successful and sustainable implementation of the system.

#### 2.3.1. Executive Management

There is no point going down to the purchasing route, if you don't establish the need and get the authority to move forward upfront. The process usually starts by identifying a need for a LIMS to either improve efficiency or as a result of feedback from those in the front line. Upper management will make the decision on how to address these problems and challenges with the view of resolving any issues directly to do with ongoing compliance and/or improving efficiencies.

#### 2.3.2. Budget Holders

It is critical to ensure there is financing available for a LIMS solution once all stakeholders have been consulted. Hence, there will no point going down that the purchasing route to be blocked by budget holders at the last minute. A key question budget holder's want answer is the comparison of making the LIMS operational expense or a capital expense. They will analyze the difference of paying a monthly subscription fee (operational expense) for a service-based system or paying a large upfront cost knowing for more control and choices around custom configuration (capital expense). Knowing in advance the monthly fixed costs with subscription service are always more attractive compared to unknown ongoing maintenance costs after the initial capital outlay.

#### 2.3.3. Laboratory Manager

It is highly important in the evaluation process to involve the laboratory manager, as they have a vested interest in this decision because a LIMS software solution will control the day-to-day operations of the laboratory. Most LIMS solutions collect large amounts of data around sample movement tracking and control where the laboratory manager is often targeted in the vendor evaluation process. With scientists working in different geographical locations, a laboratory manager needs to ensure a LIMS solution that can also cater to a multi-location laboratory, utilizing remote workers, or implementing mobile applications to conduct fieldwork. Laboratory managers also support remote work making a cloud-based solution as a preferred option for the added security.

#### 2.3.4. IT Manager

Any software decisions should also involve IT manager or department. The IT manager can help for the system selection and represents the needs of the upper management and laboratory managers. The IT

manager will have target specifications for any systems, as they will be required to support the implementation process and provide ongoing support during sustainability. From their perspective, they are more interested in controlling maintenance costs, whether data is kept on-premise or in the cloud. The ongoing internal costs of IT for any software solutions are a key component in the decision-making process. The overall cost to the organization includes the cost of servers, personnel to maintain the servers and applications, the cost of security, and the cost of network maintenance. These factors are equally important when making the decision of choosing a subscription service that is managed in the cloud versus a self-hosted deployment.

#### 2.3.5. Quality Manager

The implementation of a LIMS software solution affects ongoing compliance within an organization quality management system. Therefore, including quality control manager in the decision-making process is critical. Quality managers concerns involve the accuracy and efficiency of batch release from a quality perspective as well as the tracking and trending of investigations associated with unexpected results. Quality assurance team members will want to know that the system implemented has been appropriately tested, validated, and is compliant with quality management system of the laboratory.

#### 2.3.6. Laboratory researchers

Researchers also play an important role in the decision-making process as samplers need a system that is active at the point that they are taking the sample, which also provides them with easy ways to label, track, and submit for testing. Analysts are bench-level researchers who will use a LIMS solution to process samples. Their needs should be considered in deciding if a LIMS solution meets the laboratory needs. For these people, LIMS is their workhorses, using the system on a daily basis to perform laboratory jobs. Hence, ensure that experienced researchers are brought to assess a LIMS to see if it will meet their needs of day to day operations.

#### 2.3.7. System Administrator

A System Administrator's primary function is to manage the master data in the system, add user accounts, or put new instruments, test-methods, type of samples etc., on the system. Depending on the size of the organization, this may be a standalone person, a researcher who has a side role, someone in systems/IT who steps in to perform systems admin tasks. As system administrators manage the overall operational of the system, they are a key stakeholder in the decision-making process.

#### 2.3.8. Laboratory Customers

It is important to understand the requirements of your customers, and what they expect from the laboratory so that the laboratory can meet their needs with LIMS. It is also important to be sure that laboratory test reports are appropriately delivered to customers. The LIMS chosen should also support customers' additional data needs and confidentiality issue should be maintained.

## Quiz

1. What is the central reason to implement and use a LIMS?

2. What is the important of LIMS evaluation and what criteria used to evaluate?

3. Who are the stockholders are evolved to evaluate the LIMS and decision making for LIMS implementation?

4. Discuss the LIMS implementation steps after the right LIMS solution has been selected.

## **Chapter 3: LIMS/SILABFA Implementation in Africa**

To support African veterinary laboratory services, the IstitutoZooprofilatticoSperimentaledell'Abruzzo e del Molise (IZSAM) which is an institution in Teramo, Italy put in place an operational LIMS system called "SILAB for Africa" (SILAB is an Italic abbreviation which means sistema informativo laboratori). The SILAB is the type of LIMS which is currently implemented in most African countries.

The SILABFA was initially installed at Central Veterinary Laboratory (CVL) of Namibia in 2009 by IZSAM institute. The implementation of the SILABFA in Namibia especially its compliance with ISO/IEC 17025 has driven an interest from other African countries like Botswana, Zimbabwe, and Zambia for the same application. With financial support from FAO, the system was installed in 2013 in Botswana and interconnected with their national livestock identification and traceability system (LITS). In addition to the implementation of the LITS and strong surveillance system, Botswana has benefited more from the implementation of the SILAB system and it helped the country to become the most live animal and animal products exporting country in Africa. Later, the system has expanded to Tanzania, Uganda, Kenya, Ethiopia, Cameroon, Senegal, and Ivory Coast with the financial and technical support from FAO and IZSAM institute respectively. Currently, the system is implemented in 15 African countries at least at central veterinary laboratories (figure 1).



# Figure 1: SILABFA installations in Africa

# 3.1. SILABFA Implementation in Ethiopia

Ethiopian veterinary laboratories play a significant role in the control and prevention of animal diseases as well as in export testing of live animal and animal products. However, these laboratories should generate quality, reliable and a rapid test result. Such type of result can be greatly enhanced through the implementation of LIMS.A fully functional LIMS is an essential component of any veterinary diagnostic laboratory service in the contemporary world.

Ethiopian veterinary laboratories have been using paper based system to manage sample and associated data. The paper based system is inefficient and outdated system and has posed significant challenges in data and sample management, traceability, sample turnaround time and work efficiencies. To address such challenges, the Ethiopian Sanitary Phytosanitary Livestock Meat Marketing project (SPS-LMM) tried to install LIMS at AHI and national veterinary institute (NVI) in 2009, via a cooperative agreement between USAID and Texas University in partnership with the Ethiopian Ministry of Agriculture and Rural Development (MoARD). The main purpose was to help facilitate and increase live animal and meat exports from Ethiopia. On Feb 2, 2009, a team from University of Kentucky had visited the then NAHDIC (now called AHI) and suggested the use of LIMS to support Ethiopian veterinary laboratories with an enhancement of live animal and meat exporting. Starting from that time onwards, despite much

more efforts were made at different times in installing the system at AHI, it remained unsuccessful until 2017 due to financial and commitment reasons.

The LIMS what is known as SILAB for Africa was installed at AHI in July 2017 in the framework of an agreement between the IZSAM institute and FAO. Following the installation, AHI technical staff was trained by IZSAM experts to facilitate implementation. SILABFA remained in customization and practice until 2018 before its full implementation. More customization works in compliance with the AHI quality management system and the animal health service of Ethiopia were done on the system. After all, SILABFA has become fully implemented since 2019 replacing the paper based system. Currently, AHI in collaboration with FAO is working to expand the system to regional veterinary laboratories and link with other animal health systems (ADNIS, DOVAR) implemented by the Ministry of Agriculture.

## 3.2. SILABFA Architecture and application

SILABFA is web-based application, developed utilizing exclusive open source and freeware software. The application is developed with Java technologies and Apache Tomcat as web server. The relational database (RDBMS) is Oracle 11g Express Edition. The features of this freeware RDBMS (11 gigabyte of storage, 1 gigabyte of utilized memory, and 1 CPU) are sufficient to guarantee all functionalities. The report system tool is Jasper Report which is capable of generating any file format

System's installation requires a server connected to a local area network (LAN), reachable by any computers in the laboratory. Internet connection is not necessary but it became mandatory for distributed access and interconnections among external databases and to allow remote support (possible by Smartphone). Data integrity is guaranteed by using development standards as well as by the security of the network. All data are saved and stored according to a well-defined backup procedure and disaster recovery procedures, which are available to the local IT unit. The system is installed on a local server and after successful installation, laboratory staffs are trained for implementation then finally implemented and continue working for customization (if it needs) and sustainability.

## 3.3. SILABFA System operation

With the current progress on SILABFA, its functions can broadly categorized into four key sections, data entry, report generating, enquiry and system administration.

## 3.3.1. Data entry

Data entry refers to the process starting from reception and identification of a sample and associated data to the result validation. This includes data reception and registration on the system, data distribution to testing sections, result entry into the system, result correction and result validation. Data entry is a critical function since accurate and timely data is crucial for scientific research, quality control, regulatory compliance, and appropriate decision-making purposes. It's important to ensure that the entered data is complete, accurate, and consistent to prevent errors that can affect the reliability and quality of the laboratory results. Data entry can be done manually when a laboratory person enters information into the system's interface, or automatically when the system is integrated with laboratory equipment and receives data directly from this equipment through an interface. However, currently SILAB is not integrated with laboratory equipment and data is manually entering into the system.

## 3.3.2. Report generating

In SILAB, generating reports refers to the process of creating test results and statistical reports based on the data entered into the system. This can include test report elaboration and compiling, test report by section, correct sent test report, test report signature, print and deliver test report to customer, and generate information from the SILAB database for informed decision. It is important to ensure that the generated test results are accurate, complete, and comply with regulatory requirements of ISO/IEC 17025:2017. SILABFA provide functions to customize the test report templates, allowing amending the components of the report and adding any necessary details to fulfill the requirements and specific needs of the customer.

With regard to generating reports from the SILAB database, the epidemiologist can prepare the reports by selecting the relevant data that needs to be included in the report. Once the user has selected the data and ordered the report, a request to generate the report is initiated. This process can take a few seconds to a few minutes, depending on the size and complexity of the data set. The generated excel can further be analyzed using different tools and the generated information interpreted for informed decisions.

## 4.3.3. The Query

In SILAB, this is a process of requesting of information and keeping track of samples and associated data from the movement of reception and registration to the time test reports are produced and reported to the customer. This section is also important to identify users who are involved starting from sample reception and associated data registration until the creation and reporting the test report by recording the time and user responsible for any data entry, report production, any modification, or deletion on the system. Thus, this brings accountability and helps in identifying and resolving any discrepancies or errors created. This section is also very crucial for quality control, compliance, and support auditing.

#### 3.3.4. System Administration

System administration in SILABFA is crucial for managing the technical aspects of the LIMS system, ensuring its reliability, security, and optimal performance. It plays a key role in supporting laboratory operations and maintaining the integrity of laboratory data. Under this section, the key components include user management, table code management and territory management. System administration in SILABFA encompasses various tasks and responsibilities to manage and maintain the system effectively. Some of the common activities are:

**User Management:** System administrators handle user management within the SILAB. They create and manage user accounts, assign appropriate roles and permissions, and ensure data access control based on user roles and responsibilities. They also manage user authentication methods, password policies, and deactivation.

**Installation and Configuration**: System administrators are responsible for installing and configuring the LIMS software on the designated servers or computing infrastructure. This involves setting up the necessary hardware and software components, establishing connectivity to databases, and configuring system settings based on the laboratory's requirements.

**Security and Access Control:** System administrators are responsible for implementing robust security measures to protect sensitive laboratory data. This includes configuring user authentication mechanisms, enforcing strong password policies, implementing data encryption, and managing user access controls. They may also conduct security audits, vulnerability assessments, and respond to security incidents.

**System maintenance and upgrades**: System administrators perform routine maintenance tasks to keep the LIMS system running smoothly. This includes monitoring system performance, applying software patches, updates, and bug fixes, and performing database maintenance tasks such as indexing or optimizing query performance. They may also manage system backups, disaster recovery plans, and implement strategies for high availability and system redundancy.

**Troubleshooting and Technical Support:** System administrators provide technical support to LIMS users and address any system-related issues. They investigate and troubleshoot software or hardware problems, diagnose errors, and resolve system malfunctions.

**Performance monitoring and optimization:** System administrators monitor the performance of the system to identify any bottlenecks or issues. They track system resource utilization, monitor database performance, and optimize system configurations to ensure optimal performance. They also conduct

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periodic system performance assessments and make recommendations for system improvements or upgrades.

# Quiz

- 1. What is SILABFA?
- 2. What is the data entered to SILABFA at sample reception and result entry phase?
- 3. Discuss the sub feature involved in SILABFA admin part

4. Describe the steps to be followed in SILABFA from the moment of sample arrival to laboratory till report production.

- 1. What is the LIMS currently installed in veterinary laboratory diagnostic in African country?
  - A. SILABFA
  - B. ELN
  - C. ADNIS
  - D. None
- 2. Which of the following is data entry features of SILABFA?
  - A. Sample reception
  - B. Result entry
  - C. Result validation
  - D. All
- 3. Which of the following is the admin part of SILABFA?
  - A. User management
  - B. Table code management
  - C. Territory management
  - D. All
- 4. \_\_\_\_\_ is the SILABFA feature that enables the administrator to manage the "User" and the "Roles.
  - A. User management
  - B. Table code management
  - C. Territory management
  - D. All
- 5. \_\_\_\_\_ is the field allows you to register the geographic area of the sample or submitter to the system
  - A. Table code management
  - B. Territory management

- C. User management
- D. None
- 6. Which of the following is the correct order of SILABFA work flow process?
  - A. Sample reception, Sample analysis, result validation and final approval
  - B. Sample analysis, Sample reception, final approval and result validation
  - C. Result validation, Sample reception, Sample analysis and final approval
  - D. Sample reception, result validation, final approval and Sample analysis

# Chapter 4: SILABFA operational guideline

The main functional features of SILABFA include: Sample reception, Sample analysis, Test report, and Test report signature, Statistics, Query and the Admin. To access SILABFA, every user should login into the system using specific username and password. The SILABFA administrator creates and assigns a username and password for every technical staff in the laboratory. <u>https://demo.izs.it/silabfa\_eth</u> is the demo environment that supports to access and practically demonstrate the SILABFA.

LABS Infor	mation Management System	SIL AB FOR
Login Username: Password: * Remember : username and password a	Enter	Version 2.1.0

Figure 2: Shows SILABFA Login interface

# 4.1. Sample reception

This is the starting main feature of the system where receiving and registering of sample and associated data are undertaken by sample receptionists at reception section. According to the standard operating procedures (SOP) of the reception section, the receptionist uses criteria to accept and register those fit samples on the system, and reject these unfit from accepting. The sub-features under this include; sample reception, sample tracking, distribution tracking, storage management and money payment tracking.

# Sample reception

In this sub-feature, registration of a sample and associated data is carried out before distribution to testing sections. This has consisted of 4 steps; reception step-1, reception step-2, reception step-3 and reception step-4 (distribution phase). To start registering the sample and associated data on the system:

- The receptionist will go to sample reception Menu, select and click on sample reception, then a new page is displayed (Fig 3).
- To continue registration, click on the "plus" 🕄 icon located on the right side of the page to find a new page (reception step-1) where date of reception, sampling purpose and sampling type are mandatory to be filled (Fig 4).

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Search submission numbers Year: Accepting Lab: Submission number:	2022 AHI	AHI					
Date received:	•	Search	Reset				

# Figure 3: Shows starting of sample registration.

- The red-labeled fields are mandatory but those fields without red are optional (fig 4).
- At the top of the page, you will see the year, laboratory, and submission number filled by defaults.
- Once you entered all the needed information on the space provided, click on the "Save Data" button to save the information on the database.

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Market Category					X		
Sampling type							
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Case History	6 [						

Figure 4: Shows data registration at reception step-1

• After saving the information, you will be redirected to a new page (reception step-2) where customer address and sampling area must be filled (Fig 5).

			SILAB
			AFRICA
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Years	2022		
Submission number:	520		
Sustomer, Sampling Point and payment			
Senders type:	Private 🗸		
Submitter/Customer:		~ x	
Sampling point:		~ x	
	TALK BULLE		Including and the second state of the second s

Figure 5: Shows data registration at reception step-2

Depending on the sender type, the system shows certain fields: the sender can be from a government or private institutions. If the receptionist selects "institution", the Veterinarian field appears where the receptionist can indicate the name of the person who collected the sample. The receptionist must indicate the sender of the sample, who will also receive the test report.

- SILABFA offers the possibility to add, if the customer is new by clicking on the "adds new customer" button located on the right side of the page (fig 5).
- After entering all the required data and clicking the "Save Data" button, the receptionist is returned back to reception step-2.
- After all the information is entered, the data will be saved by clicking on the "Save Data" button.
- For successful registration, it will appear as "operation completed successfully "on the left-top of the page (Fig 6).
- However, in case an error occurs, the message will appear as a red.

LABS	Information Management System
Welcome text : Receptionist Sample reception -	AHI - Reception 🕹 🕹 20 M 🚯 Version 2.1.0
The operation completed successfully	Back to sample reception and acceptance Go to received samples

Figure 6: Shows successful customer address entry

• By clicking on the "Go to received samples" located on the upper left side of the page, a new page with "plus" 🕒 button will be appeared (Fig 7).

				SILAB <sub>6</sub> AFRIC	
Velcome text : Receptionist		AHI - Reception	€ 🍰 @ M	<b>0</b> §	Version 2.1.0
teceived samples					
Received samples	AHI				
Leceived samples Laboratory name: Year:	F AHI 1 2022				
teceived samples Laboratory name: Year: Submission number:	: AHI : 2022 : 524				

Figure 7: Shows data registration at reception step-3

• By clicking the "plus" 🕤 button, you will be redirected to the reception step-3 for additional data entry about the sample which includes sampling dates, number of samples received, and type of sample, species and sampling point (Fig 8).

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Sampling date to:						
N. of Samples arrived:	N. tr	acking samples:				
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Species		^ ×				
Sampling point:			^ ×			
Samples Conditions:	E					
Single identification:	Ø					
Breed:						
Animal Turner						
Check-List verified:						
Filter Check List (System-Matrix-Species):						^ ×
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Figure 8: Shows reception step-3 for additional data entry

- The "Single identification" pox must be marked to identify and enter results of each sample one by one during analysis. However,
- If a group (herd) result is needed, unmark this "Single identification" box. This condition happened for outbreak samples.
- After you fill all the mandatory fields, click on "*Save data*" button to save the registered data, and then to go to reception step-4 (distribution step).
- The receptionist must repeat this step (reception step-3) more times which is equal to the types of samples received (eg serum, tissue, swab, whole blood) or the number of kebeles sampled in a district by replacing only the sample type and the name of the kebele respectively.

# **Distribution step (Reception step 4)**

This is a step where sample and sample associated data are distributed to the various testing sections for analysis. During distribution, the receptionist has two options to follow depending on the size of the sample to be distributed.

**Option1:** When the sample size is small.

The receptionist can distribute the sample by clicking on the "*test tube*" / icon when the received sample size is small (may be less than 20) or

# **Option2**: When the sample size is large

The receptionist can use the **upload option** to distribute the sample by clicking on the "upload excel file" (1) button when the sample size received by the laboratory is large (may be greater than 20).

# **Option 1: If the sample size is small:**

- The receptionist will directly click on the "*test tube*" / icon, and then
- Will find a page with empty space for laboratory code, sample ID, sex and age.
- By clicking on the "Load" button, all the spaces under the "Laboratory code" will be automatically filled with laboratory codes given to each sample. However,
- The spaces under the sample ID, sex and age are filled manually by clicking on each space provided (Fig 9).
- The square box at the top must be also marked.

ingle identification	on			Test-Method		
Action Max lab code Lab code Start Sample Iden	inserted: 5805 ing From: 5806			Sectio Filter by Te Filter by Metho Tests-Methods	n: st: od:	× 1
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Lab code           1           2           3	Sample identification	Sex         Age		Test required: 0	Save data Rese	
#         Lab code           1	Sample identification	Sex         Age		Test required: 0	Save data Rese	

Figure 9: Shows sample distribution with option 1

# **Option2:** When the sample size is large

• Click on the "upload excel file" button, then go and download it by clicking on the "Download template" located on right side of the page (Fig 10).
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ekome text : Receptionist	AHI - Reception	6 & @ M 4	Version 2.1.
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Select the file to upload Choose File No fil	le chosen		
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Figure 10: Shows the download template

- After downloading, you will find an excel file template (Fig 11)
- Fill the Laboratory code, sample Id, sex and age of the animal on the excel template.
- Save it by giving a specific file name on the desktop.

	А	В	С	D	E	F	G	Н	I	J	K
1	Lab Code	Sample Identification	Sex	Age							
2											
3											
4											
5											
6											
7											
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9											
10											

Figure 11: Shows excel file template

- Go to the "**choose file**" to upload the saved excel file from the desktop and click on "Ok" after selecting the file.
- For successfully uploading, click on "**process the file**" to load the data from the **excel file** to the system (Fig 12).

LABS Informa	ation Aanagement S	ystem	SILABA	
Welcome text : Receptionist	AHI - Reception	6 2 0 1	<b>0</b> §	Version 2.1.0
Upload the excel file of the samples Select the file to upload Choose File No file	chosen		De	wnload Template
Result of the upload The file 524.xisx uploaded successfully				

Figure 12: Shows uploading data from desk top excel to the system.

• After clicking on the **"process file**", you will see data is loading from **excel file** to the SILAB system and then you will find a page ready for your confirmation (Fig 13).

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esults from file ts from Excel Prg.Unit Sample 32765 32766 32767	Sample Identification 87 93 102	Sex M F	Age Syrs 4yrs
esults from file ts from Excel Prg.Unit Sample 32765 32766 32767 32768	Sample Identification 87 93 102 140	Sex M F F M	Age Syrs dyrs Syrs
esults from file ts from Excel Prg.Unit Sample 32765 32766 32767 32768 32769	Sample Identification 87 93 102 140 153	Sex M F F M F	Age Syrs 4yrs Gyrs Syrs 3yrs
esults from file ts from Excel Prg.Unit Sample 32765 32766 32767 32768 32769	Sample Identification 87 93 102 140 153	Sex M F F M F	Age Syrs 4yrs Gyrs Syrs Jyrs

Figure 13: Shows excel data loading to the system.

• By clicking on the "**Confirm** "button, you will get a page containing lists of laboratory code, sample Id, sex and age of the animal on the left side, and tests and methods on the right side.

- Mark all the square poxes located on the left side to distribute the data to a testing section.
- Enter the **testing section** on space provided on the right side of this page.
- After you select the testing section, you will find the list of tests & methods of that selected section.
- Then choose and **mark** the square pox that coincides with the tests and methods requested by the customer.
- Finally, go down to the bottom of the page, and click on the "*Save data*" button to confirm the distribution.
- The phrase "**test required**" found on the bottom of this page is initially zero (0). However,
- When you click on the "*Save data*" and distribution is successful, you will get **1**, and if you distribute again this sample to other section for another test, then you will see the "**test required**" recorded as **2** (Fig 14).

Laboratory: AH Year: 2022 Submission number: 524 Lab Code: 1 N. tracking sample: 5 Beceived Samples: 5	
Distribution Date: 23-12-202 Species: BOVINE Sample: TISSUE Testing Lab: AHI	
Insert IDs and choose test-methods: Single identification Action Max lab code inserted: 32709 Lab code Starting From: Sample Identif. Prefix: Load	Test-Method         Section:       Viral Serology 1         Filter by Test:       FMD: Ag Detection         Filter by Method:       * ×         Tests-Methods       * ×         Records:       10 ~
record totali: 5         # Lab code       Sample identification       Sex       Age         1       32765       87       Male ∨       5yr         2       32768       93       Female ∨       4yr         3       32767       102       Female ∨       6yr         4       32768       140       Male ∨       5yr         5       32709       153       Female ∨       3yr	e d i FMD: Ag Detection Capture ELISA - 0 Action Save data Reset Test required: 0

Figure 14: Shows sample distribution to testing section

#### 4.2. Sample analysis

This is the main feature of SILAB where test results are able to enter into the system by laboratory analysts/signatory either manually or through integration of SILAB into laboratory instruments and applications. It contains four sub-features which include; Receive samples, Result entry, Correction results and Validation.

#### 4.2.1. Receive Samples

This is the step where laboratory analysts confirm the physical presence of the sample as well as distribution of sample associated data through the system at their testing sections. To confirm the arrival of samples and associated data:

- The analyst will go into sample analysis Menu, then select and click on "receive samples",
- Again click on "Search "button to find the distributed sample(s) to this section.
- To confirm receiving, the analyst will **mark** the square box on the right side of the page,
- Then, click on the "Get selected" button and move to the next step.

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Velo	ome text : An	alyst			II - Holecular	Diagnostic Laboratory	6 26 @ M	O B Vera	an 9.1.1
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			Years	2022					
			Tests			* x			
			Submission numbers	260					
				Searc		teset			
	2								
Recor	rds: 2				-		and the second	[( (( )) )] [	10 0
	Aut	2022	Submission number	Num Samples	Sample	Neurartie Disease Minut	Reusod V	Involved section	4
_	004	2922	260		Ossue	newcasoe bisease virus	Real Time PCR		
,	AHI	2022	260	2	FEATHERS	MD virus detection	Real Time PCR		- H

Figure 15: Shows sample receiving phase

### 4.2.2. Result entry

This is the step where test results are entered into SILAB by laboratory analysts/signatory. To enter the final test result into the system:

- The analyst will go to the "Sample analyses" Menu, then choose and click on "Result *Entry*" to see the new page.
- Now, If the submission number is known, insert it on the space provided or
- You can directly click on "**Search**" button to find all the submission numbers (all cases) which are waiting for result entry at this section.

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Welcome	text : Analys	t le's analyses +	~	AHI	I - Molecular Di	agnostic Laborato	n 65 2	2 M (		Version 2.1
Results En	try-									
			Year: 202	12						
		Submissio	on number: 524							
				Search	Res	et				
Search Re	sults: 1								c at 31	> 10 ~
	Acc.	Test.	Submission	N. of Samples	Section •	Test 💌	Method *	Species *	Sample *	
# Year *	Laboratory *	caboratory .	than to car	arrived *			The second se			

Figure 16: Shows result entry phase.

- To enter the result, now, the analyst has two options; the **pencil** <i> icon click option or the **download-upload** option.
- The download upload option is more preferred when the sample size is large and if the analyst wants to enter the result being off the system.

**Option 1**: The pencil *icon* click option

To start entering the results:

• The analyst must click on the "*pencil*" icon to find a page containing two parts (the entry result part and single result part).

- The enter result part contains sample distribution date, species, sample type and submission number, whereas the single result part have the method/SOP, test type(either screening or confirmatory) and test analysis date.
- Select either the "screening or confirmatory" from the drop-down depending on the nature of the test,
- Fill the starting and the ending testing dates, and then click on the "**Confirm**" button (Fig 17) and go to the next page.

		AFRICA
Velcome text: Analyst ample reception + Sample's analyses +	AHI - Molecular Diagnostic Laboratory 🛛 🎳 🎎 🍕	🖗 M 🚯 🚦 Version 2.1.0
inter results		
Laboratory:	AHI	
Testing Lab:	AHI	^ x
Section:	Molecular Diagnostic Labor	
Year:	2022	
Distribution Date:	24-12-2022	
Submission number:	524	
Species:	Bovine	
Sample:	Skin scraping	
Samples Distributed:	5	
Testa	Lumpy skin disease (LSD): Aetiological agent detection	
Single result		
Method/SOP:	Real Time PCR -	^ X
Unified groups:	1	
Sample condition:	Suitable for test	
Measurement units:	^ x	
Screening/confirming test:	Confirmation V	
Test start date:		

Figure 17: Shows result entry step-1

- Now enter the result on the result list of this second page, and click on any "**pencil**" icon to find the sample ID filled by default and a mandatory space to be fulfilled with the result.
- Now, enter the **result** and select its **interpretation** for the result from the drop-down depending on the status of the result (Fig 18).

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elcome text : A	unalyst		AHI - Molecular Diagnos	tic Laboratory	2. OM O B	Version 2.1.
mple reception +	Sample's analyses 👻					
			ack Redistribution			
sult list		1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-				
32765	Samples in the group	Sample ID 87	Result list	Interpretation	Disease	0
32766	1	93			LUMPY SKIN DISEASE	0
32767	1	102			LUMPY SKIN DISEASE	Q
32768	1	140			LUMPY SKIN DISEASE	0
32769	1	153			LUMPY SKIN DISEASE	0
ter results						
ter results Laborat	tory: AHI		Samples in the	group: 5		
ter results Laboral Testing	tory: AHI Lab: AHI		Samples in the	group: 5 Test: Lumpy skin di	sease (LSD): Aetiological age	ent detection
ter results Laboral Testing Sec	tory: AHI Lab: AHI tion: Molecular Diagnostic L	.abon	Samples in the	group: 5 Test: Lumpy skin di Aethod: Real Time PC	sease (LSD): Aetiological age R	ent detection
ter results Laboral Testing Sec	tory: AHI Lab: AHI tion: Molecular Diagnostic L 'ear: 2022	.abon	Samples in the N Sample con	group: 5 Test: Lumpy skin di Aethod: Real Time PC ndition: Suitable for te	sease (LSD): Aetiological age R Ist	ent detection
ter results Laboral Testing Sec Submission num	tory: AHI Lab: AHI tion: Molecular Diagnostic L fear: 2022 iber: 524	.abor	Samples in the N Sample con Measuremen	group: 5 Test: Lumpy skin di Aethod: Real Time PC ndition: Suitable for te t units:	sease (LSD): Aetiological age R st	ent detection

Figure 18: Shows result entry step-2

- On the **result** space, enter only either positive, negative, doubtful or it can be the name of the bacteria/parasite/Fungus/vector
- On the **interpretation** drop-down, select normal, if the result is negative; select abnormal if the result is positive, and select uncertain if the result is doubtful.
- Mark the "**Copy result to other tests**", to copy and insert the same result to the other samples rather than trying to enter results for each sample by clicking on the "**pencil**" icon,
- If the majority of your test results are negative, enter your result as "Negative" and select its interpretations normal, then mark the "Copy result to other tests".

- By clicking the "**Insert/Modify**" button, all negative results will be appeared in the result list. However,
- Change and fill results from negative one by one by clicking on the **pencil** icon for the remaining minority real positive results.
- Apply similar procedure in case, majority of your results are positive.

As an example, assume you have tested about 30 samples and recorded 20 positive and 10 negative results and in this case;

- First, enter the positive results
- Mark the" **Copy result to other tests**", and
- Click on the insert/Modify button to make all results positive, and
- Finally change the 10 real negative samples from positive into negative by clicking one by one on the **pencil** icon.

/Single result	
Samples in the group:	1
Lab Code:	32765
Sample ID:	87
Result:	
Interpretation:	✓
Disease description:	LUMPY SKIN DISEASE
Copy result to other tests:	
Sample ID Prefix :	
Copy prefix to other tests:	
	Insert/Modify Reset
L	
	Back Redistribution

Figure 19: Shows result entry step-2

• After you finish all, go to the top of the page, then click on the "*Save changes*" button to save the results permanently on the database (Fig 20).

	AHI	LAD2 III	Manas Manas	gement Syst	tem 🦯	
		A			SILAB	
Welcome text	t: Analyst		AHL - Holecular Dia	gnostic Laboratory 🎒		Version 2.1.6
ample reception	n • Sample's analyses •					
		Beck	Save changes	Redistribution		
Result list		Beck	Save changes	Redistribution		
Result list Lab Code	Samples in the group	Back Sample ID	Save changes	Redistribution	Disease	
Result list Lab Code 32765	Samples in the group	Back Sample ID 87	Save changes Save changes Result list Negative	Redistribution Interpretation OK	Diresco LUNPY SKIN DISEASE	2
Lab Code 32765 32766	Samples in the group 1 1	Sample 10 87 93	Save changes Result list Negative Positive	Redistribution Interpretation OK KO	Disease LUMPY SKIN DISEASE LUMPY SKIN DISEASE	1
tesult list Lab Code 32765 32766 32767	Samples in the group 1 1 1	Sample ID 87 93 102	Sive changes Result list Regative Positive Positive	Redistribution Interpretation OK K0 K0	Disease LUMPY SKIN DISEASE LUMPY SKIN DISEASE LUMPY SKIN DISEASE	1
Lesult list Lab Code 32765 32766 32767 32768	Samples in the group 1 1 1	Back Sample ID 87 93 102 140	Save changes  Result list  Regative  Positive  Negative  Negative	Redistribution Interpretation OK K0 K0 OK	DICESCO LUMPY SKIN DISEASE LUMPY SKIN DISEASE LUMPY SKIN DISEASE LUMPY SKIN DISEASE	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Figure 20: Shows saving results to the database.

**Option 2:** The download-upload option

Option 2 is more preferable when the sample size is large and if the analyst wants to enter the result into the excel being outside the network area and when the power is off.

- The analysis will click on the download icon to get the excel file with the details of the data to be fulfilled.
- The downloaded excel have two sheets: the first sheet contain information about test started date and end date, type of test (fig 21).

A	В	С	D	E	F	G	Н
START DATE	END DATE	TEST TYPE	SAMPLE CONDITION	Test	Method	Specie	Sample Type
			Fit	Salmonella spp: Id	Bacterial culture a	Caprine	Swabs

Figure 21: Shows the first sheet excel template

- The second sheet contains information about sample ID, result, diseases and interpretation (fig 22)
- The analyst will fill the result and interpretation fields and save the data by giving specific name.
- Finally, the analyst will upload the excel file by clicking the upload "  $^{\odot}$ " icon.

С	D	E	F	G	Н
Test	Labcode	Sample ID	RESULT	DISEASE	INTERPRETATION
Salmonella spp: Identification	6014	1		SALMONELLOSIS	
Salmonella spp: Identification	6015	2		SALMONELLOSIS	
Salmonella spp: Identification	6016	3		SALMONELLOSIS	
Salmonella spp: Identification	6017	4		SALMONELLOSIS	

Figure 22: Shows second sheet excel template for uploading result

### 4.2.3. Correction results

This is a stage where used to re-correct and re-enter wrongly registered test results. To re-correct test results again;

- The analyst will go to the "Sample analyses" Menu, then choose and click on "Correction results" to see a new page.
- Insert the submission number of the sample on the space provided
- Now, click on "Search" button to see and select the sample(s) that should be corrected (Fig 23).

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Welcome t	akale worku : Sup	eruser		AHI - Reception	li 🕹 🕹 📀	м 🚯 🖡	Version 2.1.0
Admin 🔻	Sample reception 👻	Sample's analyses 🔻	Test Report 🔻	Test Report Signature/Email 🔻	Statistics <b>v</b> Q	uery 🔻 Inv	entory 🔻
Correct resul	ts	Year:	2023				
		Laboratory:	AHI	^ x			
		Section: Submission number:		^ x			
<u>C</u>		Submission number:	Search	Reset			J

Figure 23: Shows result correction

# 4.2.4. Result validation

This is the stage where the head test section verifies whether each test result is correctly entered into the system or not. He also cross-checks if the interpretation matches with the result. This phase is privileged only to section head, and it needs special attention as it is difficult to re-correct results again after validation. To validate test results;

- The head of the section will go to the "Sample analyses" Menu, then choose and click on "Validation results" to see the new page (Fig 24).
- Now, If the submission number is known, insert the submission number of the sample on the space provided to get only the results to be validated or
- Directly click on the "Search" button and then find all submission numbers with all lists of results waiting for validation.
- Go to the right side of the page and select the numbers from the drop-down how many results to be validated at once.
- Mark the square box, and then scroll down and finally click on "Select validation" button to go to the next step (Fig 24).

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Vek dmir	ome ta	<mark>kale w</mark>	orku:Suj reception +	peruser Sample	's analy	585 <del>-</del>	Test Report -	Test Report Sig	AHI - Reception mature/Email +	Statistics +	2 M 🚺 🖟 Query - In	Version ventory +	2.1.0
esu	lts valida	tion		Submissi	Y Laborat Sect ion num	ear: ory: ion: ber:	2023 AHI Viral Serology 1		^ x ^ x				
eci	ords: 3 Test. borator	v Year <sup>S</sup>	Submission number	Num Samples	Lab s	Samp ID •	le Test ▼ Spi	ecific st • Method •	Result description *	Disease description	, Interpretation	( «( ) ↓ Start ↓ Date ↓	) )  10 End Date ▼
0.0	AHI	2023	62	1	5814	5814	PPR: Antigen detection	Capture ELISA	Negative	Peste des Petits Ruminants	ок	06-02- 2023	06-02- 2023
	AHI	2023	62	1	5815	5815	PPR: Antigen detection	Capture ELISA	Negative	Peste des Petits Ruminants	ок	06-02- 2023	06-02- 2023
	AHI	2023	62	1	5816	5816	PPR: Antigen detection	Capture ELISA	Negative	Peste des Petits Ruminants	ок	06-02- 2023	06-02- 2023
				Valio	dation di	ate:			pprove selected				

Figure 24: Shows result validation stage.

### 4.3. Test report

This is the main feature of the SILAB where a test report is compiled, prepared as well as opinions and interpretations are given by the head of the testing section (s) based on the test findings before the report is signed and sent to the customer. This contains many sub-features which mainly include: Test report elaboration, Test report by section, Partial test report and Correct sent test report.

## 4.3.1. Test report elaboration

This is a critical stage during a test report preparation and has two options: a test report with attachment or a test report without an attachment. To compile and prepare a test report;

- Go to the "Test Report" Menu, then choose and select a "Test Report Elaboration", and now click on either "No attachment" or "with attachment".
- Click on "No attachment", If you want to get only the **summary** of the test report. But, click on "with attachment", if you want the test report to contain **detail** information.

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Welcome	takale worku : Super	user		AHI - General Bac	teriology and N	lycology	6 2	. 🕐 M		8	Version 2.1.0
Admin	- Sample reception -	Sample's analyses +	Test Report +	Test Report Signa	ture/Email +	Statistics	- Que	y -	Invent	iory -	
			Test Report Ela	boration +	No Attachme	ent					
Kabala			Test Report by	Section	With Attach	nent					

Figure 25: Shows Test report elaboration

- Either insert the submission number on the space provided or directly click on the search button to see all the submission numbers with a pencil and a
   PDF icons
- First, click on the pencil icon 4 and write your opinions and interpretations (comments) on the space provided depending on the laboratory findings.
- Click on the "save data" button to save the given comments (Fig 26).

	Management S	ystem SILAB
Velcome text : Head of Department	AHI - Holecular Diagnostic Laboratory	5 🚠 🕢 M 🤤 🐉 - Vanion 2.10
ample's analyses *   Test Report *   Test Report Sign	ture/Email + Query +	
eport, insert Comments and Recommendations		
Year: Laboratory: Submission number: Comments and Recommendations (max 700 characters):	2022 AHI 524	
Additional information:		

Figure 26: Shows compiling a test report.

- Next, click on the "*pdf*" icon to physically create the test report and make it ready for signature
- After you click on the "*pdf*" icon, this submission number will no longer be available on this list.
- Now, go to the "Test report signature" Menu for next activities.

1	$\frown$		<b>BS</b> Information	
			Manag	gement System
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	$\sim$	LABS Information Management System SLAPPOND		
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		Year	2022	
		Submission number	524	
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Searc	h Results: 1			c ≪ ≫ >  10 ❤
#	Year 🔻	Laboratory 🔻	Submission number 🔻	Opinions/Interpretations *
			524	4 🖷

Figure 27: Shows the pencil icon and the PDF of a test report.

## Partial test report

This is a sub-feature where it is occasionally used when a sample is distributed for more than one testing sections or for different tests in one section, and if one testing section conduct test analysis and wants to prepare the report and then send to the customer a head of the other section(s) or the other test. This condition is usually happened for cases that need urgent reports like an outbreak reports. Another condition this can happen is when a testing kit or consumables are not available for either of the recommended tests. To prepare a partial test report;

- Go to the "Test Report" Menu, then choose and select "Partial test report", and click on it.
- Now, follow the same procedure as it is described at stage 4.3.1

### Correct test report/reopen case

We use this sub-feature when a test report is already produced and but the head of section to make some corrections on the test report. To make corrections on the produced and/or sent test report;

- Go to the "Test Report" Menu, then choose and select "Correct test report" and click on it.
- Insert the submission number of the test report on the space provided that needs to be corrected.

- After you click on the "Search" button, you will see a square box on the left side of the page.
- Mark on the square box and click on "Correct selected" button and continue to correct the errors.
- After correction, continue the same procedure as that of stage **4.3.1** to produce again the corrected test report and send to the customer.

## 4.4. Test Report Signature

This is another main feature of the system where a prepared and compiled test report is electronically signed by the head of the section as well as by the head of the laboratory. In addition, a test report (the PDF) is downloaded here to send through an email address to the customer or the test report is printed to be delivered in person to the customer. The sub-features under this include: Head of section signature, Final signature, and Print test report signed, and send Test report signed.

## 4.4.1. Head of section signature

This is a stage where a prepared and compiled test report is electronically signed by the head of the testing section. **To** sign on the test report;

- The head of section will go to the "**Test Report Signature**" Menu, then choose "**Head of section signature**", and click on it.
- Insert the submission number of the test report to be signed.
- After click on the "Search" button, a square box on the left side of the page will be appeared.
- Mark on the square box and finally click on "sign selected" found on the down bottom to proceed to the next step.

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Velcome text : Head of D	epartment	AHI - H	olecular Diagnostic Laborato	· · · · · · · · · · · · · · · · · · ·	м 🚯 🖡	Version 2.1
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otal: 1 Year - Test, Laborator	v • Section • Submiss	ion number +	Report State +	File Nam	e 🔻	8



# 4.4.2. Final signature

This is a sub-feature where a prepared and compiled test report is electronically signed by the head of the laboratory before the report is printed or sent to the customer. In this case, laboratory head means the deputy director or the director of AHI or any person delegated by both. For the test report to get finally signed:

- The laboratory head will go to "**Test Report Signature**" Menu, then choose and click on "**Final signature**".
- Insert the submission number of the test report to be signed.
- Click on the "Search" button to see a square box on the left side of the page.
- Mark on the square box and finally click on "**Sign selected**" button found on the down bottom to finally make the test report ready for the customer.

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elcome text : Head of Dep	artment	AJEL-	Holecular Diagnostic I	aboratory 🚳 🚠	@ M @ B	Version 2.
mple's analyses 🔹 Test Report	<ul> <li>Test Report Signat</li> </ul>	ure/Email • Qu	ery -			
st Report Signature						
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	Submission number: 5	24				
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Tear * Test. Laboratory *						



### 4.5. Print Test Report

This is a stage where a test report is finally printed to be delivered in person to the customer or downloaded to send to the customer through an email. The "Send test report" sub-feature automatically to the customer through the system is not currently working. Hence, the option at AHI now is sending the test report through email, or printing and then delivering to the customer in person. Sending through email or delivering in person depends on the agreement made between the customer and the receptionist during sample receiving. The receptionist is the only privileged body to undertake this activity. To download or print the test report and deliver to the customer;

- The data administrator will go to the "**Test Report Signature**" Menu, then choose the "**Print Test Report**", and click on it.
- Insert the submission number of the test report to be printed or downloaded.
- After click on the "Search" button, then get the report on PDF 😤 icon which is ready to be printed or downloaded.
- Finally mark on the square box located on the right side and click on the PDF < icon to get the signed test report which is now ready for delivery to the customer.

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Welcon	ne t	akale worku : Sup	eruser		AHI - Reception	۵ می	🕗 м 🍕	Version	2.1.0
Admin		Sample reception 👻	Sample's analyses 👻	Test Report 👻	Test Report Signature/Email 🝷	Statistics 🔻	Query	- Inventory -	
Print Tes	t Re	port/s	Year:	2023					

		Section:	Reception			
·		Submission number:	Search Re	eset		
Tota	l: 10				( « » >	10 ~
#	Year 🔻	Submission number 💌	Report State 🔻	File Name 🔻		
1	2023	3	Simple Report	Test_report_SIGNED_2023_AHI_3.pdf		
2	2023	7	Simple Report	Test_report_SIGNED_2023_AHI_7.pdf	D	<b>R</b>
3	2023	28	Complex Report	Test report SIGNED 2023 AHI 28.pdf		<b>R</b>

Figure 30: Shows printing or downloading a test report

#### 4.6. Statistics

In this main feature, a laboratory data is retrieved from the SILAB database to prepare a report. Monthly or quarterly or yearly or other types of reports can be prepared and presented for the laboratory head or other decision makers. From the database, get the data in the form of excel and then use any statistical tool for further simple or advanced type of analysis and interpretations. The Epidemiologist is the privileged one to handle and undertake this activity. To retrieve the excel data from the SILAB database:

- Go to the "Statistics" Menu and then click on it.
- Insert the dates (initial and final dates) to be covered by the reports.
- Go down bottom and mark on "**Full excel report**" and finally click on the "search" button to get the excel data downloaded (Fig 31).

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Welcome	takale worku : Superuser	AHI - 1	General Bacteriolog	y and Myco	ology il +	Statistics	Ouerv		Version 2.1.
Report									
	Date Received:	from	The to	-	-				
	received in Section:	from	to						
	Laboratory:	AHI			-	*			
	Testing Lab:					*			
	Section:				-	*			
	Report State:	Алу	~						
	Sampling purpose:				-	× □Pur	pose in repo	ort	
	Sampling plan:					-	× DPlan	in report	
	Disease description:				-	× Dis	ease in repo	rt	
	Senders type:	1.0			~	Client in re	eport		
	Species:				-	× Spe	cies in repo	rt	
	Sample:				*	* San	nple in repo	rt	
	Test:	1			-	×			
	Method:					*			
	Region:			- ×	Reg	ion in repo	ort		
	Districts:			* *	Dist	ricts in rep	oort		
	Kebele:			* *	Mag	istrate in	report		
	File Type:	⊖Excel ⊙Full ex	cel report OAMR e	xcel Report					



# 4.7. The Query

This is the main feature of the SILAB where it used to trace progress of the test report on the system starting from sample reception up to test report production. The laboratory head or data administrator or SILAB administrator can trace when and who received and distributed the sample; when and who did the analysis and validated the result; and finally when and who signed and produced the test report. In case of a test report delayed or any other fault done during the whole process, the laboratory head can identify the personnel and make accountable for the mistake he/shed did. To trace back a case on the system;

- The user can go to the "Query" Menu, select "Enquiry the data base" and click on it.
- Enter the submission number on the space provided and click on search button.

				•		-	CI	I AD	Var-
	_						) 	AFRIC	S.C.P.
me takale worku : Superuser			-	AHI-1	Reception	6 2.	2 M 4		Vers
Sample reception      Sample's analyses	• Test R	eport 🕶	Test Report	Signature/	/Email 🕶	Statistics •	Query	• Inve	ntory 1
ation about submission numbers									
Year:	2022								
Accepting Lab:	AHI	AHI			^	×			
Testing Lab:	_				^	×			
Section:					^	×			
Submission Number:									
Date Received:	from		💽 to						
Report State:	Any		~						
ADNIS ID event:									
Submitter/Customer type:			~						
Farm:					^	×			
Date Send:				1					
Sampling purpose:					^	×			
Disease descriptions							x		

Figure 32: Shows how information can be traced on the SILAB

 ✓ Get the reception, distribution, result, validation and production icons on the left side for each submission number (Fig 33).

Sea	arch Re	sults: 5	14						<b>₩</b>	. «	»	10 🗸
#	Rec. Lab 🔻	Test. Lab ▼	Submission Number -	Date received •	Report State 🔻	Organization/Institute -	Source -	Sampling purpose 🔻	Context - Diagno	stics	•	
1	AHI	AHI	45	13-01-2022	Results validated	Shubisa Abera	Shubisa Abera	DIAGNOSIS	ſ	•		** * ►
2	AHI	AHI	87	09-02-2022	Results validated	Bamlak Kassahun	Bamlak Kassahun	RESEARCH	ſ	•		\$ * ↓ *
3	AHI	AHI	91	10-02-2022	Results validated	Dehab Yasin	Dehab Yasin	RESEARCH	ſ	•		₩ * *
4	AHI	AHI	99	16-02-2022	Samples distributed	Ashebir Abebe	Ashebir Abebe	RESEARCH	ſ	,		14 14 14 14 14 14 14 14 14 14 14 14 14 14 1
5	AHI	AHI	218	17-05-2022	Test Report produced	DR FASIL AKLILU	DR FASIL AKLILU -	RESEARCH	ſ	•		2 / 1 * / *
6	AHI	AHI	232	19-05-2022	Results validated	Dr Belay Yaregal	Dr Belay Yaregal -	OUTBREAK	, I	•		₩× 1

Figure 33: Shows the five icons for traceability

The responsible laboratory personnel engaged in each activity can be traced by clicking on the icons displayed on the screen. In addition, the location of the report can be also traced by clicking and searching on the five different icons.

- ✓ The acceptance<sup>●</sup> icon enables to know who accepted and registered the sample and when the acceptance time was.
- ✓ The distribution ✓ icon enables to know who distributed the sample and data and when the distribution time was.
- ✓ The result entry<sup>♣</sup> icon enables to know who did the analysis and when results were entered into the SILAB.
- ✓ The validation ✓ icon enables to know who validated the result and when the validation data was.
- ✓ The result production <sup>™</sup> icon enables to know who signed on the report and when the report is produced or created.

## 4.8. SILABFA admin

The Admin main feature is the governor of the system. It enables to manage the functionality and oversight the overall operations on the system. It is consisted of three important sub-features namely: The user management, Table code management and Territory management.

	LA	BS Info	ormation Manageme	ent Sys	tem	SILABG	
Welcome takale worku : Super	user		AHI - General Bacteriology and I	Mycology 👌	🕹 🕲 M	•	Version 2.1.0
Admin - Sample reception -	Sample's analyses 👻	Test Report +	Test Report Signature/Email -	Statistics +	Query -	Inventory -	
Table code management Territory management	► Items ma	naged in	the LIMS adminis	stration p	hase		
Action		<b>Be</b>	isich Reset				

Figure 34: Shows the Admin sub-features.

#### 4.8.1. User management

This has two phases: the "User" and the "Roles". The "user" part is mainly important to create a username and password for the laboratory personnel while the "roles" part is used to determine the tasks and responsibilities of each laboratory personnel (user) on the system. To reach to these two phases, the administrator will;

Go through Admin $\longrightarrow$  User management  $\longrightarrow$  now choose either user or roles depending on the activities you want to do.

	Ĭ	LA	BS Info	ormation Manageme	ent Sy	/S	tem	1	SIL	ABC	
Welcome takale worku : S	iupe	ruser		AHI - General Bacteriology and I	Nycology	-	1	2 M			Version
Admin - Sample receptio	n -	Sample's analyses -	Test Report -	Test Report Signature/Email +	Statistics		Query	•	Inven	tory -	
Users management		Users									
Table code management	•	Roles									
Territory management	•	Method description:									
Action				arch Prest							

Figure 35: Shows the User and Roles of user management.

To enable a laboratory personnel to have a new user account on the system;

- The laboratory administrator will go to the admin→ User management →select users and click on it to get a new page (Fig 35)
- Now, first make sure that similar user account does not exist on the system by entering the name of the person and clicking on the search button.
- If the name of the person does not exist, continue registering by clicking on the plus button located on the left side to get another page (Fig 36)

User				
Surname / Name:				
Laboratory:	AHI	AHI		^ x
Subdivision/Section:				^ X
User role:			^   X	
	include	users who are no longe	r 🗌	
l		valid		J
Action				
	5	Search Reset		
				0

**Figure 36:** Shows creating a new user account (step-1)

- After the mandatory spaces are fulfilled, finally click on the "save data" button to save the information on the system (Fig 37).
- Once, the administrator assigns the username and password for the user, the user can login into the system and change his/her own password.

$\sim$						AF	RICA
elcome takale wo	rku: Sup	eruser		AHI - Reception	s 25	2 M 4	Version 2.3.
min 👻 Sample r	eception *	Sample's analyses *	Test Report *	Test Report Signature/Email *	Statistics *	Query .	Inventory *
er							
		Usemame:					
		Sumame / Name:					
		Laboratory:					
		subdivision/section:					
		User group:					
		User role:					
		Training:	-				
		Email:					
	Se	ction head delegate: [					
	Labors	atory head delegate:					

**Figure 37:** Shows creating a new user account (step-2)

There are different laboratory personnel descriptions depending on the level of the privilege that they have on the system. These include: the receptionist, analyst/signatory, and head of department, administrator and superuser.

To determine their role on the system;

- The superuser will go to the admin  $\rightarrow$  User management  $\rightarrow$  select Roles and click on it
- Now insert a description on the space provided and click on the search button to get a new page (Fig 38)
- The superuser will assign the role of each descriptions on the system by marking on the square boxes located on the left side of the page
- Once a role is assigned for each, all users belonging to the same description or group are able to access the feature and sub-features of the system linked to this description



role.	Role code:     ADM       Description:     Administrator	
Records: 102		< ≪ »>  10 ∨
#	Grant 🕆	•
1	Admin>Users management>Users	•
2	Admin>Table code management>Customers>Customer types	<b>S</b>
3	Admin>Table code management>Institutions>Institution type	ซ
4	Admin>Table code management>Activity>Activity types	<b>S</b>
5	Admin>Table code management>Activity>Request type	<b>S</b>
6	Admin>Table code management>Species	¥.,
7	Admin>Table code management>Samples	<b>d</b>
8	Admin>Table code management>Sub-Division/Sections	<del>1</del>

Figure 38: Shows roles of each description.

#### 4.8.2. Table code management

The table code management is basically important to modify or register new entry variables on the system. Some of the major variables that usually need insertion and rearrangements include; test, method, sample, customer, species, testing sections, sampling, laboratory and SOPs.

6			IBS I	nfo	ormation Manageme	ent Sy	/ster	n	SILABO	
Welcome t	akale worku : Sup	eruser			AHI - General Bacteriology and M	Mycology	۵ 🍰	2 N	4	Version
Admin 👻	Sample reception	- Sample's analyses -	Test Rep	ort 🗕	Test Report Signature/Email 🗕	Statistics	+ Quer	r -	Inventory -	
Users manag	ement >									
Table code m	anagement >	Testa		Met	hod					
Territory mar	sagement >	Activity		Test						
Action		Customers	•	Test	-Method					
		Institutions		Spe	cific Test					
L		Results	•	Test	-Section					
		Sample information		Rep	ort Template					
		Institution Vets		Test	-Report Template linkage					
		Laboratories								
		Sub-Division/Sections								
		Samples								
		Species								
		SOP								
		Accreditations								
		True Table								

Figure 39: Shows different phases of table code management

## Insertion of a new variable

As a general rule, when the laboratory administrator wants to add or insert a new variable into the system, it is strongly recommended to verify if that variable does not exist in the system by inserting the name of the variable and clicking on the search button. After checking, if that variable is not available on the system;

- Continue to add it into the system by clicking on the "Plus" 🕒 button located on the left side of the page, and go to the next steps.
- Now enter an alpha-numeric code and the name of the new variable on the mandatory spaces provided.

• Finally, by clicking on the "**Save data**" button, the new variable is added and saved on the SILAB database.



Figure 40: Shows insertion of new variable

# Insertion of new Test or Method

There are four steps that the laboratory administrator must follow in order and apply during the addition of a new test or method into the system.

# Step 1: insertion of Test or Method

Test:

- Go to the Admin menu → Table Code Management→ Tests →Test to add the new test into the system.
- After verifying the test is not available on the system, click on the plus 🕒 button to get a new page for adding
- Now, enter the name of the new test and an alpha-numeric code of the test on the mandatory spaces provided.
- Finally, click on the "Save Data" button to save the information into the system.

### Method

- Go to the Admin menu→ Table Code Management → Test → Method to insert the new method into the system.
- Check to know the availability of this method on the system by writing its name and clicking on the search button.

- After checking and if not available, continue to click on the plus 🕒 button to get a new page and add the new method.
- Now, enter the name of the new method and an alpha-numeric code of the method on the mandatory spaces provided
- Finally, clicking the "Save Data" button to save the information into the database

## **Step 2: Test-Method linkage**

For effective test report, there must be a linkage between the test and the method. To link the test with the method;

- Go through the Admin Menu $\rightarrow$  Table Code Management  $\rightarrow$  Test  $\rightarrow$  **Test-Method**.
- The administrator must verify if the linkage already exists. If not,
- Click the plus 🕒 button, and create the linkage by inserting the test and method on the obligatory spaces provided.
- Finally, click on the "Save data" button to save the information on the database (Fig 41).

6		LAB	S Inform	nation Management S	Systen	1 Sil Ai	ABAY	
Welcome	takale worku : Sup	eruser		AHI - Reception	6 20	2 M 4	Versio	n 2.1.0
Admin	Sample reception	Sample's analyses 🔹	Test Report 🔻	Test Report Signature/Email 🔻	Statistics •	Query .	Inventory *	

Test:	<b>x</b>					
Method:						
Disease description:	► X					
Fields for result:	⊙One ○Two fields, only one result on the report					
	OTwo fields, both results on the report OTwo fields, the second is calculated with the average of the results					
Expiry date:						
ion						
(	Save data Reset Back					

Figure 41: Shows linkage of test with method.

### Step 3: Test-Section linkage:

Every test has to be linked to the testing section where each type of testis carried out. To link the test with the testing section;

- Go through the Admin Menu $\rightarrow$  Table Code Management $\rightarrow$ Test $\rightarrow$ **Test-Section**.
- The administrator must verify if this connection already exists. If not,
- Clicking the plus 🕒 button, and create the connection between the two by inserting the test and section on the obligatory space provided. and
- Finally, click on the "Save data" button to save the information on the database (Fig 42).



Figure 42: Shows linkage of test with testing section

### **Step 4: True Table**

This is the final step where all the test-method, the species, the sample and the testing section are linked for a complete test report. To create a linkage among these all,

- Go through the Admin Menu→ Table Code Management →**True Table** and click on it to get the next new page.
- The administrator must verify if the test-method-section linkage already exists. If not,
- Click on the plus 🚭 button, and create the linkage through fulfilling the obligatory spaces provided.
- Here other fields like the specific test and SOP can be added.
- Finally, click on the "Save data" button to save the information on the database (Fig 43).

(		LAB	S Inform	nation Management S	System	I SILI AF	AB-07	
Welcome	takale worku : Sup	eruser		AHI - Reception	S 20	2 м 🚯	Version	2.1.0
Admin 👻	Sample reception *	Sample's analyses 🔹	Test Report 🔻	Test Report Signature/Email 🔻	Statistics *	Query •	Inventory •	

Test-Method:				~ ×
Species	ZZ	ANY		^ X
Sample type :	ZZ	ANY	^ ×	
Section:		^ X		
Specific test :			^ x	
Encoded result:				
Specific lab:				
SOP:		* ×		
Default result:				
Neasurement units:			^ x	
Range Values:	<ul> <li>None</li> </ul>	OCutoff style OAMR style		
Expiry date:				
ion				

Figure 43: Shows the true table

# 4.8.3. Territory Management

This is the sub-feature of the admin where new administration areas or sampling areas including Region, District and kebeles are added into the system (fig 44). When proficiency test (PT) or any other sample from abroad is brought to AHI, the origin of that sample is also registered in the "country" space. There is also a possibility of registering a sample at farm level but this level is not currently functioning at AHI



Figure 44: Shows Territory management and the values under it

### How to register new districts and kebeles into SILABFA

At any time and any administration level, it is common to see when new administration districts or kebeles are created or two and more district or kebeles came together. Hence, these new created districts or Kebeles must be registered on the system. To registered the new districts or Kebeles;

### District

- Go through the Admin Menu—Territory Management, then select and click on "District"
- Click on search button to know if district exists in the system, and If not
- Click on the "plus " 😳 button to open a new page

(		LAB	S Inform	nation Management S	System	SILABC	
Welcome t	akale worku : Sup	eruser		AHI - Reception	6 2 0	м 🚯 🖡	Version 2.1.0
Admin •	Sample reception +	Sample's analyses 🔻	Test Report +	Test Report Signature/Email +	Statistics • Q	uery v Inv	entory +
Districts							
		Region:		^  X			
		District Code:					
		District Name:					
Action							
			Search	Reset			
							0

Figure 45: Shows checking for registration of new district

- Now, fulfill all the mandatory fields on the opened new page.
- The district code to be inserted here is the number next to the last N<sup>th</sup> number of the recorded district.
- Finally, click on the "Save data" button to save the information on the database (Fig 46).

			LAB	S Inform	nation Management S	System	1 SI A	LAB <sub>OT</sub>	
Welco	me t	akale worku : Sup	eruser		AHI - Reception	a 25	🕐 м 🚯	Vers	ion 2.1.0
Admin	-	Sample reception +	Sample's analyses 🔻	Test Report +	Test Report Signature/Email 👻	Statistics •	Query	• Inventory	-

Region:				
District Code:				
District Name:				
District National Code:				
Comments:				
Expiry date:				
Reference new District :				
Iction				
Sa Sa	e data Reset Back			

Figure 46: Shows registering Districts on the system

### Kebele:

- Go through the Admin Menu  $\rightarrow$  Territory Management then select and click on **Kebele**,
- Click on search button to know if that Kebele exists in the system, and If not,
- Click on the "plus " <sup>(1)</sup> button to open a new page
- Now, fulfill all the mandatory fields on the opened new page.
- The Kebele code to be inserted here is the number next to the last N<sup>th</sup> number of the recorded Kebeles.
- Finally, click on the "Save data" button to save the information to the database

(		LAB	S Inforr	nation Management S	System	I SIL A	ABrore	
Welcome t	akale worku: Sup	eruser		AHI - Reception	a 🏭	🕗 м 🔍	Versio	n 2.1.0
Admin <del>-</del>	Sample reception 👻	Sample's analyses 👻	Test Report 🔻	Test Report Signature/Email 🔻	Statistics -	Query -	Inventory -	

Region.		× X
District:	^ X	
Code:		
Kebele Name:		
Internal code (number):		
Mail code:		
Area code:		
Fiscal code:		
Expiry date:		

Figure 47: Shows registering kebele on the system

### Quiz

- 1. What is the use of plus button in the SILABFA process?
  - A. To entry of new element to the system
  - B. To delete the element previous entered to the LIMS
  - C. To update the existing element
  - D. none
- 2. How the SILABFA is accessed based on web browser application?
  - A. By using user name and password
  - B. By password only
  - C. By user name only
  - D. Without user name and password
- 3. Which of the following is the role of sample reception during SILABFA data entry system?
  - A. Received samples information entry to the SILABFA
  - B. Label the sample with laboratory code
  - C. Distribution of the sample to the test section
  - D. All
- 4. Which of the following does the SILABFA register as a default

- A. Year
- B. Submission number
- C. Laboratory
- D. All
- 5. How the sample receptionist knowing wither the sample is distributed or not during SILABFA sample distribution process?
  - A. If the system register 0 on the test requested menu
  - B. If the system register the 1or 2 on the test requested menu based on the number of distribution done
  - C. SILABFA not have the distribution tracking process
  - D. All

6. \_\_\_\_\_Is the SILABFA features enable traceability of samples and associated data

- A. Query
- B. Test report
- C. Reception
- D. Territory management
- 7. Which SILABFA page enables the user to govern both the system's functionality and the oversight procedures for the operations carried out by the system?
  - A. Admin page
  - B. Query data base
  - C. Reception page
  - D. Sample analysis page
- 8. Which of the following features are managed under the administration phase of SILABFA?
  - A. User management
  - B. Table code management
  - C. Territory management
  - D. All
  - 9. From the following features of SILABFA which one is used to manage the user and role?
  - A. Table code management
  - B. Territory management
  - C. User management
  - D. None
  - 10. \_\_\_\_\_ is the field allows you to register the geographic area of the sample or submitter to the system

- A. Table code management
- B. Territory management
- C. User management
- D. None
- 11. Which administration features of LIMS is used to insert new test or method or updating the existing items?
  - A. Table code management
  - B. Territory management
  - C. User management
  - D. None

### **Practical Exercise**

**Case1.** Let's say that Dr. Tilahun Yada took 10 swab samples from 2month age of female an avian to use in an outbreak study. Salmonellosis and the Newcastle disease virus were suspected infect ions when the samples were taken on June 3, 2023. The sample was collected from Addis Ababa region, yeka subcity and woreda 01.

#### Q1: Fill in the following information to SILABFA based on the situation of case 1.

- 1. Register the information into SILABFA
- 2. Distribute the information of Newcastle disease virus in molecular diagnostic laboratory and salmonellosis in General bacteriology and mycology.
- 3. Receive the sample distributed to the section specified and enter the result
- 4. Validate the result entered to SILABFA
- 5. Create the test report and download the created report

**Case 2:** Assume that from May 1 to 30, 2023, the Animal Health Institute will be conducting serosurveillance on the PPR virus in the Oromiya region, Borana zone, Teltele worada and kelo, Sareta& saba kebeles. According to the plan 300 serum samples were collected from Ovine and caprine under six months old and submitted to AHI by Mr. Megersa Kebede and the detail information about sample is described in the below table.

ID	Species	Age	keble	No sample
1-50	Ovine	young	kelo	50
51-150	Caprine	young	Sareta	150
151-300	Caprine	young	Saba	100

# Q2: Fill in the following information to SILABFA based on the situation of case 2

- 1. Register the sample information into SILABFA according to specified species and kebeles
- 2. Distribute the sample into viral serology
- 3. Receive the distributed sample and fill the result into SILABFA
- 4. Validate the result
- 5. Create the test report

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