Democratic and Popular Republic of Algeria

Ministry of Higher Education and Scientific Research

University 8 May 1945 Guelma

Faculty of Natural and Life Sciences and Earth and Universe Sciences

Department of Biology

For Students: 1st Year applied biochemistry

LABORATORY MANAGEMENT

SHV : 37.5 hours, WHV : 1.5 hours

Credit: 3, Coefficient: 2

Course Developed by Dr. Marwa YAKHLEF

Academic Year 2023/2024

Preface

The management of modern laboratories plays a pivotal role in ensuring the accuracy, reliability, and efficiency of analytical results across various scientific fields.

Effective laboratory management is an essential skill for professionals in the field of applied biochemistry. As the scientific landscape evolves, laboratory environments are becoming increasingly complex, with a greater emphasis on precision, safety, regulatory compliance, and technological advancements. For students at the master's level, particularly in applied biochemistry, mastering the principles of laboratory management is not just a supplementary skill but a core competency that enables the seamless translation of theoretical knowledge into practical, impactful outcomes.

This course: Laboratory Management has been specifically designed for 1st year master's students to bridge the gap between biochemistry and laboratory operations. The course focuses on the unique challenges faced in biochemical laboratories, where the management of personnel, instruments, and processes must be harmonized with the scientific rigor and innovation that define this field. Whether students aim to work in research, industry, or clinical laboratories, this course provides the tools and strategies necessary for ensuring that laboratories operate efficiently, safely, and in compliance with international standards.

The course is divided into five chapters: Laboratory presentation, Process of the analysis request, Process of the biological samples, Reagents and consumables, Equipments.

The course does not rely on a single reference. Instead, it is built upon a range of textbooks and authoritative sources in the field. Together, these resources provide a comprehensive foundation and practical insights into the concepts of food microbiology covered in the course.

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Chapter 1: Laboratory presentation

1. Definition of laboratory management

Laboratory management task is to integrate and coordinate organizational resources so that quality laboratory services can be provided effectively and efficiently.

- Organizational resources include:

1. Personnel
2. Equipment
3. Money
4. Time
5. Space

2. Importance of laboratory management

It is important for biologists to understand:

1. How a laboratory functions
2. What are the different types of laboratories
3. How management system plays an important role in maintaining consistency and quality in laboratory.

3. Definition of a laboratory

Laboratory or lab is a place that is equipped with different instruments, equipments and chemicals (reagents) etc., for performing experimental works, research activities and investigative procedures.

It is a place where experiments are carried for **two purposes:**

1. Enhance scientific knowledge
2. Translate the acquired knowledge for the welfare of mankind.

4. **Research types (categories)**

Research conducted in labs can be divided into three categories (types) :

1. **Basic (pure or fundamental) research**: Aims to find answer to a scientific question and to formulate theory that explains research findings and enhance fundamental understanding of a scientific area.

Example: studying specific proteins related to the life cycle of SARS-CoV-2 virus that causes coronavirus diseases (COVID).

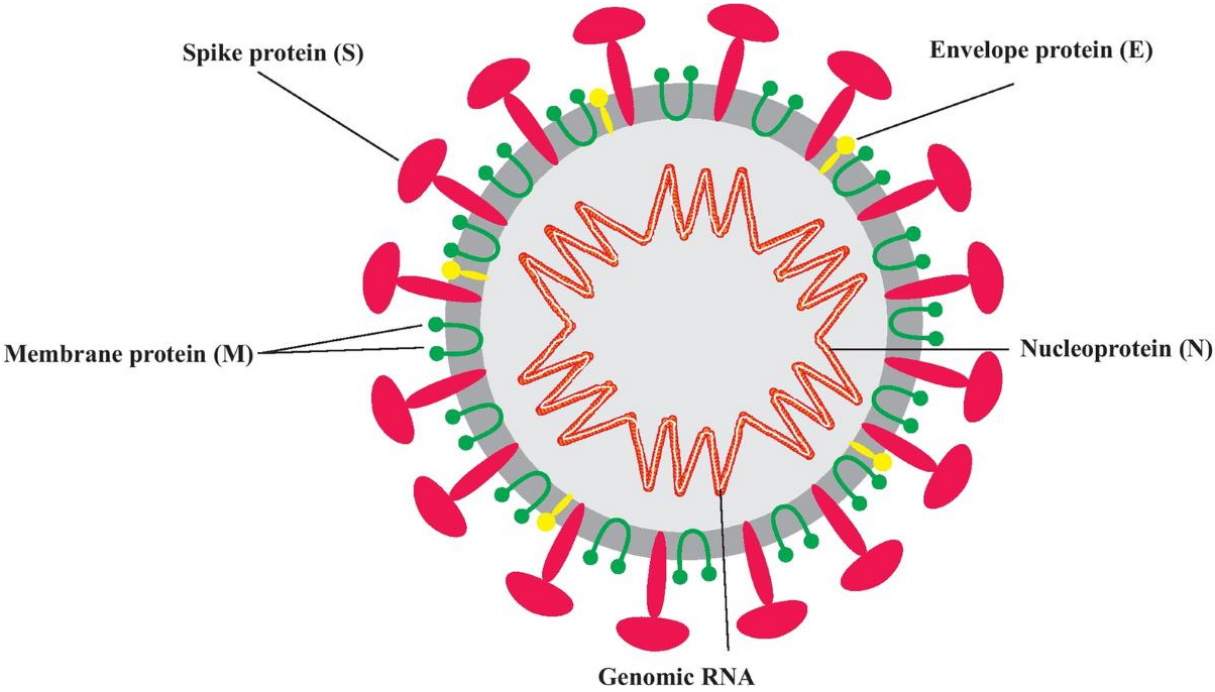

Figure 1. Structure of SARS-CoV-2 virus

2. **Translational research**

It aims to translate the basic scientific discoveries and research results into medical diagnosis and treatment practices for patients. It involves the use of the fundamental knowledge a majority of which is gained through the basic sciences.

Example: the development COVID vaccine is based on the in depth understanding of biology of the virus.

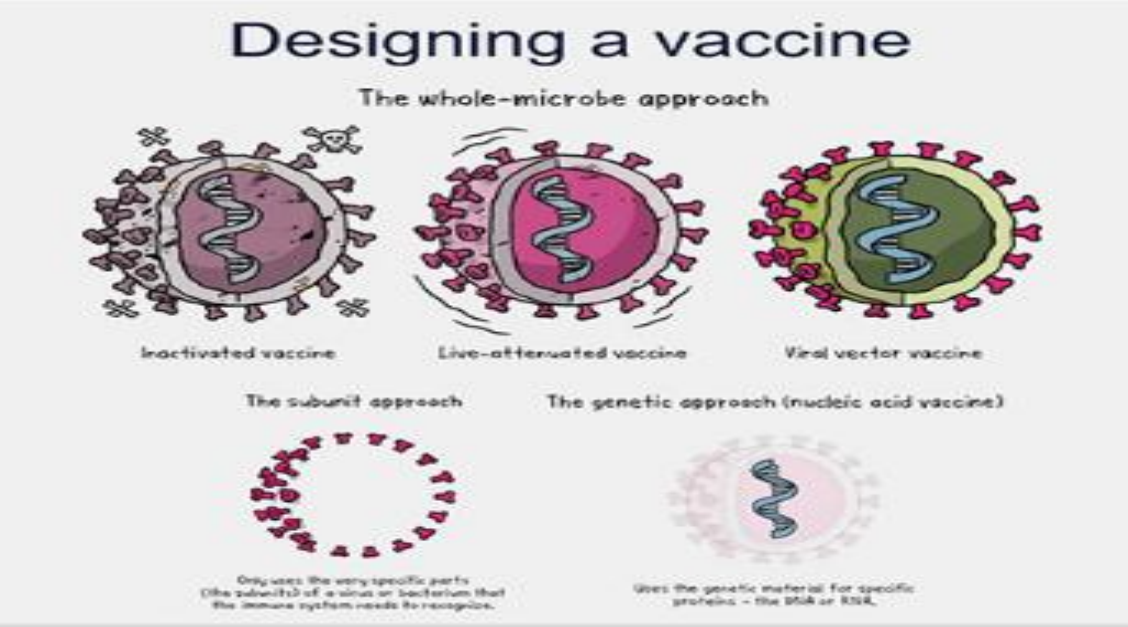

Figure 2. Vaccine design based on the structure of the virus

3. Clinical research

It involves development and evaluation of the efficacy and safety of new treatments, medications and diagnostic techniques in patients.

Example: the vaccine produced by Pfizer to prevent COVID was tested in more than 40,000 volunteers before being deemed safe for use on the general public.

The various types of research, basic, translational and clinical research **are interdependent.**

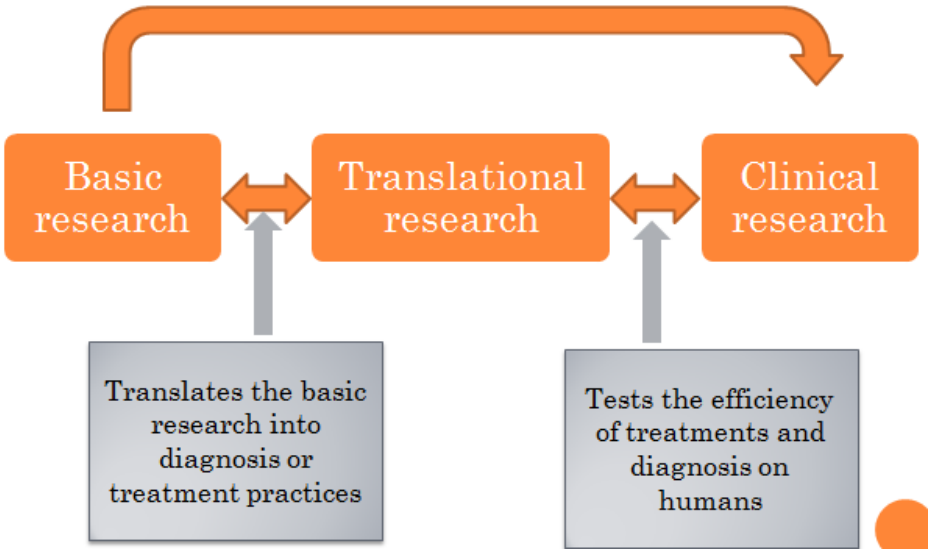

Figure 3. Correlation between basic, translational and clinical research.

5. Types of laboratories

There are multiple ways of categorizing the laboratories. Based on their localization, there are 4 different types of laboratories:

1. **Research labs in university**

In a large university, there can be different schools focusing on areas such as biology, chemistry, physics, law, etc. These labs focus on doing scientific tests by researchers or for teaching science to the students.

Example: laboratories in the university of Guelma, related to the biology department

2. **Research labs in companies**

Companies provide products and/or services utilizing biotechnology. The products produced can vary from food supplement to medications.

Example: laboratories of Saidal

3. **Core labs**

Core Lab supports biological, clinical, and animal research by providing cost-effective laboratory testing or analysis.It Supports the research of others by providing specific services. Some examples of a core lab are as follows:

- **Lab Animal Services:** Personnel in this area care for animals being used for research; monitor for proper care and treatment; maintain approved protocols and ensure appropriate use of animals per protocols.
- **Mass Spectrometry:** provides a wide variety of chemical analyses using mass spectrometry techniques for organic and biological samples.
- **Nuclear Acid and Protein Research:** Scientists in these labs are experts in techniques related to isolating and analyzing nucleic acids (DNA, RNA) and proteins

4. **Clinical labs**

It is a place where tests are usually done on clinical samples in order to obtain information about the health of a patient.

- **Hematology**: Personnel in this lab specialize in delivery and appropriate treatment with blood and blood products.
- **Microbiology:** Personnel in this lab analyze samples for pathogens such as bacteria, yeast.
- **Immunogenetics:** Personnel in this lab perform tests associated with HLA-typing.

6. **Physical aspects for labs construction**

Buildings

- The laboratory must ensure **good ventilation** everywhere by an active ventilation system.
- **Rooms** should be **spacious** to allow the **circulation of people and carts.**
- They should have a **high ceiling** and should be **painted with washable paint.**
- The **floor** must be **easily washable** and **disinfected**

Benches

- Laboratory benches should be constructed from materials that are durable and easy to disinfect.
- Do not use wood, steel will rust if washed with chlorine.
- Organize the benches according to the type of analyzes carried out.

7. **Laboratory's design**

When designing the laboratory or organizing activities, ensure that:

- **The reception** should be located as close as possible to the front door.

- **Contact** between **the public** and **the biological material** only takes place in the **sampling rooms**.
- **Patients** and **samples** do **not** take **the same routes**.
- Access to the **analysis sites**, or **stores**, must be **restricted to authorized** persons.

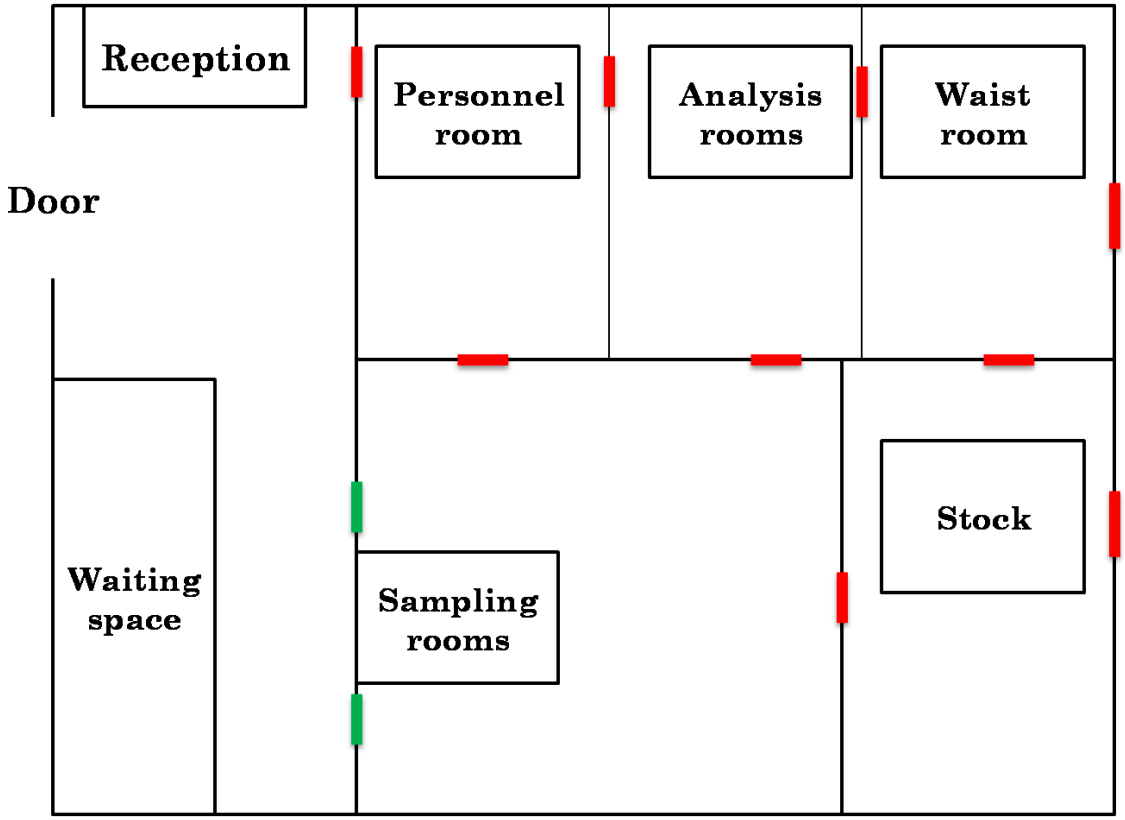

Figure 4.Example of a simplified design of a laboratory.

Doors in red are restricted to workers only. Doors in green are permitted for everyone.

Chapter 2: Process of the analysis request

In medical analysis, requests can come from two primary sources:

A. **Medical Prescription**

This type of request is made by a healthcare professional (doctor, specialist, etc.) who prescribes a specific medical analysis based on the patient's symptoms, medical history, or ongoing treatment.

B. **Personal Request**

This request is initiated by the patient themselves, without a direct prescription from a healthcare provider. The patient might request certain analyses out of personal interest, routine health checkups, or specific concerns about their health.

In both cases, the laboratory performing the analysis should ensure that the tests requested are appropriate and conducted according to medical standards. In some countries, personal requests for certain medical analyses might require a doctor's approval or be limited to non-invasive or routine tests.

1. Registration of the analysis request

To properly register a medical analysis request, the **test request form** should include the following essential information:

- **Patient Identification:**

- Full name, date of birth, and gender.
- Unique identification number (e.g., patient ID or social security number).
- Contact details, such as address and phone number, if necessary.

- **Tests Requested:**

- A clear and specific list of all tests to be performed (e.g., CBC, glucose, liver function tests, etc.).
- Code or description of the test if available.

- **Time and Date of Sample Collection:**

- Exact time and date when the sample (blood, urine, tissue, etc.) was collected, as timing can be critical for certain tests (e.g., fasting blood glucose, hormone levels).

- **Source of the Sample (when appropriate):**

- Indicate the type and origin of the sample (e.g., venous blood, urine, biopsy from a specific organ, or cerebrospinal fluid).

- **Clinical Data (when indicated):**

- Relevant clinical information that may help in interpreting the results (e.g., patient's diagnosis, medical history, symptoms, or current medications).

- **Contact Information for the Health Care Provider Requesting the Test:**

- Full name, phone number, and address of the healthcare provider.
- Provider's identification number (if applicable).
- Method of communication for reporting urgent or critical results (e.g., phone or email).

Including this information ensures the analysis request is properly processed, minimizes errors, and allows the laboratory to provide accurate and timely results.

1.1.Precautions before sampling

Before collecting a sample in a medical laboratory, several precautions must be taken to ensure the accuracy of the test results, patient safety, and the integrity of the sample. Here are the main precautions to follow:

- **Patient Preparation:**

- **Fasting**: For certain tests (e.g., blood glucose, lipid profile), the patient may need to fast for 8-12 hours. It's important to confirm whether the patient has followed the fasting requirement.

- **Medication Restrictions**: Some medications can interfere with test results. The patient should inform the laboratory about any medications they are taking, and in some cases, they may need to temporarily stop specific medications before the test.
- **Hydration**: For tests requiring urine samples, it may be necessary to ask the patient to drink water beforehand to ensure adequate sample volume.
- **Avoidance of physical activity**: For some tests (e.g., certain hormone or enzyme levels), the patient may be asked to avoid strenuous physical activity before the test.

Patient Identification:

- Ensure correct patient identification by confirming their full name, date of birth, and other identification details. Always check the patient's ID bracelet (in a hospital) or ask them to verbally confirm their identity.

Sterility and Hygiene:

- **Hand Hygiene**: Laboratory personnel must wash their hands thoroughly and/or use hand sanitizer before sample collection.
- **Use of Sterile Equipment**: All equipment (needles, tubes, containers) must be sterile to prevent contamination and infection. For example, using new and unopened needles for each blood draw.
- **Gloves and Protective Equipment**: The person collecting the sample must wear gloves and, if necessary, other protective gear (e.g., face mask, gown) to prevent contamination and ensure personal safety.

Sample Collection Area Preparation:

- **Cleaning the Collection Site**: If collecting a blood sample, the skin must be cleaned with an alcohol swab or antiseptic to prevent infection and contamination.
- **Avoiding contamination**: Ensure the collection area is clean and free from contaminants that could interfere with the sample integrity.
- **Correct Equipment:**

- **Sample Containers**: Use the correct tubes or containers for the specific test (e.g., EDTA tubes for CBC, heparin tubes for plasma samples).

- **Proper Labeling**: Ensure all containers and tubes are correctly labeled with the patient's name, the test to be performed, and the date and time of collection.

Positioning and Comfort:

- **Patient Positioning**: Ensure the patient is comfortable and in the correct position for the type of sample collection. For example, during a blood draw, the patient should be seated or lying down to avoid fainting.
- **Calming the Patient**: Patients may be nervous about the procedure, especially for blood draws or invasive sampling. Reassure them and explain the procedure clearly.

Time of Collection:

- Some tests require specific timing for sample collection (e.g., morning cortisol levels, postprandial glucose). Ensure the sample is collected at the right time as per the test requirements.

Special Considerations for Certain Tests:

- **Blood Gas Analysis**: The sample should be collected anaerobically (without air contamination) and analyzed quickly to ensure accurate results.
- **24-hour Urine Collection**: For some tests, such as a 24-hour urine test, the patient must be instructed to collect urine over an entire day. Proper instructions must be given to ensure correct sampling.

Patient Consent and Explanation:

- Obtain informed consent from the patient before the procedure, explaining the purpose of the test and any potential risks or discomfort.

Transport of the Sample:

- After collection, the sample should be properly stored and transported according to the test requirements (e.g., refrigeration, protection from light) to maintain sample integrity.

By following these precautions, the risk of contamination, errors, and compromised results is minimized, and patient safety is prioritized.

2. Making samples

2.1.Biological samples

Biological materials or biological specimens refer to substances or tissues obtained from living or deceased human subjects for the purpose of medical or scientific study. These materials are essential in research, diagnostics, and various medical applications. They can include a wide range of human-derived materials.

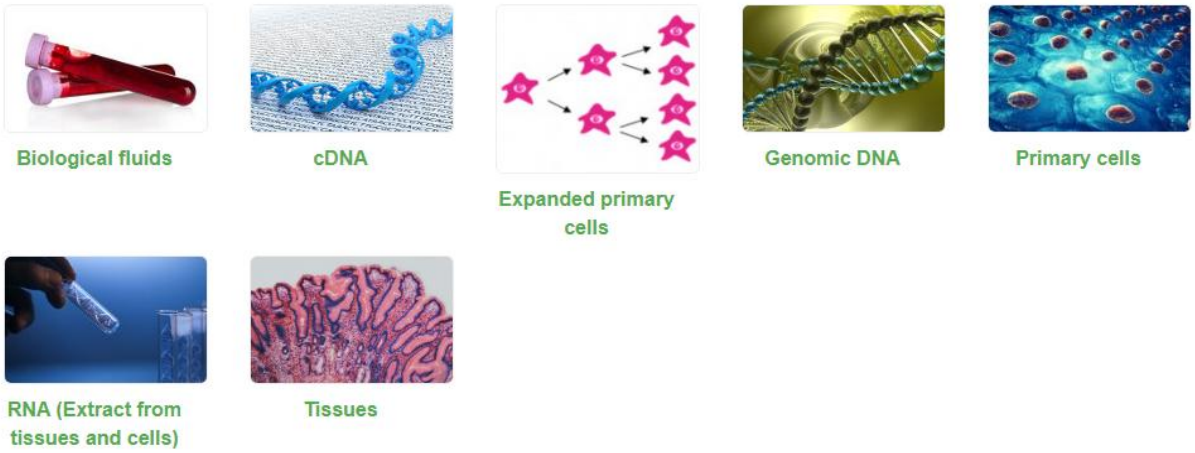

Figure 5. Different types of biological materials.

The main types of biological samples are:

- **Biofluids**: Means “Biological fluids” . These fluids can be obtained from the human body via a number of different methods:

Excreted: Eg: Urine, sweat, tears, nose discharge

Secreted: Eg: Breast Milk, Bile, Saliva

Extracted: Eg: blood, Bone Marrow Aspirate, Synovial Fluid, Cerebral Spinal Fluid

- **Tissue**

Tissue samples are samples collected from a specific organ. They are collected either through a biopsy or via a surgical procedure (surgical resection). Human tissue specimen can be fresh, frozen, fixed or processed.

- **cells**

  Cell samples are collected and isolated from either resected tissue samples, biofluid samples, or biopsy samples.

  Here is a list of common cell sample types that are used in research:

- Bone Marrow Mononuclear Cells
- Dissociated Tumor Cells
- Epithelial Cells
- Mesenchymal Stem Cells
- Purified Immune Cells (eg. T Cell, B Cells, NK cells etc.)

- **Others**

These samples are extracted/prepared from either biofluid, tissue or cell samples.

Here is a list of other common sample types that are used in research:

- Nails/hair/ skin
- RNA
- DNA
- Cell-Free DNA (cfDNA)
- Circulating Tumor DNA (ctDNA)

3. Edition, validation and reporting the analysis results

3.1.Edition &Validation

In the **edition, validation, and reporting of medical analysis results**, both the **pre-analytical** and **post-analytical phases** play crucial roles in ensuring accuracy, patient safety, and the reliability of test outcomes. Here is a detailed breakdown of each phase:

3.1.1. **Pre-analytical phase:** Make sure that**:**

1. Patient was properly prepared for sample collection
2. Sample was labeled correctly and clear
3. The request form matches the specimen
4. The date and time of collection is indicated on the request form
5. The specimen was received in acceptable condition

3.1.2. **Post Analytical phase:** Before delivering a result, they have to make sure that:

1. The report shows an appropriate result including test and result match for each test requested.
2. Proper concentration units for results are used.
3. The persons performing the tests are identified.
4. In case of results within critical intervals, a notification is indicated on the report and an immediate verification of the result is made.
5. The release of the results is dated and timed.
6. The results must be checked and validated by a specialized medical doctor with a stamp.

3.2.Reporting the results

There are various ways to report medical analysis results, each with its advantages in terms of accessibility, timeliness, and security. Here's a breakdown of the common methods used for reporting results:

3.2.1. Paper-Based Reporting:

Results are printed on paper and delivered either to the patient or healthcare provider.

3.2.2. SMS (Short Message Service):

Test results are sent via text message directly to the patient's or healthcare provider’s mobile phone.

3.2.3. Mobile Applications:

Results are delivered through a dedicated mobile app or a web-based platform that patients or healthcare providers can access on their smartphones, tablets, or computers.

Chapter 3. Biological sample processing

1. Transportation and handle of biological materials

Prior to transporting any biological materials, the following controls must be in place:

1. Emergency procedures must be known to the person carrying the materials.
2. Container must be appropriate for the material being transported and properly labeled.
3. Material must be packed so that it will stay upright during transportation.
4. Proper protective clothing must be worn during the packaging of the material.
5. 5. Hands should be washed before and after handling materials.
6. 6. Open cuts or other wounds should be covered before handling the materials.
7. 7. Ensure that the exterior surfaces of each package are free of any potential contamination by the packed material.

1.1.Preservation

Sample preservation, until the sample preparation starts, can be an important factor for correct analytical results. Biological samples must be stored under specific conditions and analyzed within the period of defined stability. The storage must avoid any **contamination**, **alteration**, or **loss of analytes**. Alteration of the sample can occur because of **physical and chemical** changes in the sample**.**

Common ways of preservation

Frozen under liquid nitrogen N_2 (−195,79 °C): used in general for biological samples (human or animal tissues, food samples)

Figure 6. The use of liquide nitrogen for samples' preservation.

Preserved by deep freeze (−20 or −80°C): used for samples with high enzymatic activity (e.g., liver, plasma, serum) or containing less stable analytes.

Figure 7. Deep freezers for the preservation of samples.

1.2. **Sterilization:** is a process used to eliminate all forms of microbial life, including bacteria, viruses, fungi, and spores, from a surface, object, or substance. This is crucial in various fields, including healthcare, microbiology, and food production, to ensure that equipment, materials, and environments are free from potentially harmful

microorganisms. It is used to preserve biological samples to destroy or eliminate microorganisms that may be present on or in the sample.

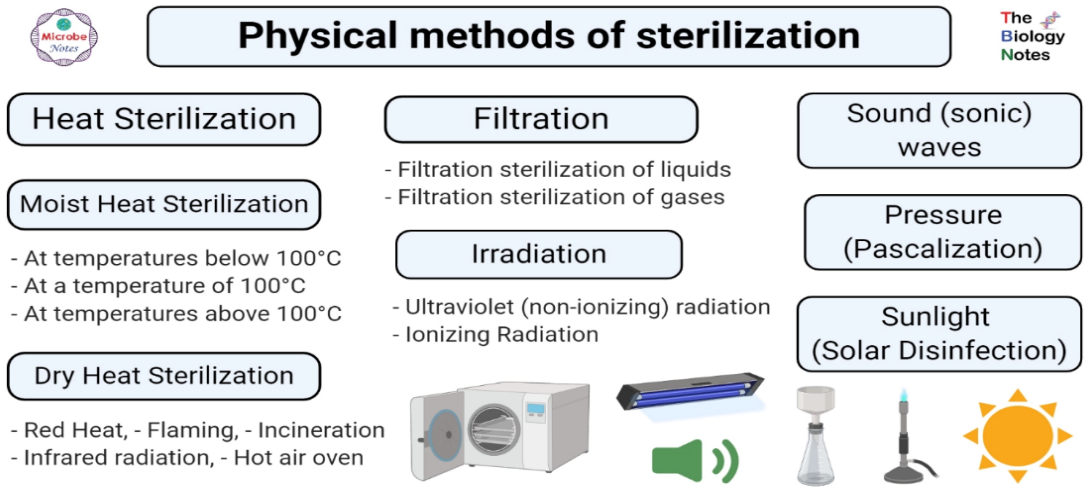

Figure 8. Physical methods for sterilization.

Heat sterilization

Practical procedures by which heat is employed are conveniently divided into two categories:

- **Sterilization by Moist Heat**

  Moist heat occurs in the form of hot water, boiling water, or steam (vaporized water).

  Sterilization at temperature below 100 °C (Pasteurization) :

  This method is suitable for the treatment of food such as milk and drinks. The normal pasteurization temperature is 63°C (145°F) for 30 minutes or 72°C (161°F) for 15 seconds. This temperature not only kills pathogenic microorganisms but also preserves the quality of food or beverage.

  Sterilization at temperature at 100 ^{o}C (Tyndallization)

  This method involves exposure of materials to steam of 100°C for 30 minutes then it is left for incubation at room temperature for 24 hours. This cycle is repeated for three days to achieve full sterilization. The first heating destroys all bacteria in vegetative form. The remaining spore form germinate in incubation and become vegetative. The next subsequent heating cycles again destroys these bacteria in vegetative form. The tyndallization procedure kills spore form of most of the bacteria.

Sterilization at temperature above 100 °C (Autoclaving):

Autoclaving process includes subjecting the material to steam under high pressure and temperature in an autoclave. The normal autoclaving temperature is 121°C (250°F) at 15 psi (pounds per square inch) for at least 15 minutes. Depending on the nature of the microorganisms present, some materials may require longer exposure durations. In autoclaving all the spore forms of bacteria also get killed. This method is suitable for sterilization of glasswares, culture media, and other equipments.

- **Sterilization by Dry Heat**

The temperature of dry heat ranges from 160°C to several thousand degrees Celsius. The dry heat kills microorganisms by protein denaturation, oxidative damage, and the toxic effect of increased level of electrolytes. Sterilization by dry heat is accomplished by the following methods; Flaming, Incineration, Hot air oven.

Figure 9. Dry heat sterilization methods: flaming, incineration and hot air oven.

Filtration

It is the only method that uses force to separate rather than to kill. When you filter a liquid or gas, it passes through a pore, which stops, or filters out, the passage of larger particles.

Filtration depends on pore sizes, the smaller the pores the more particles it can screen out, but it also takes more energy to force the liquid through it. Pore sizes can be as small as .01 μm, small enough to stop viruses from passing through, but smaller proteins can still get through. There are even really small filters called nano-filters, which stop viruses.

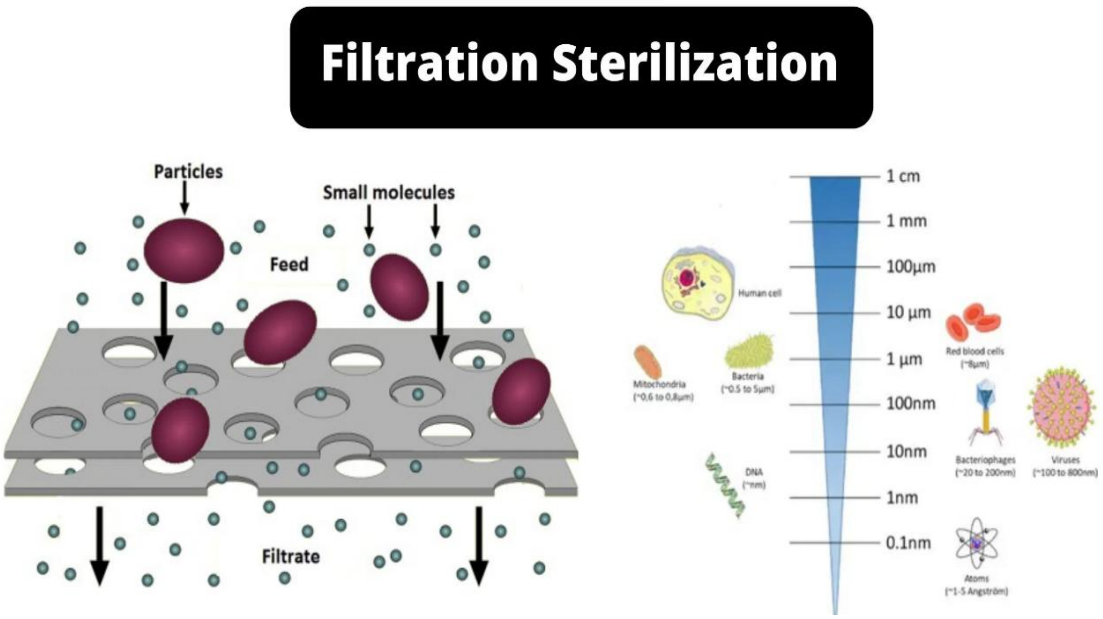

Figure 10. The principle of the sterilization by filtration.

- **Advantages of filtration :**

✓ Absolute sterilization
✓ separates particles based on size
✓ Used for heat sensitive media
✓ Removal of multiple particle sizes
✓ Allows for fairly high throughput

- **Disadvantages of filtration :**

❑ Each filter has a specific nominal pore size
❑ Unable to separate microorganisms that have the same size
❑ May require a high differential pressure

Sterilization by radiation

Radiation is a non-thermal sterilization method that destroys microorganisms in a product with gamma radiation, beta particles (electron beam), or ultraviolet light, X-rays. Radiation is an excellent alternative for products that cannot be sterilized with heat or chemicals.

Sterilization by Sonic waves

Ultrasonic Cleaning is **a cavitation process where bubbles are agitated through high-frequency sound waves to penetrate every surface of medical instruments including holes and recesses**. Ultrasonication has been studied for killing bacteria in various forms, types of bacterial species, and with various methodologies. Many studies have shown that **ultrasonic energy can disrupt cell walls and diminish bacterial growth**.

Pascalization

Also called High-pressure processing or high hydrostatic pressure processing (HPP). It is a non-thermal decontamination technology in which the food matrix is placed in a pressure transmitting medium (e.g., water), and subjected to 100–1000 MPa pressure at ambient temperature. It is a method of preserving, in which a product is processed under very high-pressure, leading to the inactivation of vegetative microorganisms and some enzymes in the food.

Sunlight

Solar disinfection is a process used for the removal of microorganisms with the help of sunlight. This process is commonly used to purify or disinfect drinking water.

Solar disinfection is based on the inactivation of pathogenic organisms as a result of the UV-A (wavelength 320–400 nm) part of the sunlight, which reacts with oxygen dissolved in the water and releases highly reactive forms of oxygen (oxygen free radicals and hydrogen peroxides).

2. **Samples identification**

Identifying patients and correctly labeling specimens are critical to ensure patient safety. If a specimen is not accurately identified, it can lead to delayed or wrong diagnoses, missed or incorrect treatments, blood transfusion errors, and more. Inaccurate results can also lead to additional laboratory testing.

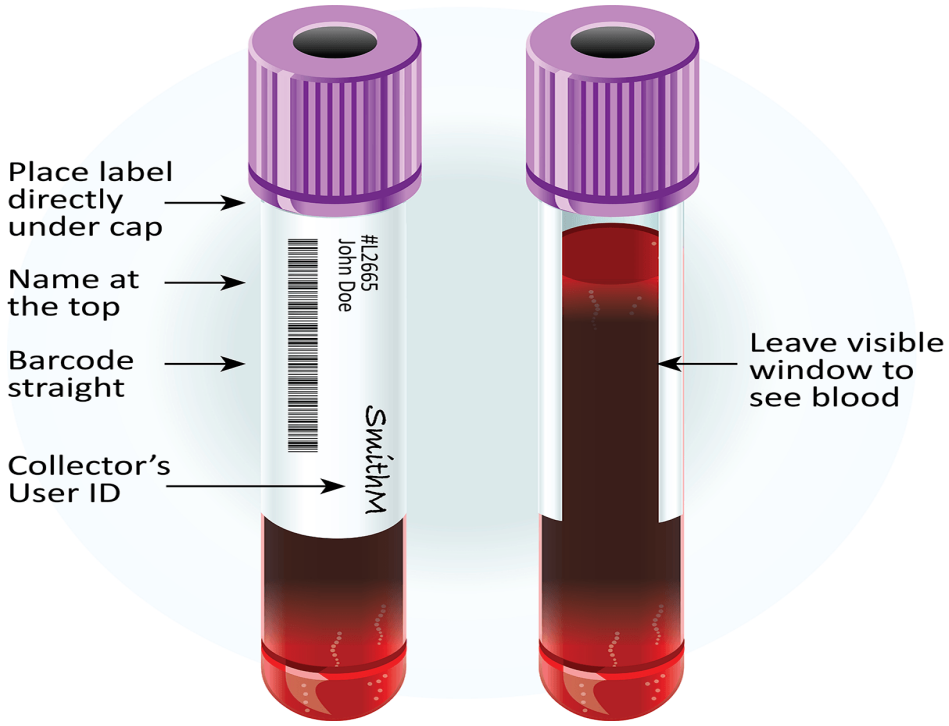

Figure 11. Proper labeling of sample tubes.

2.1.Types of tubes

In laboratory settings, various types of tubes are used for the collection, storage, and analysis of samples. Each type of tube is designed for a specific purpose, with different additives or properties to support specific tests. In the table below are the common types of tubes used in laboratories based on their cap color.

Table 1. Information on the additives their outcomes and the purpose of use of each tube based on the cap color.

Cap color	Additives	Outcome of additive	Purpose of use
Red	None	For serum	Chemistry panels, drug levels, serology tests.
lavender	EDTA	Anti coagulant for plasma Remove calcium and prevent clotting	Complete blood count (CBC), hemoglobin A1C, blood typing, and other hematology tests.
Green	Heparin (either sodium or lithium heparin).	Prevents clotting by inhibiting thrombin and fibrin formation. Used for tests requiring plasma.	Chemistry tests, particularly for plasma determinations, such as electrolytes or ammonia.

Light bleu	sodium Citrat	Prevents clotting by binding calcium.	Coagulation tests (e.g., PT, PTT, INR).

3. Analysis

The Clinical Analysis Laboratory performs analysis of hematology, microbiology, coagulation, immunology, clinical chemistry and hormonal assays. The medical personnel assist the patient in assessing the appropriateness of the request for analysis and in interpreting the results.

Caution: Handle all samples as if they are infectious.

Below are some examples of the most common test in biomedical laboratories (blood typing, blood sugar and complete blood count).

3.1.Blood typing

It is the process of determining a person's blood group based on the presence or absence of specific antigens on the surface of red blood cells. Blood typing is critical in medical situations like blood transfusions, organ transplants, and pregnancy to ensure compatibility between donor and recipient, as incompatible blood types can lead to life-threatening reactions.

Blood Typing Procedure

Blood typing is typically performed using **agglutination tests**, which involve mixing the patient's blood with specific antibodies to see how the red blood cells react.

1. **Sample Collection**: A small sample of blood is taken.
2. **Antisera Application**:
    - **Anti-A serum** (contains antibodies against A antigen).
    - **Anti-B serum** (contains antibodies against B antigen).
    - **Anti-Rh serum** (contains antibodies against Rh antigen).
3. **Observation**:
    - If the blood cells clump (agglutinate) when mixed with a specific antiserum, it indicates the presence of the corresponding antigen.
    - No clumping indicates the absence of that antigen.

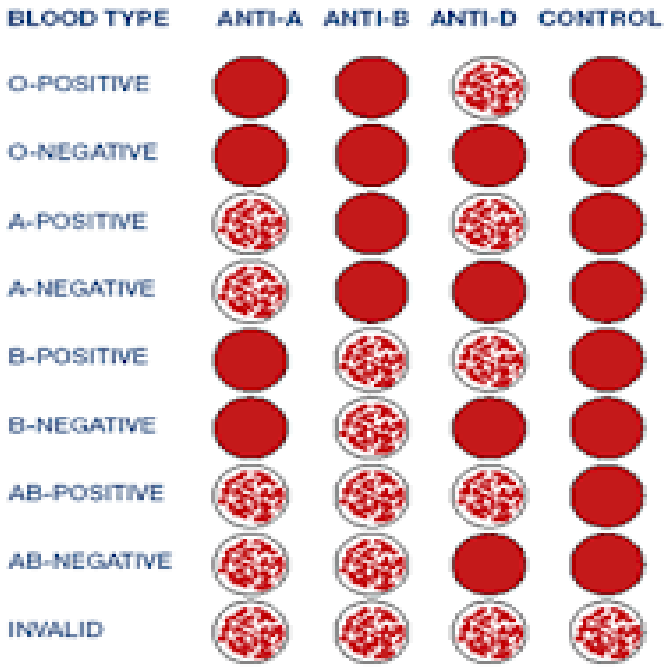

Figure 12. Results permitting the determination of the blood type of patients.

3.2.Blood Glucose (Sugar) Test

It is a diagnostic test that measures the concentration of glucose (sugar) in the blood. Glucose is a primary source of energy for the body, and maintaining its level within a healthy range is crucial. This test is primarily used to diagnose and monitor **diabetes** and other conditions that affect blood sugar levels.

Why Blood Glucose Testing is Important

- **Diagnosing Diabetes**: Helps to determine if a person has diabetes, prediabetes, or gestational diabetes.
- **Monitoring Diabetes**: Regular testing allows individuals with diabetes to manage their condition by monitoring blood sugar levels.
- **Managing Symptoms**: Ensures that blood sugar levels stay within a healthy range to prevent complications like hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar).

3.3.Complete blood count (CBC)

It's used to look at overall health and find a wide range of conditions, including anemia, infection and leukemia.

A complete blood count test measures the following:

1. Red blood cells, which carry oxygen
2. White blood cells, which fight infection
3. Hemoglobin, the protein carrying oxygen in red blood cells
4. Hematocrit, the amount of red blood cells in the blood
5. Platelets, which help blood to clot

A complete blood count can show unusual increases or decreases in cell counts.

3.4.Coagulation studies

Clotting disorders can cause a dangerous amount of bleeding or clotting. If a doctor suspects a clotting disorder, they may recommend one or more coagulation tests. These tests measure various proteins and how they function.

- **Complete blood count (CBC)**
- **Factor V assay:** This test measures Factor V, a substance involved in clotting.
- **Fibrinogen level:** Fibrinogen is a protein made by the liver.
- **Prothrombin time (PT or PT-INR):** Prothrombin is another protein the liver produces. The prothrombin time (PT) test measures how well and how long it takes the blood to clot. It normally takes about 25 to 30 seconds.

4. Validation

Once a sample enters the laboratory, it has to be verified to validate it.

There are a number of steps needed prior to testing.

1. Verify the sample is properly labelled, adequate in quantity, in good condition and appropriate for the test requested.

2. The test request must be complete and include all necessary information.
3. Record sample information into a register or log.

Apply procedures for handling samples, including sample rejection when necessary.

4.1.**Rejection of samples**

The laboratory should establish rejection criteria and follow them closely. It is the responsibility of the laboratory to enforce its policies on sample rejection so that patient care is not compromised.

The following are examples of samples that should be rejected:

1. Unlabelled sample
2. Broken or leaking tube/container
3. insufficient patient information
4. sample collected in wrong tube/container (e.g. using the wrong preservative or a nonsterile container);
5. inadequate volume for the quantity of preservative
6. insufficient quantity for the test requested;
7. long transport time or other poor handling during transport.

Chapter 4. Reagents and consumables

Reagents and consumables are essential components in a laboratory, playing critical roles in conducting experiments, performing analyses, and ensuring accurate and reliable results.

Laboratory commodities can be classified into three categories:

1. **Reagents**
2. **Consumables**
3. **Durables: equipment**

Reagents in laboratory

Reagents are chemicals and biological agents that are used in laboratory testing for detecting or measuring an analyte.

Those chemicals have a specific shelf life (under ideal storage conditions), storage temperature, and packaging information.

Reagents	Shelf Life	Storage Temperature	Packaging
Blood typing sera	24 months	2°–8°C	5 mL bottle (6 bottles in a package)
Bacteriological media	36 months	21°–30°C	500 g bottle
Chemistry reagent kits	12 months	2°–8°C or 21°–24°C	100 tests per kit
CD4 antibody reagent	≥7 months	2°–8°C	50 tests per kit
Stains, dry powder	60 months	21°–30°C	25 g bottle

Figure 13. Illustrative list of reagents and their storage information

Consumables in laboratory

Consumables are items that are used once while performing a test and are not reused. Consumables can include such test-specific items as microscope slides, gloves, pipette tips, syrenges and Petri dishes.

Figure 14. Example of some consumables used in laboratories.

1. Purchase

Laboratories that purchase directly should look very carefully at vendors' and manufacturers' qualifications, examining such things as specifications and methods of transport.

At the outset, the laboratory should:

- Define criteria for supplies or materials to be purchased;
- Look for the best price, taking into account the qualifications and credibility of the supplier;
- Consider the advantages and disadvantages of purchasing "brand name" vs."generic" products, e.g., is it better to purchase specific pipette tips for a specific pipette, or is it just as effective to use generic pipette tips that cost less?

2. Stocking

Stock management helps avoid waste that occurs if reagents and consumables are not stored properly, or if reagents expire before they are used.

Having a stock **management** program in place will ensure that (importance):

Consumables and reagents are available when needed;

High quality reagents are purchased at a reasonable cost

Reagents and consumables are not damaged due to improper storage or are not stored and used beyond the expiration date. However, it is costly and unprofitable to overstock

4.2.Quantification

Quantification is an essential part of a successful inventory management program.

Why do we quantify?

1. Ensure availability of supplies when needed;
2. Avoid overstocking, and thus the waste of expensive items.

The quantification method provides information that will allow to:

- Estimate the necessary annual budget;
- Allow a better planning;
- Make decisions and monitor the performance of the laboratory.

4.3.Types of quantification

there are two frequently used methods:

1. **Quantification based on consumption**: Estimate the quantity of wasted, expired, damaged or discarded products
2. **Morbidity-based quantification**: Estimate the frequency of the disease in question: how many cases per population unit (per 1000, 10000 etc.)

The morbidity-based quantification method, if done well, is more accurate than the actual consumption-based quantification method.

3. Waste elimination

Hospitals and laboratories manage infectious and hazardous waste. A waste management system is a systematic collection, sorting, transporting, and disposal of waste produced by an organization. A significant idea to the success of the system is waste minimization. Hospital and laboratory personnel should be encouraged to generate less waste.

The principle of 3R:

Reduce, Reuse and Recycle

3.1.Waste classification

The WHO has classified hospital (medical) waste in to nine types, based on which waste is segregated into either recycling or incineration.

1. **General waste**: no risk to human health. E.g. Office paper, wrappers, general sweeping wastes, etc.
2. **Pathological waste**: human tissue or fluid. E.g. Body fluid, body tissue, body parts.
3. **Sharps**: sharp waste items. E.g. needles, scalpels, knives, etc.
4. **Infectious waste**: can transfer bacterial, viral, or parasitic diseases. E.g. laboratory waste, used cotton , bandages, gloves.
5. **Chemical waste:** chemicals used in treatment or diagnosis, e.g. laboratory reagents, disinfectants, X-ray film developer, etc.
6. **6. Radioactive waste:** unused liquid from radiotherapy or lab research, contaminated glassware, etc.
7. **Pharmaceutical:** expired or outdated drugs
8. **Pressurized container:** gas cylinder, aerosol cans, etc.
9. **Genotoxic waste:** waste containing cytotoxic drugs used in cancer therapy

3.2.Steps of Waste Management

Waste Segregation

The first step of waste management is the segregation of waste.

Different types of waste are kept in separate color-coded and well-labeled bags or containers. Color codes for different types of waste are different country-wise.

However, the use **of red, yellow, white, blue,** and **black** bins is common.

Regular cleaning and disinfection of the garbage bin are very important.

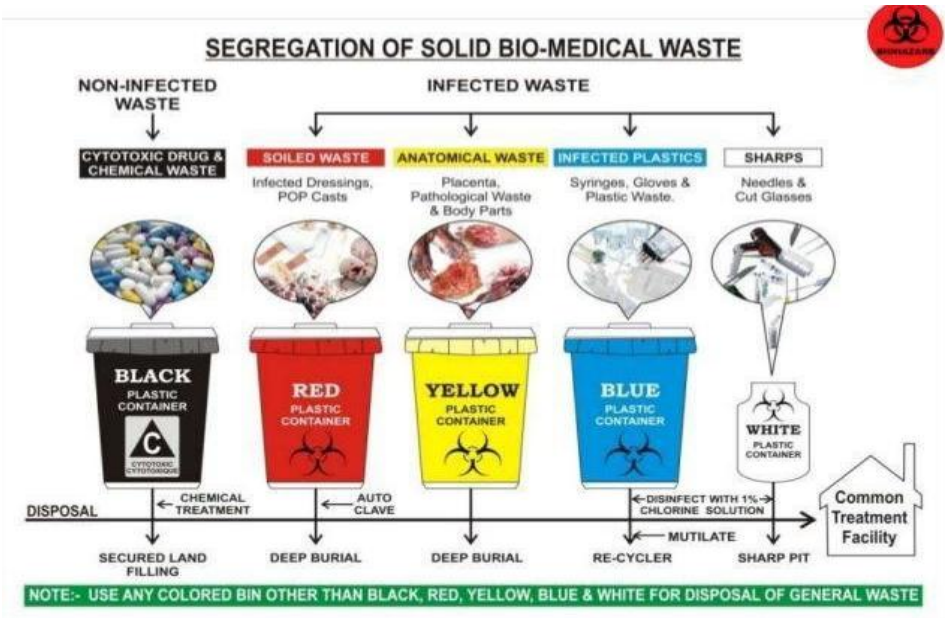

Figure 15. Segregation of solid bio-medical waste.

Storage and Transportation of Waste

Waste should not be stored for a more extended period in the generation area. It should be transported in a sealed container for treatment and disposal.

3.3. Waste treatment

1. Chemical Treatment

It is applied to all types of waste except body parts and body fluids. Users should wear protective clothes, gloves and goggles while working with chemicals.

Chemicals used in disinfection can vary according to the type of waste; some examples are **bleach, sodium hypochlorite, chlorine**, etc.

2. Microwave irradiation

effective for all except large metals and body parts. A frequency of 2450 MHz with a wavelength of 12.24 cm destroys most microbes.

The water of the waste heats, which eliminates the infectious component.

3. Autoclaving

It is applied to sterilize **dressings, gloves, syringes, specific instruments, discarded culture plates, and culture media.**

Plastics and sharp instruments should not be included in autoclaves. A temperature of 121°C under 204.7 KPa pressure is effective enough for sterilization.

4. Encapsulation

It is recommended for the safe disposal of **sharp objects**. The waste is collected in a puncture-proof container. After it becomes a three-quarter full mortar, material like cement, plastic foam, or clay is poured. After it gets dry, it is disposed of.

5. Incineration

Incineration is applied only for **most hazardous waste** that cannot be reused or recycled. An incinerator's high temperature and dry oxidation process reduce organic, combustible waste to inorganic waste in reduced volume and weight. Finally, ash is generated and disposed of in the sanitary landfill.

Chapter 5. Equipments

Equipment is one of the main elements in a laboratory. Efficient equipment management can be achieved by the following:

- **Selection and purchasing** – the purchased equipment must be according to laboratory requirements.
- **Installation** – equipment must be installed according to requirements.
- **Equipment calibration** – system for performing medical test equipment calibration processes must be in place.
- **Maintenance and trouble shooting** – preventive maintenance must be made part of maintenance. It requires developing maintenance plans and following the plan accordingly.
- **Validation** – the department should perform equipment validation before the equipment goes into operation.

Importance of equipment management

Proper functioning equipment can have many advantages, such as:

- Increased performance
- Increased confidence, and reliability in results.
- Lowers repair costs and increases service life.

1. Different equipments

- **Microscope:** It is used to magnify objects and it is mainly used for viewing cells and tissues to make them look larger. Thus it is possible to detect the presence of bacteria, virus and other infections in the blood sample.

They are also used to

- ✓ study the sediments of urine
- ✓ detect kidney problems.

Figure 16. Optical microscope.

- **Incubator**

provides a temperature-controlled environment to support the growth of microbiological cultures. Typical incubators are insulated boxes with an adjustable heater, going up to 60°C to 65°C (140°F to 149°F), though some can go slightly higher (generally to no more than 100°C).

Figure 17. The incubator used to provide the appropriate environment for bacteria's growth.

- **Centrifuges:** This type of lab equipment comes in various shapes and sizes. The equipment is capable of separating the non-soluble material from the available sample. Thus it is used for separating cells from a medium.

Figure 18. Centrifuges in different shapes and sizes.

- **Haematology Analyzer**

It is a sophisticated piece of laboratory equipment used to perform automated blood tests. It provides detailed information about the various components of blood, which is essential for diagnosing and monitoring a wide range of medical conditions.

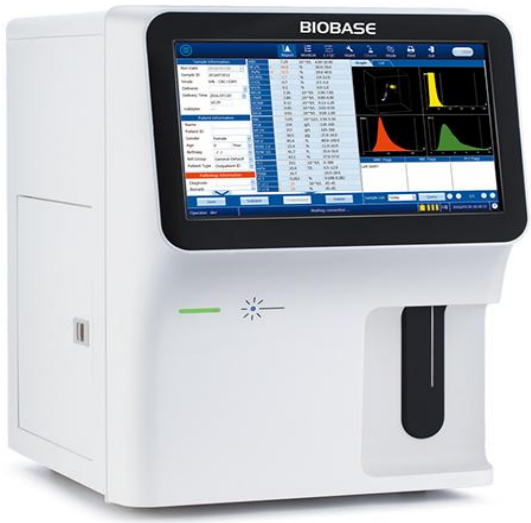

Figure 19. Heamatology analyzer used for the automated blood tests.

Functions and Features of Hematology Analyzers

1. **Blood Cell Counting**:
    - **Complete Blood Count (CBC)**: Measures red blood cells (RBCs), white blood cells (WBCs), and platelets. Provides critical information about blood cell levels and overall health.
    - **Differential Count**: Breaks down the white blood cell count into specific types (e.g., neutrophils, lymphocytes, monocytes, eosinophils, basophils).
2. **Red Blood Cell Parameters**:
    - **Hemoglobin (Hb)**: Measures the amount of hemoglobin in the blood, which is crucial for oxygen transport.
    - **Hematocrit (Hct)**: The proportion of blood volume occupied by red blood cells.
    - **Mean Corpuscular Volume (MCV)**: Average volume of a red blood cell.
    - **Mean Corpuscular Hemoglobin (MCH)**: Average amount of hemoglobin per red blood cell.
    - **Mean Corpuscular Hemoglobin Concentration (MCHC)**: Average concentration of hemoglobin in a given volume of red blood cells.
3. **White Blood Cell Parameters**:

- **White Blood Cell Count (WBC)**: Total number of white blood cells in a given volume of blood.
- **White Blood Cell Differential**: Distribution of different types of white blood cells.

4. **Platelet Parameters**:
   - **Platelet Count**: Number of platelets per volume of blood.
   - **Mean Platelet Volume (MPV)**: Average size of platelets.
5. **Data Management**:
   - **Results Reporting**: Generates and prints reports with detailed blood parameters.
   - **Data Integration**: Can integrate with Laboratory Information Systems (LIS) for seamless data management and reporting.

- **Automated analyser**

An instrument designed to measure different chemicals and other characteristics in a number of biological samples quickly, with minimal human assistance. These measured properties of blood and other fluids may be useful in the diagnosis of disease.

These devices are integral to modern laboratories, enabling high-throughput, accurate, and efficient testing across multiple disciplines, including clinical chemistry, hematology, immunology, and microbiology.

Analytes measured on the chemistry module include albumin, ALP, ALT, creatinine, glucose, HDL, urea and bilirubin

2. Calibration and control

Calibration and control of laboratory equipment are critical for ensuring accuracy, precision, and reliability in scientific Any measurement equipment that is used to measure elements related to patient's life, diagnosis or treatement.

2.1.Calibration

Calibration involves adjusting and verifying the performance of laboratory equipment to ensure it provides measurements within a specified range and accuracy. The process includes:

- **Reference Standards**: Equipment is compared against known reference standards that have traceability to national or international standards.
- **Procedure**:
    - **Initial Test**: Measure known reference points using the equipment.
    - **Adjustment**: If discrepancies are found, adjust the equipment until it meets the required accuracy.
    - **Re-Test**: Measure the reference points again after adjustment to confirm calibration.
- **Documentation**: Calibration results must be documented, including dates, personnel, and the reference standards used.
- **Frequency**: Calibration is performed periodically (e.g., yearly) and when equipment shows signs of drifting.

2.2.Control

Control refers to the ongoing management and monitoring of equipment to maintain consistent performance. This includes:

- **Routine Maintenance**: Regular checks, cleaning, and servicing to keep equipment functioning correctly.
- **Operating Conditions**: Ensuring the equipment is used within its specified operating conditions (e.g., temperature, humidity, electrical conditions).
- **Performance Monitoring**: Continuous or periodic testing of equipment to detect any deviations in performance.
- **Automated Control Systems**:
    - **Feedback Loops**: Automated systems can adjust operational parameters in real-time (e.g., temperature control in incubators or pressure control in reactors).
    - **Data Logging**: Capturing data during equipment operation to monitor trends and detect issues early.
- **Error Handling**: Implementing protocols to detect, report, and handle errors or malfunctions in the equipment.

2.3.Equipment that Require Calibration and Control

- **Analytical Balances**: Calibration involves using certified weights to ensure precision.
- **pH Meters**: Calibrated using buffer solutions of known pH.
- **Spectrophotometers**: Calibrated using standard solutions with known absorbance.
- **Thermometers and Incubators**: Controlled to maintain exact temperatures, and calibration is done using traceable thermometers.
- **Pipettes**: Calibrated using gravimetric methods, by measuring the weight of water dispensed.

3. laboratory management system (LMS)

A Laboratory Management System (LMS), also known as a Laboratory Information Management System (LIMS)**,** is a software solution designed to manage and streamline the workflow in laboratories. It automates processes related to sample tracking, test results, data management, reporting, and compliance, helping to improve efficiency, accuracy, and overall laboratory productivity.

3.1 Key Features of a Laboratory Management System (LMS)

1. **Sample Management**:
    - **Tracking**: Track samples from collection to disposal, ensuring every sample is properly labeled and traceable.
    - **Barcoding/Labeling**: Generate barcodes and labels for easy sample identification and tracking throughout the testing process.
    - **Sample Storage**: Manage and record the storage location of samples, making it easier to retrieve samples when needed.
2. **Test Workflow Management**:
    - **Test Assignment**: Automatically assign tests to samples based on the test request.
    - **Result Entry**: Facilitate the entry of test results directly into the system, either manually or through integration with laboratory instruments.
    - **Data Validation**: Automate the validation of test results through preset rules and algorithms.
    -

3. **Result Reporting**:
    - **Automatic Reporting**: Generate detailed reports of test results in standard formats.
    - **Report Customization**: Allow customization of reports to include patient details, test interpretations, and reference ranges.
    - **Delivery Methods**: Facilitate result delivery via email, SMS, patient portals, or printed copies.
4. **Quality Control**:
    - **Data Integrity**: Ensure that test data is accurate and traceable, with audit trails to track modifications and updates.
    - **Standard Operating Procedures (SOPs)**: Integrate SOPs and ensure compliance with laboratory procedures and regulations.
    - **Instrument Calibration Tracking**: Track the calibration, maintenance, and performance of laboratory instruments.
5. **Inventory Management**:
    - **Reagents and Consumables**: Track the usage and stock levels of reagents, chemicals, and other consumables to avoid shortages.
    - **Automated Alerts**: Set up automatic notifications when supplies are running low or when reagents are nearing expiration.
6. **Data Management and Integration**:
    - **Data Storage**: Store all sample data, test results, and patient information securely in a centralized database.
    - **Instrument Integration**: Interface with laboratory instruments (e.g., blood analyzers, spectrometers) to automate data capture and reduce manual data entry errors.
    - **Historical Data Access**: Allow easy access to previous test results for comparison or review.
7. **Compliance and Regulatory Support**:
    - **Regulatory Compliance**: Support compliance with national and international regulations, such as CLIA (USA), ISO 15189 (global), GDPR (EU), and HIPAA (USA) for data privacy.
    - **Audit Trails**: Maintain detailed audit trails for every action performed within the system to ensure accountability and transparency.
    -

8. **Patient and Client Management**:
    - **Patient Records**: Store patient demographics, medical history, and test results in secure databases.
    - **Client Management**: Manage relationships with external clients, such as doctors, hospitals, or research organizations, who request laboratory services.
    - **Billing and Invoicing**: Automate billing and invoicing for tests performed, linking them to patient or client accounts.
9. **Security and Data Privacy**:
    - **Access Control**: Implement role-based access control to ensure that only authorized personnel can access sensitive patient and laboratory data.
    - **Data Encryption**: Secure data transmission and storage using encryption to protect against breaches and unauthorized access.
    - **Backup and Recovery**: Automatically back up data and provide disaster recovery options to prevent data loss.
10. **Statistical Analysis and Reporting**:
    - **Performance Monitoring**: Generate reports on lab performance metrics, such as turnaround times, test volumes, and error rates.
    - **Quality Control Reports**: Monitor quality control metrics for laboratory tests and processes.
    - **Trend Analysis**: Analyze trends in test results, patient outcomes, or laboratory operations to improve efficiency and outcomes.

3.2.Benefits of a Laboratory Management System (LMS)

1. **Improved Efficiency**:
    - Automation of routine tasks, such as sample tracking, data entry, and reporting, significantly reduces human error and improves overall lab workflow.
2. **Enhanced Data Accuracy**:
    - Integration with instruments and automated validation rules ensure more accurate data entry and minimize manual errors.
3. **Faster Turnaround Times**:
    - Streamlined processes and automated report generation lead to quicker delivery of test results to healthcare providers and patients.
4. **Regulatory Compliance**:

- Ensures that laboratories remain compliant with industry standards and regulations, reducing the risk of penalties and improving quality control.

5. **Increased Transparency and Traceability**:
   - LMS provides complete traceability of samples, tests, and results, making it easy to audit the workflow and identify any potential issues.
6. **Cost Savings**:
   - Efficient resource management, such as inventory control and labor reduction through automation, helps to lower operational costs.
7. **Better Patient Care**:
   - Faster and more accurate test results contribute to better diagnosis and treatment, leading to improved patient outcomes.

3.3 Use Cases for LMS

1. **Clinical Laboratories**:
   - Hospitals, diagnostic centers, and clinics use LMS to manage patient samples, run diagnostic tests, and report results efficiently.
2. **Research Laboratories**:
   - Academic institutions and pharmaceutical companies use LMS to manage research projects, track samples, and ensure compliance with research protocols.
3. **Forensic Laboratories**:
   - Forensic labs use LMS to manage evidence, maintain chain of custody, and ensure accurate testing for legal purposes.
4. **Environmental and Food Testing Labs**:
   - These labs use LMS to track environmental samples, food quality tests, and report results to regulatory bodies or clients.

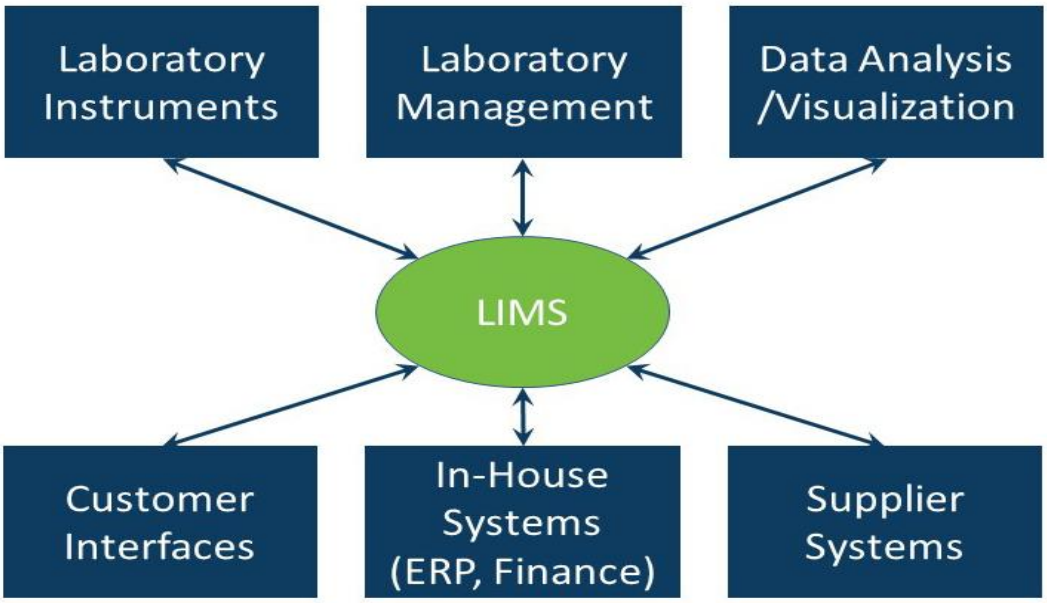

Figure 20. Chart of some of the workflows and data points that a LIMS organises

3.4.Common names of laboratory management

Laboratory Information Management System (LIMS) or management system (LMS) or Laboratory information system (LIS)

3.5.Difference between LIMS and LIS

The difference between **LIMS** (Laboratory Information Management System) and **LIS** (Laboratory Information System) primarily lies in their focus, functionality, and the type of laboratories they serve. Although both systems are designed to manage data and streamline laboratory processes, they are used in different contexts and cater to different types of laboratories.

Table 2. Main differences between LIMS and LIS

Aspect	LIMS (Laboratory Information Management System)	LIS (Laboratory Information System)
Primary Focus	Sample management, workflow automation	Patient data management, diagnostic results
Purpose	Tracks samples, automates lab processes, ensures compliance in research or industrial settings	Manages patient information and links it to diagnostic test results in clinical settings
User Environment	Research labs, pharmaceutical labs, quality control labs, environmental labs	Clinical labs, hospitals, diagnostic centers
Data Managed	Sample-centric data (e.g., storage, processing, testing)	Patient-centric data (e.g., demographics, medical history, test results)
Integration	Interfaces with lab instruments and research/quality control systems	Integrates with EHRs, Hospital Information Systems (HIS), and billing systems
Compliance Standards	GLP (Good Laboratory Practice), GMP (Good Manufacturing Practice), ISO	HIPAA (data privacy), CLIA (clinical testing standards)
Workflow	Focus on managing and tracking sample workflow across labs	Manages clinical workflows, patient orders, and test results reporting
Reporting	Generates scientific/industrial reports, QA reports	Generates clinical reports linked to patient data for healthcare providers
Result Application	Research, quality assurance, regulatory reporting	Patient diagnosis, treatment, medical decision support

Regulatory Requirements	Research, industrial, environmental regulations (e.g., FDA, ISO, GLP)	Healthcare regulations (e.g., HIPAA, CLIA)
Data Focus	Workflow data, sample status, experiment tracking	Patient medical history, diagnostic results

3.6.Popular Laboratory Management Systems (LMS/LIMS)

- **LabWare LIMS**: A widely used LIMS for a variety of laboratory types, including clinical, research, and manufacturing labs.
- **Thermo Fisher SampleManager LIMS**: Provides robust sample tracking and data management for complex laboratory environments.
- **STARLIMS**: Offers solutions for clinical, research, and environmental labs, with features for compliance and data analysis.
- **LabVantage**: A customizable LIMS that supports a range of lab workflows, including biobanking, research, and diagnostics.

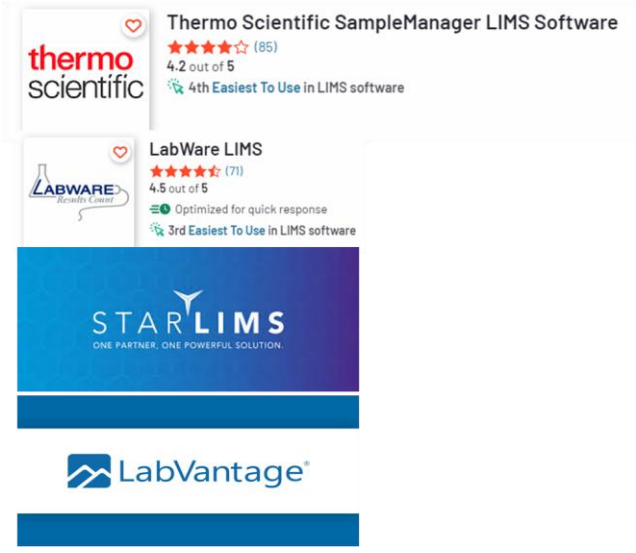

Figure 21.popular laboratory management systems.

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