INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Best Practices in Sample Management and Pre-analytical Quality Control

MYKE-MBATA, Blessing Kenechi (B.Sc, MBBS, Ph.D, FMCPath., IFCAP)

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Week 2

Telephone
+234 909 961 2133

Email Address
iipfsr@dufuhs.edu.ng

Website
www.iipfsr.com

YouTube Channel
https://www.youtube.com/@PathologyAndForensicInstitute

Zoom
https://us06web.zoom.us/j/81681874282?pwd=WOWrckA4JjKiLNbbZRCB1gRxl0m7Dh.1

Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Learning Objective

- This session aims to:
  - Highlight the essential protocols for sample collection, handling and transport.
  - Emphasize on the strategies for minimizing pre-analytical errors and maintaining sample integrity.
  - Highlight the role of digital tracking systems and automation for improved sample management.

Question 1

Automation of the pre-analytical phase of the laboratory involve

a. Random access analyzer

b. Discrete analyzer

c. Batch analyzer

d. Multiple function work station

Question 2

Which of the following is an important pre-analytical factor that is most likely to affect bilirubin result's accuracy?

a. Hemolysis

b. non-fasting

c. Exposure to sunlight

d. Age

Question 3

Which is the following is the best action when an inadequate sample volume is collected from a neonate with request for serum bilirubin?

a. Reject and discard the sample

b. Receive the sample, analyze but communicate the customer on inadequate volume

c. Discard but communicate the customer on inadequate volume

d. Reject but keep the sample and communicate the customer on inadequate volume.

Introduction

- Sample management in a laboratory" refers to the organized system of receiving, tracking, storing, processing, and retrieving samples within a laboratory, ensuring their integrity and proper identification throughout the testing process, including detailed documentation of all sample details and handling procedures.
- Essentially, it is the complete lifecycle of a sample from collection to analysis and disposal.
- Pre-analytical phase in laboratory testing encompasses all procedures before the actual analysis of a sample, including test selection, patient identification, specimen collection, handling, and transport, and is crucial for accurate results.
- Quality control (QC) in a laboratory setting is a system of procedures and protocols designed to ensure the production of precise, reliable and timely result.

Introduction – contd:

- Pre-analytical phase is complex and labour intensive and has many steps
- Potential for error increases as number of steps increase
- To ensure efficient sample management, the pre-analytical phase of the quality assurance of the laboratory should be managed efficiently.
- The human role in sample management makes complete elimination of errors associated with laboratory testing unrealistic.
- However, **Good Laboratory Practice (GLP)** routine reviews of processes and procedure and compliance with strategies for error prevention can lead to a substantial reduction in pre-analytical errors.
- Automation of sample management can greatly eliminate man-made errors in sample management.

What are The Key Aspects of Sample Management?

Sample reception

- Verifying sample details against documentation
- Checking sample integrity (volume, condition).
- Assigning unique identifiers (barcodes) for tracking

Sample processing

- Following standardized protocols for sample preparation
- Aliquoting samples as needed
- Performing necessary dilutions or manipulations

Sample storage

- Proper storage conditions based on sample type (refrigeration, freezing, etc.)
- Organized storage system for easy retrieval

Sample tracking

- Utilizing log,laboratory information management system (LIMS) to record sample details, status updates, and test results
- Maintaining chain of custody documentation

Sample disposal

- Following appropriate waste disposal procedures based on sample type and potential hazards

Why is effective sample management important?

Accuracy
- Proper sample handling ensures we have the right sample for the right test at the right time

Quality control
- Consistent procedures minimize errors and variability

Compliance
- Adherence to regulatory standards for sample handling

Efficiency
- Streamlined workflow reduces processing time and costs

What is pre-analytical quality control?

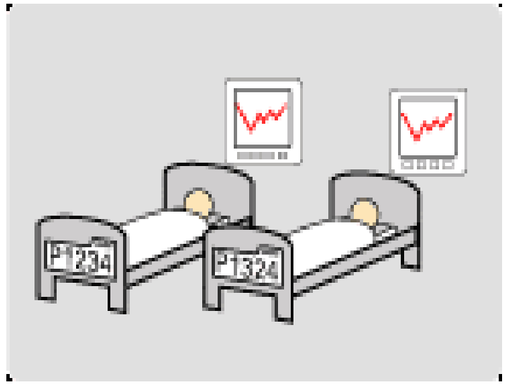
- Pre-analytical quality control involves procedures aimed at minimizing errors that can occur before sample analysis in a laboratory, covering everything from test request to sample preparation and storage.

- Errors during the pre-analytical phase are inevitable but can be prevented with a diligent application of quality control, continuing education and effective collection systems.

What is the impact of Pre-analytical Error?

Pre-analytical errors/ errors made in the period prior to the analysis of the sample ...

may influence the quality of the final measured results ...

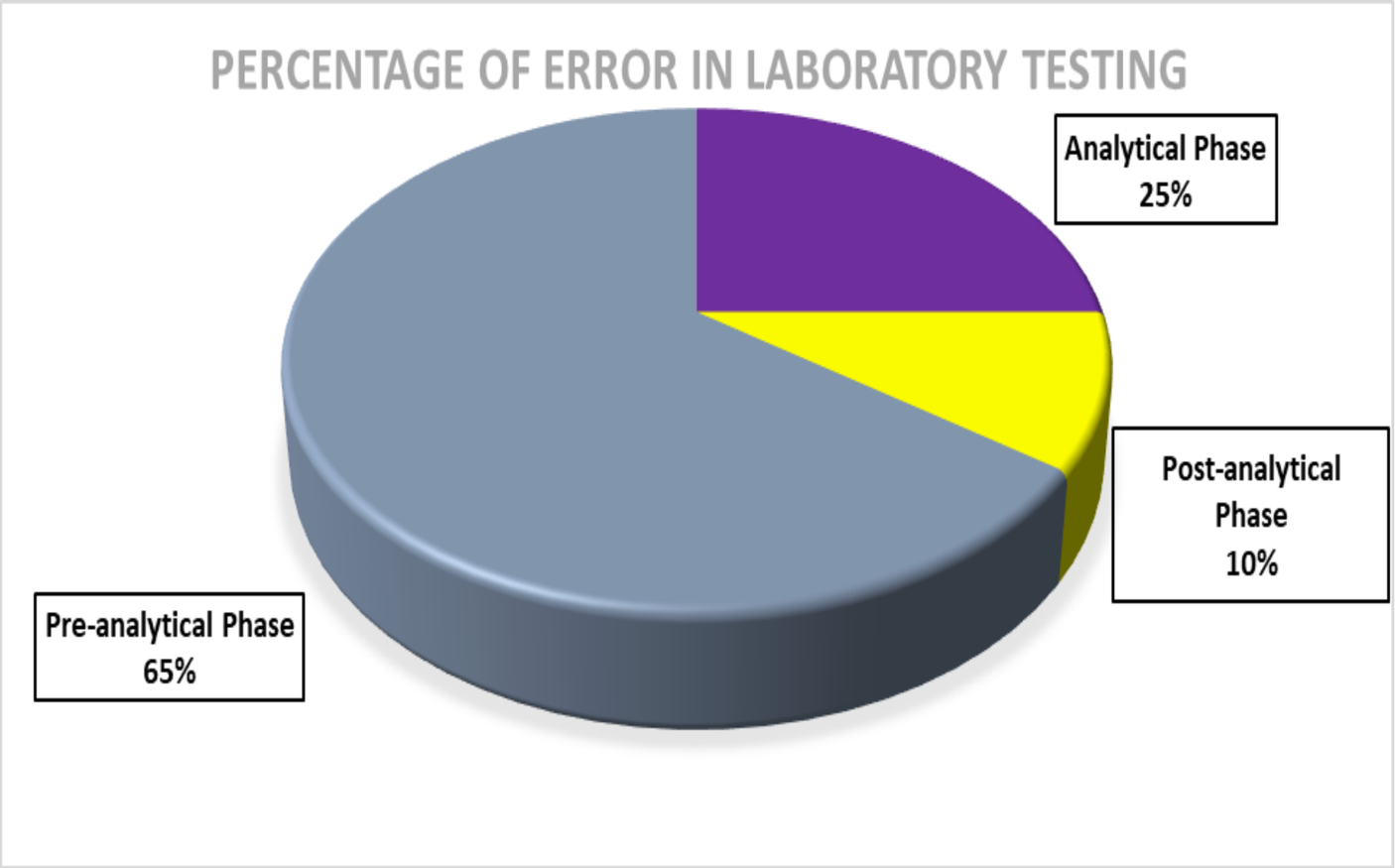


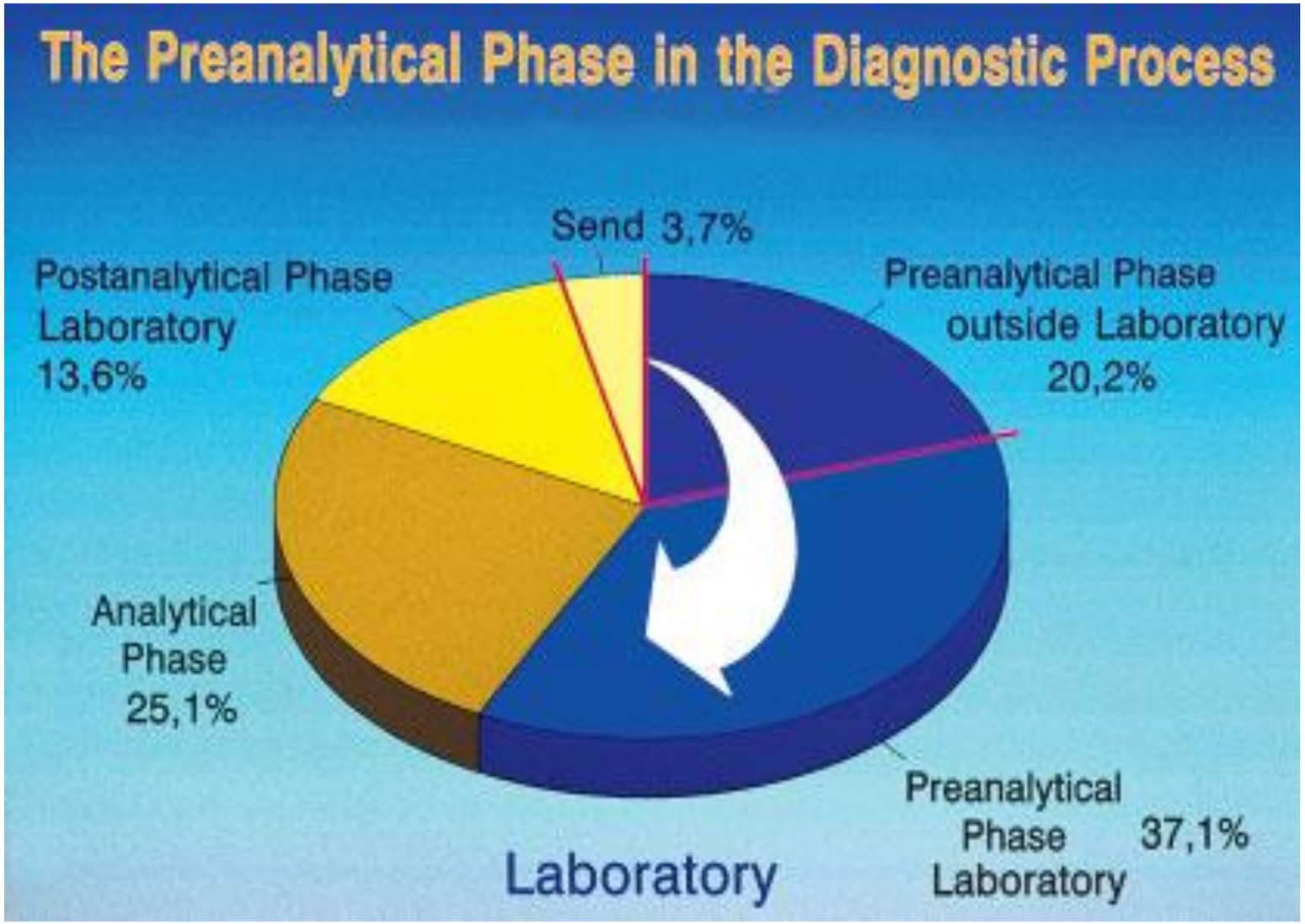
and compromise the diagnosis and treatment of the patient

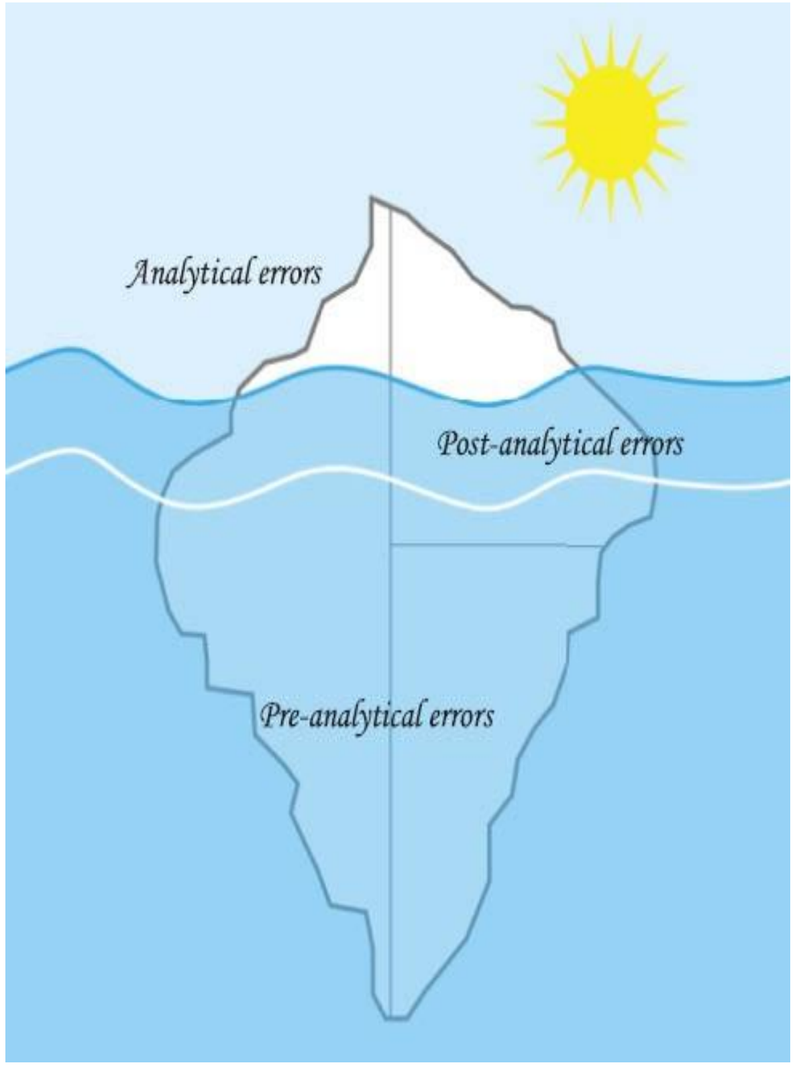
What are the effects of pre-analytical errors?

Minor Detected in laboratory	Major Error not detected
• Need to recollect	• Result accepted
• Need to recollect	• Patient wrongly treated
• Inconvenience for patient / doctor	• Detrimental to patient outcome
• Increases TAT	
• Wasted effort	
• Waste of Resources	

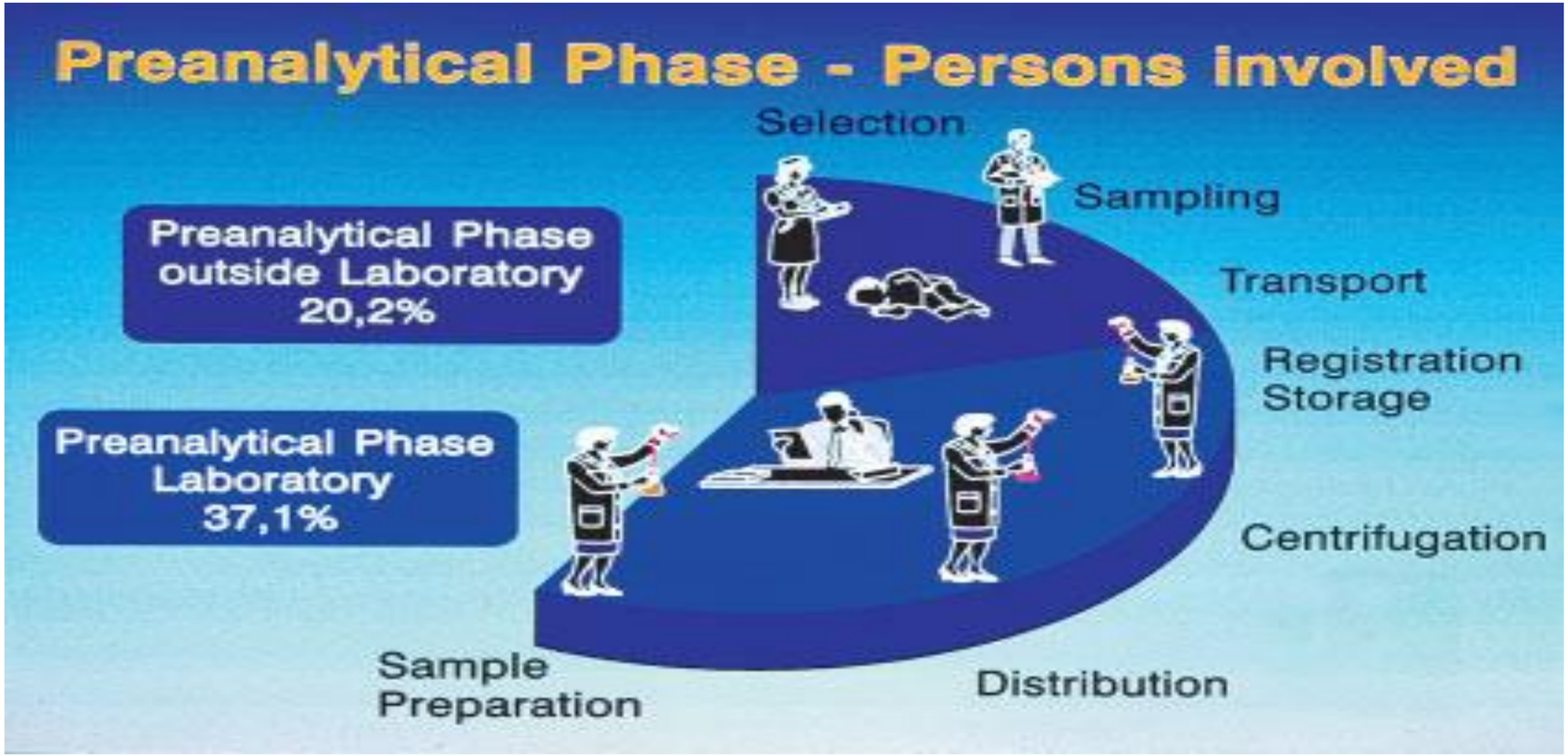
What is the percentage of pre-analytical errors in the laboratory?



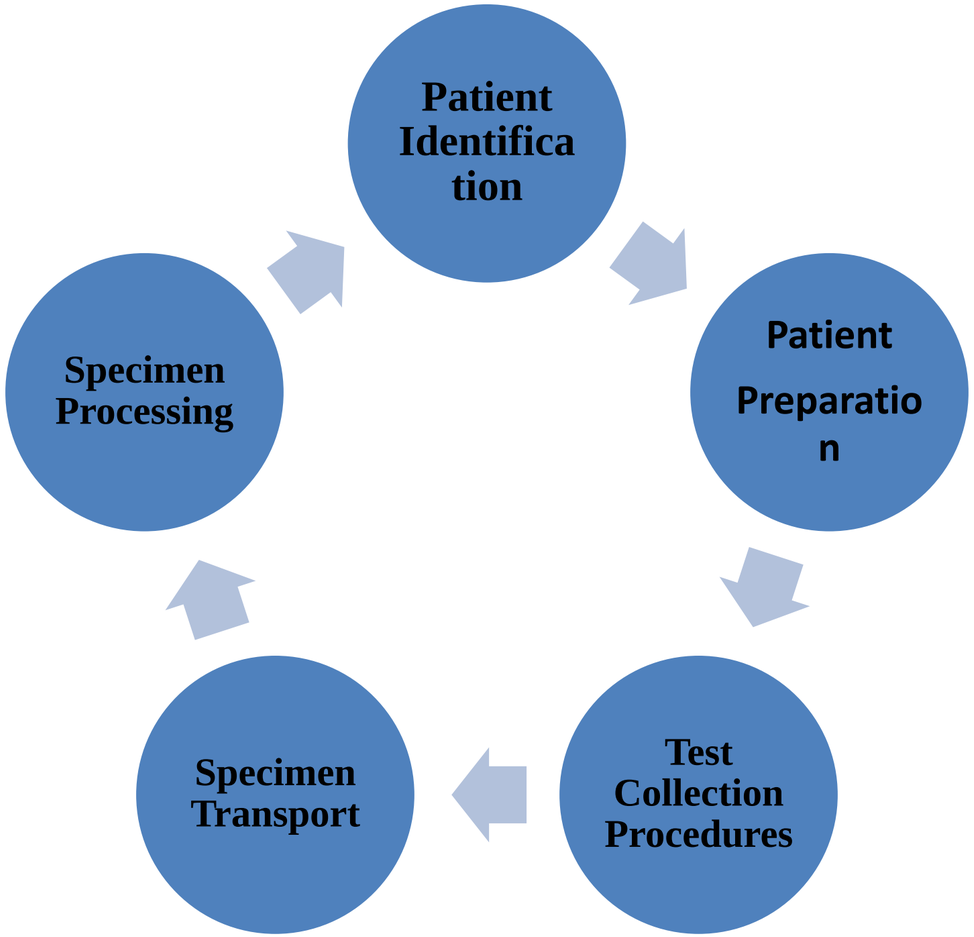

The Preanalytical Phase in the Diagnostic Process
Send 3,7%
Postanalytical Phase Laboratory 13,6%
Preanalytical Phase outside Laboratory 20,2%
Analytical Phase 25,1%
Preanalytical Phase Laboratory 37,1%
Laboratory


Analytical errors
Post-analytical errors
Pre-analytical errors

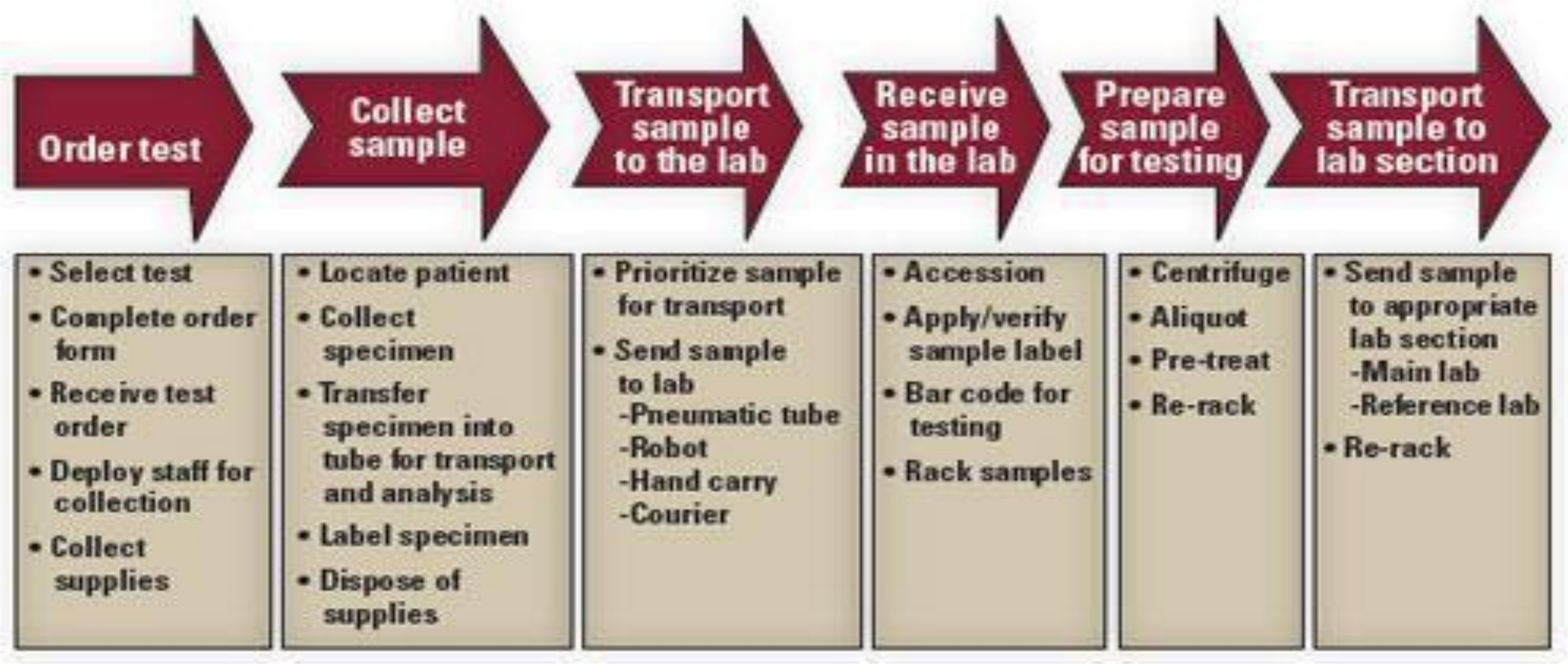
Which persons are involved in pre-analytical phase of quality control?



The Pre-analytical Phase of Quality Control



The Pre-Analytical Activities

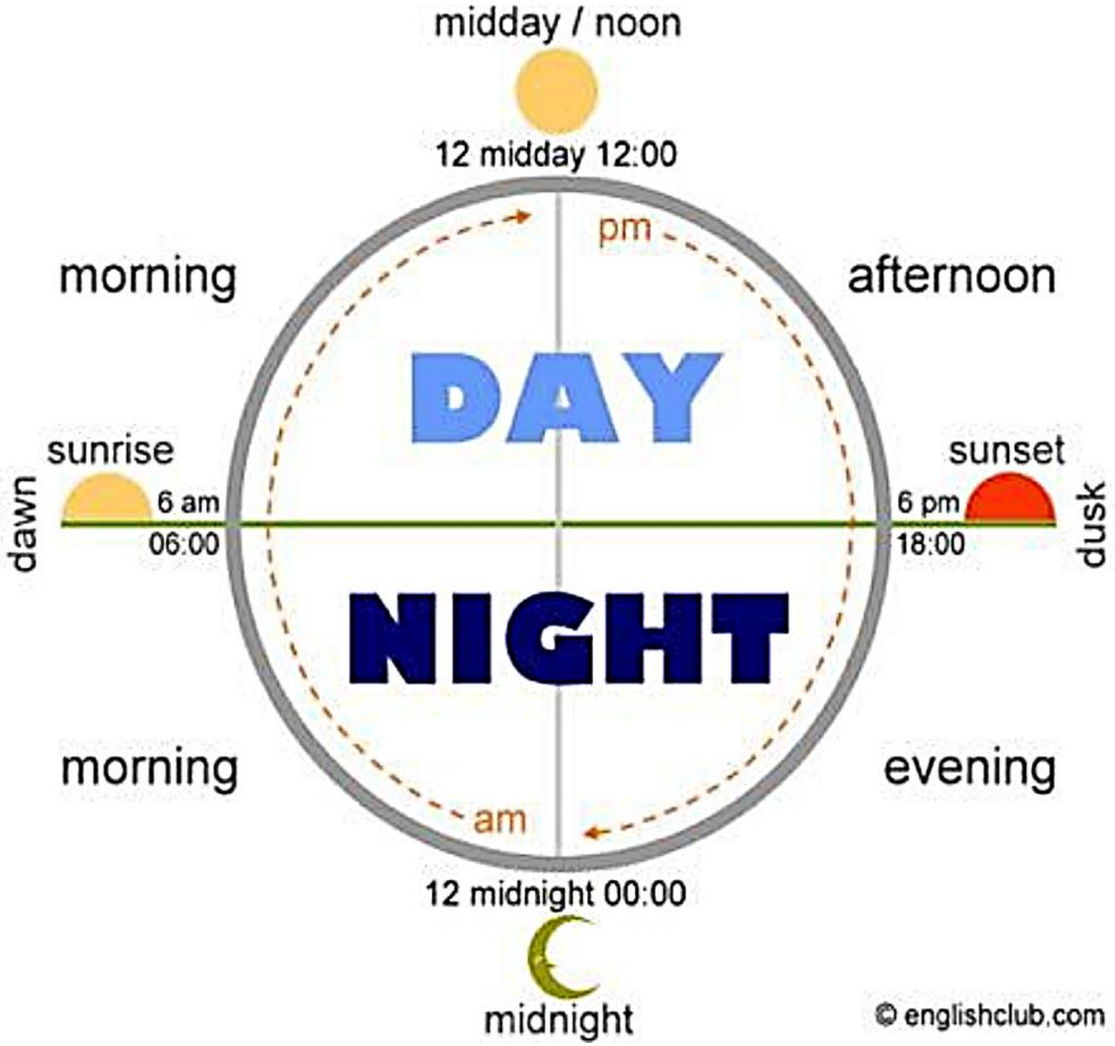


Test Requisition

- Prepare: clinician needs to choose correct test
- Form must be correctly filled in –all relevant information
- Clinician must order correct test on correct patient
- Writing must be legible
- Information must be correctly transcribed

Patient Preparation

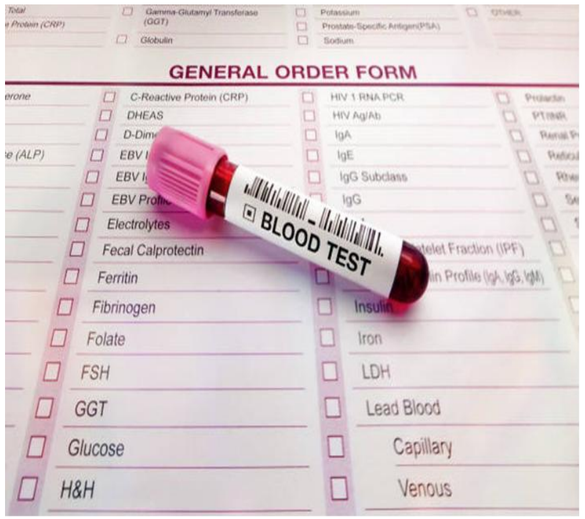
- Fasting: glucose, TG
- Special diet: OGTT, 5-HIAA
- Timing: cortisol, UAE,TSH, iron, 2hrs postprandial, Therapeutic drug monitoring
- Time in menstrual cycle: progesteronee.g therapeutic drug monitoring, 2hrs postprandial, , cortisol, iron and TSH.

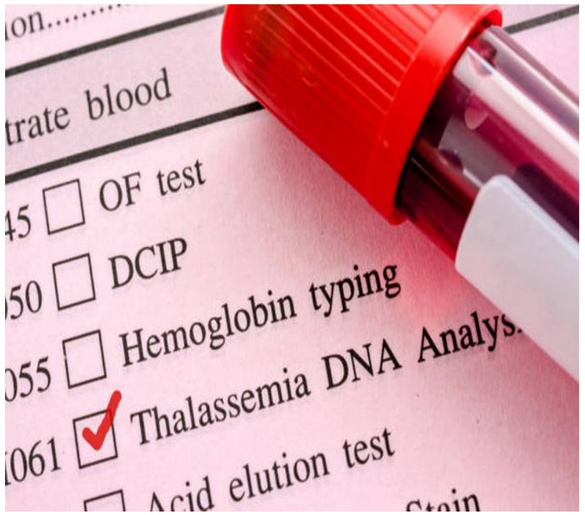


Patient Identification

- Confirm – minimum of 2 positive identifiers
  - Full name
  - Address
  - Identification number
  - Date of birth
  - Hospital No.

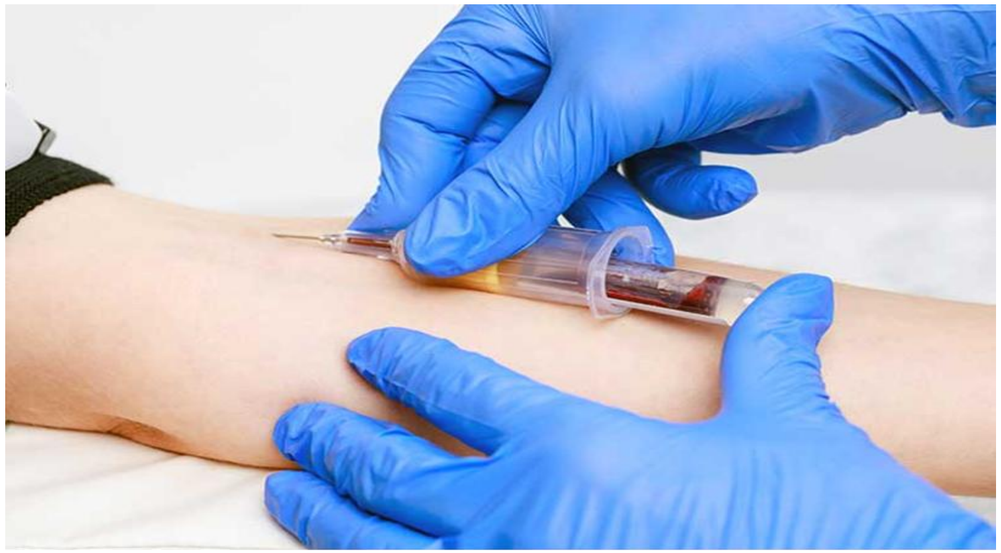
- Specimen and form must have same identification

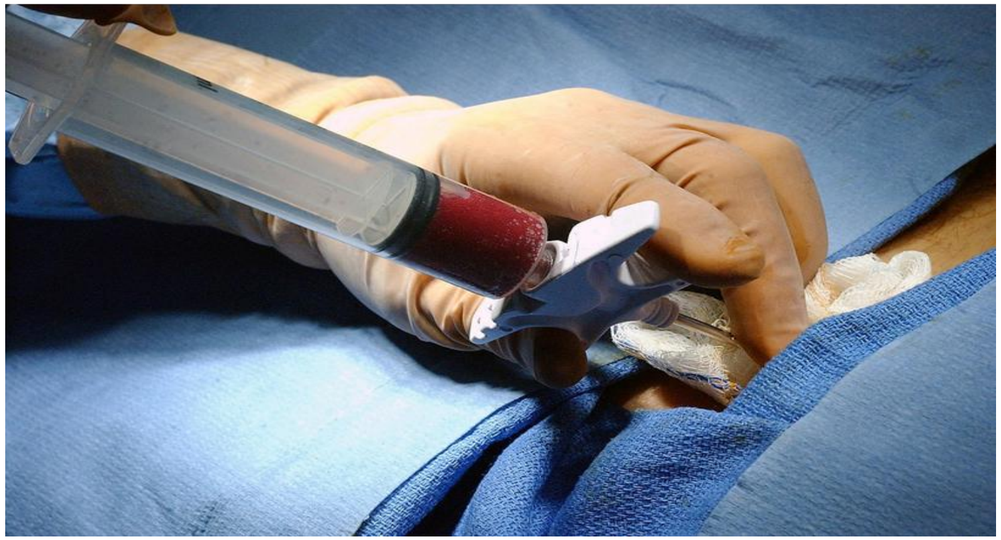




Sample Collection

- Posture
- collection site-Drip arm,mastectomy, thrombosed
- Correct collection system-right tube, right calibre of needle
- Tourniquet Application-Prolonged tourniquet
- Cleansing of venipuncture site
- *Test Collection-additive, haemolysis*
- Correct Specimen Volume
- Proper Tube Mixing
- Haemolysis –most common error



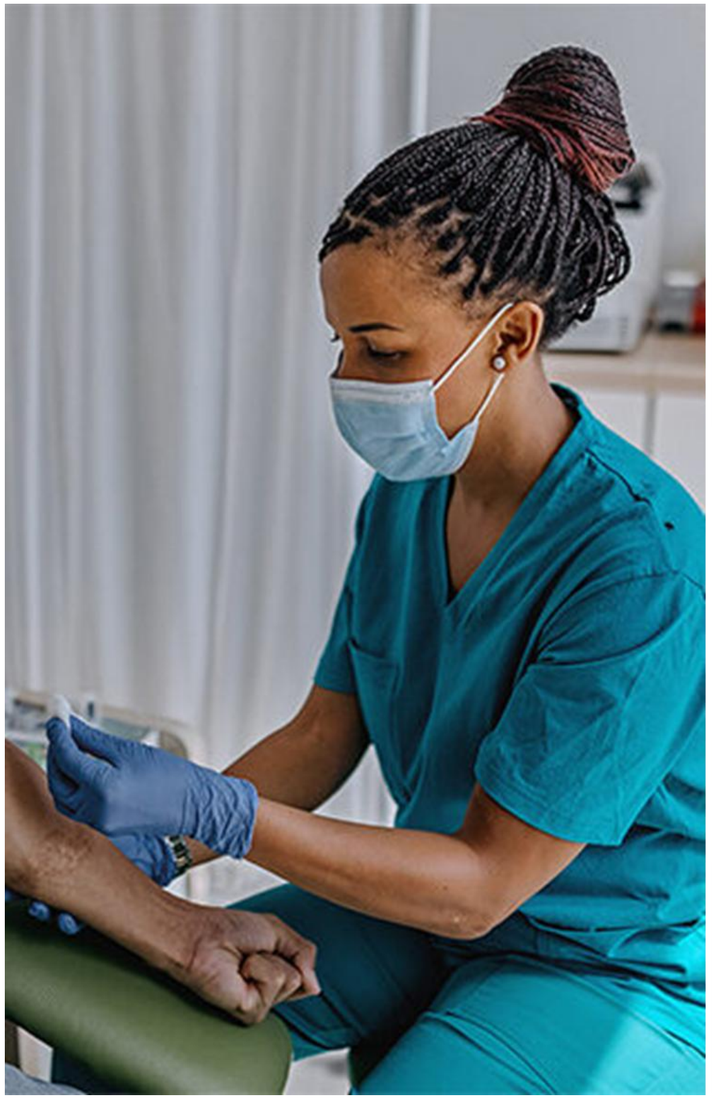


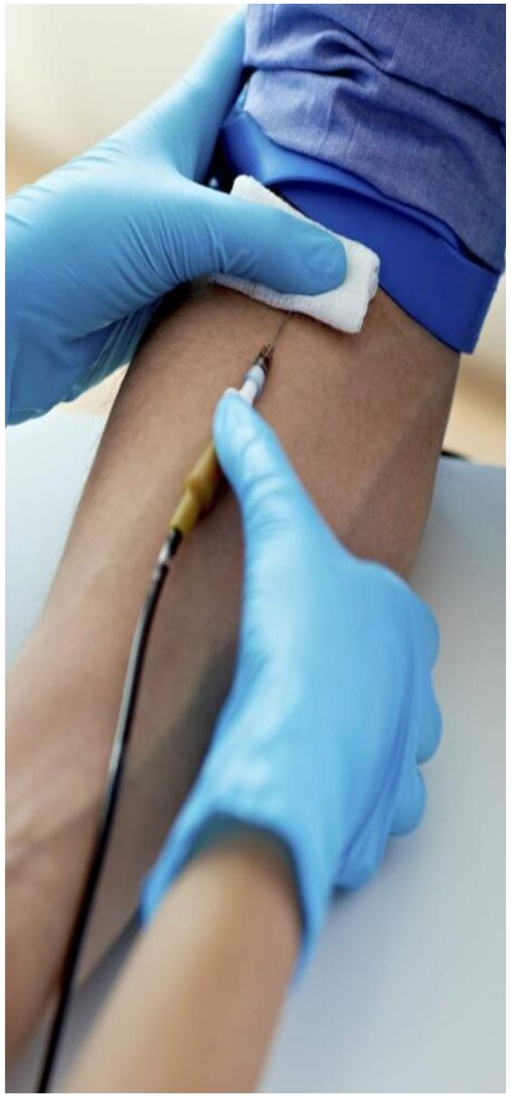
Blood Tube Guide

Order of Draw

	**Blood Cultures** **Aerobic followed by Anaerobic**	 Use winged needle collection sets Discard if coloured base is yellow or if tamper evident seals are missing
 (light blue)	Citrate	INR , APTR, Clotting screen, Coagulation studies
 (black)	Citrate	ESR
 (red)	Plain	Viral serology Antibiotic assays
 (cream)	SST Gel	All biochemistry
 (bright pink)	EDTA	FBC, X-Match, Group & Save, HbA1C
 (white)	Fluoride Oxylate	Fasting Glucose

- **Tourniquet time – 1 minute**
- **Avoid repeated fist-clenching**
- **Label all samples at bedside**
- **No pre-labelled tubes**
- **Use vacuum devices to obtain sample**





Handling of Containers Post-collection

- Invert –3 –10 times
  - If not, improper clotting or anticoagulation
  - Do not shake - haemolysis
- Protect from light if necessary
- Chill or warm
  - Avoid excessive heat or cold – haemolysis and deterioration of analytes
  - Never expose whole blood to dry ice - haemolysis

Transportation

- As efficiently as possible
- Transport Container-bilirubin
- Transport in leak-proof plastic bags in lockable rigid containers, avoid agitation
- Correct temperature - On ice: ABGs, Ammonia; Warmed - (37 C), cryoglobulins
- Delays - transported immediately after collection, for example Arterial Blood Gases
  - Before centrifugation
  - After centrifugation
  - At room temperature ▫In the fridge

Sample processing

- Registration
- Delivery To Departments
- Specimen separation:
  - Centrifuging
  - Aliquotting
- Specimens for serum or plasma chemistry testing should be centrifuged and separated within two hours
- Other samples:
  - Microbiology: swab, blood, etc MCS
  - Anatomic pathology – tissue processing

What are the causes of hemolysis?

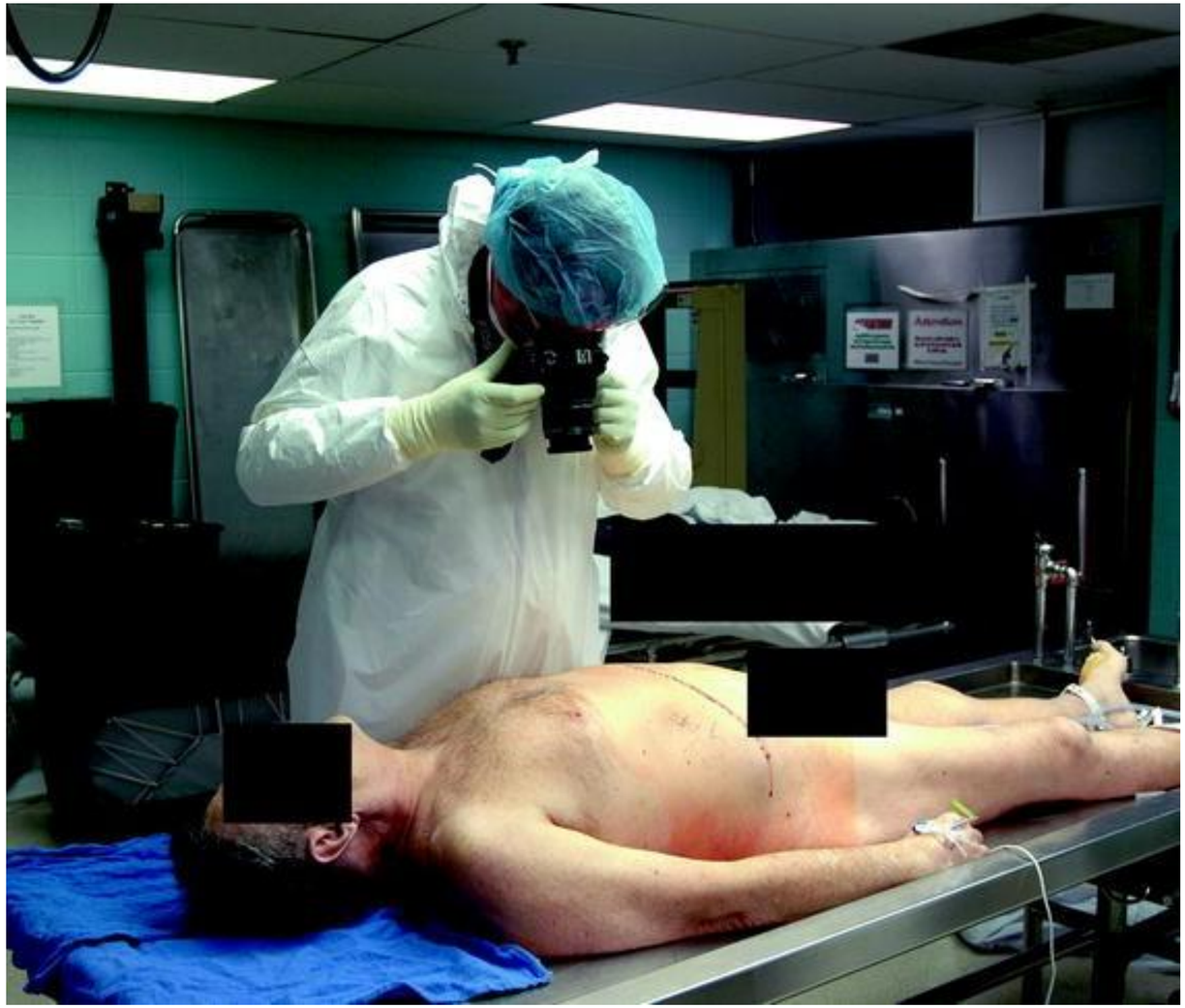
- Prolonged tourniquet
- Alcohol swab
- Small bore needle
- Tissue trauma
- Occlusion of needle lumen by vein wall
- Large bore needle and syringe causing increased pressure with plunger
- Shaking of tube
- Freezing red blood cells for transport
- Excessive heat during transport
- Prolonged contact of serum or plasma with cells

What are the Pre-analytical errors Anatomical Pathology?

- Misidentification of specimen, block or slide has been shown to be the most common error
- Patient identification
- Sample identification, e.g. left / right
- Specimen must be adequate and appropriate
- Sample processing / fixative choice
- Incorrect sectioning or staining
- Incorrect control tissue

Pre-analytical errors autopsies

- Not getting proper legal authorization
- Inability to get patient charts and relevant info from clinician
- Inability to obtain full history
- Decide which tissues / fluids to collect
- Wrong Identification of body for post-mortem



What are the Pre-analytical errors in heamatology?

- Wrong sample vacutainer selection e.g EDTA for coagulation test, EDTA for indirect comb test.
- Wrong sample separation e.g using low speed centrifugation for separation of sample meant for coagulation which will yield platelet rich plasma instead of platelet free plasma.
- Inappropriate anticoagulant to blood ratio e.g 1:9 ratio is for coagulation studies

Pre-analytical errors in microbiology?

- Errors from sample collection:
  - Inadequate sample volume
  - Incorrect labelling
  - Contamination
  - Inappropriate container

- Errors from sample handling and transportation:
  - Transport delays-microbial delay or degradation
  - Inappropriate storage
  - Exposure of sample to extreme temperature or light
  - Sample damage

What are the common pre-analytical error?

Preparation prior to sampling

- Missing or wrong patient/sample identification
- Use of the wrong type or amount of anticoagulant
- Inadequate removal of flush solution in a-lines prior to blood collection

Sampling /handling

- Mixture of venous and arterial blood during puncturing
- Air bubbles in the sample
- Insufficient mixing with heparin

Storage and transport

- Incorrect storage
- Hemolysis of blood cells

Preparation prior to transfer

- Visually inspect the sample for clots
- Inadequate mixing of sample before analysis
- Failure to identify the sample upon analysis

What are the Specimen rejection criteria?

- Clotted
- Hemolyzed
- Underfilled, overfilled
- Insufficient quantity
- Incorrect labeling
- Unlabeled specimen
- Incorrect patient
- Incorrect specimen
- Contaminated
- Lost sample
- Too old to process
- Broken and leaking

What are the Good laboratory practices for efficient sample management?

1. Avoid storing of whole blood.

2. Blood samples should reach the laboratory within 45 min of collection in order to ensure that centrifugation and separation of the sample is carried out within 1 hour .

3. Avoid glycolysis to keep glucose, lactate and pH stable. Glycolysis can be avoided by the addition of an inhibitor in conjunction with an anticoagulant.

4. Avoid the effect of light otherwise there will be a fall in the values of bilirubin, vitamin C, porphyrins, creatine kinase (CK) and folic acid.

5. Reduce contact with air as far as possible. If this is not done, evaporation/sublimation will result in an apparent increase in the concentration/activity of all non-volatile components. This is particularly the case when the volume of the sample is relatively small and the surface area is relatively large.

Good laboratory practices for efficient sample management – contd:

6. Whole blood should not be stored in the refrigerator.

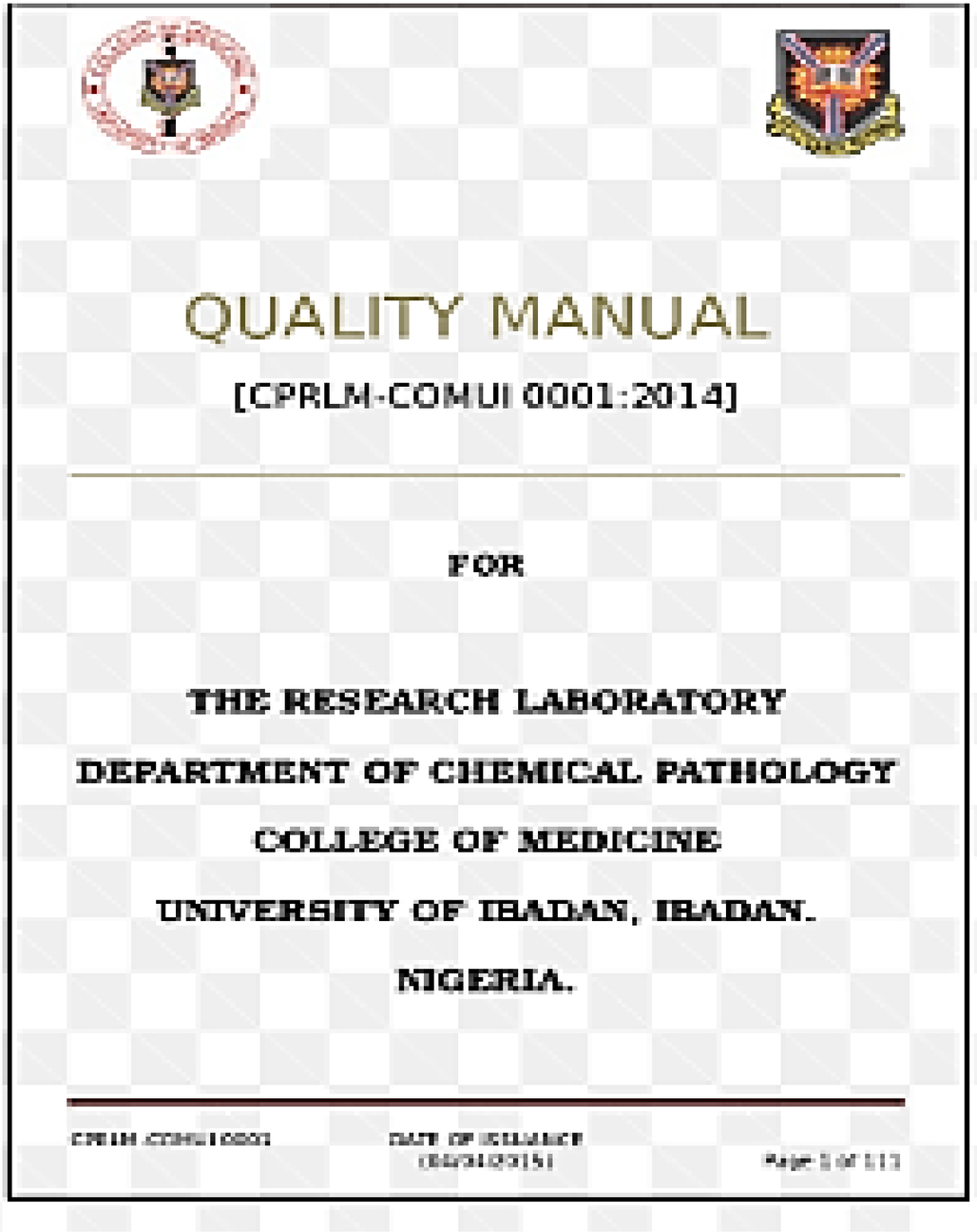
7. For certain analytes, the specimens/ samples should not be deep frozen.

8. Correct thawing: After thawing, the sample should therefore, be inverted several times, avoiding the formation of foam. Look for undissolved material and, if necessary, bring into solution by careful warming.

9. Store samples after analysis in such a way as to permit the confirming of results, checking the identity of samples or performing additional tests for medical or legal reasons.

Laboratory Quality Manual/Handbook

- A good laboratory handbook/manual must have written policies for sample management that have been created.
- Components to be addressed include:
  a. Information needed on requisitions or forms;
  b. Handling urgent requests;
  c. Collection, Packaging and labelling, preservation and transport;
  d. Safety practices (leaking detection)
  e. Evaluating, processing and tracking of samples;
  f. Storage, retention and disposal.



Clinical Case 1

- A blood sample was taken from a 38-year-old man on the accident and emergency and the results was as below:

Parameter	Result	Reference limit
Sodium	142 mmol/l	135-142
Potassium	10.5mmol/l	2.9-5.0
urea	4.2mmol/l	2.5-6.5
creatinine	77µmol/l	53-106
Corrected calcium	0.4mmol/l	2.25-2.65
phosphate	0.89mmol/l	0.60-1.40

Repeat:

Parameter	Result	Reference limit
Sodium	138mmol/l	135-142
Potassium	3.6mmol/l	2.9-5.0
urea	4.2mmol/l	2.5-6.5
creatinine	77µmol/l	53-106
Corrected calcium	2.40mmol/l	2.25-2.65
phosphate	0.90mmol/l	0.60-1.40

Clinical Case 2

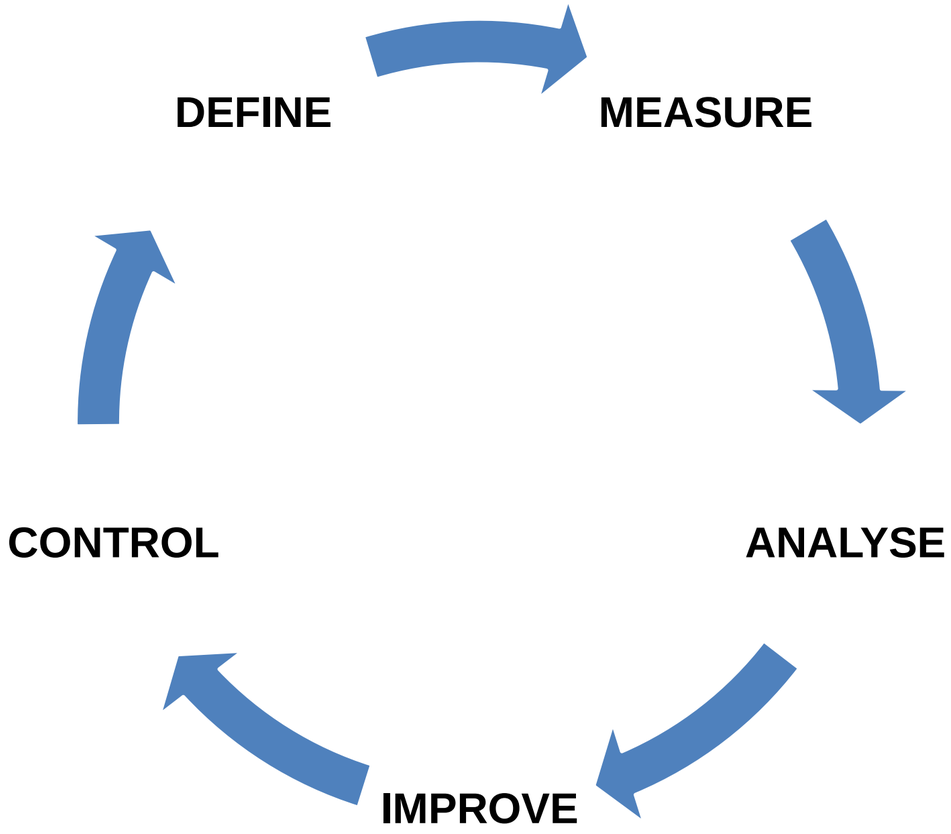
- A blood sample was taken in the morning from a 48-yearold woman in the primary health centre and sent to the tertiary health centre in the urban area but there was a delay and the sample was processed and analysed in the evening. Below are the result and repeat test.

Parameter	Result	Reference limit
Sodium	140 mmol/l	135-142
Potassium	6.2mmol/l	2.9-5.0
Urea	4.5mmol/l	2.5-6.5
creatinine	89µmol/l	53-106

Repeat

Parameter	Result	Reference limit
Sodium	145mmol/l	135-142
Potassium	4.0mmol/l	2.9-5.0
Urea	4.5mmol/l	2.5-6.5
creatinine	90µmol/l	53-106

How can sample management process be improved?



Why is automation necessary in sample management?

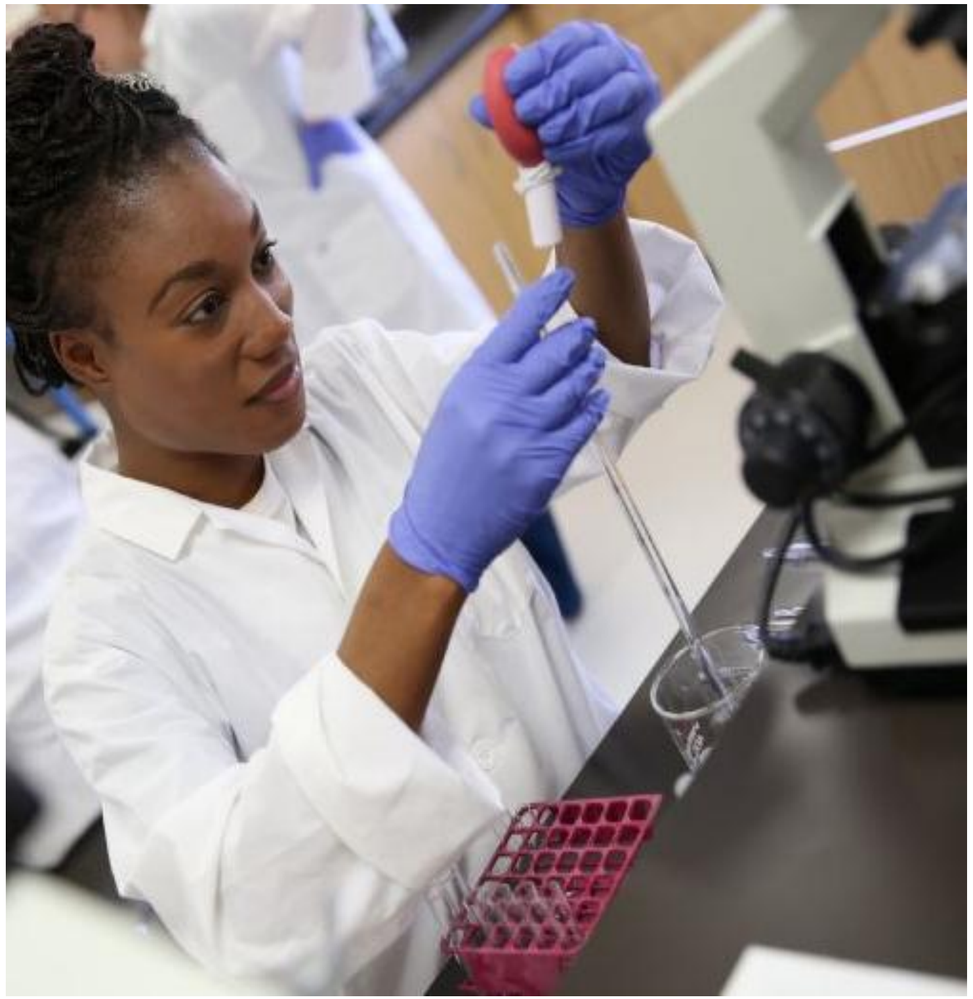
- It enhances laboratory efficiency and accuracy by streamlining processes like sample tracking, storage and preparation hence reducing human errors.
- It saves time
- Provide quick data access and audit trail
- Ensures efficient specimen tracking
- Improved turn around time
- Improves laboratory safety
- Improve productivity and reduces turn around time.

Automation of Pre-analytical Activities

- 1. **Specimen Identification: Barcoding system**
  - 1.Elimination of work lists for the system
  - 2. Avoidance of mistakes made in the placement of tubes in the analyzer or during sampling
  - 3. Avoidance of the need for analysis of specimens in a defined sequence
  - 4. Decrease in identification errors
  - Specimen Labeling/accessioning
- 2. **Specimen Preparation**
  - Use of whole blood for analysis
- 3. **Specimen delivery**
  - 1.Pneumatic tube system
  - 2.Mobile robots
  - 3.Motor tracks
- 4**. Sample preparation**
  - 1.Single function workstation-automated centrifuges, decappers, recappers, aliquotters, and sorters.
  - 2. Multiple function workstation

Conclusion

- Pre-analytical errors contribute significantly to the total laboratory errors.
- Many of these errors are from non-laboratorian which makes it difficult to control
- Therefore, continuous review and monitoring of this phase of sample processing would lead to detection of these errors and appropriate remedial and preventive measures
- On the otherhand,automation of pre-analytical phase of laboratory has enabled the elimination of man-made errors significantly and to a great extent enhance the production of accurate, reliable and timely result;
- While aspiring for full automation of sample management it is beneficial to adopt good laboratory practices to enhance the quality of our results.



Thank You

NEXT WEEK:

Strategies for quantitative and qualitative quality control:

- Internal QC techniques, including Westgard rules and Sigma metrics.
- Updates on External Quality Assessment(EQA) and Proficiency Testing.
- AI-driven quality control and automation in modern laboratory workflows

Inquiries

kcbless2001@gmail.com

Telephone

+234 909 961 2133

Website

iipfsr@dufuhs.edu.ng