Closing the Gap in Pre-analytical Specimen Quality

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Learning objectives

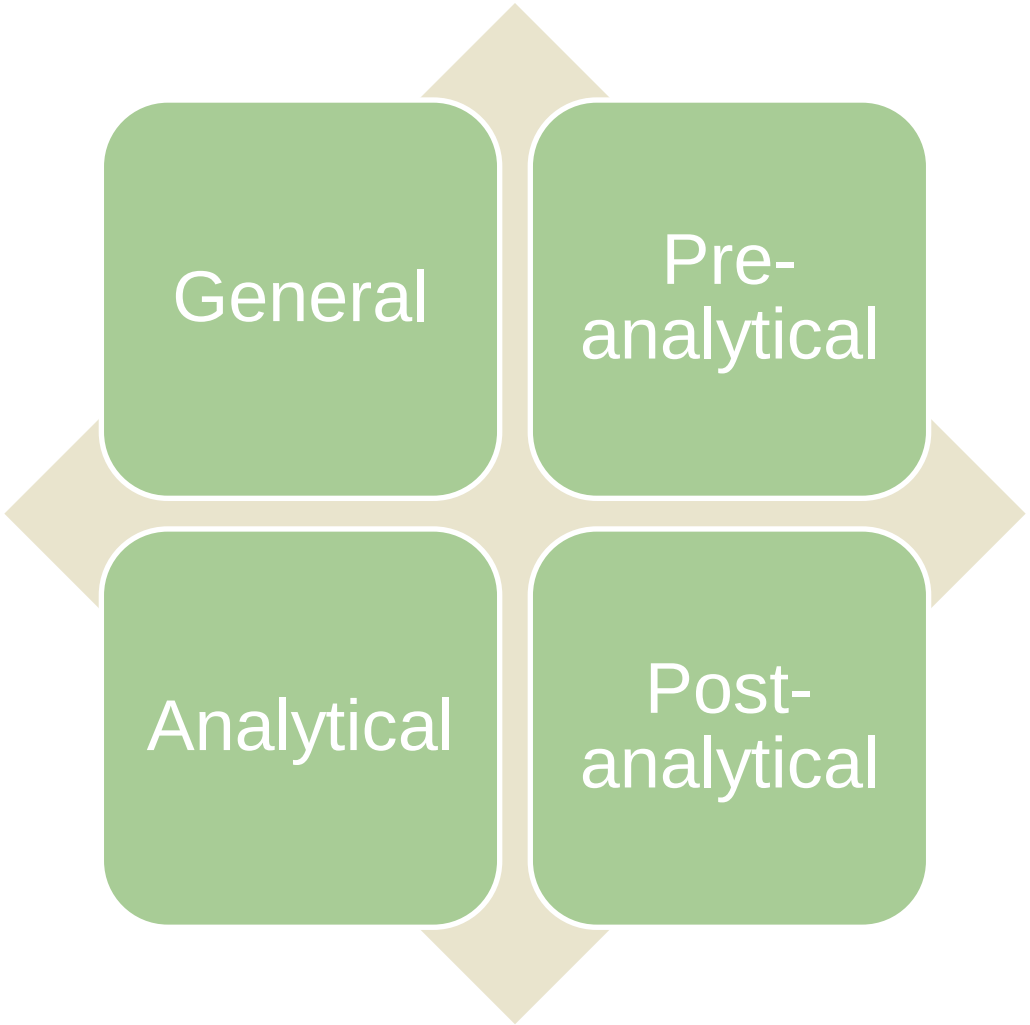
Explain the importance of proper collection, transport, and storage of specimens

Identify collection, transport and storage concerns in their own laboratory

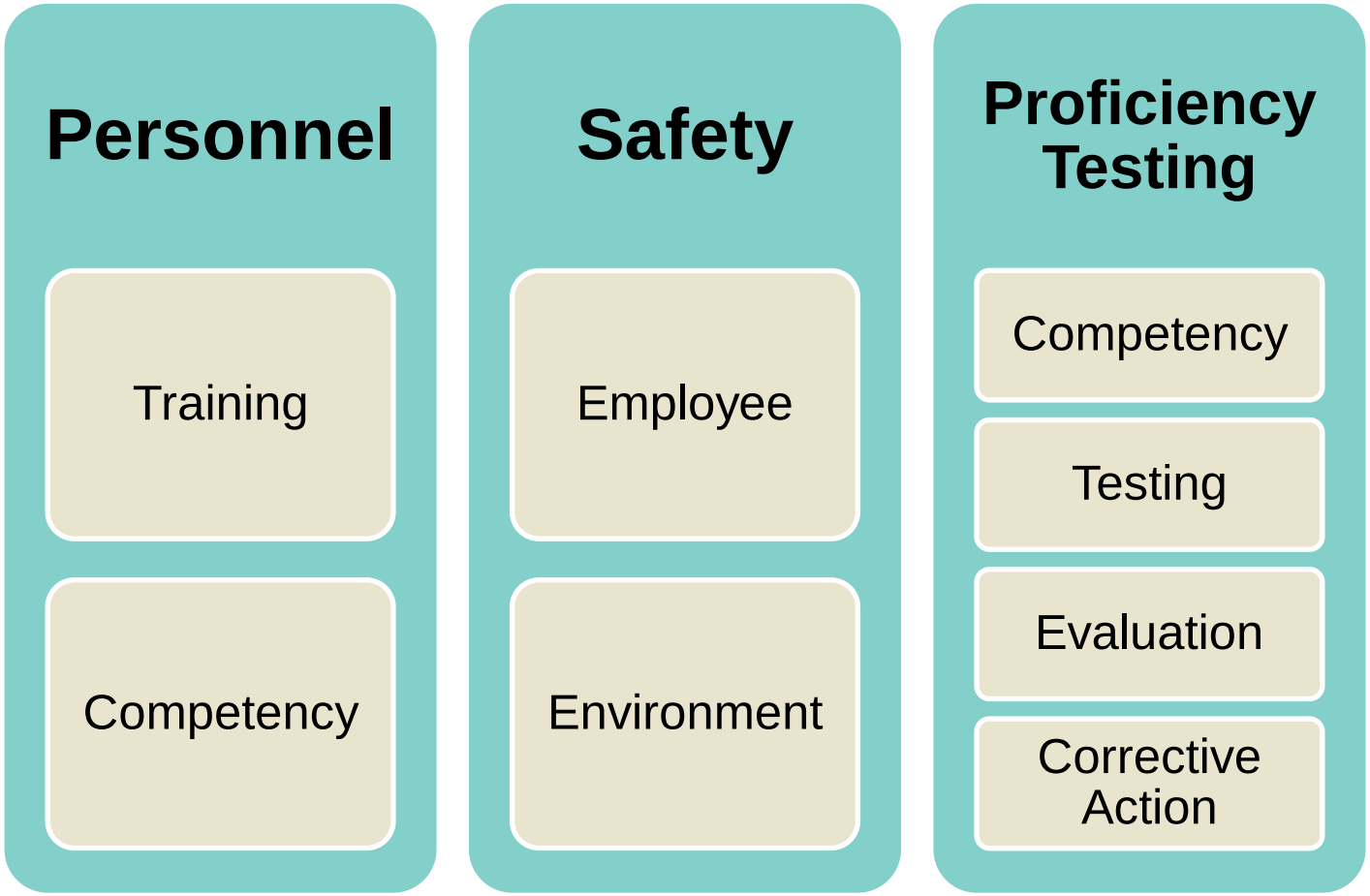
Outline improvements needed to improve pre-analytical quality in their own laboratory

Assess and evaluate the impact of these improvements

Laboratory Quality



General



Pre-analytical

1. Specimen Processing
2. Data Entry
3. Test Ordering
4. Specimen Collection
5. Transport

Analytical

Calibration

- Set points over reportable range

Quality Control

- Daily checks for accuracy

Patient Testing

- Performance within reportable range, within reference range

Result Review

- Consistent with previous results, no trends or shifts

Interpretation

- Is repeat or reflexive testing required?

Post-analytical

Result Reporting

- Results delivered to ordering physician, STAT or Priority results called

Result Archiving

- Analyzer reports saved 2 years. Computer results backed up

Specimen Management

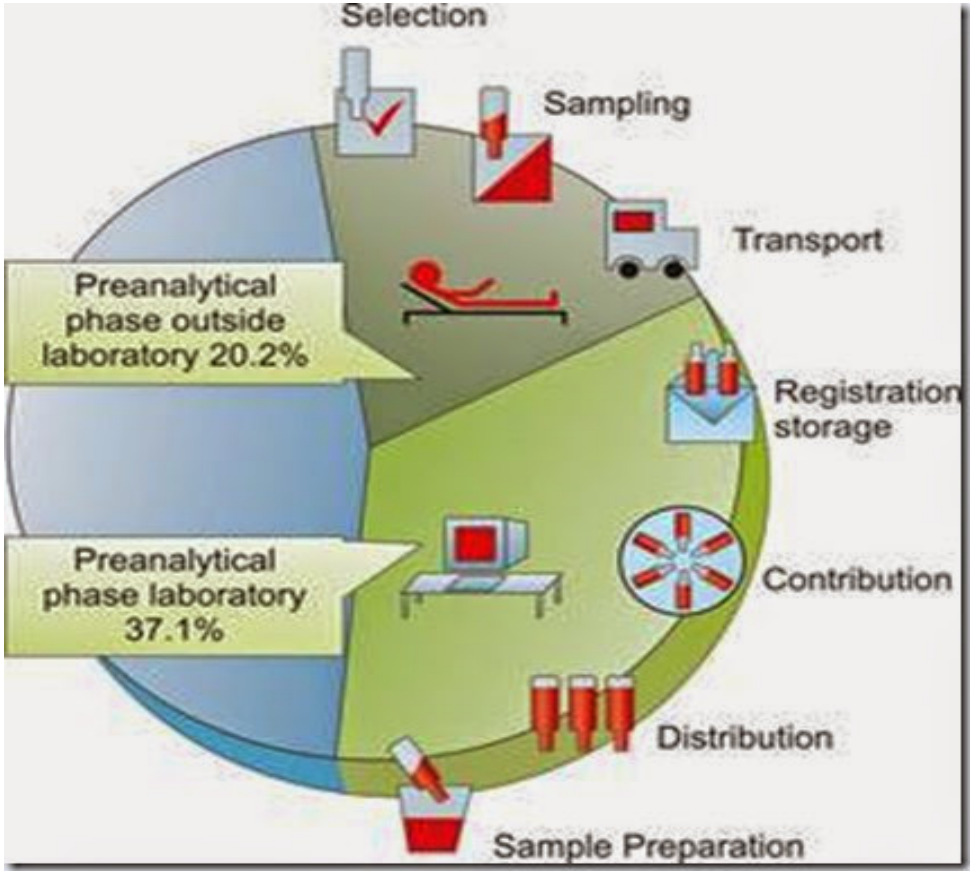
- Samples retained in refrigerator for set period. Reflex testing performed or sent out

How are we doing so far?

Pre-analytical Variables
Why do they matter?

- 70% of testing errors are in the pre-analytical phase
- Quality control does not cover these errors
- Often outside of laboratory control
- Compromised sample
  - Accurately reflect the status of the sample
  - Not necessarily the status of the patient

Where Do Errors Occur?

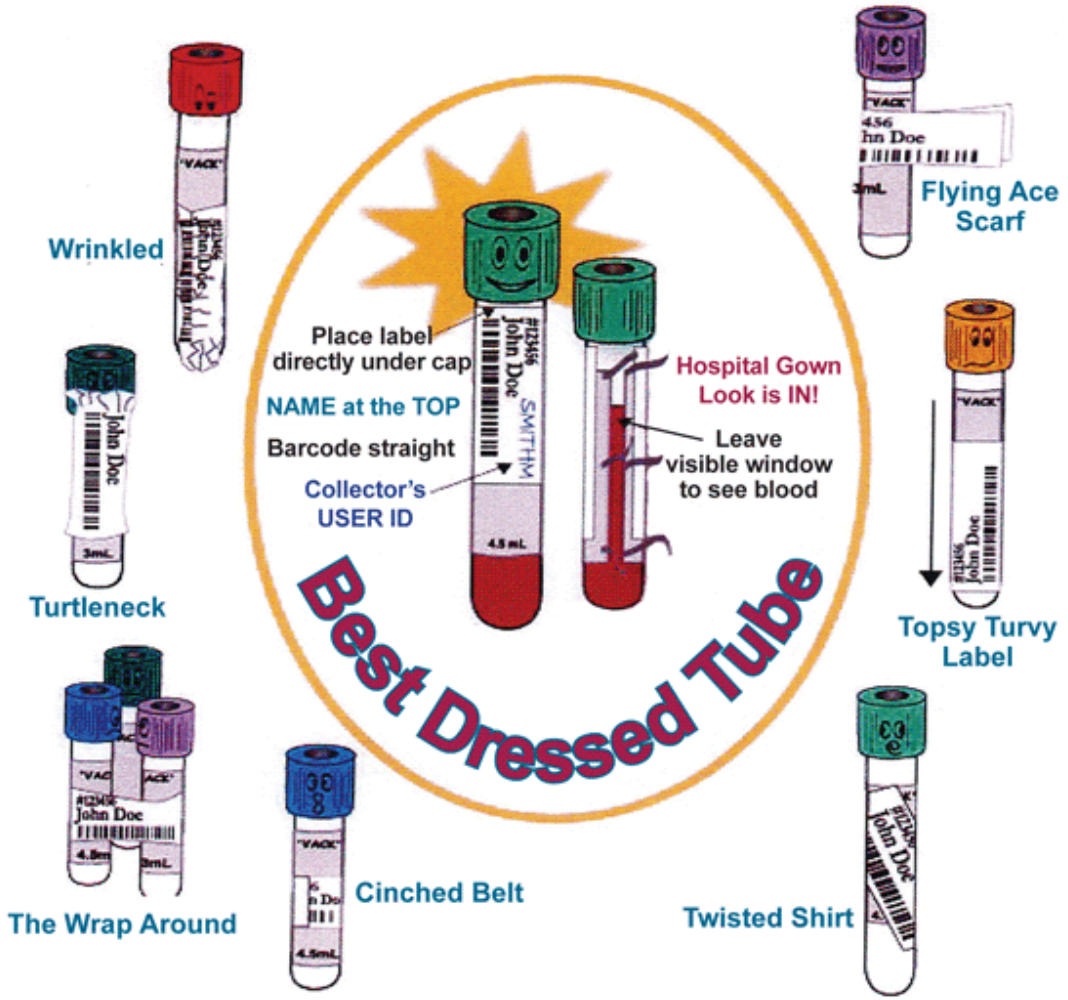


Ref: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed

Common Variables

- Collection – Wrong tube or swab, improper volume, poor technique
- Transport and storage – Centrifugation, shipping temperature, shipping container, light interference
- Processing – Timely, misread test request
- Patient variables – Fasting, before or after medication

Proper Labeling



Ref: Laboratory Alliance of Central New York, LLC
1304 Buckley Road | Syracuse, NY 13212-4302

Monitoring Pre-analytic Systems

- Test requests consistently contained the required information
- Patient specimens were collected and handled according to our protocol and were acceptable for testing
- No specimen mix-ups occurred

Monitoring Pre-analytic Systems

- Review specimens rejected by the lab
- Specimen labels were legible and firmly affixed to every blood specimen tested
- Written laboratory policies allow for the positive identification and optimum integrity of a specimen from the time of collection through the testing process

Specimen Quality

Jaundice

Lipemia

Hemolysis

Ref: 2017 Nova Scotia Health Authority

Quality Assurance Measures

Test Tracking (Requisitions)

- Evaluate data entry
- Specimen collection

Specimen Management

- Test orders
- Specimen collection
- Transport
- Processing

Test Tracking (Requisitions)

Purpose:

- To assess patient requisitions for pertinent information (Sex, DOB, Dx, date, time of collection, tubes submitted, etc.)

- To verify name and address of ordering provider are included

Test Tracking (Requisitions)

Method:

- Review randomly selected requisitions
- Verify all required information is provided

Specimen Management

Purpose:

- To assess the specimen collection and handling procedures for producing the highest quality specimens
- To verify the phlebotomists knowledge of obtaining quality specimens
- To ensure the specimen integrity is maintained all through the process
- To verify specimens are collected, handled, stored and preserved appropriately

Specimen Management

Method:

- Verify test requisitions
- Match barcode labels to name on the tubes
- Review the accession log
- Observe phlebotomy procedures
- Review specimen rejection log

Corrective Action Plan

Review Collection Procedures

Are they accurate and up to date?

Do all clients have these procedures?

Do they understand them?

Review Processing Procedures

Centrifuge speed

Timing of spin

Plasma/Serum separation and storage

Client Education

Distribute procedures

Train clients and phlebotomists as indicated

Impact of Improvements

- Repeat QA measures
- Calculate improvement
- Repeat education and training as needed

Have we met the objectives?

At the end of the session, participants will be able to:

- Explain the importance of proper collection, transport, and storage of specimens
- Identify collection, transport and storage concerns in their own laboratory
- Outline improvements needed to improve pre-analytical quality in their own laboratory
- Assess and evaluate the impact of these improvements

Questions?

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The information in this presentation is provided for educational purposes only and is not legal advice. It is intended to highlight laws you are likely to encounter, but is not a comprehensive review. If you have questions or concerns about a particular instance or whether a law applies, you should consider contacting your attorney.

Resources from today's presentation

- For questions regarding CLIA regulations on blind samples for waived testing, please go to: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

- For questions regarding competency assessment, please go to: https://wwwn.cdc.gov/clia/resources/waivedtests/pdf/readysettestbooklet.pdf

- An excellent resource for studies covering how to determine threshold/acceptable limit for number of repeat testing is: http://www.archivesofpathology.org/doi/full/10.5858/arpa.2013-0140-CP?code=coap-site

- Per the presentation, here is where you can find a copy of the proper labeling picture: http://www.laboratoryalliance.com/healthcare-providers/laboratory-services/specimen-collection-documents/laboratory-collection/

- If BD tubes are being used in your laboratory, this Q&A addresses limits of acceptable volume: http://www.bd.com/en-us/offerings/capabilities/specimen-collection/blood-collection/venous-collection/bd-vacutainer-blood-collection-tubes/vacutainer-blood-collection-tube-faq

Thank you

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