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
- Analytical
- Post-analytical
General

Personnel
- Training
- Competency

Safety
- Employee
- Environment

Proficiency Testing
- Competency
- Testing
- Evaluation
- Corrective Action
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

Ref: 2017 Nova Scotia Health Authority
## Quality Assurance Measures

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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/readysersettestbooklet.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