

Preanalytical Variables and the Impact on Quality Test Results

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Learning Outcomes

- Differentiate the phases of testing: preanalytical, analytical, postanalytical.
- List and describe preanalytical factors that impact laboratory testing.
- List errors that occur prior to specimen collection.
- Relate preanalytical errors to patient safety.
- Discuss specimen tube filling requirements.
- Describe preanalytical errors related to specimen transport, separation and storage.
- Outline steps for prevention of each preanalytical error.

Introduction

- Laboratory Science is a Complex Specialty
- Each Laboratory is Composed of Multiple Departments
- Each Department has Numerous Tests
- Each Test has Specific Specimen Requirements
- Phlebotomists Bear the Burden of Specimen Collection

Why Worry About Preanalytical Errors?

Let's Look At Some Facts and Statistics

Perceptions

"From both the clinical and laboratory sides there is a widespread perception that errors prevailingly occur in the analytical phase mostly due to instrument malfunctions...the great majority of laboratory flaws occur...in the extra analytical phases of the total testing process."

(Lippi, Giuseppe and Guide, Gian, "Risk Management in the Preanalytic Phase of Laboratory Testing.")

Facts

- The preanalytical phase of the testing process is complex and labor intensive
- The more steps involved in a process, the more likely there will be errors committed.
- "Between 32 and 75% of all test errors occur in the preanalytical phase."

(Stankovic, Ana K. et al. "Quality Improvements in the Preanalytical Phase: Focus on Urine Specimen Workflow." Clinics in Laboratory Medicine, Vol 28, 2008, pp 339-350.)

Causes

- "Most errors within the preanalytic phase result from system flaws and insufficient audit of the operators involved in specimen collection and handling responsibilities."
- "...most of them result from poor system design whereby the designers simply expect too much of the users."

(Lippi, Giuseppe and Guidi, Gian. "Risk Management in the Preanalytic Phase of Laboratory Testing."

More Causes

- "The great majority of these errors, however, occur for individual or system design defects in extra analytical phases of the total testing process, especially in the preanalytical phase..."

(Lippi, Giuseppe. "Causes, consequences, detection and prevention of identification errors in laboratory diagnostics." *Clinical Chemistry and Laboratory Medicine*. Vol. 47, Issue 2, 2009, pp. 143-153.)

Knowledge

- Errors fall into two broad categories: Cognitive and Noncognitive
- Cognitive errors are those of that occur due to factors that fall in the range of the medical personnel's awareness. (Things we know)
- Noncognitive errors occur due to factors that do not fall into the knowledge base of the employee. (Things we do not know)

Noncognitive Factors are
Difficult to Control Due to the
Fact that the Employee is not
Aware that the Factors Exist.

This Webinar Attempts to
Strengthen the Cognitive
Factors and Eliminate Some of
the Noncognitive Factors
Associated The Preanalytical
Phase of Laboratory Testing.

Application of Industry's
Process Approach to
Laboratory Science

Process Approach

- Industry views each production as a process that produces an endpoint
- This “process approach” may be applied to healthcare.
- Specific application can be related to laboratory testing

Process Approach

General Principle

INPUT ⇒ PROCESS ⇒ OUTPUT

Process Approach

Application to the Clinical Laboratory

- Laboratory procedures are a series of processes.
- Each step in a process builds on the previous step and is required for the next step.
- A “chink in the armor” at any step will impact on all future steps

Laboratory Application to the Process Approach

PREANALYTIC ⇒ ANALYTIC ⇒ POSTANALYTIC

Patient Variables Performance of Tests Test Reporting Variables
Specimen Variables

- Collection
 - Handling
 - Processing
- ↳ Recording
 - ↳ Reporting
 - ↳ Interpreting

Additional Terminology

- ISO - International Organization for Standardization

PREANALYTIC ⇒ ANALYTIC ⇒ POSTANALYTIC

PREEXAMINATION ⇒ EXAMINATION ⇒ POSTEXAMINATION

Impact of Preanalytic Phase on Laboratory Test Outcomes

- Preanalytic Steps are Labor Intensive
- Steps in Specimen Collection are Many and Varied
- Potential for Error Expands as the Number of Steps Increase
- Studies State that "32 to 75%" of Inaccurate Test Results Originate from the Preanalytic Phase

Expanded View of the Preanalytical Phase

- Order Test
 - Collect Sample
 - Transport Sample to Lab
 - Receive Sample in Lab
 - Prepare Sample for Testing
 - Transport Sample to Lab Section

(Adapted from: Stankovic, Ana K, et al. "Quality Improvements in the Preanalytical Phase: Focus on Urine Specimen Workflow." *Clinics in Laboratory Medicine*. Vol 28. 2008. pp 339-350.)

Preanalytic Steps Prior to Phlebotomist or Laboratory Involvement

Ordering Steps

- Test Dictionary is Complete and Correct
- Practitioner Orders Test on Correct Patient
- Practitioner Orders Appropriate Test
- Written Orders are Legible
- Written Orders are Correctly Transcribed

Patient Preparation

- Fasting
- Postprandial
- Before or After Medication Dosage
- Upon Rising or after being awake for a specific period of time
- At specific time in a hormonal cycle

Equipment Factors

- Storage : Follow Manufacturer's Instructions
 - Never Use Beyond Expiration Date
 - Deterioration of Additives
 - Loss of Vacuum
 - Temperature and Environmental Conditions
 - Excessive Heat will Cause Loss of Vacuum
- Altitude
 - High altitude: Causes Loss of Vacuum

Factors Under Control of Phlebotomists

Patient Identification

- Positive Identification Required
 - Minimum 2 Positive Identifiers
- Attached Wrist Band
- Bar Coded Scanning Device
 - Print Labels at Bed Side
- Radiofrequency Identification (RFID)
 - Chip Follows Sample from Order through Analysis

Specimen Collection

- Each Step is a Process
- Every Output is Vital to the Next "Process"
- Each Process in the Collection Series May Produce A Preanalytical Impact
- The Final Factor Impacted is the Test Result

Review of Specimen Collection Steps Required for a Quality Sample

Correct Phlebotomy Technique

- Site Selection
 - Choice of Collection Area
 - Least Physical Hazard to the Patient
 - Optimal for Collection of Sample
 - Minimal Amount of Previous Trauma
 - Below Any Indwelling IV Lines

Correct Phlebotomy Technique

- Tourniquet Application
 - Minimal Time
 - No > 1 Minute
 - Decreases Possibility of Hemolysis
 - Distal to Collection Site
 - Avoiding Previous Trauma or Bruising

Correct Phlebotomy Technique

- Skin Preparation
 - Correct Technique
 - Concentric Circles
 - Covering Entire Area
 - Allow for Complete Drying of Alcohol

Correct Phlebotomy Technique

- Selection of Correct Needle Size
 - 18 to 25 Gauge May Be Used
 - Minimum Size to Achieve Quality Sample
 - Small Needle More Likely to Hemolyze
 - Large Needle More Likely to Cause Trauma
 - Smaller Needles Inappropriate for Large Volume Blood Draws

Complete Fill of Tubes

- Optimally, Tubes Should be Filled to the Fill Line
- A Full Tube Provides the Proper **Blood: Anticoagulant Ratio**
- Under Filling Tubes is Acceptable in Some Instances

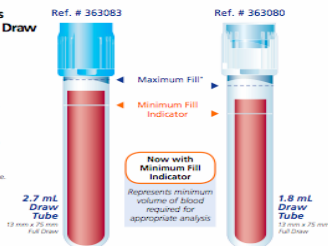
Coagulation Tube Filling

BD Vacutainer® Plus Plastic Citrate Tube

BD Vacutainer® Plus Plastic Citrate Tube Draw Volume Guide

Sufficient volume achieved if blood drawn fills above minimum fill indicator. For blood transfer, **do not** fill above illustrated dashed maximum line.

Note: The quantity of blood drawn into evacuated tubes varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure and filling technique.



*According to CLSI guidelines, Dec. 2003, Doc. H41-A4, Vol. 23, No. 33

Blood to Anticoagulation Ratio= 9:1

Correct Phlebotomy Technique

- Correct Order of Draw
 - Minimize Carry Over
 - Anticoagulant Additives
 - Minimize Skin Contamination
 - Vital for Blood Cultures
 - Maximize Effect of Additives by Absence of Dilution Impact

Blood Collection from Indwelling Lines

- Collection by Alternate Healthcare Providers
- Education is Key for Healthcare Team
- Specimen Quality Issues
 - Hemolysis
 - Fluid Contamination
 - Dilution of Samples

Sample Procedure for Lab Fish

1. Hubster with a minimum of 2.5 inches of depth for the feet and space will lay across the tubercle in place.

2. After using a discard syringe (minimum 35ml) should be withdrawn to be analyzed. The discard should be without a dilute.

3. Following step 2, the blood sample may be used.

4. After blood collection, the fish should be returned to its institution.

Order of Draw

BD Vacutainer® Order of Draw for Multiple Tube Collections

Designed for Your Safety

Closure Color	Collection Tube	Mix by Inverting
Red	BD Vacutainer® Blood Collection Tube (plain or plain II)	0 to 10 times
Yellow	• Citrate Tube	0 to 4 times
Green	• BD Vacutainer® SST® SST Separator Tube	0 times
Light Blue	• Serum Tube SST Separator Tube	0 to 10 times
Light Green	• Heparin Tube	0 to 10 times
Light Purple	• BD Vacutainer® SST® SST Separator Tube with Heparin	0 to 10 times
Dark Purple	• EDTA Tube	0 to 10 times
Black	• Fluoride Spigot® Tube	0 to 10 times

BD Microtainer® Tubes with Microgard® Closure Tube Guide and Order of Draw

Closure Color	Additive	Mix by Inverting	Labeling Use
Red	No additive	No	Use whole blood for all laboratory tests.
Yellow	EDTA	No	Use for all laboratory tests requiring EDTA.
Green	Heparin	No	Use for all laboratory tests requiring heparin.
Light Blue	Serum Separator	No	Use for all laboratory tests requiring serum.
Light Green	Heparin	No	Use for all laboratory tests requiring heparin.
Light Purple	EDTA	No	Use for all laboratory tests requiring EDTA.
Dark Purple	EDTA	No	Use for all laboratory tests requiring EDTA.
Black	Fluoride	No	Use for all laboratory tests requiring fluoride.

BD Microtainer® Tubes with Microgard® Closure

BD Global
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BD Customer Service
1.888.237.2762
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(Courtesy and © of Becton Dickinson)

Proper Handling of Tubes Post Collection

- Invert as per Manufacturer's Instructions
 - 3-10 times (Additive Driven)
- Protect from Light if Necessary
 - Amber Tubes or Aluminum Foil
- Chill or Warm
 - Chill -- Slurry of Ice and Water
 - Warm -- Return Immediately to Lab to a Heat Block or Incubator

Effects of Improper Inversion

- Clotted Samples
 - Improper Mixing of Anticoagulant with Collected Blood
 - Clotting Process Utilizes Clotting Factors
 - Clotted Samples Can Not Be Analyzed in Instrumentation
 - Require Re-Collection

Avoid The "Excessives"

- Do NOT SHAKE
 - Causes Hemolysis
- Avoid Excessive Heat or Cold
 - Causes Hemolysis
 - Deterioration of Analytes
- Never Expose Whole Blood to Dry Ice
 - Freezing Causes Hemolysis

Labeling

- Label All Samples at the Bedside
- Handwritten Labels Must be Legible
- All Labels Must Contain Required Information
- Attached Labels Should Follow Guidelines for Optimum Usefulness

BD Vacutainer® Plus Plastic Tubes

Help to ensure your lab's efficiency. Integrated secondary labeling tracks each and every specimen in the lab. To help minimize the time of the laboratory staff, BD Vacutainer Plus Plastic Tubes have been designed to include a color guide for proper placement of secondary labels.

Examples of misaligned secondary labels

Steps to properly align secondary labels

Step 1
Align the secondary label on the color guide on the tube.

Step 2
Align the secondary label on the color guide on the tube.

Benefits of using secondary labels

- Sample tracking
- Ability to track the tube tube
- Error-free labeling
- Consistent bar code location, ensuring instrument readability

Essential Positive Specimen Identification

- Essential Positive Specimen Identification
- Visibility of Contained Sample (Volume 4)
- Accessibility of Additive Contents on Label
- Consistent Bar Code Locations for Instrumentation

Personnel Considerations

- Individuals That Perform Specimen Collection Should be Identified
- Entire Process Should be Evaluated
- All Individuals MUST be Trained and Assessed for Competency
- All Steps Documented


Expanded Healthcare Team Approach

- Specimen Collection Training
- Updating Manuals
- Providing Hands-on Training
- Remediation When Necessary
- Service Excellence
- Working with Internal Customers to Achieve Perfection

Special Labeling Considerations

- ## Blood Bank Samples
- Special Labeling Guidelines
 - May Require Banding of the Patient with Specific Band System
 - Band System has Corresponding Labels for Attachment to the Units
 - Band is Applied in Addition to the Hospital Identification Band

Securline® System



- Blood Bank Band System
- Band
- Specimen Labels
- Blood Unit Labels

Reprinted with permission of Precision Dynamics Corporation.

Hematrax-ID System By Digi-Trax



Reprinted with permission of Digi-Trax Corporation

- Bar Code Scanning
- Wristband Printed at Bedside
- Labels Printed at Bedside
- Matching Labels Forwarded to Blood Bank for Units

Transportation

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

- Transport All Samples to the Laboratory as Efficiently as Possible

Pneumatic Tube System



- Rapid Specimen Transport
- Adds to "Lean" Philosophy
- Limited Use
- May Cause Hemolysis

Laboratory Specimen Processing

- ## Basic Steps
- Temporary Specimen Storage
 - Specimen Separation
 - Centrifuging
 - Aliquoting
 - Delivery to Departments

Centrifuge



- Two Main Types
 - Swinging Bucket
 - Fixed Angle
- Time
 - Type Dependent
 - Additive Dependent
- Relative Centrifugal Force (RCF)
 - 1100-1300

Reprinted with permission from Iris Sample Processing

Preanalytical Issues Associated with Specimen Processing

- Hemolysis
 - Allow complete clot formation to occur
 - Centrifuge promptly - allowing the serum or plasma to be in contact with cells may result in hemolysis
 - Centrifuge only one time - Repeat centrifugation may push hemolyzed serum from under the gel separator

Hemolysis

- The presence of hemolysis in the serum or plasma of a sample appears as a pink or red color to the liquid. See the sample to the right.



Comprehensive Causes of Hemolysis

- Prolonged tourniquet application with leak of interstitial fluid into tissue
- Incomplete alcohol drying following site preparation
- Shear stress and subsequent rupture of red cells when collected with small bore needle
- Tissue trauma during collection
- Slow blood flow
- Occlusion of needle lumen by vein wall
- Use of a large bore needle and syringe causing increased pressure with plunger

- Vigorous shaking of collection tubes
- Frothing of blood resulting from a loose connection of the blood collection assemblies when performing line draws
- Freezing of red blood cells during storage or transportation
- Exposure of cells to excessive heat during storage or transportation
- Prolonged contact of serum or plasma with cells

Variable Analyte Levels

- Potassium
 - ↑ by Hemolysis
 - ↑ by Centrifuging SST Tubes > 1 Time
- Glucose
 - ↓ When Cells and Serum are Not Promptly Separated

Shared Specimens

- Prioritize
 - Perform Tests Requiring Immediate Results first (e.g. Stat or Short TAT)
- Split into Appropriate Volume Aliquots
- Divide into Proper Containers
- Store at Appropriate Temperature

Department Delivery

- Deliver all Specimens to Appropriate Department Promptly
- Notify Department Staff of Stat or Priority Samples
- Place Samples in Designated Area

Impact of Preanalytical Errors

- Unusable Samples due to Quality Issues
- Specimen Rejection
- Specimen Recollection
- Compromise of Quality Analysis
- Delay or Inaccuracy in Diagnosis and Treatment
- Possible Compromise of Patient Safety

Training and Competency Assessment

- Expand the Number of Factors that are Cognitive
Cognitive → Noncognitive
- Eliminate all Noncognitive Factors
- Expand Training and Competency Assessment Across Discipline Lines
- All Personnel Collecting Laboratory Samples Should be Included

Timing of Training

- Orientation
- Process Modification
- Institution of New Process
- Periodically
- Remediation (if deemed necessary)

Competency Assessment

- Required by All Accrediting Agencies
- Essential for All Processes
- Orientation
- Periodically
- Documented in Employee's Record

Competency Assessment Methods

- Pencil and Paper Tests
- Check Lists
- Direct Observation
- Identification of Objects
- Demonstration of Methods
- Role Playing

Summary

- Preanalytical Errors Occur Too Frequently
- Cognitive and Noncognitive
- May Occur at Any Step of Any Process
- Eliminate by
 - Providing Information
 - Educating
 - Assessing Competency
 - Remediation if Necessary
 - Working as a Healthcare Team

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Questions?

Thank You for Attending

Remember to Take the Post-Test on the NCCT Web Site to Receive Continuing Education Credit.
