# IQCP for POCT in the Pre-Analytic State: Identifying and Preventing the Most Common Sources of Error

**Prof. Maria Stevens Hardy, IMA (ASCP), AHI & CLC (AMT)**
President & CEO
Medical, Laboratory & Technology Consultants, LLC

MLT CONSULTANTS LLC
MEDICAL, LABORATORY & TECHNOLOGY CONSULTANTS
WWW.MLTCONSULTANTS.COM

# Objectives

- Identify a variety of pre-analytical errors that may be avoidable based on patient criteria
- Observe proper Order of Draw and specimen collection techniques
- Review risk mitigation procedures for the pre-analytic stage of testing

# VARIABLES IN PHASES OF TESTING

Many variables can affect the accuracy and precision of laboratory test results. Laboratories must be aware of these variables in order to minimize them, as the diagnosis and treatment of patients can be impacted. These variables are divided into preanalytical, analytical, and post-analytical.[1]

- **Preanalytical** variables include specimen collection, transport, and processing
- **Analytical** variables include those associated with the actual testing process
- **Post-analytical** variables include results transmission, interpretation, follow-up, and retesting

# Why is this a problem?

- Errors occurring during the **preanalytical** phase – from the time the test is ordered by the physician until the sample is ready for analysis – can account for up to 93% of the errors currently encountered during the total diagnostic process, a review of multiple studies in 2002 showed similarly high levels of errors.

- Overall, **insufficient specimen quality and quantity** may account for over 60% of preanalytical errors. [2]

# Why is this important to me?

- Medical Assistants/Phlebotomists/Nurses/Collection Techs, etc. collect samples for laboratory testing and are a critical part of the Preanalytical phase of testing

- January 1, 2016 Centers for Medicare and Medicaid Services (CMS) Individualized Quality Control Plan (IQCP) Interpretive Guidelines went into effect [3]

- Ensure proper understanding of the five elements to be reviewed: Test system, testing personnel, specimen, reagents, laboratory environment

# Why is this important to me?

- POCT testing teams need to work diligently to ensure that there is a clear guideline that is created and utilized system-wide for proper IQCP compliance

- The following summarizes preanalytical errors in specimen collection that can affect laboratory test results and/or cause injury to the patient.

# Preanalytical Variables

- **Patient identification errors:** These identification errors occur when the incorrect patient drawn, incorrect patient labels affixed to tubes, tubes not labeled at time of collection, tubes labeled by someone other than the individual who collected the patient.

- **Patient complications:** These include drawing non-fasting patients for fasting lab tests, patient allergies to alcohol / iodine used to prepare venipuncture site, fainting, etc.

- **Vein selection:** The basilic vein should be last choice as puncture may injure the median nerve causing damage.

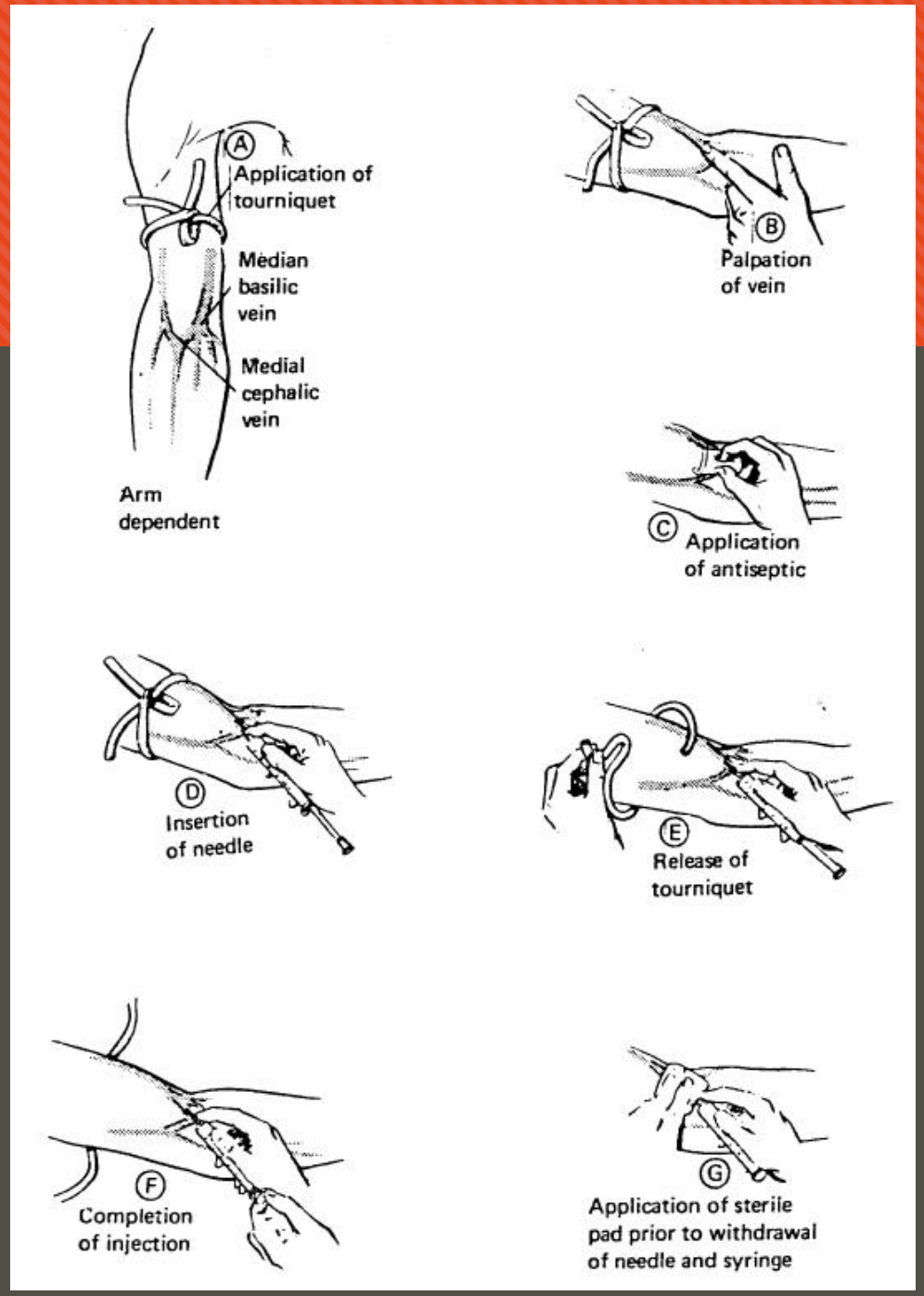
# Preanalytical Variables

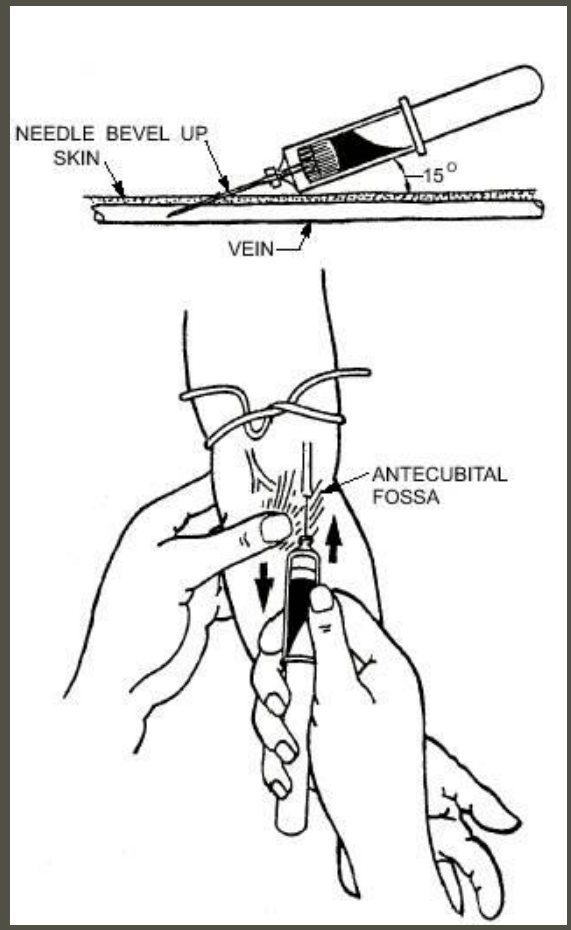
- **Site selection**: Avoid sites with IV, on side of a mastectomy, edema, hematoma, burns, and scarring as test results can be affected or injury caused to the patient.

- **Tourniquet**: Hemoconcentration, which may affect test results, can occur if the tourniquet is left on for more than one minute.

- **Cleansing of venipuncture site:** Alcohol must be allowed to dry to assure any bacteria present have been killed. Additional cleansing of site is necessary for blood culture collections to ensure sterility of the sample.

# Venipuncture technique



# Preanalytical Variables

- **Selecting collection method most appropriate for patient:** Use of evacuated tube system, winged infusion sets, syringe, or skin puncture should be decided based on the location, depth, and accessibility of the patient's veins.

- **Proper angle of needle insertion/anchoring of vein**: This assures the needle enters the vein successfully.

- **Order of draw**: Inaccurate test results can occur if an additive from a previous tube contaminates the tube being collected.

# NEW ORDER OF DRAW FOR BLOOD COLLECTION TUBES - November 2009

| DRAW IN THIS ORDER | STOPPER COLOR | ADDITIONAL INFORMATION AND ADDITIVES | IMPORTANT INFORMATION |
|---|---|---|---|
| 1st |  | RED CAP/WHITE LABEL<br>Isolator tube for culture Mycobacterium (TB/AFB) | Fill all tubes completely to fill lines. Failure to do so may result in specimen refusal by the testing lab. |
| 2nd |  | BLUE CAP AND LABEL<br>Aerobic blood culture | |
| 3rd |  | LAVENDER CAP AND LABEL<br>Anaerobic blood culture | |
| 4th |  | Yellow top tube<br>ACD | |
| 5th |  | Navy Blue top; serum, no additive*special testing get from Core Lab x6-2345 as needed | NEW ORDER OF DRAW: RED AFTER Light BLUE |
| 6th |  | Light Blue top,<br>Sodium Citrate | |
| 7th |  | Red top tube (4 and 10 ml)<br>Serum. Additive - spray coated with a clot activator | |
| 8th |  | Dark green top<br>Sodium heparin | Invert all tubes 8-10 times |
| 9th |  | Light Green top<br>with Gel (PST)<br>Lithium heparin | |
| 10th |  | Navy Blue top; with EDTA<br>*special testing, get from Core Lab x6-2345 as needed | Failure to follow the order of draw may result in erroneous test results and/or refused testing. |
| 11th |  | Lavender top, (3 and 10 ml)<br>EDTA | |
| 12th |  | Gray top (2ml)<br>Sodium Fluoride/Na2 EDTA | |

***If in doubt, check it out!***

Clinical and Laboratory Standards Institute* Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, H3-A6. October 2007

# Sally brings really good grease and leaves the gravy.

**S**ally = **s**terile

**B**rings = **b**lue

**R**eally = **r**ed

**Go**od = **go**ld

**Gre**ase = **gre**en

and

**L**eaves = **l**avender

the

**Gra**vy = **gra**y

# What are these tubes for?

| Order of Draw | Tube Stopper Color | Additive | Dept. | Tests | Liquid Part post - centrifugation |
|---|---|---|---|---|---|
| 1 | Yellow  | Sodium polyethanol sulfonate (SPS) | Microbiology | Blood Culture | Plasma |
| 2 | Light Blue  | Sodium Citrate | Coagulation | PT, PTT | Plasma |
| 3 | Red (plain)  | No additive | Tube Blood Bank | Type, RH, antibody screen, type & crossmatch | Serum |
| 4 | Red & Grey or Gold  | Clot Activator | Routine Chemistry | All STAT tests + Iron, folate | Serum |
| 5 | Green  | Heparin | STAT Chemistry | BMP, CMP, Glucose, K, Troponin, Bilirubin | Plasma |
| 6 | Lavender  | K2EDTA | Hematology | CBC, ESR | Plasma |
| 7 | Pink  | EDTA | Gel Blood Bank | Type, RH, antibody screen, type & crossmatch | Plasma |
| 8 | Gray  | Sodium Flouride (inhibits glycolysis) | Chemistry | Lactic Acid, Gluc (not run right away) | Plasma |

# Remember to invert - do not shake!

- Tubes containing additives must be gently inverted (i.e., not shaken) immediately after collection to assure that blood quickly comes into sufficient contact with the additive.

- Failure to adequately mix the blood specimen with the anticoagulant will produce a specimen unacceptable for testing or inaccurate patient test results.

# What's in the tube?

**The following substances are anticoagulants. Their presence in tubes prevents the blood from clotting.**

- K2EDTA (potassium ethylenediamine tetra-acetic acid)
- Na2EDTA (sodium ethylenediamine tetra-acetic acid)
- Sodium citrate
- Sodium heparin
- Lithium heparin
- Potassium oxalate
- ACD (acid citrate dextrose)
- SPS (sodium polyanethol sulfonate)
- CTAD (citrate, theophylline, adenosine, dipyridamole)

# What's in the tube?

**The following substances are additives.**

- Thrombin (helps the blood clot quicker)
- Sodium fluoride (prevents glucose in the blood from decreasing in quantity)
- Gel (during centrifugation, moves up in the tube to form a barrier between red cells and serum/plasma)

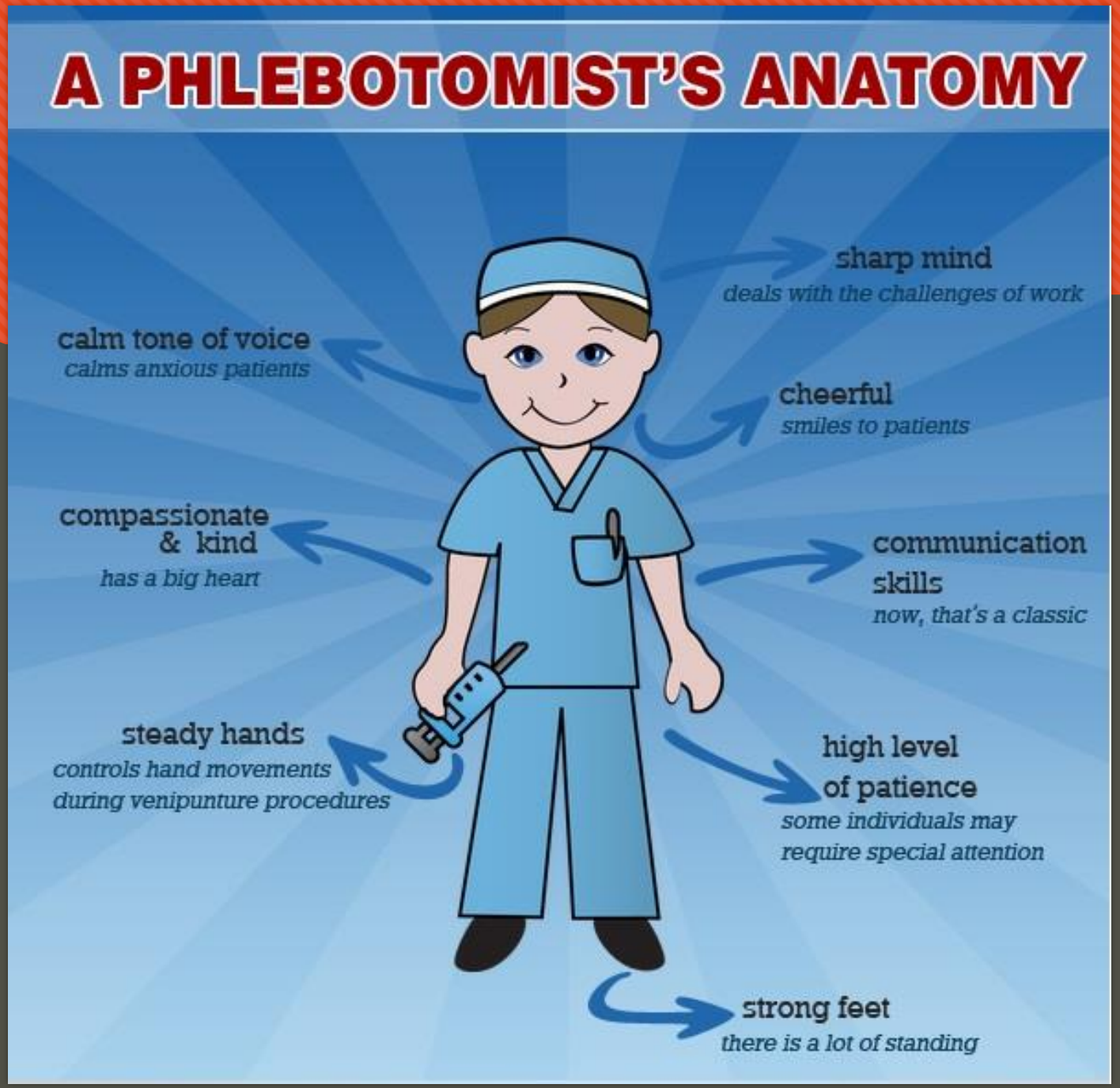
# Preanalytical Variables

- **Hemolysis**: Traumatic venipuncture, blood collected from area with a hematoma, vigorous shaking of tubes after collection, use of small gauge needle with regular size evacuated tubes, pulling too hard on a syringe barrel can all cause the blood specimen to hemolyze, which can affect test results.

- **Timing of specimen collection:** If specimens are not collected at the appropriate time for timed draws, peak/trough levels for therapeutic drug monitoring, fasting, etc., the test results will not correctly represent the patient's condition which can lead to improper treatment.

- **Collection tubes:** Incorrect tube drawn, incorrect fill volume, tubes with additives and anticoagulants not thoroughly mixed will all affect laboratory test results.

# A PHLEBOTOMIST'S ANATOMY



# POINT OF CARE TESTING SPECIFIC CONCERNS

**From a Point of Care Testing viewpoint there are many concerns that are specific and may not apply to other testing protocols.**

- Many testing personnel – medical assistants, nurses, phlebotomists, collection techs, etc.
- Many testing devices
- Many testing locations
- Many patient populations

A proper Risk Assessment is the only way to identify all of the concerns and more will always arise!

| | Potential Error | Risk Assessment | Risk Level | Risk Mitigation |
|---|---|---|---|---|
| SPECIMEN | | | | AGE CRITERIA<br>preparation<br><br>N: venous whole<br>blood<br>R: plain plastic<br>20 gauge<br><br>25 mL<br>ately ( within<br>draw)<br>ronic ordering<br>s are received<br>lection occurs<br>staff shall<br>ers for duplicate<br>different<br>priate<br><br>ify time of draw<br>r PM) |

## SPECIMEN ACCEPTANCE / STORAGE CRITERIA

- Includes tube type, patient preparation and specimen storage
  - ASSAY NAME: iSTAT
  - ACCEPTABLE SPECIMEN: venous whole blood or arterial whole blood
  - SPECIMEN TUBE COLOR: plain plastic syringe (3cc with 16 to 20 gauge needle)
  - MINIMUM VOLUME: 0.25 mL
  - STORAGE: Test immediately ( within one minute of patient draw)
- Physicians may utilize electronic ordering through the EMR. The orders are received in the LIS and specimen collection occurs by phlebotomy. Laboratory staff shall review these electronic orders for duplicate tests, needed calculations, different specimen types and appropriate specimens collected.
- Ordering clinician can specify time of draw for patient specimen (AM or PM)

| | Potential Error | Risk Assessment Can this be detected or | Risk Level | Risk Mitigation (Included in QC Plan) |
|---|---|---|---|---|
| | | | | 5 to verify or without<br><br>ge if you are ollow the s for Blood atocrit<br><br>y collection anced gases)<br><br>eparin ansfer<br><br>lood gas or the assays t of heparin arin/mL of blood)" |

Contacted Abbott on 12/28/2015 to verify collect device to be used (with or without anticoagulant)
"It is ok to use a plain plastic syringe if you are running immediately. Other wise follow the instructions I sent you." "Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for electrolytes and blood gases)

Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device.

Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin that will prevent clotting (10 U heparin/mL of blood)"

| | Potential Error | Risk Assessment Can this be detected or prevented by existing | Risk Level | Risk Mitigation (Included in QC Plan) |
|---|---|---|---|---|
| | | | | ith d be al or of this tion of nown t<br>pharmacological compounds may also affect the results of this test.<br>Note will be added to results reporting for reference range regarding potential patient medication result variation. |

Certain medications may interfere with assay performance. All results should be interpreted with respect to the clinical picture of the patient.

- Platelet dysfunction, hereditary or acquired, may affect the results of this test. This includes the administration of pharmacological compounds known as platelet inhibitors which affect platelet function.
- Factor deficiencies, dysprothrombinemias, other coagulopathies, and other pharmacological compounds may also affect the results of this test.

Note will be added to results reporting for reference range regarding potential patient medication result variation.

# POCT Pre-analytical Solutions

**Effective Communication**

- Ensure that ALL Testing personnel are aware of IQCP requirements
- Ensure proper training of Testing Personnel on all applicable aspects of testing
- Ensure proper documentation of all applicable aspects of testing

# POCT Pre-analytical Solutions

**Quality Matters Day to Day**

- How are testing devices stored?
- Has everyone been formally trained on how to use instruments? Not just OTJ training or shadowing
- How often are devices cleaned?
- Are devices properly charged for use? End of shift, between patients? Is it in someone's pocket?

# Summary

- The majority of errors in laboratory testing occur in the Preanalytic phase of testing [8]
- By being aware of what errors may happen you are preparing yourself to proactively prevent them
- January 1, 2016 each stage of laboratory testing is being assessed and must be compliant according to CMS Interpretive Gudielines

# References


1. *Phlebotomy Order of Draw. WHO, WHAT, WHEN, WHERE, WHY, & HOW* National Center for Competency Testing. August 2013
2. Preanalytical Variables: Room for Improvement http://www.specimencare.com/main.aspx?cat=711&id=3085#R1
3. Individualized Quality Control Plan (IQCP) http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
4. Venipuncture Technique Image Venipuncture Method. http://www.tpub.com/corpsman/227.htm
5. *Order of Draw* Image. www.vianaredes.com.br
6. Order of Draw Chart. www.jengetsschooled.com
7. *Phlebotomist's Anatomy Image*. www.phlebotomyguide.org
8. Preanalytic Error Tracking in a Laboratory Medicine Department: Results of a 1-Year Experience. Giuseppe Lippi, Antonella Bassi, Giorgio Brocco, Martina Montagnana, Gian Luca Salvagno, and Gian Cesare Guidi. Clin. Chem., Jul 2006; 52: 1442 - 1443.

# Thank you!


700 12th Street NW, Suite 700
Washington, DC 20005
202-810-4140

INFO@MLTCONSULTANTS.COM