University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Title: **Lab Specimens**

SOP Number: **CO03**

Date Created: **November 1, 2010**

Version Date: **January 1, 2023**

PURPOSE: This standard operating procedure (SOP) outlines the basic steps required when handling laboratory specimens from collection through processing, labeling, and shipping so that the integrity of the specimen is preserved for analysis and so that stored specimens can easily be retrieved, and/or inventoried, thus providing information leading to appropriate treatment decisions or safety assessment of the participant during a clinical trial.

SCOPE: This SOP applies to all Clinical Research Center (CRC) personnel who are involved (or may be involved) laboratory specimen collection, transport, processing, labeling, and storage for a clinical research trial.

PERSONNEL RESPONSIBLE: Nurses may draw blood samples via venipuncture and vascular access devices per Nebraska Medicine (NM) Nursing Policy and Procedures. Research Assistants may draw blood via venipuncture only.

PROCEDURES:

All research protocols that involve the collection, processing, storage, or disposal of biological samples will follow the Clinical Research Biosafety Protocol.

Specimen Collection

Impeccable clinical practice must be utilized when obtaining specimens from research participants, as these specimens represent important data required by the investigator. Methods used by staff when obtaining specimens must be accurately performed per the study protocol. All patients are identified with at least two patient identifiers (patient's name and date of birth - room number cannot be used) whenever taking blood samples or other lab samples per Nebraska Medicine Policy RI10.

1. **Venipuncture and Vascular Access Blood collection**

- Attention must be given to the accuracy of collecting the specimens at the proper time, using the correct collection tubes, drawing in the correct order, handling appropriately, and transporting in the proper manner. All CRC personnel will follow NM Policy and procedures related to venipuncture and/or the applicable vascular access device blood collection.

2. **Urine Specimens**

- Random Urine Specimens - can be collected at any time; they are usually obtained without prior participant preparation.
- Clean Catch Urine Specimens – are collected after the patient appropriately wipes the area. They must start the urine stream, then stop and restart to collect the sample being

careful not to contaminate the inside of the sterile collection cup that needs to be used. They must carefully recap the container without contaminating the inside of the lid or the inside of the container.

- One-time composite urine specimens are collected over a period that may range from 2 to 24 hours. To collect a timed specimen, instruct the participant to void and discard the first specimen. This is annotated as the start time of the test. All subsequent urine is saved in a special container for the designated period of time. A preservative may be used to maintain stability during the collection period, or the container can be kept on ice or refrigerated. Instruct participants not to void directly into the container as some preservatives are acids, which should not be splashed on the skin. At the end of the specified time period, the participant should void and add this urine to the container; thereby completing the collection process. The collection container should be labeled with the participant's name or study identification number, the starting date/time, the ending date/time, the name of the test, and the preservative (if any). Indicate on the laboratory request any medications that may affect test results.
- All urine specimens must be placed in a sealed container, labeled, and delivered to the appropriate laboratory.

3. Other Specimens

- Stool Specimens, Saliva, CSF, swabs (anything other than blood and urine) – all need to be handled underneath a laminar flow hood unless they are handed to us in a close/sealed container that does not need to be re-opened.

4. Specimen handling and processing

- Protocols often require special handling of specimens from the time of collection until they are processed. Protocols that specify special handling will be accurately followed.
- Specimens for ammonia, blood gas determinations, acid phosphatase, lactate, pyruvate and certain hormone tests must be kept at 4ºC from the time the blood is drawn until the specimens are analyzed or until the serum or plasma is separated from the cells.
- Specimens for bilirubin, carotene or Vitamin D must be protected from light to avoid photo degradation.
- Since improper handling and specimen processing can result in unusable specimens, great care must be taken to ensure that blood or urine specimens are handled and processed properly until analysis. Review thoroughly the Clinical Trial protocol and lab manual procedures for a study prior to handling and processing of specimens for the study. This information will be communicated to all staff involved with the protocol.
- CRC has access to a -20º and -80ºC freezer for freezing and storing specimens.

- Specimens will always be labeled with two identifiers when processed.

5. Specimen Labeling

- Collect and label the specimen in the presence of the patient and after specimen collection. The responsibility for labeling the specimen resides with the person who obtains the specimen. If labeling is delegated, the person collecting the specimen must verify correct labeling before the specimen is sent.

    1. All specimens collected and/or stored should be labeled securely
        - Labels will be affixed directly to the primary specimen container, and anything printed should be in black permanent ink.
        - If using a self-adhesive label on a specimen to be frozen, apply the label appropriately and then reinforce with tape all the way around the tube unless otherwise indicated by the protocol or labels are freezer safe. This will ensure that the label will remain intact when frozen.
    2. Each specimen will be labeled consistently with adequate information to identify the specimen by following the protocol specific instructions including the date and time of the collection and other specified identifiers such as:
        - Subject unique identifier
        - Study name
        - Sponsor-designated Study ID
        - Locally assigned Study ID
        - Barcode that matches a sample collection requisition form that contains appropriate patient identification
        - Date & time of draw
- During EPIC downtime, each specimen label will be verified by a second RN, coordinator, or research associate for accuracy prior to the specimen leaving the CRC (i.e., sent for local lab analysis, shipped to a central lab, or sent to another lab on campus).
- During the planning stages of a study, CRC staff consult the study protocol, operations manual, or the central lab regarding special requirements for specimen labeling or storage. This information will be documented in the nursing guidelines and laboratory manual and communicated to all appropriate CRC staff.

6. Shipping Specimens

- Ship lab specimens according to study-specific lab manuals and/or protocols.

- IATA certification must be completed and up to date in order to ship specimens.

ASSOCIATED FORMS:

Quality collections: the phlebotomist's role in pre-analytical errors

CLIA waiver

Phlebotomy Skills Checklist

Specimen Processing Competency Checklist

RESOURCES:

Nebraska Medicine:

- **RI10 Patient Identification**
- **TX06 Laboratory Specimen Labeling**

Nebraska Medicine Nursing Policy and Procedures:

- **Lab-7, Venipuncture Blood Collection by Evacuated Tube, Syringe Method, or Butterfly Device**
- **Lab-1 Laboratory Testing, Ancillary: Blood Glucose**
- **Lab-2 – Laboratory Testing, Ancillary: Fecal Occult Blood – Fecal Application only**
- **Lab-9 Laboratory Testing, Ancillary: Fecal Occult Blood-Application and Test Development**
- **VAD-2 Intravenous Catheter Flushing: Push Pause Technique**
- **VAD-4 Blood Draws via Central Lines**

Department Approval

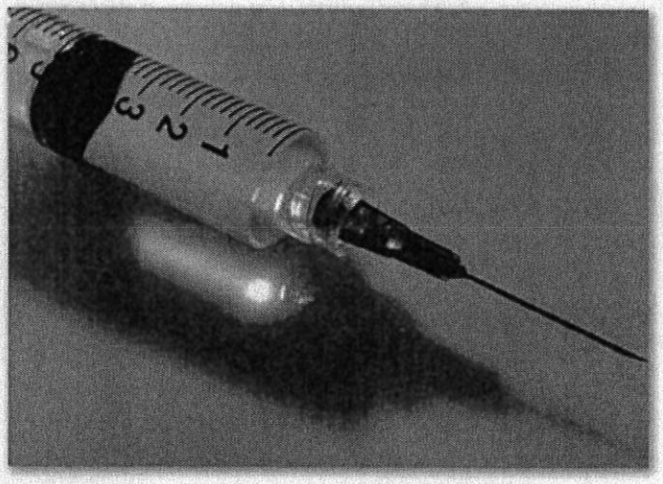
Signed Serena Gaines Date: 5/3/2023
Research Nurse Manager

Signed Date: 5/3/2023
Assistant Vice Chancellor for Clinical Research

Quality collection: the phlebotomist's role in pre-analytical errors

By Dennis J. Ernst, MT(ASCP), and Lisa O. Ballance, MT(ASCP)

Medical error has been defined as a "failure to process."[1] The ultimate consequences of pre-analytical errors introduced during the specimen-collection process span a broad spectrum of negative outcomes. For the patient, these outcomes range from no detected harm to death. When patient blood specimens are required for examination, the collection process demands the knowledge and skills of a competent phlebotomist. From receipt of the physician's order until examination of the specimen begins, the phlebotomist is often the primary guardian of specimen quality.



Studies have shown that a dedicated blood-culture team and/or phlebotomists are less likely than other healthcare workers to contaminate blood-culture specimens.

Unfortunately, in today's various healthcare settings, the role competent phlebotomists play in assuring specimen quality has been undervalued. Evidence that their role is underestimated includes:

- disregard among other healthcare professions for the complexity and invasive nature of phlebotomy procedures;
- decentralization of phlebotomy services;
- lack of nationally established minimum training and/or certification requirements for those assigned blood collection responsibilities; and
- lack of emphasis on, or access to, phlebotomy continuing education.

Here, we explore some of the critical concepts all specimen-collection personnel must master in order that physicians are not misled by laboratory results which constitute 70% of the objective information they receive on their patients' status. Strict adherence to blood-collection procedures is the most effective means to ensure specimen quality during the collection and processing phases of laboratory testing. Studies show up to 56% of laboratory errors occur during the pre-analytic phase of testing.[2] The expertise of the collector, therefore, is a pivotal link in the laboratory's chain of total quality-management activities.

Patient identification

The most potentially fatal pre-analytical error is improper patient identification. This is basic but bears mentioning. Failure to properly identify patients can lead them to be treated, diagnosed, medicated, and managed according to another patient's health status.

According to the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) an inpatient should be asked to state her full name, address, birth date, and/or unique identification number. The information provided must be compared with the information on the identification bracelet, which must be attached to the patient, and the test requisition or computer-generated labels brought to the bedside. All discrepancies must be reported to the appropriate caregiver according to facility policy and resolved before collection.

What if the patient is unable to speak her name due to language barriers or the patient's state of consciousness? The standards require a caregiver or family member provide the information on the patient's behalf before drawing the specimen.[3] This requirement is justified in part by studies that show up to 16% of identification bracelets contain erroneous information.[4] Documenting the name of the verifier is good risk management.

Emergency-room patients should be tagged with some sort of identification even if it is only a temporary number. The following items are not acceptable substitutes for an identification bracelet:

- charts on the wall;
- water pitchers;
- bed tags; and
- identification bracelets *not* attached to the patient.

There is no substitute for either having a hard identifier attached to the patient, having the patient speak her name, or having a caregiver verify the patient's identity.

For outpatients, CLSI recommends having the patient state her name address, birth date, and/or unique identification number and comparing that information with the requisition or forms the patient brings to the draw station. Neither inpatients nor outpatients should be asked to affirm their name as in "Are you Jane Doe?" Patients who may be hard of hearing might misunderstand and respond "yes" just to be polite. A wiser solution is to ask the patient to tell you her name.

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Special-collection requirements

Special testing requirements must be met prior to collection. Fasting specimens must be collected after a 10- to 12-hour complete dietary restriction of everything except water and medications. Although fasting for glucose must be overnight, studies show the difference between an overnight fast and a six- to nine-hour daytime fast for lipids is not clinically significant.[5]

Because of the threat over- or under-medication can have on the patient, strict adherence to the timing of therapeutic drug collections is imperative. Likewise, requirements that the patient be recumbent must be met in order for the physician to properly manage the patient's health. Regular reviews of the laboratory's test requirements help specimen-collection personnel remain mindful of time- and posture-dependent tests.

Collection restrictions

Few therapies threaten accurate blood-test results more than the infusion of intravenous fluids. CLSI and most textbooks recommend avoiding draws from the same arm as an active IV unless absolutely necessary. If unavoidable, CLSI recommends having the nurse or appropriate caregiver shut off the IV for two minutes, apply the tourniquet below the infusion site, and withdraw the specimen below the tourniquet. Some authors recommend discarding the first 5cc (cubic centimeters) of blood if possible.[2,6] Document the arm from which the specimen was collected as well as the fact that it was drawn below an infusion site.

Drawing above an IV that has been temporarily shut off is discouraged due to the potential for analyte contamination.[3] Drawing blood at the same time that dyes for radiological procedures are being or have been recently infused should be avoided if possible.

Neither venipunctures nor skin punctures should be performed on the affected side of patients who have had a prior mastectomy.[3,7] Not only is there a risk of fluid imbalance in the affected limb, which can lead to erroneous results, the procedure puts the patient at risk of painful short- or long-term lymphedema.

Site preparation

Specimen collection personnel should also avoid sites that appear infiltrated, infected, edematous, or burned — not only to protect the patient from further complications but also to safeguard against collecting specimens that could be altered by the condition. CLSI advises against drawing arterial specimens as a substitute for venous blood when veins are difficult to locate.

The best way to ensure a successful capillary collection is to pre-warm the intended puncture site for three to five minutes. Applying a commercial infant heel warmer or warm compress not exceeding 42°C to the skin increases blood flow to the area up to sevenfold.[7] Taking the time to perform this step promotes higher quality specimens because the blood is obtained more quickly and with less tissue compression.

For routine venipuncture and capillary collections, cleansing the site with 70% isopropyl alcohol is sufficient. Allowing the site to air dry improves the alcohol's antiseptic effect, as well as prevents hemolysis and contamination of the specimen that residual alcohol can cause.[7] For capillary lead levels, a thorough scrub with soap and water of the finger and nail area may be required.

For blood cultures, the probability that a positive blood culture represents infection rather than contamination is a function of the effectiveness of skin antisepsis at the time of the venipuncture. Growth of skin contaminants may not only be confusing to clinicians but also can be expensive for both the patient and the institution.[8] The traditional recommendation for skin preparation has been the application of 70% alcohol followed by or in conjunction with a 30- to 60-second friction scrub. Apply chlorhexidine, povidone-iodine or 2% iodine tincture, and allow to air dry. For infants above two months of age, and for patients with iodine sensitivity, chlorhexidine gluconate is recommended.[3] Regardless of the type of skin preparation used, meticulous care and aseptic technique are essential to reduce contamination. Studies have shown that a dedicated blood-culture team and/or phlebotomists are less likely than other healthcare workers to contaminate blood-culture specimens.[8]

Collection technique

The phlebotomist's ability to select the appropriate supplies and equipment for each draw, based on an assessment of the patient and specimen test requirements, is crucial to assuring a successful collection. Equipment and supplies should be checked for acceptable expiration dates and sterility, as appropriate.

When collecting capillary specimens, proper positioning of the finger or heel will enhance blood flow. To minimize the risks of tissue fluid contamination and hemolysis, the collector should wipe away the first formed drop of blood and avoid exerting excessive pressure to the surrounding tissue. When more than one microcollection tube is required, the order of draw for capillary collections as established by CLSI should be followed.[7] To prevent the formation of platelet clumps, microcollection tubes containing EDTA should be collected first, followed by other-additive tubes and then non-additive tubes. Additive tubes should be mixed periodically during collection, according to the tube-manufacturer's instructions. Once the appropriate volume of blood has been obtained, tubes should be immediately capped and the blood mixed well by gentle inversion.

The appropriate number of test circles on newborn screening cards should each be filled with one well-formed drop of blood that saturates the filter paper front to back. Care should be taken not to press the filter paper against the infant's heel. Any technique that might scratch, compress, or indent the paper's fibers should not be used.

Hemolysis is the most common reason laboratories reject specimens.[2] During venipuncture, rupture of red blood cells may occur for several reasons, including use of small bore needles (i.e., 25-gauge), excessive pulling pressure on the syringe plunger, poor needle placement within the vein resulting in a slow draw, and aggressive mixing of the sample. To minimize the effects of hemoconcentration during collection, the tourniquet should be released as soon as possible after blood flow is established. Because vigorous hand-pumping may also alter the concentration of certain analytes in the blood, this practice should be discouraged.

For venipunctures, unless otherwise established by facility protocol, tubes should be collected following the order of draw established by CLSI in 2003 to prevent additive carryover.[3] Additive carryover cannot be detected by the laboratory and, as a result, may lead to disastrous consequences for the patient when medical decisions are based on altered results. It is imperative all additive tubes be filled in the proper order and adequately mixed according to the tube manufacturer's instructions. Collection

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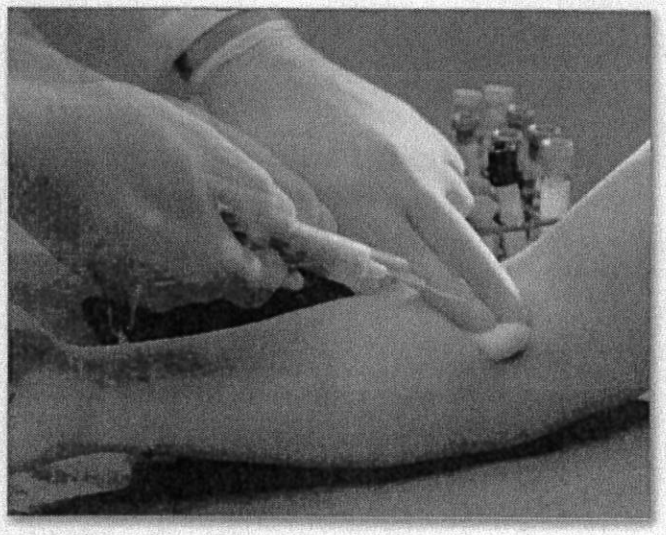
tubes should be available in a variety of sizes to ensure minimum fill requirements are met when presented with difficult or pediatric draws. According to CLSI, the order of draw is as follows:

1. Blood-culture tubes;
2. Sodium-citrate tubes (e.g., blue stopper);
3. Serum tubes with or without clot activator, with or without gel separator (e.g., red, gold, speckled stopper);
4. Heparin tubes with or without gel (e.g., green stopper);
5. EDTA tubes (e.g., lavender stopper); and
6. Glycolytic inhibitor tubes (e.g., gray stopper).[3]

Underfilling of additive tubes alters the desired blood-to-anticoagulant ratio and, in the case of EDTA tubes, causes red-blood-cell shrinkage. An underfilled sodium-citrate tube will produce a falsely lengthened aPTT result.[2] Manual filling of additive tubes should also be avoided.

When using a winged blood-collection set, a discard tube must be used to prime the tubing when a coagulation tube is the first or only tube drawn. For blood cultures, if both anaerobic and aerobic bottles are included in the set, the aerobic bottle should be filled first, to remove air from the tubing. Underfilling of blood- culture bottles may result in failed recovery of organisms present in small quantities, whereas overfilling of blood- culture bottles may elicit a false-positive result during incubation.[2] In any case, improperly filled additive tubes and culture bottles may result in specimen rejection or, if tested, yield inaccurate results that jeopardize patient care.



In an age of technological advancement, phlebotomy remains a manual procedure.

Collections from vascular access devices (VADs) should be avoided since they pose an increased risk of contamination by intravenous fluids and exhibit a higher rate of hemolysis compared to venipuncture.[2] It has also been shown that blood cultures collected from VADs are more likely to be contaminated than those obtained by venipuncture.[8] When warranted, a healthcare professional trained in IV management should perform the draw and include a 5-cc discard.

Specimen labeling

To prevent specimen mix-up or rejection, specimens should be properly and permanently labeled at the patient's side, bearing at least the following:

- the patient's first and last names;
- an identification number;
- the date;
- the time (as required); and
- the collector's identification.[3]

If a bar-coding system is used, facility protocol should be followed.

Figure 1.

Analytes that are affected by prolonged exposure to red blood cells:

- APTT
- Bicarbonate
- Calcium
- Chloride
- Glucose
- HDL cholesterol
- Iron
- Lactate dehydrogenase (LDH)
- Magnesium (ionized)
- Phosphorous
- Potassium

Specimen handling and processing

Because improper handling and delays in specimen processing can compromise specimen integrity and result in erroneous test results, the phlebotomist must transport specimens in an appropriate and timely manner, according to the facility's established protocol. A working knowledge of analyte stability is necessary for specimen processing and in evaluating requests for additional testing of a previously collected specimen.

To prevent excess agitation of tube contents that could induce hemolysis, filled collection tubes should be transported in an upright position whenever possible. Pneumatic transport systems should be evaluated to determine which analytes are affected during transport. The temperature at which specimens are transported may also compromise analyte stability. Unless collection protocol requires chilling of the specimen (e.g., renin, ammonia, and so on), specimens should be transported at room temperature (22 °C to 25°C). Because of the deteriorating effects of light on photosensitive analytes, such as bilirubin, steps must be taken to protect such specimens from light exposure.

Newborn-screening specimens should be protected from potential sources of contamination (i.e., direct contact with other blood spot specimens, sprays, lotions, glove powder, and so on) while allowed to air dry on a flat surface for a minimum of three hours. Exposure to direct sunlight and environmental extremes, such as heat and humidity, should also be avoided.[9]

Serum specimens should be allowed to fully clot prior to centrifugation. For optimal specimen quality, serum or plasma should be separated from specimens as soon as possible unless there is evidence that the analyte(s) requested will be not be affected by prolonged exposure to cells. Calcium, glucose, LDH, and potassium are some analytes that change significantly when serum or

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plasma is kept in contact with cells beyond two hours (see Figure 1).[10] Generally, chemistry specimens should be centrifuged and separated within two hours of collection.[10] Tubes should remain closed until time of testing to prevent evaporation.

Coagulation specimens to be tested for aPTT can remain at room temperature after collection, but should be tested within four hours in order to be reliable.[11] When testing patients on unfractionated heparin, specimen processing personnel should centrifuge the specimen, remove the plasma from the cells within one hour and perform the test within four hours of collection.

Prothrombin times are more forgiving and remain stable for up to 48 hours at room temperature, even uncentrifuged, as long as the stopper has not been removed.[11] If the tube is refrigerated, however, the PT results have been shown to increase after seven hours.[12] Freezing citrated plasma has been shown to effectively preserve PT and PTT results up to 21 days at -70°C.

The phlebotomist's role in the workplace

In an age of technological advancement, phlebotomy remains a manual procedure, requiring critical decisions and human skills that will never be automated. The competent phlebotomist recognizes and prevents pre-analytic variables that may introduce error, fulfilling a vital role in the laboratory's quality-management system. Because diverse interactions and specialized knowledge are required, the phlebotomist profoundly impacts patient care, patient relations, and the accuracy and efficiency of the laboratory's path of workflow. Facilities striving for excellence in these areas should begin by examining the value they place on the phlebotomist's role in the workplace. After all, that is where quality collections begin. □

Dennis J. Ernst MT(ASCP) is the Director of the Center for Phlebotomy Education and has participated in the revision of several CLSI specimen collection standards. **Lisa O. Ballance**, a regional laboratory improvement consultant with the North Carolina State Laboratory of Public Health in Raleigh, NC, served on CLSI's Skin Puncture Subcommittee for the NCCLS H4-A5 standard approved in June 2004, was the event organizer for the inaugural *North Carolina Clinical Lab Tech Day* educational conference in 2005, and is the course director for the *North Carolina Public Health Phlebotomy Initiative.*

References

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CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS

CLINICAL RESEARCH CENTER
987400 NEBRASKA MEDICAL CENTER
4350 DEWEY AVENUE
OMAHA, NE 68198-7400

CLIA ID NUMBER

28D0896348

EFFECTIVE DATE

01/06/2023

LABORATORY DIRECTOR

JENNIFER L LARSEN MD

EXPIRATION DATE

01/05/2025

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Gregg Brandush, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

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- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CO03 Phlebotomy Skills Checklist

Trainee (PRINT): _____Date: _____
Staff Member Providing Training (PRINT): _____

Skills	Pass	Fail
1. Introduce self and explains procedure.		
2. Properly identifies patient.		
3. Verify that correct tubes for test ordered and necessary supplies are present at patient location.		
4. Wash or sanitizes hands.		
5. Dons gloves.		
6. Ask about blood drawing history and explains procedure if necessary.		
7. Apply tourniquet properly (note time of application).		
8. Ask patient to clench fist.		
9. Properly palpate appropriate vein to be used for venipuncture.		
10. Properly cleanse site using appropriate technique.		
11. Select and prepares appropriate needle based on chosen vein.		
12. Position evacuated tube in holder, uncaps needle and briefly inspects for defects.		
13. Properly grasp holder between thumb and fingers in drawing hand.		
14. Anchor vein.		
15. Insert needle bevel up, at the correct angle, and in the same direction of the vein.		
16. Stabilize holder while pushing evacuated tube onto needle in holder.		
17. Fill evacuated tubes in the correct order.		
18. Fill evacuated tubes with the correct volume.		
19. Stabilize tube holder during tube change to prevent movement of needle in the vein.		
20. Invert vacutainer container 6-8 times (unless otherwise indicated) to ensure blood mixes with additive.		
21. Release tourniquet (or prior, if necessary. Ideally, do not leave on longer than a minute.).		
22. Remove last tube from holder.		
23. Place cotton ball or gauze over puncture site, remove needle before applying pressure to site.		
24. Immediately activate needle safety device using correct technique while applying pressure to site.		
25. Ask patient to apply pressure to puncture site.		
26. Invert tubes several times if not done previously; label properly mixed tubes immediately after drawing at patient's side.		
27. Label tubes with date and time.		
28. Inspect puncture site to make sure bleeding has stopped, apply bandage.		
29. Discard all used materials appropriately (sharps, biohazard, or regular trash); disinfect work area.		
30. Remove gloves and immediately wash or sanitizes hands.		
Total Number of Checks		

Trainee Signature: _____

Clinical Staff Evaluator: _____

Instructions:

1. The mentor / staff member should complete the *Skills Checklist* page by placing a check mark in the appropriate column for each listed skill.
2. Competency skills are either “Pass” or “Fail”.
    a. The trainee should have a total of 23 out of 30 checks with no checks in the shaded “fail” boxes to be deemed entry level competent.
    b. A check in the shaded “fail” box indicates a failure of a critical competency skill.
3. Tally the number of checkmarks in both the “Pass” and “Fail” columns at the bottom of the page.
4. Based upon the information obtained, check the “Pass” of “Fail” competency box at the bottom of the page.

CO03 Specimen Processing Checklist

Trainee (PRINT): _____Date: _____

Staff Member Providing Training (PRINT): _____

Skills	Pass	Fail
1. Access to protocol specific lab manual.		
2. Explains to patient how to obtain urine specimen: • Random Urine • Clean Catch • 24 Hour		
3. Whole blood processed within two hours of collection.		
4. Gently inverts device containing an anticoagulant 5 to 10 times after collection.		
5. Tubes are kept stoppered at all times.		
6. Blood volume in tube is accurate.		
7. Wears appropriate PPE.		
8. Access to centrifuge operating manual.		
9. Balances centrifuge with tubes of water.		
10. Adjusts centrifuge time and temperature requirements per protocol.		
11. Cleans centrifuge monthly and documents.		
12. Knows where spill kit is located.		
13. Transfers specimens per study specific protocol.		
14. Properly dispose of biohazardous waste.		
15. Stores specimens in refrigerator or freezer per protocol.		
16. Monitors and documents freezer/refrigerator temperatures daily.		
17. States food or medicine cannot be located in freezer/refrigerator marked biohazardous material.		
18. Properly packages specimen according to protocol so that they arrive safely at the laboratory.		
19. Obtains appropriate amount of dry ice and obtains it in a timely manner for shipping.		
20. Attends training and obtains certification to ship human specimens and dry ice.		
Total Number of Checks		

Trainee Signature: _____

Clinical Staff Evaluator: _____

Instructions:

1. The mentor / staff member should complete the *Skills Checklist* page by placing a check mark in the appropriate column for each listed skill.
2. Competency skills are either “Pass” or “Fail”.
    a. The trainee should have a total of 15 out of 20 checks with no checks in the shaded “fail” boxes to be deemed entry level competent.
    b. A check in the shaded “fail” box indicates a failure of a critical competency skill.
3. Tally the number of checkmarks in both the “Pass” and “Fail” columns at the bottom of the page.
4. Based upon the information obtained, check the “Pass” of “Fail” competency box at the bottom of the page.