Purpose:
To define the organization’s compliance with waived testing criteria and the need for a certificate of laboratory services. To comply with the Clinical Laboratory Improvement Act (CLIA) of 1998.

Considerations:
1. The Clinical Laboratory Improvement Act (CLIA) of 1998 requires all clinical laboratories to possess a CLIA Certificate in order to perform testing on human specimens.
2. CLIA lists certain tests on a waived list. Homecare agencies that elect to perform these tests must maintain a current certificate of CLIA waiver on file.
3. Waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”
4. A complete list of waived testing can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm. Generally, waived tests including the following:
   a. Dipstick or tablet urinalysis (nonautomated)
   b. Fecal occult blood
   c. Ovulation test using visual color comparison.
   d. Urine pregnancy test using visual color comparison.
   e. Erythrocyte sedimentation rate.
   f. Hemoglobin by copper sulfate method.
   g. Spun microhematocrit.
   h. Blood glucose using certain devices cleared by the Food and Drug Administration (FDA) specifically for home use.
   i. Hemoglobin by single anayte instruments self contained specimen/reagents interaction with direct measurement and readout.
5. CLIA-approved laboratories will be utilized when the homecare agency receives physician orders for laboratory tests that are not CLIA waived.
6. An application for a certificate of CLIA waiver is available online at www.cms.hhs.gov/clia or from your State Agency.

Equipment:
None

Procedure:
1. The homecare agency will maintain a current certificate of CLIA waiver on file.
2. The homecare agency will perform only CLIA-waived tests in the home.
3. Procedures for each type of waived test performed will include, at a minimum:
   a. Indications and purpose of the CLIA waived test(s) the agency has elected to perform.
   b. Tests will be conducted following manufacture’s instructions for performing the test.
   c. Personnel responsible for performing and supervising waived testing.
   d. Documentation of staff competency in performing waived testing.
   e. Procedure to ensure accuracy of machines used to perform CLIA waived tests.
   f. Parameters for requiring follow-ups or referral in testing done in community settings.
4. CLIA-waived tests may be performed by trained staff upon receipt of a physician’s order.
5. Staff competency is verified and documented prior to performing waived testing and on an ongoing basis, as needed.
6. Staff will document test results and follow-up in the clinical record.

Aftercare:
1. Staff will document test results and follow-up in the clinical record.
2. Physicians will be notified of results per physician’s orders.

Reference:
Strength of Evidence Level: Blank
PURPOSE:
To obtain blood specimen for blood cultures.

CONSIDERATIONS:
1. Refer to Venipuncture: Vacutainer.
2. Avoid contaminated blood culture collection by following strict technique. Cleansing the skin adequately is key. It is not just the scrubbing the venipuncture site, but also allowing it to completely dry. The germs are killed through the drying process.
3. Cleansing of skin may be done in the following ways:
   a. Antimicrobial swabs/wipes (such as ChloroPrep)
   b. 70% alcohol & betadine swabs/wipes
   c. Antimicrobial approved by your agency policy
4. After skin is cleansed and air dried you may not re-palpate the site with your finger. If you think you must re-palpate then wear sterile gloves.
5. Verify the number of blood cultures requested by the physician. Multiple blood cultures are drawn from separate sites and 5 to 30 minutes apart. Example: Two blood culture bottles (one aerobic, one anaerobic) are used per blood culture. If the physician orders blood cultures times two, then 4 culture bottles will be used.
6. Specimen bottle tops must be cleansed with alcohol and totally dry before specimen is transferred into them. It is advisable to cleanse them at same time you are cleansing the skin.
7. General order of sample collections:
   a. First: Blood culture tubes or vials.
   b. Second: Coagulation tube (e.g., blue-top tubes).
   c. Third: Serum tube with or without clot activator or gel (e.g., red, gold, or speckle-top tubes).
   d. Fourth: Heparin tubes (e.g., green-top tubes).
   e. Fifth: EDTA tubes (e.g., lavender-top tubes).
   f. Sixth (Last): Oxalate/fluoride tubes (e.g., gray-top tubes).
8. Blood cultures should be left at room temperature and sent to the lab as soon as possible, no more than 2 hours from time obtained.

EQUIPMENT:
Gloves
Antimicrobial applicator (wipe/swab/disk/ampule)
Alcohol applicator (wipe/swab/disk/ampule)
Blood culture bottles (aerobic and anaerobic)
Self-adhesive bandages
2x2 gauze sponges, sterile (2)
Tourniquet
Tape
Puncture-proof container/Sharps container

Specimen bag

PROCEDURE:
1. Adhere to Standard Precautions/wash hands.
2. Explain the procedure and purpose to the patient/caregiver.
3. Assemble the equipment on a clean surface close to the patient.
4. Place patient in comfortable position, making sure that site is accessible.
5. Assemble blood specimen collection equipment.
6. Apply tourniquet above selected puncture site.
7. Don gloves.
8. Select vein by palpation and inspection.
9. Clean site with appropriate cleansing agent. Allow to air dry. DO NOT blot. DO NOT re-palpate site.
10. Anchor vein by holding skin taut.
11. Remove needle cover and insert needle into vein at 15-30 degree angle with bevel facing up.
12. Fill specimen bottles, fill anaerobic first then aerobic bottle. Need minimum of 5 mL. DO NOT put more than 10 mL of blood per specimen bottle.
   [Note: If you are unsure you can get an adequate amount of blood for both bottles, fill aerobic bottle first.]
13. Release tourniquet.
14. Place sterile 2x2 gauze over puncture site, then withdraw needle slowly. Needle should be removed at an angle nearly flush with the skin to prevent injury to the wall of the vein.
15. Apply firm pressure to area.
16. After specimen placed in specimen bottle. Invert culture bottle gently 5 to 6 times to mix the sample thoroughly. DO NOT shake the bottles.
17. Apply self adhesive bandage to puncture site.
18. Remove gloves and wash hands.
19. Discard soiled supplies in appropriate containers.
20. Label tube with patient's name, date, time drawn. Do not refrigerate blood cultures.

AFTER CARE:
1. Complete Lab Requisition. (See Laboratory, Specimens and Venipuncture - Obtaining and Transporting and Requisition Documentation.)
2. Document in patient's record:
   a. Procedure and observations.
   b. Blood samples drawn, identity and location of laboratory where specimens taken.
   c. Appearance of venipuncture site.
   d. Patient's response to procedure.
   e. Instructions given to patient/caregiver.
PURPOSE:
To obtain blood specimen via fingerstick.

CONSIDERATIONS:
1. This technique is used to obtain a blood specimen sample from adults or children when only a small amount of venous blood is needed and venipuncture would be too invasive or not possible.
2. Capillary puncture may be done on earlobes, fingertips, heels or toes; however, in adults the best location is the fingertips. To use one of the other areas, an order should be obtained.
3. The site of choice is the distal lateral aspect of the fingertip, usually the 2nd (middle) finger or 3rd (ring) finger on the non-dominant hand.
4. Avoid the tips of the fingers or the center of fingers (pads).

EQUIPMENT:
Gloves
Lancets
Alcohol applicator (wipe/swab/disk/ampule)
Test strip or capillary tube
2x2 gauze sponges
Puncture-proof container
Impervious trash bag

PROCEDURE:
1. Adhere to Standard Precautions.
2. Explain the procedure and purpose to the patient. If patient’s hands are cold, encourage patient to wash hands with warm, soapy water or rub hands together briskly to warm hands up.
3. Assemble the equipment on a clean surface close to the patient.
4. Place patient in comfortable position, making sure that site is accessible.
5. Gently massage finger from hand to finger tips several times to increase blood flow. Avoid excessive squeezing or “milking” which will cause tissue fluid to be expressed, compromising specimen integrity.
6. Clean site with alcohol pad. Allow to air dry.
7. Hold the lancet between the thumb and forefinger.
8. Grasp the patient’s finger firmly with other hand.
9. Firmly place the lancet to the finger and prick the finger.
10. Wipe off the first droplet of blood with a sterile gauze or cotton ball.
11. Allow drop of blood to form. If blood flow is inadequate, gently massage the proximal portion of the finger and then press firmly on the distal joint of the finger.
12. A well-beaded drop of blood should form at the puncture site.
13. Absorb the blood drop with the test strip or capillary tube. Ensure that there is adequate blood sample.
14. Hold firm pressure of puncture site with a 2x2 gauze until bleeding stops.
15. Activate safety device and discard lancet in appropriate sharps container.
16. Follow manufacture’s directions to run test as appropriate.
17. Apply self-adhesive dressing to puncture site if needed.
18. Discard soiled supplies in appropriate containers.

AFTER CARE:
1. Document in patient’s record:
   a. Procedure and observations.
   b. Blood samples drawn.
   c. Appearance of puncture site.
   d. Results of test, as appropriate
   e. Patient’s response to procedure.
   f. Instructions given to patient/caregiver.
PURPOSE:
To provide guidance for obtaining and/or transporting lab specimens in order to minimize staff exposure to bloodborne and other pathogens. To provide guidance for accurate completion of lab requisition forms.

CONSIDERATIONS:
1. Follow appropriate procedures for specimen procurement.
2. Specimen is obtained using caution to avoid accidental exposure through spills, spatters, sprays or needle sticks. Spills should be cleaned up promptly. (See Handling of Blood and Body Fluid Spill.)
3. Attention should be paid to changes in temperature that may affect transportation of specimens and follow individual laboratory recommendations.
4. Individual labs may have specific requirements for requisition requests.

EQUIPMENT:
None

PROCEDURE:
1. Adhere to Standard Precautions.
2. Blood and other specimens are:
   a. Labeled with patient’s name, patient’s address, date of birth (DOB), and date and time of specimen collection.
   b. If the outside of the specimen container is visibly contaminated with blood or body fluids, clean with a disinfectant, i.e., 5.25% sodium hypochlorite (household bleach), diluted 1:10 water (1 part bleach with 9 parts water) or 70% to 90% isopropyl alcohol. Disinfectant is to be in contact with container at least two minutes or an outer bag should be used.
   c. Place specimen in specimen bag.
   d. Place in an impervious, leak-proof container, e.g., cooler. Use ice pack to maintain consistent temperature per laboratory recommendations.
   e. Container must be labeled with biohazard label or be red in color.
   f. If a specimen could puncture the primary container, it must be placed in a secondary puncture-proof, labeled or red container for transport.
   g. Delivered to the lab or left for courier for transport per agency policy.

AFTER CARE:
1. Document in patient's record according to agency policy.
2. Complete lab requisition per laboratory policy with complete patient information including, but not limited to:
   a. Patient Name.
   b. Patient Address.
   c. DOB.
   d. Ordering Physician.
   e. Insurance information.
   f. Diagnosis. Make sure it is appropriate for the labs being drawn.
   g. Ordered test.
   h. Date, time, and initial of clinician collecting specimen.
Strength of Evidence Level: 3

PURPOSE:
To monitor PT/INR levels for the management of anticoagulation therapy.

PT/INR (Prothrombin Time/International Normalized Ratio) Testing will be performed using the CoaguChek XS Monitoring System by a qualified clinician who has completed training and performance evaluation.

TRAINING:
Training will be all inclusive from specimen collection through to test reporting. Each person using the system will be trained and will demonstrate competency before performing any tests. Ongoing competency will be demonstrated annually thereafter. All training and competency evaluation will be documented.

SAFETY:
As a result of performing this procedure, exposure to blood/body fluids may occur. Protective barriers recommended include: hand hygiene, gloves, waste disposal. Other barriers should be used as necessary.

EQUIPMENT AND SUPPLIES:
CoaguChek XS meter.
CoaguChek XS Test Strips (at room temperature). Check expiration date.
Alcohol wipes and gauze.
21-23 gauge safety lancet.
Microsafe blood collection tube (optional). Non-sterile gloves.
Sharps container.

PROCEDURE PT/INR TESTING:
A. Obtain and verify physician order.
B. Gather supplies (see section: Equipment and Supplies)
C. Review manufacturer’s instructions for test procedure if necessary.
D. Identify patient.
E. Explain procedure to patient.
F. Perform hand hygiene. Put on gloves.
G. Follow standard precautions.
H. Prepare PT/INR meter following the manufacturer’s instructions.

- Make sure that the three number code on the test strip container matches the three-number code on the code chip. If opening a new box of test strips you will need to replace the code chip: With the meter powered off, remove the old code strip and throw it away. Slide the new code chip into the code chip slot until it snaps into place. (Each new box of test strips contains 2 bottles of strips and 1 coordinating code chip.)

I. Perform the test following the manufacturer’s instructions.

a. Remove a test strip from its container and immediately re-cap the container. The blood sample must be applied to the test strip within 10 minutes of removing the test strip from the container.

b. Turn the meter on by inserting the test strip into the CoaguChek XS machine; slide strip in the direction of the arrows. Display will light.

c. Match the code on the display to the code on the test strip container. Then PRESS “M” to confirm the match.

- An hour glass appears indicating warm up for 30 seconds followed by a flashing test strip. The meter will begin to count down.

d. You have 180 seconds to apply blood to the test strip.

e. Stick the side of finger with a lancet. Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard. The minimum sample size is 8 µL of whole blood and must be applied to the test strip within 15 seconds of fingerstick.

- You may apply blood to the top or the side of the test strip. When enough blood is sampled the meter will beep. Do not add more blood to the test strip.

f. Apply pressure to puncture site with gauze.
J. Read test results and record results and/or any error message record on log sheet.
   a. If error message appears, refer to CoaguChek XS Users’ Guide for appropriate action.
   b. If value <0.8 or >8 appears, repeat test.
   c. If value <0.8 or >8 appears a second time, contact physician.
K. Discard test strip and other materials as appropriate.
L. Perform hand hygiene.
M. Notify physician for dosage adjustments and results outside of the patient’s therapeutic range.
   Document results on CoaguChek XS log and in the patient’s medical record per “Process for CoaguChek XS Meter Log”.

QUALITY CONTROL:
- Quality control (QC) is important to ensure the user’s technique, integrity of the test strip and performance of the system. The meter immediately performs the Quality Control (QC) test. As it runs, the letters QC flash on the meter’s display.
- When the QC test is successful, a checkmark will appear. Then the meter continues to run the blood test.
- If the QC test fails, the meter displays the word “error” and “QC”. This indicates that the test strip failed the internal quality control check and is unusable. Power the meter off, remove and discard the test strip. Repeat the test using a new test strip and blood taken from a new fingerstick on a different finger.
- If the monitor continues to give error messages call Roche diagnostics technical service center 1-800-428-4674. If the issue cannot be resolved, perform a venous draw and send the sample to the lab.

MAINTENANCE/METER CLEANING:
CoaguChek XS housing should be cleaned in between patient use and when visibly soiled. Test strip guide should be cleansed when visibly soiled and prior to being returned to the clinician’s bag at end of day. Follow the procedures below to clean and disinfect the meter. Failure to follow these procedures may cause malfunction of the meter.
- Do not use sprays of any sort.
- Ensure that swab or cloth is only damp, not wet.

Cleaning/disinfecting the meter housing (the exterior of the meter)
- Use only 70% isopropyl alcohol or 10% bleach solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)
- Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.
- With the meter powered off, wipe the meter’s exterior clean.
- Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
- With a lint-free tissue, dry the meter.
- Wipe away residual moisture and fluids after cleaning the housing.
- Allow wiped areas to dry for at least 10 minutes before performing a test.

Cleaning/disinfecting the meter test strip guide slot
- Use only 70% isopropyl alcohol or 10% bleach solution.
  1. With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.
  2. To clean the test strip guide:
     • Hold the meter upright with the test strip guide facing down
     • Clean the easily accessible areas with a cotton swab.
     • Ensure the swab is only damp, not wet.
     • Apply cleaning agent for a contact time of >1 minute
  3. Wipe away residual moisture and fluids. Let the inside of the test strip guide dry for at least 10 minutes.
  4. Close the test strip guide cover and make sure it snaps into place.
Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.

LIMITATIONS OF THE PROCEDURE:
A. The drop of blood must be a minimum of 8uL.
B. This system should only be used with fresh capillary whole blood or non-anticoagulated venous whole blood.
C. Meter must be kept level while running the test.
D. Test strips may be use until the last day of the expiration month.
Strength of Evidence Level: 3

PURPOSE:
To obtain a sample from oropharynx for diagnostic purposes.

CONSIDERATIONS:
1. This procedure must be performed carefully in order to avoid stimulation of the patient's gag reflex.
2. Requires physician order.

EQUIPMENT:
Tongue blade
Flashlight
Currette®
Impervious bag
Personal protective equipment, as indicated

PROCEDURE:
1. Adhere to Standard Precautions.
2. Explain procedure to patient.
3. Position patient in semi-Fowler's or Fowler's position with head well supported and slightly tilted back.
4. Instruct patient to open mouth. Press down firmly on the midpoint of the arched tongue with tongue blade so that oropharynx is visualized.
5. With flashlight, inspect the oral and pharyngeal mucosa in order to identify the area to be cultured.
6. Gently and quickly, swab the tonsillar area side to side, making contact with inflamed or purulent sites. Carefully withdraw swab without striking other oral structures.
7. Return swab to tube as specified in manufacturer's instructions.
8. Label specimen with patient's name, address and date and site of collection.
9. Discard soiled supplies in appropriate containers.

AFTER CARE:
1. Return patient to position of comfort.
2. Complete Lab Requisition. (See Laboratory, Specimens & Venipuncture- Obtaining and Transporting and Requisition Documentation) and transport specimen per agency policy.
3. Document in patient's record:
   a. Appearance of oropharynx.
   b. Date and time of procedure.
   c. Patient's response to procedure.
   d. Lab where specimen was delivered.
PURPOSE:
To obtain blood specimen for diagnostic analysis using a vacutainer system.

CONSIDERATIONS:
1. Patient preparation is important for successful venipuncture, especially with difficult sticks. Taking the time to prepare patient will enhance the outcome. Consider the following:
   a. Instruct patient to hydrate prior to venipuncture.
   b. If able prior to venipuncture, have patient take a hot bath or shower or apply heat to the area for about 5–10 minutes to dilate the veins.
   c. Keep extremities warm prior to venipuncture, e.g., wear a long sleeve sweater, if air conditioner is on.
   d. Place extremity in a dependent position.
2. Position patient comfortably in bed with arms resting at sides or upright in chair with arm supported on armrest or table. 
   [Note: Position yourself comfortably also, sit or stand so that you have adequate lighting and access to the vein.]
3. Determine if patient is allergic to anything that may be placed on the skin, such as latex, iodine or adhesive.
4. Obtain needed equipment, supplies and tubes prior to venipuncture. Have a least two tubes of each kind that you will need.
5. Avoid drawing blood from extremity used for intravenous (IV) infusion. If one must collect blood near an IV site, choose a location below it to prevent erroneous results.
6. Most common venipuncture sites are the antecubital fossa, median antecuital vein, cephalic vein and metacarpal veins.
7. Apply tourniquet 4-6 inches above the venipuncture site and have patient make a fist several times. 
   [Note: Depending on the vein dilation the tourniquet may need to be tighter. If there is too much dilation it may be loosened.]
8. If unable to find an adequate vein within 5 minutes, release the tourniquet to allow blood flow before reapplying the tourniquet.
9. No more than three attempts should be tried. If not successful, notify physician.
10. General order of sample collections:
   a. First: Blood culture tubes or vials.
   b. Second: Coagulation tube (e.g., blue-top tubes).
   c. Third: Serum tube with or without clot activator or gel (e.g., red, gold or speckle-top tubes).
   d. Fourth: Heparin tubes (e.g., green-top tubes).
   e. Fifth: EDTA tubes (e.g., lavender-top tubes).
   f. Sixth (Last): Oxalate/fluoride tubes (e.g., gray-top tubes).

EQUIPMENT:
Gloves
Tourniquet
Alcohol applicator (wipe/swab/disk/ampule)
Vacutainer tubes (color-coded)
Tube holder
Double-ended needle (gauge dependent on venous status) or butterfly needle
2x2 gauze sponge, sterile
Self-adhesive bandage
Tape
Puncture-proof container/Sharps container
Specimen bag

PROCEDURE:
1. Adhere to Standard Precautions/wash hands.
2. Explain the procedure and purpose to the patient/caregiver.
3. Assemble the equipment on a clean surface close to the patient.
4. Place patient in comfortable position, ensuring that site is accessible.
5. Screw double-ended needle into tube holder and slip vacutainer tube into holder but do not puncture rubber top.
6. Apply tourniquet above selected puncture site.
7. Don gloves.
8. Clean site with alcohol applicator. Allow to air dry.
9. Anchor vein by holding skin taut.
10. Remove needle cover and insert needle into vein at 15-30 degree angle with bevel facing up.
11. Gently push vacutainer tube into needle so the blood enters the tube. (It is important to hold needle and tube holder still to prevent perforating the vein.)
12. When blood starts to fill specimen tube, release tourniquet.
13. When tube is filled, gently pull back stabilizing tube holder and needle with one hand. For multiple samples, insert appropriate color-coded tube and repeat the procedure until all samples are obtained.
14. After specimens are obtained, release tourniquet, then place 2x2 gauze over puncture site and withdraw needle slowly. Needle should be removed at an angle nearly flush with the skin to prevent injury to the wall of the vein. Activate safety device (cover needle with protective shield.)
15. Apply firm pressure to area until bleeding stops.
16. Those tubes containing additives should be gently inverted 5-6 times to mix the sample thoroughly. DO NOT shake the tube.
17. Apply self-adhesive bandage to puncture site.
18. Remove gloves and wash hands.
19. Discard soiled supplies in appropriate containers.
20. Label tube with patient's name, date, time drawn.
AFTER CARE:

1. Complete Lab Requisition. (See Laboratory, Specimens and Venipuncture - Obtaining and Transporting and Requisition Documentation)

2. Document in patient's record:
   a. Procedure and observations.
   b. Blood samples drawn, identity and location of laboratory where specimens taken.
   c. Appearance of venipuncture site.
   d. Patient's response to procedure.
   e. Instructions given to patient/caregiver.