





Helping Clinicians Make Better Decisions

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Purpose

To describe the correct procedure for accurate specimen collection, storage, packaging and shipping, and completion of requisitions and other documentation necessary for timely and accurate testing of patient samples.

Scope

Applies to all specimens and specimen types collected by Aegis Sciences Specimen Collectors.

Associated Documents

- 1. Laboratory Requisition Form
- 2. Aegis Insurance Information Form
- 3. Specimen Tracking Form
- 4. Hazardous Materials Packaging and Shipping SOP
- 5. Bloodborne Pathogens and Biosafety Manual

Responsibilities

Aegis Specimen Collectors are responsible for:

- 1. Adhering to all steps in this SOP
- 2. Documenting any deviations from the SOP
- 3. Adhering to all Aegis safety requirements

Materials

- 1. PPE: Disposable medical gloves, lab coat, safety glasses
- 2. Blood Collection Package includes everything needed to collect clinical chemistry blood samples
- 3. Biological sharps waste container, if applicable
- 4. Centrifuge, if applicable
- 5. Laboratory Request Form
- 6. Specimen bag with absorbent pad
- 7. Shipping containers

Procedure Instructions

For every successful collection procedure:

- 1. Have a professional and courteous manner in all contact with the patient.
- 2. Positively identify the patient.
- 3. Wash and dry your hands.

Blood – Clinical Labs

Please note: You must be a trained Phlebotomist to perform a blood collection.

- 1. Obtain and complete the applicable Laboratory Request form (instructions are included in Appendix I). It is crucial to record the date and time of collection.
 - 1.1. Write the donor's name and date of birth on the adhesive Label and Requisition Form.
 - 1.2. Enter remaining requisition data.
 - 1.3. Verify with the donor their name and date of birth.
- 2. Check the blood collection tube(s) and straight needle (21 gauge) to ensure the expiration date has not been exceeded.
 - 2.1. See Appendix IV for order of draw for the different blood tube types.
 - 2.2. See Appendix VI for Clinical Labs tests offered at Aegis Sciences Corporation by test tube type.
 - 2.3. Do not use expired tubes otherwise the vacuum may not be sufficient to draw an adequate sample.
 - a. Order more supplies.
 - b. Discard expired tubes.
- 3. Wash hands with soap and water.
- 4. Put on a new pair of medical gloves.
- 5. Ask the following three questions before touching the patient:
 - 5.1. Does the patient have a sensitivity and/or allergy to latex?
 - a. Use latex-free gloves and tourniquet if answer is yes.
 - 5.2. Does the patient have a history of fainting during blood collection?
 - a. If the patient does have a history of fainting, then the patient should be asked to lie down for the blood to be drawn.
 - 5.3. Ask the patient if they have a preference of site based on previous phlebotomy experience. Has the patient had an arm shunt, mastectomy or lymphedema?
 - a. If the patient has had an arm shunt, mastectomy or lymphedema then blood should be drawn from the other arm.
- 6. Assemble the appropriate needle for collection.
- 7. Ask patient to sit in a comfortable position with their arm extended.
- 8. Explain each procedure so the patient is informed and understands what is about to take place.
- 9. Select the vein for venipuncture:
 - 9.1. First inspect the area you plan to use. Avoid areas with scar tissue, burns, or visible trauma.
 - 9.2. Apply the tourniquet about midway between elbow and shoulder (4-5 finger widths above the site) and have the patient clench his or her hand. The tourniquet must be applied with enough tension to compress the vein, but not the artery.
 - 9.3. It may be necessary to release the tourniquet for a few seconds and reapply; prolonged obstruction of blood flow by the tourniquet may affect test results.
 - Tourniquet application should not be placed for an extended period of time (no longer than 1-2 9.4. minutes); if mottling occurs release the tourniquet, cease blood collection and allow blood flow to
 - 9.5. Always palpate or feel for the vein even when the vein can be seen. This gives you practice in finding deeper, unseen veins. The vein will feel like an elastic tube that gives under pressure. Arteries pulsate, so make certain the structure you feel is not pulsating. If a vein is difficult to find, ask the patient to extend their arm downward for a few minutes and if appropriate, offer them water to drink (not allowed if there is an NPO comment).
 - 9.6. Attempt to locate the median cubical or cephalic veins on either arm before considering alternative veins. Due to the proximity of the basilic vein to the brachial artery and the median nerve, the basilic vein should only be considered if no other vein is more prominent.
- 10. Scrub the venipuncture site with an alcohol pad in a circular motion moving outward from the center.
- 11. Hold vein "fixed" or taut during the puncture.



- 12. Insert the needle with the bevel up at about a 25-degree angle with the skin.
- 13. Attach the appropriate blood collection tube to the housing, ensuring that tube has completed filling before removing. (Once tube has been removed from hub, Gently invert prior to placing next tube.)
 - 13.1. Gold-Top or Tiger Top SST tubes; Red-Top serum tubes Fill the tubes to capacity (1/2 to 3/4 full) since partial filling will result in higher serum concentration of tube additives, which are known to alter the results of some tests
 - a. Only one Tiger-Top SST tube is needed in order to complete the required tests.
 - b. Two Gold-Top SST tubes are needed in order to complete the required tests.
 - 13.2. Lavender-Top whole blood tubes Fill the tubes to capacity (1/2 to 3/4 full) since partial filling will result in distortions caused by the osmolality of the anticoagulant. Under-filled blood collection tubes will not be accepted for testing.
 - a. Only one Lavender-Top whole blood tube is needed in order the complete the required tests.
- 14. Release the tourniquet before removing the needle.
- 15. Remove needle from the vein. Handle needle with extreme care to avoid accidental exposure to bloodborne pathogens through needle stick.
- 16. Apply pressure with a dry gauze pad or a Band-Aid®.
- 17. Observe the site for hemostasis (complete clotting) before the site is bandaged in any way.
- 18. Discard tourniquet after each patient.
- 19. Invert the tube(s) back and forth according to the table in Appendix V.
 - 19.1. Gold-Top or Tiger-Top SST tubes; Red-Top serum tubes Failure to invert the tube the appropriate amount of times will result in incomplete clotting and incomplete separation of red cells from serum. Hemolysis of even a small number of red cells remaining above the gel in contact with serum will spuriously elevate results of tests, such as serum potassium and LDH.
 - 19.2. Whole blood lavender top tubes Incomplete mixing or delay in mixing after phlebotomy will result in microscopic partial clotting of the sample, which can cause spuriously low platelet counts.

20. Sample Centrifugation - Gold-Top or Tiger-Top SST tubes and Red-Top serum tubes ONLY:

- 20.1. Serum samples must be centrifuged following collection.
- 20.2. Do not remove the stopper at any time during centrifugation.
- 20.3. Do not centrifuge immediately after drawing blood.
- 20.4. Allow the blood to clot in an upright position for at least 30 minutes, but not longer than 1 hour before centrifugation.
- 20.5. Centrifuge for at least 10 minutes (horizontal) or 15 minutes (fixed-angle) at 1250 to 1600 RCF (relative centrifuge force) within 1 hour of collection.
 - a. Centrifuges supplied by Aegis produce between 1450 (fixed-angle rotor) and 1600 RCF (horizontal rotor) when operating within the instrument manufacturer's specifications. This equates to 3450 and 3380 +/- 50 RPM (revolutions per minute), respectively.
 - b. Always make certain the centrifuge is properly balanced. If you notice any unusual noises or shaking, stop the centrifuge immediately and confirm rotor is balanced.
 - c. Sample tubes must remain securely capped/closed while in the centrifuge. Sealed rotor heads and/or centrifuge safety cups can be used.
 - d. Ensure that the centrifuge comes to a complete stop before opening cover. Check for leaks/spills. If leak/spill is noticed, keep centrifuge cover closed for at least 30 minutes to reduce aerosolization of biological material. Follow spill, exposure, and incident reporting instructions.

21. Sample Transfer – Red-Top serum tubes ONLY

- 21.1. Transfer the clear Red-Top serum to a properly labeled transport vial and cap tightly.
 - a. Do NOT submit Red-Top serum tube to the laboratory; serum from the Red-Top tube must be transferred to a transport vial.
 - b. Only serum should be transferred; do not transfer cellular material.
- 21.2. Utilize safe work practices to prevent the production of aerosols such as:

- a. If using a transfer pipette, drain pipette with tip against the inner wall of the tube. Never forcibly expel any serum from the pipette.
- b. Utilize a Biological Safety Cabinet, if available.
- 21.3. Attach the label from the Test Requisition, if applicable.
- 22. Dispose of needle(s) directly into a puncture-resistant sharps container.
- 23. If applicable, properly clean up any blood spill/droplets with bleach or equivalent disinfectant (not to be used on patient).
- 24. Remove disposable gloves and discard according to your facility's waste protocol.
- 25. Wash hands with soap and water.
- 26. Make certain each specimen is clearly labeled and the top(s) are securely closed.
- 27. Clinical Labs specimens should be stored refrigerated until time of packaging and/or shipment
 - 27.1. Specimens should be packaged for shipment as close to pickup as possible.
 - 27.2. DO NOT FREEZE Clinical Labs specimens.
- 28. Specimen Shipment
 - 28.1. Place the closed collection tubes into the specimen bag with the absorbent pad.
 - 28.2. Fold and place the completed Laboratory Request Form along with a copy of the donor's insurance card in the back pouch of the Aegis specimen bag.
 - a. If the patient does not have an insurance card, you must obtain and verify their social security number and document it in the demographics section of the Laboratory Request Form.
 - b. It is important that the specimen and pad be in one compartment and the paperwork in the other to avoid contamination of the requisition in the event of specimen leakage.
 - 28.3. Seal the bag using the zip-top closure.
 - 28.4. Immediately place the sealed specimen bag into the proper shipping container.
 - 28.5. Clinical Labs specimens must be shipped with an ice pack in an insultote.
 - a. Ice packs should be frozen flat for at least 24 hours prior to shipping.
 - b. To ensure freezing, do not store ice packs stacked in the freezer.
 - c. To ensure freezing, do not store ice packs stacked in the freezer.
 - 28.6. Ship to the laboratory using the pre-printed FedEx/UPS label provided by Aegis.
 - a. When possible, specimens should be shipped the **same day** as collection to be received by the laboratory within 24 hours of collection.
 - b. Samples not shipped same day should be shipped as soon as possible. Keep samples refrigerated until transport time; **DO NOT FREEZE.**
- 29. Difficulties in Drawing Specimen:
 - 291. Precautions:
 - a. Hematoma (bruising) if a hematoma develops, apply a pressure bandage and elevate the arm. If a sever hematoma occurs, another specimen should be collected. Hemolysis may be present.
 - b. If enough blood is not obtained from the first puncture, the opposite arm or another vein in the hand may be examined. If the second try is also unsuccessful, do not try again.
 - c. Ask the practitioner if an alternative specimen may be collected.
 - 29.2. Adverse Reactions
 - a. If the patient experiences any adverse reactions during a blood collection, please seek medical assistance immediately and document with an incident report.

References

None



Appendix I – Paper Requisition Instructions

Diagnosis Code(s)

NOTE: All requisitions must have a valid ICD-10 code provided by the physician to support the medical necessity of the order. Diagnosis codes are 3-7 characters (e.g., M79.604). The first digit is alpha, 2nd and 3rd are numeric, and 4-7 can be alpha and/or numeric.

- 1. Codes beginning with a numeric digit are not valid. All diagnosis codes must begin with a letter
- 2. V58.69 is not a valid code

Billing/Insurance

Obtain insurance information and ALWAYS validate the information with the patient. Mark the appropriate check box on the Laboratory Request Form.

If Worker's Comp, Letter of Protection (LOP), or Auto:

Completely fill out the Aegis Insurance Information Form and make a copy of the applicable Letter of Protection (LOP), the front and back of the auto insurance card and the patient's health insurance card and send in with the specimen.

Patient Information

Patient Demographics

Fill in patients complete Social Security Number, First Name, Middle Initial, Last Name, Sex, Date of Birth, Address, City, State, Zip Code and Phone Number

Patient Signature

Ask the patient to verify their information and get their signature

Collection Information

Collector's Initials

Legibly write your initials in the box.

Date Collected

This is the Date of Service (DOS).

Test Information

Select the test(s) requested by the provider.

Provider Information

Provider Name

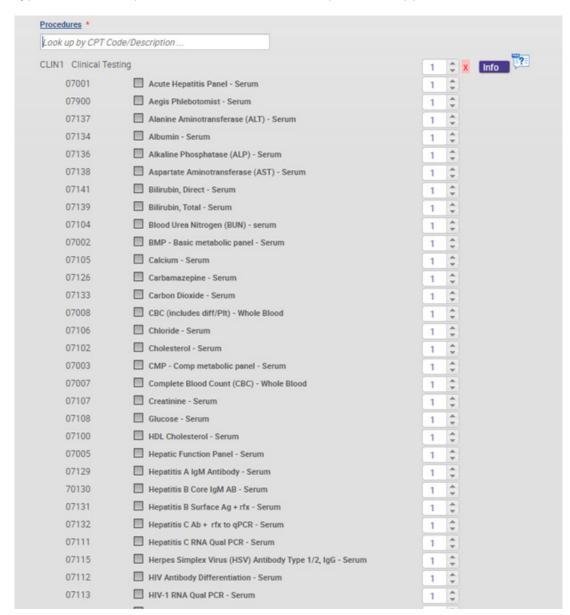
Select or legibly write the appropriate requesting provided (Choose only one).

Provider Signature

Obtain the physician's signature.

Order Manager Instructions

Type "CLIN" in the procedures field and a list of options will appear:



Appendix II – Packaging and Shipping Samples

At the end of the business day, package all secured specimens for shipment. Select the appropriate container based on the number of specimens. Schedule pickup by calling Client Services at 615-255-2400, option two.

Reference the Hazardous Materials Packaging and Shipping SOP. Shipping must comply with IATA and DOT shipping regulations.

FedEx Medium Shipping Box





Appendix III – Clinical Labs Tests Offered at Aegis Sciences Corporation by Test Tube Type *Clinical Labs Tests Turn-Around-Time (TAT) is 24 hours

TESTING TUBES:



Gold Top

(Two Required for Testing)

or



Tiger Top (One Required for Testing)

TUBE TYPE: SST with Gel

ADDITIVES: Contains Separating Gel and Clot Activator

Stable 72 hours from date of collection

TESTING AVAILABLE:

Acute Hepatitis Panel

- Hepatitis A IgM AB
- Hepatitis B Core IgM, AB
- Hepatitis B Surface (HBs) AG w/ Reflex to HBs AG Confirm
- Hepatitis C Antibody w/ Reflex to Hep C RNA Qual PCR

Basic Metabolic Profile (BMP)

- Glucose
- Calcium
- Sodium
- Potassium
- Carbon Dioxide
- Chloride
- Blood Urea Nitrogen
- Creatinine

Comprehensive Metabolic Profile (CMP) BMP + the following:

- Albumin
- **Total Protein**
- Alkaline Phosphatase (ALP)
- Aspartate Aminotransferase (AST)
- Alanine Aminotransferase (ALT)
- Bilirubin, Total

Renal Function Panel BMP + the following:

- Albumin
- Phosphorus

Hepatic Function Panel

- Albumin
- **Total Protein**
- Alkaline Phosphatase (ALP)
- Alanine Aminotransferase (ALT)
- Aspartate Aminotransferase (AST)
- Bilirubin, Direct
- Bilirubin, Total

Lipid Panel (Standard)

- HDL Cholesterol
- · LDL Cholesterol Calculated
- Cholesterol
- · Triglycerides

Other Add-on Tests Available

- · General Chemistry:
 - Alanine Aminotransferase (ALT)
 - Albumin
 - Alkaline Phosphatase (ALP)
 - Aspartate Aminotransferase (AST)
 - Bilirubin, Direct
 - · Bilirubin, Total
 - Blood Urea Nitrogen
 - Calcium
 - · Chloride
 - Creatinine
 - Folate (Folic Acid) Glucose
 - Human Chorionic Gonadotropin (HCG)
 - Magnesium

Other Add-on Tests Available (Cont.)

- Phosphorus
- Potassium
- Prolactin
- Prostate-Specific Antigen (PSA), Total
- Prostate-Specific Antigen (PSA), Total w/ Reflex to PSA, Free
- Sodium
- · Total Protein
- Vitamin B12
- · Vitamin D, 25-Hydroxy

· Lipids:

- Cholesterol
- · HDL Cholesterol
- Triglycerides
- · Infectious Disease:
 - · Hepatitis A IgM AB Hepatitis B Core IgM, AB
 - Hepatitis B Core Antigen (HBC) Total AB (Anti-HBC)
 - Hepatitis B Surface (HBS) AB (Anti-HBS)
 - · Hepatitis B Surface (HBs) AG w/ Reflex to HBs AG Confirm
 - Hepatitis C Antibody w/ Reflex to Hep C RNA Qual PCR
 - Hepatitis C RNA Qual PCR
 - HIV 1/2 AG-AB, 4th w/ Reflex
 - · HIV-1 RNA Qual PCR
 - HIV-1 and HIV-2 AB Confirm/ Differentiation HSV Antibody Type
 - Syphilis Antibody (IgG/IgM) w/ Reflex
- · Opioid Induced Endocrinopathy:
 - · Testosterone, Total
- · Thyroid:
 - Triiodothyronine (T3), Free
 - · Thyroxine (T4), Free

Post Collection Procedure (Refer to Clinical Labs Blood Collection Instructions for Additional Details)

- · Invert tube 5 times
- · Allow blood to clot in an upright position for 30 - 60 min (Do not exceed 1 hour)
- · Centrifuge for at least 10 minutes (horizontal) or 15 minutes (fixed-angle) at 1250 to 1600 RCF (relative centrifuge force) within 1 hour of collection
- · All samples should be stored refrigerated prior to being shipped



TESTING TUBE:



Red Top with Transfer Tube

TUBE TYPE: Serum

ADDITIVES: None

Stable 72 hours from date of collection

TESTING AVAILABLE:

Therapeutic Drug Monitoring

- Carbamazepine
- Lithium
- · Valproic Acid, total

Post Collection Procedure

(Refer to Clinical Labs Blood Collection Instructions for Additional Details)

- Invert tube 5 times
- Allow blood to clot in an upright position for 30 60 min (Do not exceed 1 hour)
- Centrifuge for at least 10 minutes (horizontal) or 15 minutes (fixed-angle) at 1250 to 1600 RCF (relative centrifuge force) within 1 hour of collection
- Transfer the clear Red-Top serum using a disposable pipette to a properly labeled transport vial and cap tightly
 - Do NOT submit Red-Top serum tube to the laboratory; serum from the Red-Top tube must be transferred to a transport vial
 - · Only serum should be transferred; do not transfer cellular material
- · All samples should be stored refrigerated prior to being shipped.

TESTING TUBE:



Lavender Top

TUBE TYPE: EDTA

ADDITIVES: EDTA (Anti-Coagulant)

Stable 48 hours from date of collection

TESTING AVAILABLE:

Hematology:

- Complete Blood Count (CBC)
- Complete Blood Count (CBC) w/ Differential
- Hemoglobin A1C

Post Collection Procedure

(Refer to Clinical Labs Blood Collection Instructions for Additional Details)

- Invert tube 8-10 times
- · All samples should be stored refrigerated prior to being shipped

