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Guidelines for Specimen Acceptability

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Adopted on 10/14/22 by Laboratory Director Dr. J.Mills Barbeau JMBarbeau MD

Annual Review:

Reviewed by Medical Director	Date	Reviewed by Medical Director	Date
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evisions:

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Clinical Significance:

Many variables including anti-coagulant volume and concentration, type of tube additive, duration and temperature of specimen storage, centrifugation affect coagulation testing. The reliability and accuracy of patient test results depnds up a variety of parameters..

The purpose of this procedure is to ensure that the integrity specimens for coagulation tests is maintained for all testing and at all times. The technologist on duty is responsible for the appropriate processing, preparation and identification, testing and storage of the specimen in the coagulation lab.

Specimen:

- **Coagulation tests (plasma) and Platelet Function testing (whole blood):** 3.2 % Sodium Citrate (0.105M) collected in a ratio of 1 part anticoagulant to 9 parts blood.

  Blue top tube: the ratio of anticoagulant to blood is essential for accurate testing. To process specimens with high hematocrit (56 % or greater), see procedure "Adjusting Specimens with High Hematocrit" for special instructions.

- **IgG specific Heparin Induced Thrombocytopenic Antibody (HITA) test:**
  - Effective June 2020: White cap tube is no longer acceptable.
  - 3.2% Sodum Citrate (0.105M) collected in ratio of 1 part anticoagulant to 9 parts blood. Centrifuge 20 minutes/3500 rpm, freeze plasma -80C. Thaw plasma 37 C waterbath/5 minutes prior to assay.

Specimen Acceptability:

1. **Acceptable Specimen:** A specimen is acceptable for coagulation processing when it meets the requirements for:
- **Volume**: Filled to +/- 10% of maximum fill
- **Hematocrit** does not exceed 56 %,
- **Stability:** less than 4 hours old* Exceptions: Ddimer and PT
- Ddimer, Prothrombin time (PT) are stable for 24 hrs at room temperature
- **Not Clotted**: Sodium Citrate tubes should not be clotted

2. **No Hemolysis: PFA, Verify Now Aspirin (ASAEF), Clopidogrel (CLEFF)**
3. Complete specimen identification information..
   - Patient's full name,
   - Patient's date of birth/hospital identification number
   - Initials of phlebotomist.

Unacceptable Specimens:

Specimens which are those specimens that are clotted, QNS (quantity not sufficient) have a hematocrit that is greater than or equal to 56%, are more than 4 hours old, (24 hrs for PT, and Ddimer) are improperly filled.

Specimens that do not have complete specimen identification information and **cannot be processed and must be redrawn**. Notify the unit and record in the LIS with the appropriate footnote:

- Quantity Not Sufficient,
- Clotted
- High Hematocrit >55%
- Too Old
- Overfilled
- Improper Identification
- **Hemolyzed, Icteric, Lipemic specimens**
  PT, PTT, Fibrinogen, AXA testing may be performed in the presence of varying degrees of hemolysis icterus and lipemia. Gross hemolysis, bilirubin or lipemia may interfere with clot detection by the ACL TOP. Interference from these substances will be accompanied by error codes/flags, that may prevent or interfere with result determination. Testing may be performed on alternate instrument to obtain results.

2. **Unacceptable Specimen Identification:** A specimen is unacceptable for testing when:
   - Specimen is not labeled with phelobotomist's initials
   - Patient identification is insufficient, and/or questionable; Patient medical record number, Date of Birth, specimen order required
   - Time and/or date of specimen collection cannot be verified to ensure that age of the specimen falls within laboratory guidelines

   a. If the specimen does not match the patient identity/date/time of collection on barcode label, the specimen cannot be processed. A new specimen must be collected.

   Examples of unacceptable identification are:
   - Specimen has two labels, each with a different name.
   - Specimen barcode label with incorrect date.
   - Unit notifies laboratory specimen collected on wrong patient.
   - Phlebotomist initials are absent from specimen label.

   b. Verification of specimen identification by phone or in person is not sufficient.

   c. Report as "Not Performed" in the LIS and include a comment footnote to describe the reason that the specimen cannot be processed.

3. **Lipemic, Icteric Specimens**
   - Specimens that are lipemic or icteric can be processed the analyzers.
   - Highly unusual/unacceptable results for lipemic, icteric specimens will be accompanied by error codes/flags indicating that accurate results could not be determined.
   - Record results as ".See Note" with comment "Unable to obtain reproducible results". Lipemic specimens may be centrifuged to remove lipemia. See PT, PTT procedures for detailed instructions.

4. **Sample Volume Requirements:**
   4.5 ml blood blue top/Na citrate vacutainer
   3.2 ml blood blue top/Na citrate vacutainer
   2.7 ml blood blue top/Na citrate vacutainer
   1.8ml blood blue top/Na citrate vacutainer
   See Procedure: Guidelines for Specimen Volume Acceptability.

Transportation:

1. PT, PTT Fibrinogen, Ddimer Anti-Xa, Special Coagulation Testing (With the exception of platelet function testing PFA, VerifyNow): Transport as soon as possible, on ice. Frozen specimens should be transported on dry ice, and must remain frozen during transport, and arrive in frozen state at our laboratory.

2. Specimens collected in 3.2% Na citrate should be no more than 4 hours old for all testing and no more than 24 hours old for Prothrombin Time (PT) and Ddimer.

3. Whole blood specimens for Platelet Function Testing (PFA100, Verify Now, Platelet Aggregation Studies) should be transported/stored at room temperature. Specimens should not be transported in a container with cold packs; specimens shipped in this manner are unacceptable for testing . Stability is 4 hours at room temperature from time of collection.

Centrifugation:

Upon receipt in the laboratory, centrifugation of specimens for routine and special coagulation (plasma) testing should occur as soon as possible, preferably within one hour of specimen collection.

1. All routine/stat specimens are processed immediately and centrifuged according to procedure "Guidelines for Specimen Acceptability, Sample Collection & Preparation" :

2. Routine Specimens Platelet poor plasma (<10,000 platelets/ul) is prepared in this manner and is acceptable for routine testing: PT, PTT, Fibrinogen, Ddimer, Anti-Xa

Routine Testing Specimens: Platelet poor plasma <10,000 plts/ul

- Beckman Allegra 10 minutes at 3500 rpm
- AccuSpin 8C centrifuge 10 minutes at 3500 rpm
- Stat Spin Express 3: 3 minutes/7200 rpm
- Stat Spin Express 3: 5 minutes/5600 rpm
- DASH Apex 12 centrifuges, 5 minutes at 5200rpm.

Processing Time:

1. All routine specimens are to be processed as soon as possible upon receipt in the laboratory and within the acceptable stability period from specimen collection time.

2. STAT specimens are to be processed as soon as possible, within 1 hour of being received by the laboratory.

3. Specimens for special studies are to be prepared and frozen at -70 degrees C or below, for later testing. Specimens are centrifuged/frozen as soon as specimens are received in the laboratory.

Frozen Specimen:

Platelet free plasma <5000 platelets/ul is suitable for freezing and for all plasma based tests.

Storage

Storage of acceptable specimens after completion of testing and any unacceptable/rejected specimens, is accomplished by electron tracking and storage at room temperature. Specimens are discarded as biohazard waste after 24 hours.

Disposal:

Universal Precautions and Hazardous Waste Procedures are to be followed. Dispose of all samples in biohazard container.

Reference:

Clinical and Laboratory Scientific Institute Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Based Assays, Approved Guideline CSLI Document H21-45, (2008)