

LabNotes[†]

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Managing Preanalytical Variability in Hematology

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Controlling the preanalytical variability in hematology testing is a critical factor for ensuring accurate results. Preanalytical factors such as specimen collection, specimen handling, interfering substances and patient factors are common causes of inaccurate test results. Improper specimen collection and processing can influence the outcome of analytical results. By minimizing errors at any step in the preanalytical phase, a laboratory can improve the quality of analytical results, reduce the number of re-collected specimens, and improve turnaround time and patient management.

Collecting a Quality Specimen

An accurate result starts with a quality specimen. Proper patient identification is critical. Test forms should be compared to the inpatient's wrist bracelet or verbally confirmed with the outpatient. Venipuncture or skin puncture may be used based on the patient's physical condition and the amount of blood required for analysis. Selection of the appropriate blood collection system should be based on the patient's physical condition. The evacuated blood collection system is preferred

over the needle and syringe since it is a safer method to use and provides a better quality blood specimen. In addition, winged blood collection sets may be used to aid the phlebotomist with the more challenging collections.

The preferred sites for venipuncture are the larger median cubital and cephalic veins of the arm or the dorsal wrist and hand veins. The site should be cleansed with 70% isopropyl or ethyl alcohol and allowed to air dry to ensure proper disinfection. Air-drying

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Photo courtesy of Beckman Coulter, Inc. Brea, CA

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LabNotes



From The Editor

In this issue of LabNotes we focus on Hematology. Understanding the effects of inappropriate collection, handling and processing of hematology specimens is crucial for accurate results. Our feature article addresses common preanalytical variables seen in Hematology and gives advice on how to overcome them.

There has recently been some confusion in the clinical laboratory community regarding OSHA's position on the reuse of tube holders. In October 2003, OSHA posted a Safety and Health Information Bulletin (SHIB) clarifying its original position on this issue. The SHIB restates the fact that removing a contaminated needle from a tube holder is prohibited. Using a Question and Answer format, the Best Practice section takes you through all the relevant information you need in order to understand this OSHA requirement.

Lastly, we would like to take the opportunity to salute all medical laboratory professionals as we celebrate National Medical Laboratory Week, April 18-24, 2004. This is a good time to remind the medical community and the public about the critical role laboratorians play in every aspect of healthcare.

We hope you enjoy this issue of LabNotes. Thank you for all your valuable comments. We appreciate your feedback as always.

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LabNotes is published by BD Diagnostics-Preanalytical Systems, Franklin Lakes, NJ, providing the laboratory community with laboratory products, including the BD Vacutainer® Brand System, the BD Unopette™ Brand System, BD Microtainer® Brand Tubes, BD Vacutainer® Safety-Lok™ Needle Holder, BD Vacutainer® Safety-Lok™ Blood Collection Set, BD Vacutainer® Needle Disposal Container, BD Vacutainer® Eclipse™ Blood Collection Needle, BD Microtainer® Quikheel™ Lancet, BD Microtainer® Genie™ Lancet, and BD Vacutainer® Blood Collection Tubes.

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will also help prevent hemolysis and prevent burning sensations during phlebotomy. If a tourniquet is used, it should be released within one minute of tying. Venipuncture should be performed with the patient's arm in the downward position with the needle in the bevel-up position. Tubes should be mixed as per the manufacturers' recommendation immediately after they are filled. After blood is drawn, the needle is removed and pressure is applied to the puncture site. The needle is then disposed of according to the facility's protocol.¹

Skin puncture is performed on newborn heels, and fingers of adults and children when a venipuncture is not otherwise advisable. There are numerous lancet designs including puncture, incision, and laser devices. Skin puncture blood can be obtained from the palmar surface of the distal phalanx of older children and adult fingers, the lateral or medial plantar

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National Medical Laboratory Week



April 18-24, 2004

BD salutes all medical laboratory professionals as we celebrate National Medical Laboratory Week.

Plan a great Lab Week with your colleagues. Visit the ASCP website for your Planning Guide.

www.ascp.org

What is CAP?

www.cap.org

The **College of American Pathologists** (CAP) is a medical society serving more than 15,000 physician members and the laboratory community throughout the world. It is the world's largest association composed exclusively of pathologists and is considered a leader in providing laboratory quality improvement programs.

The College maintains a staff of almost 400 persons in its Northfield, Illinois headquarters and Division of Government and Professional Affairs in Washington D.C.

The CAP Laboratory Accreditation Program is widely recognized as the "gold standard" and has served as a model for various federal, state, and private laboratory accreditation programs throughout the world.

CAP also offers a Laboratory Management Index Program, a laboratory fiscal management tool.

For detailed information about CAP, visit their website at www.cap.org. The site also includes the following: CAP history, CAP directory, Staff/Job Openings, Committees, Calendar, Membership Application, Technical Environment, FAQs, and more. You can also link to the CAP website through www.bd.com/vacutainer via to the Technical Services web page.

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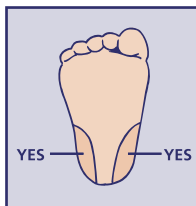
Advancing Excellence

As a service to our customers, BD can provide clinical documentation to help satisfy your laboratory's CAP checklist requirements. Contact BD Global Technical Services at 1-800-631-0174 for more details.

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surface of the infant heel and plantar surface of an infant's big toe.

The skin puncture site should be cleansed with isopropyl alcohol and allowed to air dry completely. The puncture device should be held flush against the



finger or heel prior to puncture. After the puncture, the first drop of blood should always be wiped away with a gauze pad. The first drop is most likely to contain excess tissue fluid that may cause clotting or sample dilution.

Blood films may be prepared from a drop of blood at the bedside or from a specimen collected in EDTA. For all other hematological tests, specimens should be anticoagulated with EDTA. When the tip of the microcollection device comes in contact with the second drop of blood, the drop will flow into

the tube by capillary action. Scraping of the skin with the collection device should be avoided, since it may initiate clotting. Gentle tapping of the tube may facilitate the flow of the blood into the tube. Tubes should be capped and immediately mixed by complete inversion according to the manufacturer's recommendations.

Order of Draw

The correct order of draw should be followed to eliminate the risk of additive cross-contamination during venipuncture and to reduce the risk of clotting in the EDTA or other anticoagulant microcollection tubes. For venipuncture procedures using plastic or glass tubes, the recommended order of draw is blood cultures, sodium citrate tubes, serum tubes with or without clot activator, with or without gel, heparin and heparin gel tubes, EDTA tubes and then fluoride tubes. When performing skin puncture

techniques, the order of draw differs from that of venipuncture. EDTA is drawn first to ensure adequate volume and accurate hematological results. Other additives are collected next and serum samples are last.³

EDTA

EDTA (ethylenediaminetetraacetic acid) is the anticoagulant used by the hematology laboratory because the cellular components and morphology of the blood cells are preserved. The EDTA salts (disodium, dipotassium, and tripotassium) are required to be used as the anticoagulant in blood collection tubes, as opposed to the free acid, which is not soluble in an aqueous media. EDTA anticoagulates blood by chelating calcium. Calcium is necessary in the coagulation cascade and its removal inhibits and stops a series of events, both intrinsic and extrinsic, which cause clotting. Dipotassium

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BEST PRACTICE: OSHA's Position on the Reuse of Blood Collection Tube Holders

On October 15, 2003, the Occupational Safety and Health Administration (OSHA) posted a Safety and Health Information Bulletin (SHIB) to clarify the OSHA position on reusing tube holders during blood collection procedures. The purpose of the SHIB was to reiterate OSHA's earlier statement that the best practice to prevent needle-stick injuries following phlebotomy procedures is the use of a sharp with engineered sharps injury protection (SESIP)(e.g. safety needle) attached to the blood tube holder and the immediate disposal of the entire unit after each patient's blood is drawn.

Q. What are the steps that need to be taken to evaluate my current work practices versus the latest OSHA SHIB?

The OSHA SHIB provides a step-by-step Evaluation Toolbox for a facility to follow (see sidebar).

Q. When does the OSHA SHIB go into effect?

The OSHA SHIB is simply a clarification of the OSHA Bloodborne Pathogens Standard [29 CFR 1910.1030 (d) (2) (vii) (A)]. The standard prohibits the removal of a contaminated needle from a medical device. Prohibition of needle removal is addressed in the 1991 and 2001 standards, the OSHA compliance directive (CPL 2-2.69), as well as a 2002 letter of interpretation. Therefore, there is no grace period.

Q. Does the OSHA SHIB apply to all phlebotomy devices?

Yes, it applies to any needle device that has an unprotected back end needle, including the following safety-engineered needle devices: multiple sample needles, winged blood collection sets and luer adapters.

Q. Are there any situations in which it is still acceptable to remove a needle from a blood collection device?

According to the OSHA SHIB and OSHA's 2001 Compliance Directive (CPL 2-2.69), there may be situations that necessitate using a syringe to draw blood. The blood collected into the syringe would then need to be transferred into a tube before disposing of the contaminated syringe.

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OSHA SHIB Evaluation Toolbox

- Employers must first evaluate, select, and use appropriate engineering controls (e.g., sharps with engineered sharps injury protection), which includes single-use blood tube holders with sharps with engineered sharps injury protection (SESIP) attached.
- The use of engineering and work practice controls provide the highest degree of control in order to eliminate potential injuries after performing blood draws. Disposing of blood tube holders with contaminated needles attached after the activation of the safety feature affords the greatest hazard control.
- In very rare situations needle removal is acceptable.
 - If the employer can demonstrate that no feasible alternative to needle removal is available (e.g. inability to purchase single-use blood tube holders due to a supply shortage of these devices),
 - If the removal is necessary for a specific medical or dental procedure.
- In these rare cases, the employer must ensure that the contaminated needle is protected by a SESIP prior to disposal. In addition, the employer must ensure that a proper sharps disposal container is located in the immediate area of sharps use and is easily accessible to employees. This information must be clearly detailed and documented in the employer's Exposure Control Plan.
- If it is necessary to draw blood with a syringe, a syringe with engineered sharps injury protection must be used in which the protected needle is removed using safe work practices, and transfer of blood from the syringe to the tube must be done using a needleless blood transfer device.

To view the OSHA SHIB in its entirety, visit the OSHA website at <http://www.osha.gov/dts/shib/shib101503.html>

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BD Vacutainer® Blood Transfer Device

In these situations, a syringe with an engineered sharps injury prevention feature and safe work practices should be used whenever possible. Transfer of the blood from the syringe to the test tube must be done using a needleless blood transfer device. The BD Vacutainer® Blood Transfer Device (reference number 364880) can help to satisfy this OSHA requirement.

Q. What holder products does BD offer that are intended for single use?

The BD Vacutainer® One Use Holder (reference number 364815) is a clear plastic needle holder that is clearly marked with the words “Do Not Reuse” and “Single Use Only.” Once a venipuncture is completed, the entire needle and holder assembly is

disposed in a sharps container.

The needle should not be removed from the holder.

This new needle holder is similar in feel to the reusable BD Vacutainer® Standard Yellow Holder. Thus, no change in venipuncture technique is required when transitioning to a single use holder policy. The BD Vacutainer® One Use Holder will be easy to implement into your venipuncture procedures, as it is compatible with the entire BD Vacutainer® Venous Blood Collection System, including BD Vacutainer® Eclipse™ Needles, BD Vacutainer® Safety-Lok™ Blood Collection Sets and BD Vacutainer® Multiple Sample Luer Adapters.



BD Vacutainer® Eclipse™ Blood Collection Needle



BD Vacutainer® Safety-Lok™ Blood Collection Set



BD Vacutainer® Multiple Sample Luer Adapter

The use of engineering and work practice controls provide the highest degree of control in order to eliminate potential injuries after performing blood draws.

— OSHA SHIB Evaluation Toolbox

Q. Will BD have enough of the One Use Holders when demand for these products increases?

Yes. BD is in the process of notifying hospitals, medical suppliers and other facilities that it has an ample supply of the BD Vacutainer® One Use Holder to meet the changing needs of its customers.

Q. Will there be any other changes to the needle holder products that BD is currently offering?

The BD Vacutainer® Standard Yellow Needle Holders (reference numbers 364888 and 364983) have been discontinued (not available after 1/31/04) and are no longer available as a stand-alone holder for use with blood collection devices. They will still be used as a component for other safety products, such as the BD Vacutainer® Blood Transfer Device, BD Vacutainer® Direct Draw Adapter, and BD Vacutainer® Luer-Lok™ Access Device.

Q. What happens if a facility does not comply with OSHA regulations?

As with any OSHA rule or regulation, non-compliance may result in the issuance of citations by an OSHA compliance officer after the completion of a site inspection. It is the responsibility of each facility to evaluate their work practices, implement appropriate engineering controls, and institute all other applicable elements of exposure control in order to achieve compliance with current OSHA rules and regulations. ■

To view the OSHA SHIB in its entirety, visit the OSHA website at <http://www.osha.gov/dts/shib/shib101503.html>

For more information, or to receive samples of the BD Vacutainer® One Use Holder, please contact your local BD Diagnostics, Preanalytical Systems Sales Consultant, or call our BD Global Technical Services Department at 1.800.631.0174.

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EDTA is now the recommended anticoagulant for hematology by the International Council for Standardization in Hematology (ICSH) and the NCCLS.

Dipotassium EDTA is recommended due to its good solubility and stable microhematocrit results.³

In some individuals, EDTA may cause inaccurate platelet results. These anomalies, platelet clumping and platelet satellitism, may be the result of changes in the membrane structure occurring when the calcium ion is removed by the chelating agent, allowing the binding of pre-formed antibodies. In this instance, sodium citrate tubes are sometimes collected to obtain more accurate platelet counts.³

Proper mixing of the whole blood specimen ensures that EDTA is dispersed throughout the sample. Evacuated blood collection tubes with EDTA should be mixed by 8-10 end-to-end inversions immediately following venipuncture collection.⁴ Microcollection tubes with EDTA should be mixed by 10 complete end-to-end inversions immediately following collection. They should then be inverted an additional 20 times prior to analysis.⁵

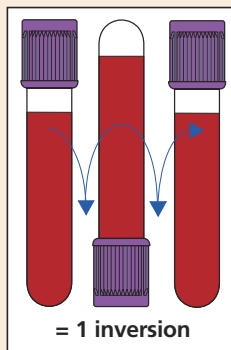
Specimen Storage and Transport

Evacuated EDTA blood collection tube specimens should be analyzed within six hours of collection.⁶ Prior to analysis, they should be stored at room temperature. Microcollection EDTA tube specimens should also be stored at room temperature and analyzed within four hours.²

Processing (Mixing) of Tubes

Why

- Most tubes contain an additive or clot activator that needs to be mixed with the blood sample.
- Tubes with anticoagulants such as EDTA need to be mixed to ensure that the specimen does not clot.



How

- Holding tube upright, gently invert 180° and back.
- Repeat movement as prescribed for each tube.

When

- Immediately after drawing.

Consequences if not mixed properly

- Tubes with anticoagulants will clot.
- Specimen may need to be redrawn.

Specimen Integrity at Analysis

Care should be taken to ensure specimen integrity at analysis. The following steps will help prevent preanalytical errors from occurring at the time of analysis:

1. Specimens should be checked for proper labeling. Improperly labeled or unlabeled specimens should not be analyzed; corrective action as per the facility's protocol should be taken.
2. Tubes should be checked for proper blood fill volumes and appropriate action should be taken based on hospital protocol if tubes are underfilled.
3. Whole blood specimens should be mixed adequately by end-to-end inversion just prior to analysis.
4. Blood smears for differentials from acceptable specimens should be prepared within two hours of collection.³

5. Blood counts from acceptable venipuncture specimens should be performed within six hours of collection.⁶

6. Blood counts from acceptable skin puncture specimens should be performed within four hours of collection.²

Unused tubes should be stored at 4 – 25° C (39 – 77° F) unless otherwise noted on the package label. Increased temperatures may lead to short draws, incorrect blood-to-additive ratios and erroneous results.

Whole blood specimens are not to be chilled (2 – 8° C) unless there are documented recommendations for doing so. Extended storage (24 hours) is generally not recommended

because stability can vary to a considerable degree. Stability depends on reagents, system, instrumentation, etc.⁷

Underfilling the EDTA blood collection tube can lead to erroneously low blood cell counts and hematocrits, morphologic changes to RBCs, and staining alteration. Excess EDTA can shrink red cells. Conversely, overfilling the blood collection tube will not allow the tube to be properly mixed and may lead to platelet clumping and clotting. NCCLS recommends the tube be filled to ± 10% of the stated draw volume.⁸

Physiological Variables

A number of physiological variables can be associated with certain patient factors, such as age.⁹ For example, at birth red blood cell count (RBC) and hemoglobin values are significantly

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Understanding Additives: Heparin

Heparin is an anticoagulant commonly used in chemistry and special chemistry testing. It is the recommended anticoagulant for many determinations using whole blood or plasma specimens because of its minimal chelating properties, minimal effects on water shifts, and relatively low cation concentration.

Heparin acts primarily through a complex that it forms with antithrombin III. This complex accelerates the inhibition of thrombin and activated Factor X to prevent clotting or activation of thrombin, which in turn prevents the formation of fibrin from fibrinogen. The source of heparin is usually either bovine or porcine lungs and intestines.

There are currently three salts of heparin that are commonly used in blood collection devices: ammonium, lithium and sodium. Lithium heparin is the recommended form of heparin to be used because it is least likely to interfere when performing tests for other ions. Lithium heparin is essentially free of extraneous ions. It should not be used for collection of blood for lithium levels.

Heparin is the only anticoagulant that should be used in a blood collection device for the determination of pH, blood gases, electrolytes and ionized calcium. Heparin should not be used for coagulation or hematology testing.

The heparin used in BD Vacutainer® Blood Collection Tubes and BD Microtainer® Tubes is preservative free. The recommended range of heparin in evacuated tubes is 10 to 30 USP units of heparin/mL of blood. Plastic microcollection tubes may contain less than 15 USP units/mL of blood. Tubes containing heparin should be inverted 8 to 10 times after collection to ensure thorough mixing of the additive with the blood and, therefore, complete anticoagulation of the sample.



References:

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higher than they are in adults, due to the relatively low levels of oxygen *in utero*. Within the first few months of life they fall substantially and continue to decrease and level out to adult values at about the age of fifteen. In addition, lymphocyte counts change throughout life; they are highest in children and lowest in the elderly.

Smoking, high altitude, patient stance, exercise and pregnancy are some additional patient-related variables over which the lab has no control; yet, they may affect patient test results.¹⁰

Additionally, white blood cell (WBC) and platelet counts can be affected by cryoglobulins. When blood specimens cool from body temperature to room temperature, the cryoglobulins aggregate and may be falsely identified as platelets and/or WBCs by the hematology analyzer. Cold agglutinins have been known to cause spurious reporting of

macrocytosis and decreased RBC counts. Some automated instruments may also report falsely high WBC counts and platelet counts.³ The blood smear may show agglutination of RBCs.

Platelet satellitism is a phenomenon that only occurs in EDTA anticoagulated blood. This is due to EDTA-dependent IgG autoantibodies and occurs at room temperature. When platelet satellitism is present, there may be a false elevation of cell counts.¹⁰

In Conclusion

The awareness of the preanalytical variables and their effects on hematology testing is the first step in ensuring that the results are consistently accurate. By minimizing the incidence of preanalytical errors, patient care would be optimized, laboratory costs reduced and the physician-laboratory relationship enhanced. ■

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Just how much is enough?

Important information regarding product availability

Reminder

Effective May 31, 2004, BD will stop producing several BD Vacutainer® Glass Blood Collection Tubes. The remaining product array will continue to provide you with the same clinical performance you have come to expect from BD products, while meeting your requirements for compliance, enhanced safety, efficiency and reliability.

Please visit our website at www.bd.com/vacutainer for a list of the affected products and for additional information regarding this product discontinuation.

Glass to plastic support materials can be obtained from the BD Global Technical Services Department at 1-800-631-0174.

Thank you for your continued patronage and support.

CLMA/ASCP 2004



Conference & Exhibition March 27-30, Atlanta, GA

Visit BD in booth #728, where we'll be demonstrating our next-generation safety initiatives for healthcare workers and patients, like the BD Vacutainer® Push Button Blood Collection Set. Visit the home of the BD Vacutainer® Brand and find out about all of our families of products in venous, capillary and urine collection.

BD is the proud sponsor of the CLMA-Lyle Rosser, Jr., Continuing Education Scholarship. Created to commemorate the legacy of Lyle Rosser, Jr., a CLMA member who embodied a love of education, this scholarship provides financial support for laboratory professionals with managerial and/or supervisory responsibilities who want to attend the CLMA/ASCP Conference.



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