Plastic Collection Tubes Decrease Risk of Employee Injury

Although plastic collection tubes have been available for over ten years, laboratories have been slow to convert usage from glass to plastic for many reasons. Regardless of the barriers to plastic tube conversion, some labs have overcome them all for only one overriding reason: employee safety.

➤ A clinical laboratory worker took the stopper off a lavender-top tube for CBC testing. He didn’t realize that the tube was cracked. When he removed the stopper, the broken glass cut his left thumb.

➤ A laboratorian sat down at his bench and was preparing to enter information into the computer on specimens that had just come into the lab for testing. When he rested his hands on the desktop, he felt something sharp in the palm of his hand; a shard of bloody glass had pierced his palm.

➤ As a phlebotomist was filling a glass blood collection tube, the tube broke in her hands. Startled, she accidentally stuck herself with the needle that she had just removed from an AIDS-infected patient. Nine months later, she tested positive for HIV. Her health deteriorated rapidly, and she died several years later.

Each of these exposures might have been prevented had the healthcare worker handled collection tubes made from plastic instead of glass. With the current focus on safety...

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From The Editor

In this issue of LabNotes, we have tried to address two topics that we know can be of great concern to our readers, namely healthcare worker safety and specimen quality issues.

Over the past few years, the majority of healthcare facilities have been taking great strides to ensure the safety of their employees from sharps injuries by introducing safety-engineered needle products, in compliance with the Federal OSHA Needlestick Safety and Prevention Act. Fewer facilities, however, have taken the next step in safety — converting from glass blood collection tubes to plastic. This issue’s feature article, “Plastic Collection Tubes Decrease Risk of Employee Injury,” considers the safety and efficacy of plastic blood collection tubes, given the serious threat to medical professionals posed by glass tubes.

Other pressures that clinical laboratories currently face include the reduction of turnaround times for patient testing. One of the ways to achieve this in the chemistry lab has been to switch from serum to plasma specimens, thereby eliminating the clotting time required for serum tube specimens. This has brought on new questions regarding the routine use of plasma and its quality. Our second feature article, “Why Doesn’t My Heparinized Plasma Specimen Remain Anticoagulated?,” has a pertinent discussion on latent fibrin formation.

As always, we welcome your comments as we try to make LabNotes a source of relevant information in this ever-changing healthcare environment.

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needles, exposure to glass sharps has not been getting as much attention as some argue it deserves. Though not as prevalent as accidental needlesticks, cuts from contaminated glass pose just as great a risk of transmitting hepatitis, HIV and other infectious diseases and are just as preventable.

The barriers to universal use include economics, complacency, and the resistance to change, but many experts believe that industry-wide conversion is inevitable. More clinical evidence is becoming available every day that supports this move from glass to plastic tubes. Medical professionals are beginning to realize the serious threat posed by broken glass tubes and that there are solutions, namely plastic tubes, to address this threat.

EPINet™, the nationwide exposure surveillance system at the University of Virginia’s International Healthcare Worker Safety Center, has recorded 48 exposures to broken glass from blood specimen containers since it started monitoring exposures in 1995.1 Of those, 32 occurred in clinical laboratories. This figure, however, does not take into account the number of unreported exposure incidents. If laboratory managers are as negligent about reporting broken glass exposures as they are accidental needlesticks—up to 97 percent underreporting according to one study—the actual frequency of broken glass exposure would appear alarmingly high.

Janine Jagger, MPH, PhD, the director of the International Health Care Worker Safety Center at the University of Virginia School of Medicine, argues that managers

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should implement the use of products that minimize the risk of broken-glass exposures as often as possible.

“There should be plastic substitution for all glass items for which plastic substitution is possible. The top priority should be directed toward glass specimen containers and glass equipment that contain or make contact with body fluids or tissue specimens,” she said.

Jagger identifies glass specimen collection tubes, capillary tubes, pipettes, and glass slides as top candidates for substitution, but she recognizes that not all glass can be eliminated. “If there are specific circumstances under which plastic cannot be used, they need to be described, justified, and kept to an absolute minimum,” she said. “The language put forth by OSHA in the Federal Register on January 18, 2001, relating to the new law explicitly includes glass devices in their definition of contaminated sharps.”

Jagger is referring to the Needlestick Safety and Prevention Act signed into law to modify the OSHA Bloodborne Pathogen Standard to mandate the use of devices that protect against exposure to contaminated sharps.

Barriers to Industry-Wide Conversion

Although plastic collection tubes have been available for more than ten years, they aren’t widely used. Manufacturers and industry experts point to a multitude of factors that have kept facilities from converting. One of these is the necessity for parallel studies to assure that results will not be compromised. NCCLS has published guidelines that clearly define the requirements for such studies. Yet, many laboratories balk at the prospect of having to design studies, test specimens in parallel, record raw data, and evaluate the results.

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Industry experts suggest that the transition can be simplified when incorporated with other laboratory transitions. For example, if a laboratory is converting to new instrumentation, incorporate tube conversions with that change.

Another obstacle is the perception that plastic tubes are more expensive than glass. However, plastic tubes are only marginally more expensive to produce than their glass counterparts, and the cost of safer tubes should not be considered alone. Shatter-resistant plastic blood collection tubes weigh less than glass and can be more efficiently incinerated, thereby decreasing medical waste expense. Therefore, when you calculate in the reduction of the weight of a facility’s biohazardous waste, plastic tubes cost significantly less to use overall.

The potential savings increase further when managers consider the costs associated with an accidental exposure to a contaminated sharp. One study reports that the cost of treating an employee infected with HIV while he/she is performing routine procedures can exceed $500,000. The immediate cost to treat a percutaneous exposure has been estimated to be up to $4,000, including testing both patient and worker and administering HIV prophylaxis. If the exposure results in an acquired disease, the cost skyrockets. In the case of hepatitis, a liver transplant can cost an employer $150,000 or more; the average lawsuit for occupationally acquired HIV settles for $2 million to $5 million. Armed with these estimates, managers and healthcare professionals can build a convincing case for converting to shatter-resistant plastic collection tubes.

As pervasive as these barriers are in the industry, Dr. Jagger sees them falling away.

“Plastic substitution, especially for blood collection tubes and capillary tubes, got off to a slow start but is picking up steam. Each product category requires a focused initiative. Initial industry efforts were directed toward needles. But the focus on glass has recently increased. The Joint Safety Advisory on the risks of glass capillary tubes issued by the FDA, NIOSH, CDC, and OSHA in February 1999 provided tremendous momentum in the transition away from glass capillary tubes. Glass is on the way out but everyone including manufacturers, purchasers and users need to push to complete this transition as quickly as possible.”


EPINet is a trademark of the University of Virginia
The Evolution of Heelsticks:

1991

NCCLS Guidelines

Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture*

- Section 9.0 Techniques for Puncturing the Skin

- Section 9.1 Depth: In small premature infants, the heel bone (calcaneus) may be no more than 2.4 mm beneath the plantar heel skin surface and half this distance at the posterior curvature of the heel. Puncturing deeper than 2.4 mm on the plantar surface of the heel of small infants may therefore risk bone damage.

- Section 9.2 Blood Vessel Location: The major blood vessels of the skin are located at the dermal-subcutaneous junction, which in the newborn's heel is 0.35 to 1.6 mm beneath the skin surface. Therefore, even in the smallest infant, a puncture 2.0 to 2.4 mm deep on the plantar surface of the heel will penetrate the major skin vasculature and not risk puncture of the bone.

*NCCLS Document H4-A3, Vol. II No. 11, July 1991

Today

Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard – Fourth Edition*

- Section 9.0 Skin Puncture Techniques

- Section 9.1 Depth: In small or premature infants, the heel bone (calcaneus) may be no more than 2.0 mm beneath the plantar heel-skin surface and no more than half this distance at the posterior curvature of the heel. Puncturing deeper than 2.0 mm on the plantar surface of the heel of small infants may therefore risk bone damage.

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*NCCLS Document H4-A4, Vol. 19 No. 16, September 1999

The BD Solution:

BD Quikheel™ Infant Lancet
Reference #368101

- Type of Device – Incision Technology
- Depth – 1.0 mm
- Width – 2.5 mm
- Blood Volume – High
- Meets Fed OSHA Standards – YES
- Meets 1999 NCCLS Guidelines – YES

BD Quikheel™ Preemie Lancet
Reference #368100

- Type of Device – Incision Technology
- Depth – 0.85 mm
- Width – 1.75 mm
- Blood Volume – Low
- Meets Fed OSHA Standards – YES
- Meets 1999 NCCLS Guidelines – YES

BD Safety Flow™ Yellow Lancet
Reference #365759

- Type of Device – Puncture Technology
- Depth – 2.2 mm
- Width – 1.0 mm
- Blood Volume – High
- Meets 1991 NCCLS Guidelines – YES

*NCCLS Document H4-A3, Vol. II No. 11, July 1991
Instructions for Use:

➤ Place the filled collection cup upright on a clean, flat surface. Note: If a very small urine volume is obtained, the sample may be insufficient to fill the BD Vacutainer Plus Plastic Conical Urinalysis Preservative Tube to the minimum level as indicated on the tube label and may be insufficient for testing.

➤ The BD Vacutainer Plus Plastic Conical Urinalysis Preservative Tube has an 8mL fill volume.

➤ When using an integral sampling device or transfer straw, allow the vacuum to completely fill the tube to 8mL with urine and thoroughly mix 8 to 10 times. If there is very little urine volume collected, the stopper of the preservative tube may be removed and the urine poured from the specimen container into the tube to the minimum mark.

➤ The MINIMUM amount of urine needed in the tube is 7mL. (See Min Fill Line on tube) At this volume, the correct urine-to-additive ratio is maintained. If this volume requirement cannot be met, then please follow the NCCLS guideline stated on the following page.

Through the past decade, testing practices have changed rapidly and an increasing number of specimens are transported to remote or core laboratories. The laboratories are faced with transport effects on the specimens. BD recommends collecting urine specimens in the BD Vacutainer™ Plus Plastic Conical Urinalysis Preservative Tube because specimen integrity is maintained for up to 72 hours without refrigeration.

The conical bottom of the BD Vacutainer Plus Plastic Conical Urinalysis Preservative Tube aids in sediment collection for microscopic analysis. It can be used with the KOVA® pipette system, therefore maintaining a 12:1 urine-to-sediment ratio.

The urine preservative is comprised of chlorhexidine, ethyl paraben, and sodium propionate.

In the event that a urine preservative system is not used, NCCLS recommends that the urinalysis testing be performed within 2 hours of specimen collection. If testing cannot be performed within this time frame, refrigeration (2 to 8°C) is adequate for some chemical components (exceptions being bilirubin and urobilinogen). At these stor-
age temperatures, the specimen can precipitate amorphous urates or phosphates, which obscure the microscopic field. The length of time refrigeration can serve as a preservative has not been determined.

NCCLS also recommends, “If ‘urine preservation’ systems are used, they should first be evaluated by the laboratory”. It is generally accepted that after standing 2 hours at room temperature, the chemical composition of unprocessed urine changes, and formed elements begin to deteriorate.

The following are changes that may occur:

- **pH↑** – bacteria converts urea to ammonia, CO2 lost
- **pH↓** – bacteria and yeast convert glucose to acids and alcohols
- **Glucose↓** – utilization by bacteria (glycolysis)
- **Ketones can↓** – caused by volatilization of acetone
- **Bilirubin↓** – destroyed by light, oxidized to biliverdin
- **Urobilinogen↓** – destroyed by light
- **Nitrites↑** – bacterial reduction of nitrate
- **Nitrites↓** – nitrite converted to nitrogen, which evaporates
- **Turbidity↑** – due to bacterial growth, crystal formation, precipitation of amorphous material
- **Bacteriuria↑** – multiplication of bacteria

**Cells and casts disintegrate** in dilute urine (SG < 1.010) and urine that becomes alkaline upon standing (pH > 7.0)

BD performed evaluations of the BD Vacutainer™ Plus Plastic Conical Urinalysis Preservative Tube stored at room temperature (RT). The tube was compared to the BD Vacutainer™ Plus Plastic Conical Tube (RT) at initial time and at 72 hours after tube fill for urine dipstick chemistries. The preservative tube demonstrated some urine analyte results outside the normal reference ranges. Statistical analysis for urine dipstick chemistries showed that over 72 hours there were no clinically significant differences observed between the BD Vacutainer Plus Plastic Control Tube at RT and the BD Vacutainer Plus Plastic Conical Urinalysis Preservative Tube.

References:
5. BD Vacutainer Systems, Preanalytical Solutions, Evaluation of 16 x 100mm BD Vacutainer Plus Plastic Conical Tubes with a Urinalysis Preservative for Urine Dipstick Chemistries and Microscopic Analysis Using the Clinitek Atlas and KOVA Methods, literature code VS5930.

KOVA is a trademark of Hycor Biomedical, Inc.

In the event that a urine preservative system is not used, NCCLS recommends that the urinalysis testing be performed within 2 hours of specimen collection.

All plastic blood collection tubes need to be stored at the proper temperatures to ensure that they function properly. BD recommends that storage temperatures for all BD Vacutainer™ Blood Collection Tubes not exceed 25°C or 77°F. If plastic tubes reach higher temperatures, as they might if they were stored in the trunk or on the dashboard of a car, the tubes may lose their vacuum or implode.
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This newsletter that you’ve enjoyed receiving in the mail is now also viewable on the internet.

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• package inserts
• educational information
• product literature
• our Tech Talk technical bulletins

Visit our company website for additional valuable information and links to helpful web features.

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Changes to California Phlebotomy Training Programs

California is often a pioneer in healthcare industry workplace regulations. We wanted to inform LabNotes readers of this very important change taking place in California in the area of phlebotomy certification, as it may be the start of a trend that other states or the federal government will soon follow.

As of January 9, 2003, long-awaited phlebotomy regulations were signed into law by California's Secretary of State. These regulations took effect on April 9, 2003. As of this date, all phlebotomy training programs must obtain approval from Laboratory Field Services (LFS) before offering any phlebotomy instruction. Please be aware of one area of serious concern to existing training programs:

• Instructors: Phlebotomists with three out of five years of current experience and presently employed as phlebotomy instructors may continue to teach up to December 31, 2003. However, from now until December 31, 2003, the instructors must become a “Certified Phlebotomy Technician I or II” under the new standards. This means that they must attend an approved training program and pass a certifying examination given by an approved certifying organization. Licensed instructors (MD, RN, CLS, CLB, RPT) must pass a certifying examination by December 31, 2003 in order to continue teaching in the future.

In order for a training program to prepare for the approval process once the regulations go into effect, the program personnel can obtain from Laboratory Field Services (LFS) the following documents:

1. Application Form labeled “LAB 180”
2. Instruction Sheet
3. New Regulations and Statute
4. Excerpts From California Statutes and Regulations Governing Unlicensed Laboratory Personnel Performing Phlebotomy
5. “How to Obtain a Phlebotomy Certificate”
6. Regulation Overview
7. Regulation Time line
8. Internet Addresses
9. FAQ’s
10. Certifying Organizations List

The above information was taken from a letter issued by the California Department of Health Services. For further information, please contact the authors Gwen Wong (510) 873-6449 or Nancy Stone (510) 873-6434 at the California Department of Health Services, Laboratory Field Services 1111 Broadway, 19th Floor, Oakland, CA 94607-4036 or visit the website at www.dhs.ca.gov.
**Why Doesn’t My Heparinized Plasma Specimen Remain Anticoagulated?**

A Discussion on Latent Fibrin Formation in Heparinized Plasma

**Introduction**

The ‘instability’ of heparinized plasma for the purposes of this article is defined as the formation of a precipitate in the plasma after a certain period of time post-centrifugation. The identity of this precipitate is controversial and not clearly understood. However, based on the knowledge of the composition of blood, coagulation and heparin, there are several hypotheses that could be proposed. First, it may be beneficial to review some facts on coagulation and anticoagulation. 

Figure 1 is useful as a reference to the coagulation cascade and steps where heparin interferes with coagulation. The coagulation of plasma occurs through this cascade of interconnected pathways initiated by the ‘surface contact’ step (intrinsic pathway), as coagulation factors become activated upon contact with a negative surface, such as a glass tube wall. Similar to whole blood coagulation, plasma coagulation also involves the cellular component from cells remaining in the supernatant (extrinsic pathway). Each of these pathways results in the generation of fibrin.

**Centrifugation of Whole Blood**

Centrifugation is the process of separating lighter portions of a mixture or suspension from heavier portions by centrifugal force based on their relative densities. The separation of anticoagulated blood components by centrifugation is driven by differences in density and cell size. The heavier and larger red blood cells and white blood cells sediment more quickly than platelets. Hence, platelets are the primary cell type that can be found in plasma and the plasma obtained under most recommended centrifugation conditions used in chemistry is not completely acellular. The centrifuge speed, time and temperature, as well as patient cell counts, can influence the purity of the plasma.

**Action of Heparin**

Heparin interferes with clotting by complexing with anti-thrombin III (AT) and catalyzing the inhibition of thrombin. Heparin preparations used as pharmaceuticals and anticoagulant additives for evacuated blood collection tubes are comprised of a heterogeneous population of sulfated polysaccharides that carries a net negative charge. Because of heparin’s composition, it tends to bind to a variety of plasma proteins and cell membranes and thus exhibits unpredictable pharmacokinetics. However, only ~20% of the molecules in the heparin are active in binding to AT. Additionally, heparin binds to other plasma and cellular proteins in addition to AT (e.g., platelet factor 4, or PF 4) that compete

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**Figure 1**

**Schematic Diagram of the Coagulation System**

- **INTRINSIC**
  - Contact surface
  - XII
  - PK
  - HMWK
  - XI
  - Xla
  - Xla
  - VIII
  - Ca^2+ PF3-Vila
  - VII
  - Ca^2+ PF3-Vila
  - V
  - Xa Va-PF3 Ca^2+
  - II

- **EXTRINSIC**
  - Cellular breakdown
  - Tissue thromboplastin
  - X
  - Ca^2+ PF3-Vila
  - II
  - Xla
  - Fibrinogen

* Heparin + AT III Inhibition

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with AT for heparin binding, thereby reducing the availability of heparin for anticoagulation. The extent of this so-called heparin neutralization is dependent upon the number of cells remaining in the plasma after centrifugation. The more platelets in the supernatant, the greater the heparin neutralization. Conversion of fibrinogen to fibrin in heparin anticoagulated blood varies widely, dependent on individual number of cells and the concentrations of AT and other plasma proteins. It is also known that the heparin/AT complex inactivates activated Factors XII, XI, X, and VII, as well as other coagulation factors, in addition to thrombin.

The contact activation of Factor XII, high molecular weight kallikrien (HMWK), etc. is accelerated at low temperatures (<37°C) irrespective of the presence of heparin. Cold promoted Factor VII activation is the result of activation by both activated contact proteins and the trace amounts of thrombin they generate. Since this activation is accelerated at reduced temperatures, refrigeration predisposes these factors to activation under refrigeration, driving the reaction towards clotting, and thus may be antagonistic to the anticoagulant action of heparin. For coagulation testing, it has been shown that heparinized patient specimens, but not specimens from other patient populations, may demonstrate clinically significant shortening of the aPTT when stored uncentrifuged at room temperature. The mechanism of this aPTT shortening has been related to platelet activation and release of PF 4 which electrostatically neutralizes the heparin present in the specimen. This occurs with heparin levels achieved clinically in anticoagulated patients, levels significantly lower than the heparin levels present in evacuated tubes. This aPTT shortening supports the hypothesis that, in the presence of heparin, platelet activation may occur in vitro with resulting neutralization of heparin's anticoagulant effect.

Furthermore, a major side effect of heparin therapy is heparin-induced thrombocytopenia (HIT), when patients previously sensitized by earlier exposure to heparin are re-exposed to heparin. HIT (a low platelet count which may be associated with life-threatening thrombosis) occurs because of heparin-induced platelet aggregation. These aggregated and activated platelets also release PF 4 which, as described above, promotes clotting by neutralizing heparin. Thus, heparin may exert two opposing actions—anticoagulation and heparin-induced platelet activation. The net effect of these two actions may vary in different patient populations, particularly depending upon whether the patient has previously been sensitized to heparin.

**Plasma Instability**

The formation of fibrin, in vitro, in heparinized plasma is complex. There are three mechanisms that may potentially be involved in the ‘instability’ of heparinized plasma. They are as follows:

1. Cell sequestration and/or binding of heparin. It is well documented in the literature that heparin binds to cells (and other plasma proteins), but the

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The Clinical Laboratory Improvement Amendments of 1988 (CLIA) is a regulation specifying that all laboratories must meet certain conditions to perform testing on human specimens.

The original Clinical Laboratory Improvement Act was established in 1967 to regulate laboratories engaged in interstate commerce. In 1988, with the passage of CLIA ’88, the definition of the laboratory was broadened to include laboratories located in physicians’ offices or other small healthcare facilities. With CLIA ’88 the level of regulation was determined by the complexity of the tests performed rather than the performance site. Physician office laboratories, dialysis units, health fairs and nursing homes are all covered, along with other previously exempt laboratories. At the same time, advancements in technology and information processing greatly increased the number and complexity of tests that could be performed in the smaller laboratory.

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The effective date for all requirements of CMS-2226F was April 24, 2003.

For further information, contact the Centers for Medicare and Medicaid Services (CMS) at (877)267.2323.

What’s New With CLIA?

- Printed in the January 24, 2003 Federal Register is the final rule for The Centers for Medicare & Medicaid Services CMS-2226F, which completes the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

- This final rule documents the following:

1. Provides one set of quality control (QC) standards for nonwaived testing.

2. Reduces QC frequency in most of the subspecialty and specialty areas, and merges moderate and high complexity QC requirements to simplify compliance.

3. Removes the prospective FDA review of manufacturers’ QC instructions for compliance with CLIA that was to occur after the end of the QC phase-in period on January 1, 2003.

4. Eliminates redundancy, clarifies, simplifies and uses plain language where possible.

5. Reorganizes the existing requirements to parallel the flow of a patient specimen through the laboratory, facilitating the prevention of errors. Studies indicate that most laboratory errors occur in the pre-analytical (specimen collection and handling) phase of testing. Thus, all CLIA requirements applicable to this phase of testing are in one place in logical order, and CLIA anticipates that this will help the laboratory decrease errors.

6. Retroactively “grandfathers” individuals with a doctoral degree without board certification who have served or are currently serving as a director of a laboratory performing high complexity testing and requires board certification for all future doctoral-degreed directors of high complexity testing. This provision became effective on February 24, 2003.

7. Requires that moderate complexity laboratories validate a test once before use to ensure the test works accurately before patients are tested.

- The final rule applies to laboratory testing in all settings, including commercial, hospital and physician office laboratories.

- Of the 176,000 laboratories certified under CLIA, the new rules will have the greatest impact on the 38,000 labs that are authorized to perform high or moderate complexity testing.

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time dependence of this reaction has not been well described. The heparin concentration in BD Vacutainer™ Blood Collection Tubes is 14-17 U/mL; of this only 2.8-3.4 U/mL have the polysaccharide sequences that permit binding to AT.

2. Intrinsic contact activation that may occur both in the presence and absence of heparin is accentuated at temperatures <37°C.

3. Platelet activation in the presence of heparin which increases with time.

The net effect of these mechanistic ‘stresses’ opposes the anticoagulant action of heparin, and this can result in the subsequent formation of fibrin.

**Specimen Management**

Adhering to the following recommended specimen processing steps will help to ensure that you are getting a good quality plasma sample, and will aid in minimizing the formation of latent fibrin.

- Fill evacuated blood collection tubes to the stated draw volume. This will ensure the proper blood to additive ratio in the tube, and help alleviate fibrin formation due to overfilled tubes.
- Invert tubes 8 to 10 times immediately after collection to be sure that the blood and heparin are mixed thoroughly.
- Centrifuge tubes at the higher end of the recommended centrifugation range (1000-1300 g) for the full ten minutes. This will minimize the presence of residual cells in the plasma.
- Store heparinized plasma at room temperature (20-25°C) to minimize intrinsic contact activation at extreme temperatures.
- Evaluate and enforce “add-on testing” policies that your facility has validated for analyte stability in plasma, including the effects of specimens containing latent fibrin.
- Always follow your facility’s protocol and guidelines for proper specimen handling and processing.

**REFERENCES**


