CCLS Connection

"Your partner in health care ... together we make a difference"

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Medical Laboratory Professionals Week

Medical Laboratory Professionals Week is celebrated April 20-26 and provides an opportunity to increase public understanding of and appreciation for clinical laboratory staff.

Join CentraCare Laboratory Services and guest speaker Pathologist Brad Curtis on May 5 at CentraCare Health Plaza, Windfeldt room starting with a 5:30 p.m. social and dinner. Dr. Curtis will discuss Blood Products Utilization: Current Guidelines and Recommendations.

For more information or to register, call 320-251-2700, ext. 57324 or email morisettec@centracare.com. Registration deadline is May 1.

About Clinical Laboratory Science:
Whether a technologist, phlebotomist or pathologist, there are over 300,000 practitioners of clinical laboratory science in the United States. Since the development of this career group in the 1920s, the clinical laboratory science professional has played an increasingly vital role in the diagnosis and prevention of disease. Today, the clinical laboratory professional is a key member of the health care team.

Thank you for allowing us to partner with your team!

Inside this issue:

Mission Statement

As part of **CentraCARE Health,** we are a team of dedicated health care professionals whose mission is to provide quality service, expert consultation and comprehensive medical laboratory information to Central Minnesota.

Point of Care update

Submitted by: Melissa Schmidt, Point of Care Specialist

Collection of blood or other specimens does not require Clinical Laboratory Improvement Amendments (CLIA) certification. Rather, it is the ***testing of*** specimens that is regulated and requires a CLIA certificate.

CLIA requires all entities that perform even one test, including waived test on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

These regulations also apply to testing performed in facilities without conventional laboratories, such as care and service residential facilities (nursing homes), ambulances, health fairs, home health agencies, pharmacies, end stage renal dialysis facilities, etc. Testing performed in residential health care settings is generally included in the tests allowable under a CLIA Certificate of Waiver, e.g., whole blood glucose testing. So if your facility performs glucose meter testing, you must have a CLIA certificate.

CLIA applications (form CMS 116) are available via the federal CLIA site at http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf.

Monitoring Heparin and using anti-Xa assay

Submitted by: Matthew Paul, Hematology Specialist

There have been many recent inquiries about monitoring unfractionated heparin (UH) and low molecular weight heparin (LMWH) by way of an anti-Xa assay including its use, result interpretation and interference.

In normal coagulation the function of factor Xa is to cleave its naturally occurring substrate known as pro-thrombin. When this cleaving occurs pro-thrombin is converted to thrombin which allows for the formation of a fibrin clot. When we introduce heparin into this process it will bind to Anti-Thrombin III (ATIII) to form a complex. This complex will trigger an inhibitory action against factor Xa leading to the anticoagulation state we want to achieve in certain patient populations. For many years this anticoagulation has been monitored with the Activated Partial Thromboplastin Time (aPTT) assay which still is used in certain cases.

CentraCare Laboratory Services has implemented a liquid anti-Xa assay for monitoring UH therapy using the factor Xa reagent and a chromagenic substrate to determine plasma levels of UH. The assay is set up without ATIII as one of the reagents, therefore relying on the ATIII bound to heparin in the patient. The reaction that occurs is one involving addition of substrate to patient plasma containing ATIII and heparin. Once this occurs, factor Xa is added which causes hydrolysis of the substrate. At this point, inhibition of factor Xa occurs by the ATIII+heparin complex from the patient plasma. This inhibition will continue to occur until equilibrium is reached at which point the level of paranitroaniline being released is measured. This measurement has an inversely proportional relationship to heparin which allows for the level of heparin to be determined.

These assays are not without their faults as certain scenarios can cause falsely decreased

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results.

Since this assay relies on ATIII bound to heparin, if a patient is deficient with ATIII they do not bind as much heparin. Therefore the assay cannot effectively determine the heparin level. Another cause of falsely low heparin results includes release of Platelet Factor 4 (PF4) by platelets in the whole blood sample prior to centrifugation. When PF4 is released it can have a neutralizing effect on the heparin in the sample causing a falsely decreased result. Heparin levels also can be decreased by patients who are on direct thrombin inhibitors such as Argatroban, Dabigatran and Apixaban. Other factors such as lipemic, icteric or hemolyzed samples or timing of sample collection in relation to heparin administration should all be considered when evaluating low results.

Some schools of thought argue that ATIII should be utilized within the reagents and some assays offer this feature. However studies also have shown that when ATIII is utilized as a reagent in the assay, the additional ATIII can cause a falsely increased result for heparin. This could lead some to conclude that the patient is over anticoagulated, resulting in a reduced heparin dose and subsequently putting the patient at higher risk for clot formation.

Due to the increased specificity of the anti-Xa assay, some conditions (mild hemophilia, chronic liver disease, diffuse intravascular coagulation, shock liver, recent warfarin administration, dilution coagulopathy, acquired vitamin K deficiency during a prolonged hospital stay) can increase the risk of bleeding if monitored with the anti-Xa assay only. It may be appropriate to initiate a baseline PT and aPTT to rule out any common coagulation defects that might increase bleeding risk but may not be picked up with monitoring of heparin levels. Some studies recommend that PT or aPTT be monitored at least once weekly or as a patient's clinical situation changes to rule out any acquired coagulopathy such as vitamin K deficiency.

With all of these variables, some may wonder why focus on the anti-Xa assay. As this assay essentially measures the ability of the ATIII+heparin complex's ability to inhibit Xa, it more directly measures the heparin effect as opposed to the aPTT which measures the whole coagulation cascade for the intrinsic pathway. The anti-Xa assays also have shown minimal interference from the presence of biologic factors such as Lupus anticoagulants, elevated factor VIII, and administration of oral anticoagulants.

Also, the importance of achieving rapid therapeutic anticoagulation after a thrombotic event has been well established. Studies have shown that when monitoring patients with the anti-Xa assay, the mean time to achieve therapeutic anticoagulation was 3.5 times faster in the first 24 hours than when monitoring with the aPTT.

Lastly, an additional contributing factor to shift to the anti-Xa assay is decreased use of resources when compared to aPTT monitors. Evidence shows that patients who are monitored with anti-Xa assay require fewer laboratory tests as well as a reduction in the number of bolus doses and infusion rate changes.

Happy Spring!

TRALI mitigation and its effects

Submitted by: Rachelle Hoeft, Transfusion Services Specialist

Effective April 1, 2014 the American Association of Blood Banks (AABB) implemented a new Standard!

*"**5.4.1.1.1** Plasma and whole blood for allogeneic transfusion shall be from males, females who have not been pregnant or, females who have been tested since their most recent pregnancy and results interpreted as negative for Human Leukocyte Antigen (HLA) antibodies."*

The incidence of reported Transfusion Related Acute Lung Injury (TRALI) cases has decreased since the implementation of efforts to collect transfusable plasma from lower-risk donors, predominately males. The FY2010 FDA annual Fatalities Reported to the FDA Following Blood Collection and Transfusion report stated that TRALI fatalities attributed to plasma transfusion had declined by 83% from the peak of 23 cases in 2006 (pre-mitigation) to four cases (post-mitigation) in 2010.

In a recent plasma-mediated TRALI reaction report by the American Red Cross (ARC) from 2008-2011, 83% of reported reactions involved female donors. HLA antibody testing was performed as part of a post-reaction investigation. In 95% of the tested cases an HLA antibody-positive female donor was identified. This suggested that a substantial number of TRALI cases could have been prevented if plasma from HLA antibody-positive female donors had not been transfused.

Since the initial implementation of the TRALI risk mitigation, 99% of non-AB plasma products are collected from male donors by the ARC. However, type AB donors are only 4% of the donor pool and approximately 40% of the AB plasma distributed by ARC was derived from female donors before the new standard was implemented. Since AB plasma is considered a universal product (can be given to all blood types) the demand from ARC is over 10% system-wide. Standard 5.4.1.1.1 has the potential to substantially decrease the AB plasma donor population.

The American Red Cross has responded to the standard in three ways:

1. Apheresis collection has been implemented at multiple sites nationwide and a call for type AB male donors has been made.
2. Screening has been implemented for type AB female donors. All female apheresis donors with a history of pregnancy since their last donation are being tested for HLA antibodies. Those testing positive are being directed to whole blood donation, but the plasma is not distributed for transfusion.
3. ARC has also reached out to hospitals asking them to judiciously manage this resource.

The third point is the most crucial for hospitals and one we as stewards of the blood supply can fully embrace. Suggestions such as establishing and maintaining plasma transfusion guidelines, utilizing other forms of Coumadin reversal when applicable, using type specific plasma if time permits, and educating physicians and other patient care staff on proper use of products, are all ways to properly utilize our resources. For more education opportunities refer to the ARC Success website www.success.redcross.org

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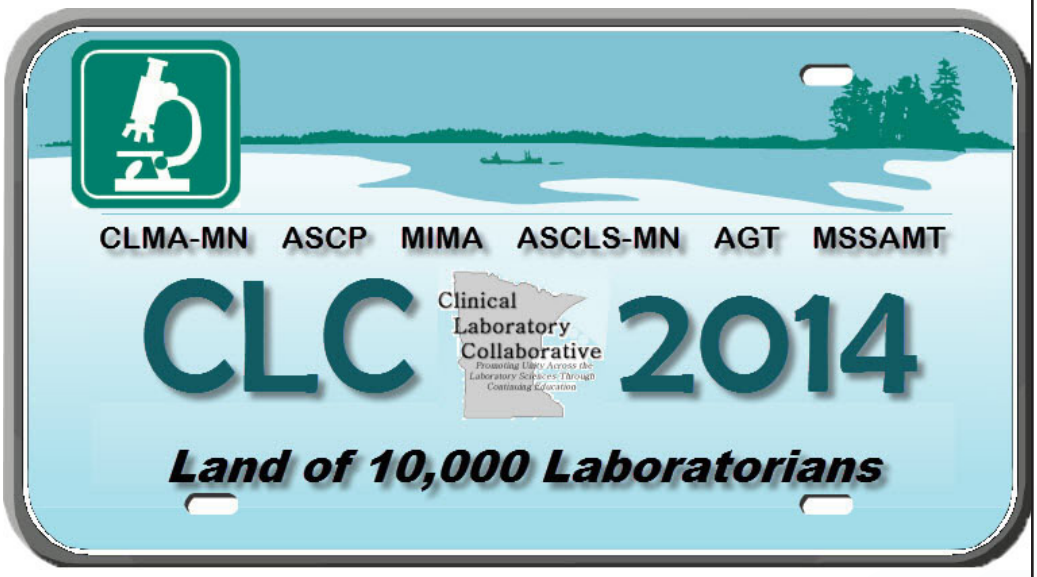
2014 Minnesota Clinical Laboratory Collaborative

April 30 – May 2

Marriott Northwest
(Formerly the Northland Inn)
7025 Northland Drive North
Brooklyn Park, MN 55482

This annual state-wide conference will allow opportunities for attendees to participate in a variety of educational sessions, meet with vendors in the exhibit hall, raise laboratory scholarship funds through a silent auction and contribute to a charity event to sponsor Open Arms of Minnesota. Open Arms is the only nonprofit organization in Minnesota that cooks and delivers free meals specifically tailored to meet the nutritional needs of individuals living with HIV/AIDS, MS, ALS, breast cancer and more than 60 other diseases. We hope you can join us!



For additional CLC meeting and registration information, visit www.asclsmn.org