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SUPPLEMENTAL TECHNICAL BULLETIN
ST – 2011 – 02

Title: Summary of ISTH 2009 Meeting - Updated Guidelines for Lupus Anticoagulant Detection

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This Supplemental Technical Bulletin (ST) has been developed as a laboratory aid. This ST does not alter, revise or change the information provided in the Technical Bulletin included with each product. In accordance with Good Laboratory Practice and regulatory requirements, each laboratory must develop, validate and adopt its own written procedures.

Summary of ISTH 2009 Meeting - Updated Guidelines for Lupus Anticoagulant Detection

At the ISTH meeting in Boston on July 11, 2009, the Scientific and Standardization Committee on Lupus Anticoagulant, chaired by Vittorio Pengo, MD, of the University Of Padua School of Medicine, Dr. Pengo and distinguished members of the committee presented an update of the Lupus Anticoagulant (LA) Detection Guidelines, first published in 1995.

Here are some of the highlights.

- Appropriateness for testing is graded low: arterial or venous thromboembolism (VTE) in elderly patients; moderate: unexpected prolonged partial thromboplastin time (PTT) in asymptomatic subjects, recurrent spontaneous early pregnancy loss or provoked VTE in patients <50 years of age; and high: unprovoked VTE or arterial thrombosis <50 years of age, thrombosis at unusual sites, late pregnancy loss, any thrombosis or pregnancy morbidity in patients with autoimmune diseases.
- Double centrifuge to ensure platelet poor plasma (PPP, <10,000/uL), quick-freeze if testing is delayed, thaw at 37°C.
- Test using two clot-based assays employing separate clotting principles. The dilute Russell Viper Venom Time assay is the most robust. The other may be low-phospholipid PTT with silica activator. PTTs with kaolin activator are problematic in automated coagulometers, ellagic acid is insensitive to LA and both are contraindicated.
- The following tests are not recommended: Dilute Prothrombin Time, Ecarin and Textarin times, and Kaolin Clotting Time.

- Perform a thrombin time to detect therapeutic heparin and absorb heparin or collect at another time.
- For mixing studies, pooled normal plasma (PNP) is prepared "ad hoc" (home-made) by double centrifugation to ensure it is PPP. It must provide 100% activity for all clotting factors. Commercial lyophilized or frozen normal plasmas can be used if they fulfill these specifications.
- For mixing studies, the cut-off is the 99th percentile of the distribution or an Index of Circulating Anticoagulant (ICA): computed as follows…

  ICA% = [(clot time of patient-PNP mixture – clot time of PNP)/clot time of patient] x 10

- The confirmatory test may use bilayer or hexagonal phase phospholipid. Freeze/thawed platelets are not recommended because of poor batch-to-batch consistency.
- Confirmatory test cut-off is defined as follows…

  [(screen – confirm)/screen] x 100

- Cut-off values are developed using the local reagent/coagulometer combination on at least 40 adult healthy donors <50 years of age.

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