

Updates: New β -hCG assay offers enhanced testing

New β -hCG assay to detect pregnancy

The laboratory is using a new β -hCG assay to detect pregnancy. The new reagent offers enhanced testing capabilities through an extended measuring range (2.39-15,000 IU/mL), as well as improved sensitivity and precision. The new assay can be performed on serum, heparinized plasma or EDTA plasma.

The reference ranges have been modified for the new assay. The reference range for healthy, non-pregnant individuals is 0-5 IU/L. The concentrations of β -hCG measured in pregnant females at defined gestational ages are summarized below:

Weeks from LMP	IU/L
1-10 weeks	64-151,000
11-15 weeks	11,800-152,000
16-22 weeks	9380-61,400
23-40 weeks	1740-98,6000

Five-unit cryoprecipitate pools available

The American Red Cross is now offering cryoprecipitate pools of five units. As with all cryo components, they are tested to ensure levels of Factor VIII and fibrinogen meet FDA and AABB standards.

Red Cross suspends local manufacture of transfusable plasma

Following a positive test for West Nile Virus (WNV) in

three Minnesota donors, local blood suppliers suspended manufacturing of transfusable plasma. To assure product availability in hospitals, the blood suppliers began importing plasma products from regions not experiencing WNV-positive donors. The suppliers also began importing Cryoprecipitate AHF (CRYO).

Laboratories to convert to new troponin assay

This fall, the laboratories will convert systemwide to a new troponin I reagent. The manufacturer has developed an improved assay with an upper reference limit (URL) of 0.034 μ g/L. This assay is consistent with the recommendations of the Joint European Society of Cardiology-American College of Cardiology Committee-American Heart Association (ESC-ACC-AHA) consensus document for acceptable imprecision in a high sensitivity troponin I assay. This new reagent also offers a decrease in heterophilic antibody, hemoglobin interference and high-dose hook effect, compared to the current assay. High-dose hook effect results in underestimation of a very high result when the concentration of the analyte exceeds the antibody

present in the reagent, thereby causing underestimation of the analyte's concentration.

A prospective study of 395 patients verified previous clinical studies that showed patients with minor increases in cTnI values provide important prognostic information about the long- and short-term risk of death for patients with acute coronary syndrome (ACS). The data indicate that patients with baseline cardiac troponin I values above the 99th percentile upper reference limit (0.034 μ g/L) had a significantly higher short-term risk of death or recurrent ischemic events.

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Specification	VITROS Troponin I (Current Assay)	VITROS Troponin I ES (New Assay)
Upper Reference Limit	0.08 μ g/L	0.034 μ g/L
AMI Cut-Off	0.4 μ g/L	0.120 μ g/L
Risk Stratification Claim	No	Yes
Clinically Reported Range	Less than 100 μ g/L	Less than 80 μ g/L

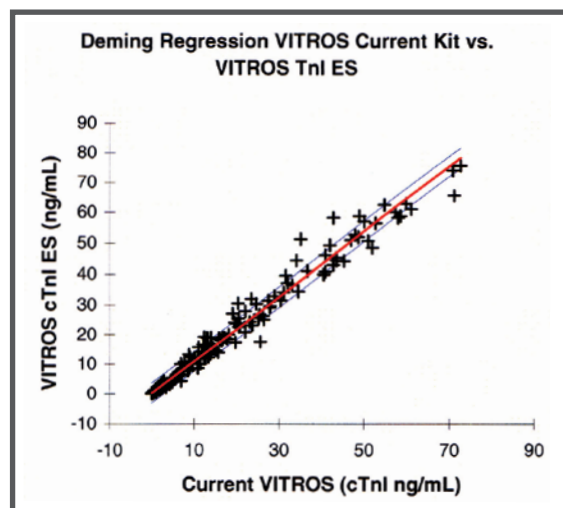


Fig legend: New vs. old VITROS Troponin I method comparison. Deming regression: New TnI = 1.0743 x Old TnI + 0.2199, r = 0.991.

Testing bone marrow versus venous blood

When intravenous access cannot be easily secured, it is acceptable to use blood samples taken from the bone marrow cavity for laboratory analysis and an intraosseous line for infusion of fluids or pharmacological agents. These methods are used primarily in neonates and children following extensive burns, severe dehydration, severe trauma or gross edema.

Two studies have compared bone marrow blood chemistries and blood gases with venous blood. Both specimens were obtained at about the same

time. Good correlation between the bone aspirate and venous samples was obtained for pH, bicarbonate, base excess, PCO₂, hematocrit, hemoglobin, urea, creatinine, sodium and chloride. Poor correlations were obtained for potassium, PO₂, ionized calcium and glucose. All patients were hemodynamically stable, so the correlations may vary in other clinical situations. The studies concluded that the bone marrow aspiration specimen is an alternative to the venous specimen when it is difficult to obtain venous blood.

In the United Kingdom, medical personnel are taught

the technique for obtaining intraosseous access for fluid or pharmacological therapy in the Advanced Trauma Life Support training course. Banerjee, et al., reported that the time required to obtain venous access in the course was significantly longer than for intraosseous access in severely dehydrated children. The effectiveness of both therapeutic routes was equal for treating dehydration. Intraosseous lines were used in 129 of 23,489 pediatric trauma cases who were more severely injured and had a higher mortality rate than those patients with an intravenous

line. Animal models have been used to evaluate bone marrow specimens for laboratory tests and intraosseous lines for fluid therapy.

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Irradiation errors down, but samples still mislabeled

Report of the University of Minnesota Medical Center, Fairview transfusion committee to the lead quality committee, August 2007

Irradiation errors down

Prior to intensive interventions, irradiation errors occurred, on average, every 36 days. We began irradiating all platelets in November, 2004, implemented VeriSafe in June, 2006, and implemented a standard physician transfusion order form in January, 2007. VeriSafe ensures standard work at blood issue from the Blood Bank. As of August 16, 2007 we have had 519 consecutive days without a mishap.

Transfusion order update

The adult physician transfusion order was implemented on University

campus adult units in January 2007. Implementation of a standardized pediatric order is planned for this fall. Adult and pediatric orders will be built in Fairview Clinical Information System (FCIS) for computerized physician order entry (CPOE), facilitating rollout on all units of the new blood administration process using VeriSafe.

Mislabeled patient specimens

The laboratory has used VeriSafe for all inpatient specimen collections since June 2006. A specimen labeling analysis performed for the first six months of 2007 found:

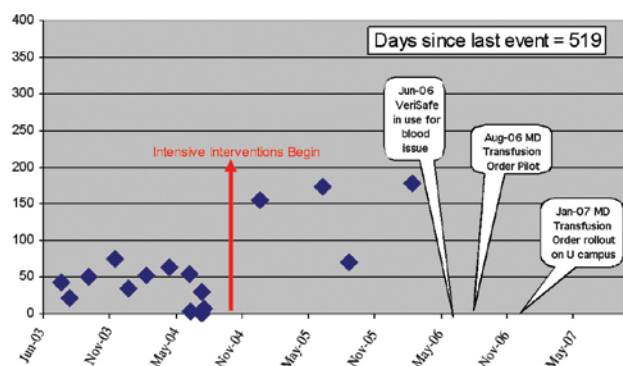
- Approximately 350 samples were improperly labeled; 8 percent were lab errors where VeriSafe was not available.
- More than 1600 tests were cancelled as a result.
- More than 40 patients had the wrong results reported to their medical record.
- When VeriSafe was used as intended for sample

labeling, only one sample was mislabeled. All of these errors except one occurred when manual processes were used. The wider application of VeriSafe seems to offer a solution.

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Days Between Irradiation Events



Irradiation errors in the University of Minnesota Medical Center, Fairview Blood Bank have decreased following intensive interventions.