



CPAL

Central Pennsylvania Alliance Laboratory

Technical Bulletin

No. 83

November 18, 2010

β hCG Assay: Pre-Analytical Factors can Contribute to Falsely Elevated Results.

Contact:

Dr. Jeffrey Wisotzkey, 717-851-1422
Technical Director, CPAL

Stephanie Williams, MT(ASCP), 717-852-4768
Operations Manager, CPAL

Summary:

CPAL has received a notice (URGENT PRODUCT CORRECTIVE ACTION) from the manufacturer of the β hCG assay used in our laboratory. Beckman Coulter has confirmed that non-reproducible falsely elevated test results may occur when using the Access Total β hCG assay. These elevated results are often attributed to pre-analytical factors and are particularly noted at the low end of the analytical measuring range.

The role of pre-analytical factors in laboratory testing has been described in a variety of published literature.

- The effect of pre-analytical factors on total β hCG results is discussed in the FDA communication “Blood Human Chorionic Gonadotropin (hCG) Assays: What Laboratorians Should Know about False-Positive Results.”
- The impact of improperly collected, handled, or stored blood specimens on β hCG test results is described in the Clinical Laboratory Standards Institute (CLSI) guideline, “Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests” and the CLSI standard, “Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture.”

Issued on: November 15, 2010

For questions about this and other information, call Central Pennsylvania Alliance Laboratory at 1-888-480-1422.

ACTION/RESOLUTION:

CPAL reminds our clients that proper specimen handling is imperative for all laboratory specimens submitted for analysis, including specimens submitted for β hCG analysis.

- Any total β hCG result that is questioned due to lack of clinical correlation should be brought to the attention of the laboratory and repeat testing may be indicated.

NOTE: Due to the clinical utility of the Access Total β hCG assay as a biomarker of pregnancy, Beckman Coulter feels it is unnecessary to require a review of all previously obtained Access Total β hCG test results. The Access Total β hCG assay is intended as a marker for pregnancy at the time of testing. A discrepant or questionable result would have been brought to the attention of the laboratory. The pregnancy status of a patient at this point, post testing, would be known to the patient and the physician.

- Please share this information with your laboratory staff and your phlebotomy director and/or phlebotomy staff and retain this notification as part of your laboratory Quality System documentation.

Keys to proper specimen handling for the β hCG assay:

- Store collection tubes according to the manufacturer's recommendations.
- Collect all blood samples observing routine precautions for venipuncture.
- Mix the contents of tubes properly at the time of collection to prevent incomplete clot formation.
- Allow serum samples to clot completely before centrifugation.
- Within two hours of centrifugation, transfer at least 500 uL of cell-free sample to a tightly stoppered storage tube.
- Store samples at room temperature (15 - 30°C) for no more than eight hours. For storage longer than eight hours, refrigerate the specimen (2 - 8°C).
- If the assay will not be completed within 48 hours, freeze the specimen at - 20°C or colder.

In cases when a β hCG test result does not match the patient's clinical presentation, it is important that the physician gather all the available information and reassess the patient. The physician may:

- Consider the possibility that some other clinical condition may be causing an elevated β hCG level
- Communicate with the laboratory staff about the test result and ask the laboratory to rule out technical errors, analytical interfering factors, and device malfunction.
- Consider repeating the blood draw and retesting.
- Consider testing with urine.
- Review the clinical presentation and consider additional diagnostic testing and bear in mind that the β hCG test result is only one piece of the diagnostic puzzle.

References:

1. Blood Human Chorionic Gonadotropin (hCG) Assays: What Laboratorians Should Know about False-Positive Results. Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting, 2009.
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109390.htm>
2. Approved Guideline—Fourth Edition, Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, H18-A4, 2010; Clinical Laboratory Standards Institute.
3. Approved Standard —Sixth Edition, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, H3- A6, 2007; Clinical Laboratory Standards Institute
4. URGENT: PRODUCT CORRECTIVE ACTION Access Total β hCG for use on Access Immunoassay Systems **PCA-15144** Beckman Coulter, Inc. (Letter Dated 11/11/2010).