



CPAL

Central Pennsylvania Alliance
Laboratory

Technical Bulletin

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Method Change: Hepatitis B Surface Antigen

Effective September 15, 2003, testing for Hepatitis B surface antigen (HBsAg) will be changed to the Ortho's HBsAg Test System 3.0. Since January 2003, the current kit for HBsAg (Bio-Rad Genetic Systems HBsAg EIA 2.0) has been producing significantly higher numbers of false positives compared with historical data. CPAL staff has worked with Bio-Rad to trouble shoot the problem during this period of time. Meanwhile, manufacturers have been developing a more sensitive test for HBsAg to meet the new FDA recommendation. The current kit (Genetic systems HBsAg EIA 2.0) has been discontinued. CPAL has evaluated the latest version of the HBsAg test kits from two vendors, Bio-Rad and Ortho. Initial evaluation of these two HBsAg 3.0 systems showed that the Ortho HBsAg 3.0 test system is more specific and sensitive than the current Genetic Systems HBsAg EIA 2.0. In one of the evaluation runs consisting of 90 specimens, the Ortho HBsAg 3.0 test system did not produce a single positive result whereas Genetic Systems HBsAg EIA 2.0 gave 13 false positive results on the same specimens.

CPAL will implement an automated plate processor, Ortho's OSP system, in the near future. Ortho's HBsAg Test System 3.0 is the only assay for HBsAg validated on the OSP by Ortho. The automated plate processor will help to ensure the positive ID of a specimen and improve the reproducibility of the assay.

The actual positive rate by the Ortho's HBsAg Test System 3.0 on our blood donor population is unknown at this point. We anticipate that the false reactivity rate associated with HBsAg testing will be reduced. We will monitor the positive rate on a monthly basis once we start the new Ortho's HBsAg Test System 3.0 kit. We will further inform you with the results.

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