



New Device Approvals

Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit - P000044

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit
Manufacturer: Ortho-Clinical Diagnostics
Address: 100 Indigo Creek Drive, Rochester, New York 14626-5101
Approval Date: April 27, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000044a.pdf>

What is it? This kit is used with the Ortho-Clinical Diagnostics' Vitros ECi Immunodiagnostic System to identify certain virus proteins associated with hepatitis B virus (HBV). If these virus proteins are present, then the patient is likely to be infected with HBV.

How does it work? A sample of the patient's blood is placed into wells coated with antibodies to HBV. If the blood sample contains HBV proteins, they will bind to the antibodies in the wells. This reaction is detected by another substance that produces light, which is then measured to determine the amount of HBV in the blood. If this first test is positive, the patient's blood is retested to confirm the presence of HBV.

When is it used and What will it accomplish? This test is used to confirm whether or not a person has HBV. It is also used on pregnant women to see if the child may be at high risk for HBV infection.

When should it not be used? This test should not be used for screening blood donors because FDA has not licensed it for this purpose.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p000044.html>

Other:

CDC: <http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm>

Liver Foundation site: (click on liver dysfunction and disease; select hepatitis B)

<http://www.liverfoundation.org/html/livheal.dir/livheal.htm>

(Updated August 2, 2001)