



New Device Approvals

Elecsys® HBsAg Immunoassay, Elecsys® HBsAg Confirmatory, and PreciControl HBsAg - P990012

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: Elecsys® HBsAg Immunoassay, Elecsys® HBsAg Confirmatory, and PreciControl HBsAg
Manufacturer: Roche Diagnostics Corporation
Address: 9115 Hague Road, PO Box 50457, Indianapolis, IN 46250-0457
Approval Date: June 1, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990012a.pdf>

What is it? Laboratory test used to detect an antigen associated with hepatitis B virus (HBV).

How does it work? A sample of the patient's blood is placed in contact with HBV antibodies. (Antibodies are substances produced by the body to fight against foreign substances called antigens, such as HBV.) If the patient is infected with HBV, antigens will be present, and these will cause a chemical reaction to occur when the test is run. The physician will analyze the results of this reaction and determine the status of HBV in the body.

When is it used? To determine whether a person is infected with the hepatitis B virus and to help determine what stage the disease is in. Also to test pregnant women to see if the unborn baby is at risk for HBV infection.

What will it accomplish? This test helps to determine the stage of HBV infection and what treatment may be needed.

When should it not be used? This test should be used only when prescribed by a doctor. Also, it should never be used for screening blood donors, because it has not been proven effective for this purpose.

Additional information: Summary of Safety and Effectiveness and labeling are available

at: <http://www.fda.gov/cdrh/pdf/p990012.html>

Other:

- CDC: <http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm>
- Liver Foundation (click on liver dysfunction and disease; select hepatitis B)
<http://www.liverfoundation.org/html/livheal.dir/livheal.htm>

(Updated 10/3/2001)