Roche Elecsys® Anti-HBs Immunoassay & Elecsys® PreciControl Anti-HBs - P010054

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 Anti-HBs Immunoassay and Elecsys PreciControl Anti-HBs
Manufacturer:	Roche Diagnostics Corporation
Address:	9115 Hague Road, P.O. Box 50457, Indianapolis, IN 46250-0457
Approval Date:	February 27, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010054a.pdf

What is it? A laboratory test that indicates how immune a person is to hepatitis B virus (HBV) and to follow the course of disease following hepatitis B infection. It does this by measuring the level of *antibodies to hepatitis B surface antigen* (anti-HBs) in a sample of blood. These antibodies, which were formed either during a previous hepatitis B infection or because of receiving the hepatitis B vaccine, help protect against future infections with hepatitis B.

How does it work? A laboratory uses this test only with its Roche Elecsys 2010 immunoassay analyzer. To perform the test, certain chemicals are added to the patient's blood sample. This produces a light reaction which is measured inside the analyzer. The amount of light produced shows the level of anti-HBs in the blood. A second device, the Elecsys PreciControl Anti-HBs, helps assure that the test performs accurately.

What is new about this device?

- It allows a laboratory with the Roche Elecsys 2010 analyzer to measure the level of anti-HBs in a blood sample.
- Its accuracy relies on World Health Organization standards.
- It will show directly whether the level of immunity is greater than 10 mIU of anti-HBs/mL, the lowest level of anti-HBs that produce immunity, according to the Centers for Disease Control and Prevention.

What will it accomplish? This test can help show whether a person should have the HBV vaccine to prevent future infection.

When should it not be used? This test should not be used for screening blood donors-that is, for showing which donors have not had HBV.

Additional information: Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p010054.html

Other:

- Centers for Disease Control and Prevention-Viral Hepatitis: http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm
- What I Need to Know About Hepatitis B-NIH-NIDDK Site: http://www.niddk.nih.gov/health/digest/pubs/hep/hepb/hepb.htm#6

(Updated 7/2/2002)