



# New Device Clearance

## Devices for Testing the Hepatitis B Virus (HBV)

*This is a brief overview of information related to FDA's clearance to market this product.*

**Manufacturer:** DiaSorin S.r.l.

**Address:** Via Crescentino, Saluggia (VC) 13040, Italy

**What is it?** This is a series of products consisting of six different laboratory tests to detect antigen(s) or antibodies associated with hepatitis B virus (HBV) infection. The table below describes these tests.

### DEVICES FOR TESTING THE HEPATITIS B VIRUS (HBV)

<u>PMA#</u>	<u>Product Name</u>	<u>What Does It Detect?</u>
<a href="#">990038</a>	DiaSorin ETI-MAK-2 PLUS ASSAY	HBV <b>surface</b> antigen
<a href="#">990041</a>	DiaSorin ETI-AB-EBK PLUS ASSAY	Antibodies to HBV <b>e</b> antigen
<a href="#">990042</a>	DiaSorin ETI-AB-AUK Plus ASSAY	Antibodies to HBV <b>surface</b> antigen
<a href="#">990043</a>	DiaSorin ETI-EBK PLUS ASSAY	HBV <b>e</b> antigen
<a href="#">990044</a>	DiaSorin ETI-CORE-IGMK PLUS ASSAY	IgM antibodies to HBV <b>core</b> antigen
<a href="#">990045</a>	DiaSorin ETI-AB-COREK PLUS ASSAY	Total antibodies to HBV <b>core</b> antigen

**How does it work?** A sample of the patient's blood is placed in contact with either HBV antibodies or HBV antigens. (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 and eventually antibodies 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.

**What will it accomplish?** The tests help to determine the stage of HBV infection and what treatment may be needed. Depending on the results of these assays, the doctor may recommend vaccination.

**When should it not be used?** These tests should be used only when prescribed by a doctor. Also, they should never be used for screening blood donors, because FDA has not approved them for this purpose.

**Additional information:** Summary of Safety and Effectiveness and labeling will be available at

[P990038](#) DiaSorin ETI-MAK-2 PLUS ASSAY

[P990041](#) DiaSorin ETI-AB-EBK PLUS ASSAY

[P990042](#) DiaSorin ETI-AB-AUK Plus ASSAY

[P990043](#) DiaSorin ETI-EBK PLUS ASSAY

[P990044](#) DiaSorin ETI-CORE-IGMK PLUS ASSAY

[P990045](#) DiaSorin ETI-AB-COREK PLUS ASSAY

**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 6/25/2001)*