Consumer Information on: Elecsys & #xae; Anti-HBc IgM Immunoassay and Elecsys & #xae; PreciControl Anti-HBc IgM for use on the MODULAR ANALYTICS E170 Immunoassay Analyzer - P11002...

U.S. Food & Drug Administration

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 Data (SSED) 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-HBc IgM Immunoassay and Elecsys® PreciControl Anti-HBc IgM for use on the MODULAR ANALYTICS E170 Immunoassay Analyzer
PMA Applicant: Roche Diagnostics
Address: 9115 Hague Road, Indianapolis, IN 46250 USA
Approval Date: December 14, 2011
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110025a.pdf [1]

What is it? The Elecsys® Anti-HBc IgM Immunoassay is a laboratory test used to detect antibodies associated with the hepatitis B virus (HBV) [2] infection. Antibodies are proteins produced by the body to fight against foreign substances, such as viruses and bacteria. The presence of these specific IgM-class antibodies against the hepatitis B core antigen can help determine if a person is currently infected or has recently been infected with HBV. This test is designed for use on the MODULAR ANALYTICS E170 analyzer, which runs the assay and analyzes the results.

How does it work? A person's blood sample is added to a tube (vial) with the test chemicals. If there are IgM antibodies to the hepatitis B core antigen in the blood, they attach to special microparticles to affect the production of a light signal. The light signal is measured by the MODULAR ANALYTICS E170 analyzer. The Elecsys PreciControl Anti-HBc IgM is used as a quality control to ensure that the test is working properly.

When is it used? The test result is used in combination with other clinical information and blood tests to aid in the diagnosis of individuals with signs and symptoms of hepatitis, or in individuals at risk for hepatitis B infection.

What will it accomplish? Results of this laboratory test, in combination with other clinical information and laboratory blood tests, may be used by the clinician to aid in the diagnosis of patients with the symptoms of hepatitis or who may be at risk for HBV infection.

When should it not be used? The Elecsys Anti-HBc IgM Immunoassay should not be used for monitoring of HBV disease or therapy.

Additional information: Summary of Safety and Effectiveness and labeling [3] are available online.

Other Resources:

- American Association for the Study of Liver Disease – Practice Guidelines Archive [4]

SOURCE [5]

Source URL (retrieved on *07/12/2014 - 6:40pm*):
http://www.mdtmag.com/news/2011/12/consumer-information-elecsys-xae-anti-hbc-igm-immunoassay-and-elecsys-xae-precicontrol-anti-hbc-igm-use-modular-analytics-e170-immunoassay-analyzer-p11002?qt-most_popular=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110025a.pdf
[2] http://www.nlm.nih.gov/medlineplus/hepatitisb.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110025
[4] http://www.aasld.org/practiceguidelines/Pages/ArchivePracticeGuidelines.aspx
[5] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm284416.htm