



New Device Approvals

Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators

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 Anti-HBs Reagent Pack and Calibrators
Manufacturer: Ortho-Clinical Diagnostics
Address: 100 Indigo Creek Drive, Rochester, New York 14626-5101
Approval Date: September 29, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000014a.pdf>

What is it? The *Reagent Pack and Calibrators* are used with the Ortho-Clinical Diagnostics' Vitros ECi Immunodiagnostic System to detect antibodies to the hepatitis B virus (anti-HBs). The purpose of the test is to determine if the patient has been previously infected with the hepatitis B virus.

How does it work? Patient blood serum being tested for anti-HBs is placed into wells coated with antigen. An antigen is any substance your body regards as dangerous and will produce an antibody to defend itself against. If there are anti-HBs in the blood, they stick to the coating of antigen in the wells. The wells are washed to remove excess blood. *Reagent Pack* solution is then added to the wells. If there are antigens stuck in the coating in the wells, they react with the *Reagent Pack* solution to produce light. The amount of light produced is measured and gives the amount of anti-HBs that were in the patient's blood serum.

Calibrators help ensure that the test gives the correct results. They help assure that the test system shows the status of a patient's immunity to hepatitis B virus consistent with current Centers for Disease Control and Prevention's recommendation.

When is it used? When it is necessary to determine whether a patient has produced antibodies as a result of a previous infection by hepatitis B virus. A patient that has antibodies may not need a vaccination.

What will it accomplish? Test results help determine whether a patient should be advised to receive the hepatitis B virus vaccine.

When should it not be used? It should not be used if it is not ordered by a physician. This test is a prescription device. This test has not been FDA licensed for screening blood donors.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p000014.html>