

FDA-Approved HBsAg Assays (Updated 8/29/2012)

Tradename	Method	Sample Type	Manufacturer	Sample Volume (microliters)	Initial Test Result = Reactive (S/CO \geq 1.00) ¹	Confirmation Requirements	Confirmation Protocol
PRISM HBsAg Reagent Kit ²	Chemiluminescent Immunoassay (ChLIA)	Serum/Plasma	Abbott Laboratories	100 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using PRISM HBsAg Confirmation Assay	Neutralization
ARCHITECT HBsAg Reagent Kit	Chemiluminescent Microparticle Immunoassay (CMIA)	Serum/Plasma	Abbott Laboratories	200 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using ARCHITECT HBsAg Confirmation Assay	Neutralization
ARCHITECT HBsAg Qualitative Reagent Kit	Chemiluminescent Microparticle Immunoassay (CMIA)	Serum/Plasma	Abbott Laboratories	200 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using ARCHITECT HBsAg Qualitative Confirmation Assay	Neutralization
AxSYM HBsAg Reagent Kit ³	Microparticle Enzyme Immunoassay (MEIA)	Serum/Plasma	Abbott Laboratories	194 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using AxSYM HBsAg Confirmation Assay	Neutralization
GS HBsAg EIA 3.0 Reagent Kit	Enzyme Immunoassay (EIA)	Serum/Plasma	Bio-Rad Laboratories	100 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using GS HBsAg Confirmatory Assay 3.0	Neutralization
ETI-MAK-2 Plus Reagent Kit ⁴	Enzyme Immunoassay (EIA)	Serum/Plasma	DiaSorin Diagnostics	100 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using DiaSorin HBsAg Confirmatory Assay	Neutralization
VITROS HBsAg Eci Reagent Kit ⁵	Chemiluminescent Immunoassay (ChLIA)	Serum/Plasma	Ortho-Clinical Diagnostics	80 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using VITROS HBsAg Confirmatory Assay	Neutralization
ELECSYS HBsAg Reagent Kit	Electrochemiluminescent Immunoassay (ECLIA)	Serum/Plasma	Roche Diagnostics	50 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using ELECSYS HBsAg Confirmatory Assay	Neutralization
Immulite HBsAg Reagent Kit (1000/2000) ⁶	Chemiluminescent Enzyme Immunoassay (ChLIA)	Serum/Plasma	Siemens Healthcare Diagnostics	100 μ L	Retest in duplicate	HBsAg confirmation required (repeatedly reactive specimens) using Immulite HBsAg Confirmatory Assay	Neutralization
ADVIA Centaur HBsAg Reagent Kit ⁷	Magnetic Particle Chemiluminescent Immunoassay (ChLIA)	Serum/Plasma	Siemens Healthcare Diagnostics	100 μ L	Retest in Duplicate	HBsAg confirmation required (repeatedly reactive specimens) using ADVIA Centaur HBsAg Confirmatory Assay	Neutralization

1. The Signal to Cut-off Ratio (S/C) for all HBsAg/Anti-HBs assays is \geq 1 (reactive) and $<$ 1 (non-reactive). This is the index value where 10mIU/mL = 1 Index Value Unit.

2. Screening assay for donated blood to prevent transmission of HBV to recipients of blood and blood components.

3. The assay may be used to test for HBV in pregnant women.

4. This assay may be used to screen for hepatitis B infection in pregnant women to identify neonates who are at high risk of acquiring HBV during the perinatal period.

5. In instances when HBsAg is used as a stand-alone assay (e.g., in pregnant women being screened to identify neonates who are at risk for acquiring HBV during perinatal period), supplemental testing performed with VITROS HBsAg Confirmatory Kit must be used to confirm the result.

6. When Immulite is used as a stand-alone assay for screening pregnant women to identify neonates who are at risk for acquiring HBV during perinatal period, supplemental testing performed with Immulite HBsAg Confirmatory Kit must be used to confirm the test.

7. When the ADVIA Centaur HBsAg is used as a stand-alone assay (e.g., screening for pregnant women), all results $>$ 1.00 should be considered initially reactive. Repeat testing, and supplemental testing performed with ADVIA Centaur HBsAg Confirmatory Assay must be used to confirm the result.