

FDA-Approved Anti-HBs Assays (Updated 8/29/2012)

Tradename	Method	Sample Type	Manufacturer	Sample Volume (microliters)	Quantitative/Qualitative Results	Lowest Level to Detect Immunity	Assay Measuring Range	Dilution Protocol	Rules for Repeat Testing if Initial Result is in the "Gray Zone" ¹
ARCHITECT AUSAB (Anti-HBs)	Chemiluminescent Microparticle Immunoassay (CMIA)	Serum/Plasma	Abbott Laboratories	200µL	Quantitative/Qualitative	≥12.0mIU/mL	0.00mIU/mL-1000mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥8.0mIU/mL and <12.0mIU/mL) ²
AxSYM AUSUB (Anti-HBs)	Microparticle Enzyme Immunoassay (MEIA)	Serum/Plasma	Abbott Laboratories	200µL	Quantitative/Qualitative	>12.0mIU/mL	0.00mIU/mL-500mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥8.0mIU/mL and ≤12.0mIU/mL) ³
Monolisa Anti-HBs EIA	Enzyme Immunoassay (EIA)	Serum/Plasma	Bio-Rad	100µL	Quantitative/Qualitative	>11.0mIU/mL	0.00mIU/mL-1000mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥9.0mIU/mL and ≤11.0mIU/mL) ⁴
ETI-AB-AUK Plus (Anti-HBs)	Enzyme Immunoassay (EIA)	Serum/Plasma	DiaSorin	100µL	Qualitative Only	>10.0mIU/mL	Not Applicable	Not Applicable	Retest in Duplicate: (Absorbance within 90-100% of Immunity Cutoff) ⁵
VITROS Anti-HBs ECI Reagent Kit	Chemiluminescent Immunoassay (ChLIA)	Serum/Plasma	Ortho-Clinical Diagnostics	80µL	Quantitative/Qualitative	≥12.0mIU/mL	4.23mIU/mL-1000mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥5.0mIU/mL and <12.0mIU/mL) ⁶
ELECSYS Anti-HBs Reagent Kit	Electrochemiluminescent Immunoassay (ECLIA)	Serum/Plasma	Roche Diagnostics	40µL	Quantitative/Qualitative	≥11.5mIU/mL	3.5mIU/mL-1000mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥8.5mIU/mL and <11.5mIU/mL) ⁷
Immulite Anti-HBs Reagent Kit (1000/2000)	Chemiluminescent Enzyme Immunoassay (ChLIA)	Serum/Plasma	Siemens Healthcare Diagnostics	50µL	Quantitative/Qualitative	≥10.0mIU/mL	3.0mIU/mL-2000mIU/mL	None Listed in package Insert	None Listed in package Insert
ADVIA Centaur Anti-HBs Reagent Kit	Microparticle Chemiluminescent Immunoassay (ChLIA)	Serum/Plasma	Siemens Healthcare Diagnostics	100µL	Quantitative/Qualitative	≥12.5mIU/mL	2.8mIU/mL-1000mIU/mL	Specimens with an anti-HBs value exceeding 1000 mIU/mL require dilution as described in package insert.	Retest in Duplicate: (≥7.5mIU/mL and <12.5mIU/mL) ⁸

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

2. Gray Zone: One or both of the duplicate retests are repeatedly gray zone. Gray Zone for anti-HBs and the immune status of the individual should be further assessed by considering other factors such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information.

3. Gray Zone: One or both of the duplicate retests are repeatedly gray zone. Or one retest is reactive and the other nonreactive; Gray Zone for anti-HBs and the immune status of the individual should be further assessed by considering other factors such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information.

4. Test results ≥9 and ≤11 are considered borderline. For borderline specimens, the subject can be re-collected in 2-3 weeks for additional testing. In conjunction with these results, the immune status of the subjects should be evaluated based on their clinical status, related risk factors, and other diagnostics test results.

5. If a specimen is found repeatedly equivocal, the pattern of other hepatitis B serological markers should be used to identify status of disease or another sample should be collected and tested at a later date.

6. A result of ≥5.0mIU/mL and <12.0mIU/mL indicates the sample is indeterminate for anti-HBs and should be retested in duplicate. The result is indeterminate if both repeats are ≥5.0mIU/mL and <12.0mIU/mL. If the result remains indeterminate, the immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors and the use of additional diagnostic information.

7. A result of ≥8.5mIU/mL and <11.5mIU/mL indicates the sample is indeterminate for anti-HBs and should be retested in duplicate. The result is indeterminate if both repeats are ≥8.5mIU/mL and <11.5mIU/mL. If the result remains indeterminate, the individual should be further assessed by associated risk factors and the use of additional diagnostic information.

8. Retest Zone: Samples with an initial value ≥7.5mIU/mL and <12.5mIU/mL. If results are within the retest zone after initial testing, samples are to be retested. After retesting, if 3 results are available and 2 results ≥1.00, the sample is considered to be reactive. If 3 results are available and 2 results are <1.00, the sample is considered to be non-reactive.