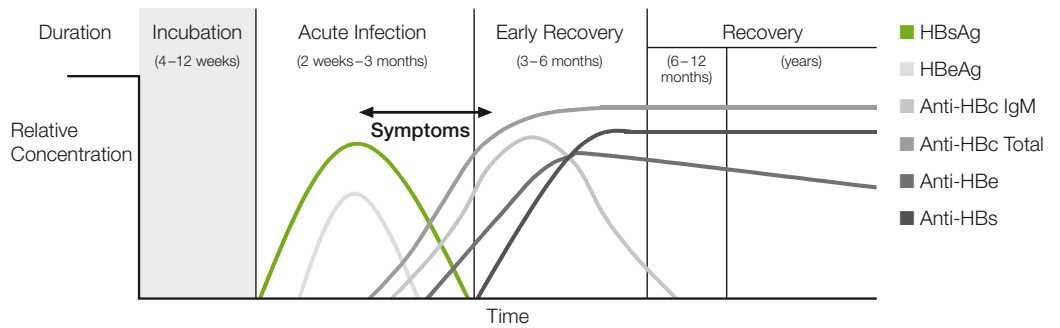




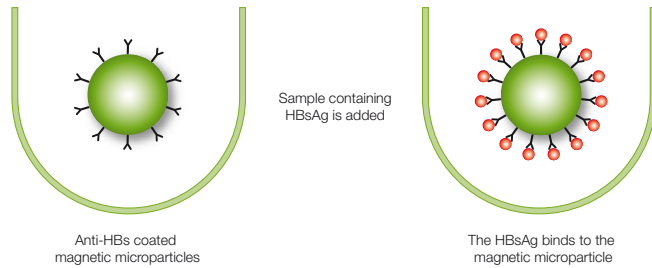
# ARCHITECT HBsAg

## Product Description

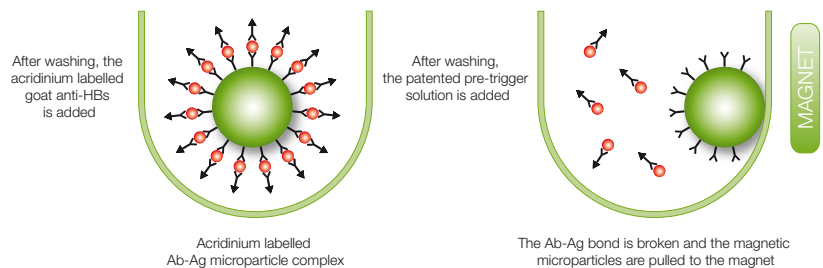
The ARCHITECT HBsAg assay is a two-step immunoassay Chemiluminescent Microparticle Immunoassay (CMIA) technology, with flexible assay protocols referred to as Chemiflex, for the quantitative determination of Hepatitis B surface Antigen (HBsAg) in human serum and plasma.



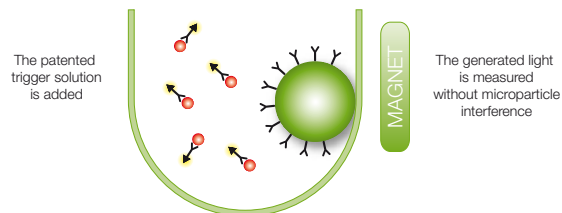
### HBsAg



### HBsAg



### HBsAg



- The ARCHITECT HBsAg assay provides you with a complete automation for the Detection and Quantitation of the Hepatitis B Surface Antigen (HBsAg), thus ensuring a consistent test procedure.
- Superior HBsAg mutant detection when compared to other HBsAg assays.
- Offers exceptional sensitivity and specificity (blood donors as well diagnostic patients) to meet your laboratory needs.
- ARCHITECT HBsAg quantitation can help in the HBV therapy monitorization decision.
- Your laboratory can produce reliable results in approx. 28 minutes from sample loading with a high throughput of 200 tests/hour.
- ARCHITECT HBsAg assay has high reproducibility, which gives you confidence in the results.

## Specifications

Features																																																																									
<b>Standard Calibrators</b>	2 Calibrators (0 IU/mL and 5 IU/mL)																																																																								
<b>Controls</b>	Negative Control (0.00 IU/mL), Positive 1 and Positive 2 Control (0.25 IU/mL and 175.00 IU/mL)																																																																								
<b>Quality Control Procedure</b>	A single sample of each control tested once every 24 hours.																																																																								
<b>Assay Sensitivity*</b>	The overall sensitivity was estimated to be 99.52% (418/420) or $\leq 0.05$ IU/mL with a range from 0.15 to 0.29 ng/mL using a HBsAg <i>ad/ay</i> reference panel. Excellent mutant detection, the most prevalent HBsAg mutant Gly145Arg was readily detected with a sensitivity equivalent to detection of wild type HBsAg.																																																																								
<b>Assay Specificity*</b>	The overall specificity was estimated to be 99.87% (6001/6009). 5043 Volunteer Whole Blood donors, 500 Hospital patients, 333 Medical Conditions Unrelated to HBV Infection and Potential Interfering Substances and 50 Plasma Specimens from matched Serum/Plasma pairs																																																																								
<b>Interpretation of Results</b>	Specimens $\geq 0.05$ IU/mL are considered reactive.																																																																								
<b>Minimum Sample Volume</b>	Routine = 150 $\mu$ L, plus 75 $\mu$ L to each, additional test. Priority = 75 $\mu$ L plus 50 $\mu$ L for each additional test.																																																																								
<b>Sample Type</b>	Human serum (including serum collected in serum separator tubes). Plasma collected in potassium EDTA, lithium heparin, sodium heparin, sodium citrate, ACD, CPDA-1, CP2D, CPD, and potassium oxalate.																																																																								
<b>Sample Dilution</b>	Specimens with a HBsAg value exceeding 250 IU/mL, are flagged with the code "> 250.00 IU/mL" and may be diluted 1:500 manually.																																																																								
<b>Reagent Stability</b>	The ARCHITECT HBsAg assay reagent kit may be stored on-board the ARCHITECT / System for a maximum of 30 days.																																																																								
<b>Reagent Preparation</b>	None																																																																								
<b>Time to 1st result</b>	28 minutes																																																																								
<b>Throughput</b>	200 tests per hour																																																																								
<b>Reproducibility*</b>	<table border="1"> <thead> <tr> <th>Panel Member</th> <th>Total No. Replicates</th> <th>Grand Mean (IU/mL)</th> <th>Intra-Run SD</th> <th>Intra-Run %CV</th> <th>Inter-Run SD</th> <th>Inter-Run %CV</th> <th>Total SD</th> <th>Total %CV</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>180</td> <td>0.23</td> <td>0.011</td> <td>4.6</td> <td>0.016</td> <td>6.7</td> <td>0.018</td> <td>7.7</td> </tr> <tr> <td>2</td> <td>180</td> <td>4.68</td> <td>0.191</td> <td>4.1</td> <td>0.290</td> <td>6.2</td> <td>0.339</td> <td>7.2</td> </tr> <tr> <td>3</td> <td>180</td> <td>23.76</td> <td>1.205</td> <td>5.1</td> <td>2.179</td> <td>9.2</td> <td>2.268</td> <td>9.5</td> </tr> <tr> <td>4</td> <td>180</td> <td>96.61</td> <td>4.617</td> <td>4.8</td> <td>7.587</td> <td>7.9</td> <td>8.913</td> <td>9.2</td> </tr> <tr> <td>5</td> <td>180</td> <td>182.07</td> <td>9.448</td> <td>5.2</td> <td>14.352</td> <td>7.9</td> <td>21.705</td> <td>11.9</td> </tr> <tr> <td>Positive Control 1</td> <td>180</td> <td>0.23</td> <td>0.018</td> <td>7.8</td> <td>0.020</td> <td>8.8</td> <td>0.022</td> <td>9.7</td> </tr> <tr> <td>Positive Control 2</td> <td>180</td> <td>177.36</td> <td>11.889</td> <td>6.7</td> <td>12.969</td> <td>7.3</td> <td>16.126</td> <td>9.1</td> </tr> </tbody> </table>	Panel Member	Total No. Replicates	Grand Mean (IU/mL)	Intra-Run SD	Intra-Run %CV	Inter-Run SD	Inter-Run %CV	Total SD	Total %CV	1	180	0.23	0.011	4.6	0.016	6.7	0.018	7.7	2	180	4.68	0.191	4.1	0.290	6.2	0.339	7.2	3	180	23.76	1.205	5.1	2.179	9.2	2.268	9.5	4	180	96.61	4.617	4.8	7.587	7.9	8.913	9.2	5	180	182.07	9.448	5.2	14.352	7.9	21.705	11.9	Positive Control 1	180	0.23	0.018	7.8	0.020	8.8	0.022	9.7	Positive Control 2	180	177.36	11.889	6.7	12.969	7.3	16.126	9.1
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\* Representative performance data are shown. Results obtained at individual laboratories and with different populations may vary.