

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0490 / Batch #10778009

## OVERVIEW

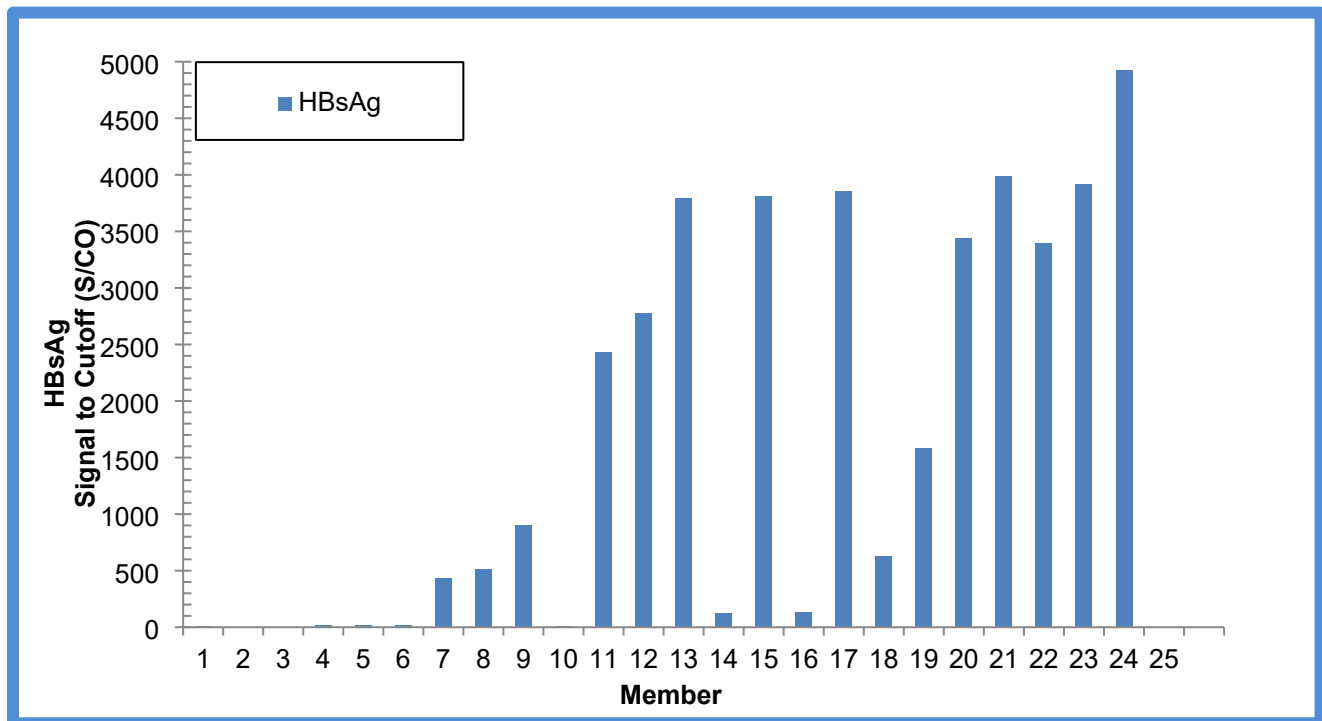
AccuSet™ HBsAg Mixed Titer Performance Panel 0805-0490 / Batch #10778009 is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HBsAg. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HBV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of reactivity for HBsAg test methods. Additional tests performed on HBV DNA, HBeAg, Anti-HBc IgM, Anti-HBc and Anti-HBs are also provided. One sample is included as a non-reactive sample and is negative for all HBV test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HBsAg; all were found negative for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates reactivity amongst panel members from the Abbott ARCHITECT HBsAg Qualitative test method.

# AccuSet<sup>™</sup> HBsAg Mixed Titer Performance Panel

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## Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9219797	BD200250	29-Oct-2007
02	9233734	BD107169	17-Dec-1999
03	9233739	BD107170	13-Jul-2000
04	9145711	NA	03-Sep-1995
05	9145118	BD110654	30-Jun-2002
06	9145779	NA	26-May-1999
07	10267026	BD328507	18-Dec-2015
08	9106121	BD110469	30-Apr-1999
09	BM202047	BD100936	20-Aug-2002
10	10267024	BD328506	04-Jan-2017
11	9233773	HBA5373	11-Sep-1998
12	10118399	BD245052	10-Apr-2013
13	9222259	NA	31-Aug-1997
14	10000788	NA	22-Jan-1997
15	9197827	NA	13-Apr-2006
16	10000624	NA	09-May-1998
17	9214337	BD104482	07-Apr-2007
18	9120447	BD110514	24-Aug-2000
19	9233770	HBA5373	29-May-1998
20	10000814	NA	18-Sep-1998
21	9219555	NA	08-Sep-2006
22	9233790	BD107200	09-Jul-2001
23	9222250	NA	NA
24	10653063	BD512830	12-Jan-2021
25	10591298	BD487505	25-Feb-2021

NA = Not Available

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## HBV DNA<sup>1</sup>

Panel Member	Roche cobas® 6800/8800 HBV (IU/mL)
01	<b>1.60E+01</b>
02	<b>9.42E+02</b>
03	<b>1.83E+03</b>
04	<b>2.34E+03</b>
05	<b>3.70E+02</b>
06	<b>1.01E+04</b>
07	<b>&lt;1.0E+01, 1.80E+01*</b>
08	TND
09	<b>1.55E+01</b>
10	TND
11	<b>3.46E+03</b>
12	<b>4.00E+01</b>
13	<b>5.17E+03</b>
14	<b>2.82E+04</b>
15	<b>1.29E+02</b>
16	<b>2.30E+04</b>
17	<b>4.01E+02</b>
18	<b>1.48E+05</b>
19	<b>2.29E+03</b>
20	<b>8.90E+02</b>
21	<b>7.55E+01</b>
22	<b>1.74E+04</b>
23	<b>5.50E+03</b>
24	<b>1.79E+02</b>
25	TND
Test Date	17-Oct-2025, 22-Oct-2025, 26-Dec-2025
Test Site	RL
Kit Part Code	NA
Kit Lot No.	NA
Kit Exp. Date	NA

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

\*Interpretation variability; individual replicates reported.

RL = Reference Lab; NA = Not Available

TND=Target Not Detected

# AccuSet™ HBsAg Mixed Titer Performance Panel

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## HBsAg<sup>1</sup>

Panel Member	Abbott ARCHITECT HBsAg Qualitative (S/CO)	Abbott Alinity s HBsAg (S/CO)	Abbott Alinity i HBsAg Next Qualitative (S/CO)	Roche Elecsys HBsAg II (COI)	Bio-Rad GS HBsAg EIA 3.0 (S/CO)
01	<b>8.38</b>	<b>10.07</b>	<b>39.73</b>	<b>7.52</b>	<b>5.78</b>
02	<b>1.89</b>	<b>2.18</b>	<b>8.77</b>	<b>1.46</b>	<b>1.74</b>
03	<b>4.05</b>	<b>4.68</b>	<b>13.53</b>	<b>2.51</b>	<b>3.51</b>
04	<b>15.30</b>	<b>17.56</b>	<b>53.36</b>	<b>8.55</b>	<b>12.85</b>
05	<b>14.30</b>	<b>22.82</b>	<b>48.70</b>	<b>8.02</b>	<b>11.92</b>
06	<b>17.92</b>	<b>22.82</b>	<b>52.90</b>	<b>11.64</b>	<b>14.63</b>
07	<b>430.49</b>	<b>565.87</b>	<b>576.86</b>	<b>223.90</b>	<b>36.12</b>
08	<b>514.11</b>	<b>608.97</b>	<b>893.51</b>	<b>259.70</b>	<b>36.00</b>
09	<b>903.48</b>	<b>1117.51</b>	<b>925.23</b>	<b>408.30</b>	<b>39.49</b>
10	<b>10.29</b>	<b>12.41</b>	<b>41.49</b>	<b>6.72</b>	<b>4.34</b>
11	<b>2430.12</b>	<b>2752.22</b>	<b>2347.74</b>	<b>1654.00</b>	<b>&gt;40.00</b>
12	<b>2771.91</b>	<b>3175.40</b>	<b>4436.53</b>	<b>1454.50</b>	<b>&gt;40.00</b>
13	<b>3789.18</b>	<b>4065.23</b>	<b>4056.07</b>	<b>2598.50</b>	<b>&gt;40.00</b>
14	<b>119.42</b>	<b>143.44</b>	<b>3105.00</b>	<b>62.26</b>	<b>34.54</b>
15	<b>3807.19</b>	<b>3839.69</b>	<b>4001.06</b>	<b>2509.00</b>	<b>&gt;40.00</b>
16	<b>131.22</b>	<b>161.78</b>	<b>3035.20</b>	<b>65.23</b>	<b>34.78</b>
17	<b>3854.23</b>	<b>4149.11</b>	<b>4173.90</b>	<b>2472.50</b>	<b>&gt;40.00</b>
18	<b>629.91</b>	<b>672.97</b>	<b>4255.44</b>	<b>410.55</b>	<b>38.92</b>
19	<b>1583.69</b>	<b>2126.35</b>	<b>1762.91</b>	<b>994.85</b>	<b>&gt;40.00</b>
20	<b>3435.91</b>	<b>4014.72</b>	<b>4005.12</b>	<b>2081.00</b>	<b>&gt;40.00</b>
21	<b>3989.94</b>	<b>4555.33</b>	<b>4085.34</b>	<b>2796.00</b>	<b>&gt;40.00</b>
22	<b>3393.78</b>	<b>3929.81</b>	<b>3384.86</b>	<b>2592.50</b>	<b>&gt;40.00</b>
23	<b>3917.53</b>	<b>4383.99</b>	<b>4272.18</b>	<b>2786.00</b>	<b>&gt;40.00</b>
24	<b>4927.80</b>	<b>5623.98</b>	<b>5304.27</b>	<b>2872.00</b>	<b>&gt;40.00</b>
25	0.19	0.24	0.29	0.42	0.27
Test Date	16-Oct-2025 18-Dec-2025	18-Oct-2025 19-Dec-2025	10-Feb-2026 11-Feb-2026	29-Oct-2025 12-Jan-2026	16-Oct-2025 23-Dec-2025
Test Site	LGC	RL	RL	RL	LGC
Kit Part Code	4P53	NA	NA	NA	32591
Kit Lot No.	75156FZ00 77512FZ00	72222FZ00 75365FZ00	81572FZ00	798142 834995	429WCC-05
Kit Exp. Date	30-Nov-2025 30-Jan-2026	10-Feb-2026 18-Apr-2026	NA	28-Feb-2026 31-Aug-2026	31-Jan-2026

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.  
LGC= LGC SeraCare; RL = Reference Lab; NA = Not Available

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## HBsAg, Anti-HBs<sup>1</sup>

Panel Member	DiaSorin LIAISON® XL Murex	Siemens ADVIA Centaur	DiaSorin LIAISON® XL Murex
	HBsAg (Index)	HBsAg (Index)	Anti-HBs (Index)
01	0.31	0.60	<b>0.18</b>
02	0.22	0.06	2.37
03	0.13	0.14	2.07
04	0.29	0.23	2.21
05	0.12	0.10	2.19, >2.40*
06	0.55	0.47	>2.40
07	<0.10	0.03	<b>&lt;0.10</b>
08	<0.10, 0.12*	0.03	<b>&lt;0.10</b>
09	<0.10	0.00	<b>&lt;0.10</b>
10	<0.10, 0.10*	0.07	2.25
11	<0.10	0.29	<b>0.15</b>
12	0.14	0.00	<b>&lt;0.10</b>
13	0.15	0.18	<b>&lt;0.10</b>
14	<b>1.48</b>	0.69	2.20
15	0.12	0.03	<b>&lt;0.10</b>
16	<b>3.93</b>	<b>2.07</b>	2.30
17	<0.10	0.04	<b>&lt;0.10</b>
18	<b>9.32</b>	<b>11.05</b>	2.27
19	<0.10	0.00	<b>&lt;0.10, 0.10*</b>
20	0.26	0.57	1.18
21	<0.10, 0.12*	0.16	<b>0.10</b>
22	<0.10, 0.11*	0.02	<b>0.10</b>
23	<0.10	0.00	<b>0.10</b>
24	<0.10, 0.22	0.09	<b>0.10</b>
25	<0.10	0.54	>2.40
Test Date	20-Oct-2025 22-Oct-2025 18-Dec-2025	28-Oct-2025 12-Jan-2026	20-Oct-2025 28-Oct-2025 18-Dec-2025
Test Site	LGC	RL	LGC
Kit Part Code	318150	NA	318160
Kit Lot No.	267010 267011	52109094	269011 269012
Kit Exp. Date	10-Aug-2026 25-Mar-2027	26-Sep-2026	24-Jun-2026 01-Jan-2027

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

\*Interpretation variability; individual replicates reported.

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## Anti-HBs, Anti-HBc<sup>1</sup>

Panel Member	Roche Elecsys Anti-HBs (IU/L)	DiaSorin LIAISON® XL Murex Anti-HBs (mIU/mL)	Alinity s Anti-HBc (S/CO)	DiaSorin LIAISON® XL Murex HBc IgM (Index)
01	<3.50	<3.00	<b>6.93</b>	<b>8.66</b>
02	<3.50	<3.00	0.27	<0.10
03	<3.50	<3.00	0.11	<0.10
04	<3.50	<3.00	0.09	0.11
05	<b>18.62</b>	<3.00	0.15	<0.10
06	<b>20.03</b>	<3.00	0.09	0.29, <0.10*
07	<b>19.26</b>	<3.00	<b>7.20</b>	<0.10
08	<b>20.97</b>	<3.00	<b>7.25</b>	<0.10
09	<b>22.58</b>	<3.00	<b>7.84</b>	0.34
10	<b>20.90</b>	<3.00	0.40	0.18
11	<3.50, 3.69*	<3.00	<b>8.39</b>	0.63, 0.73 <sup>2*</sup>
12	4.11	<3.00	<b>7.37</b>	<0.10
13	8.71	10.30 <sup>2</sup>	<b>7.86</b>	0.23
14	<b>21.51</b>	<3.00	0.12	<0.10
15	9.67	<3.00	<b>7.84</b>	0.21
16	<b>23.47</b>	<3.00	0.12	<0.10
17	9.58	<3.00	<b>7.81</b>	<0.10, 0.11
18	<b>23.72</b>	<3.00	0.07	<0.10
19	<3.50	<3.00	<b>8.35</b>	<b>1.51</b>
20	5.45	<3.00	<b>7.03</b>	<0.10
21	4.16	<3.00	<b>7.76</b>	0.45
22	<3.50	<3.00	<b>8.04</b>	<b>1.98</b>
23	9.42, <b>10.09*</b>	<b>13.75</b>	<b>7.97</b>	0.31
24	6.13	<3.00	<b>7.85</b>	0.15
25	<3.50	<3.00	0.08	<0.10
Test Date	29-Oct-2025 30-Oct-2025 12-Jan-2026	15-Oct-2025 19-Dec-2025	18-Oct-2025 19-Dec-2025	20-Oct-2025 18-Dec-2025
Test Site	RL	LGC	RL	LGC
Kit Part Code	NA	318220	NA	318140
Kit Lot No.	849557 854397	271028 271030	73577BE00 77052MM00	265015 265016
Kit Exp. Date	31-Dec-2025 28-Feb-2026	11-Jan-2026 06-Jul-2026	17-May-2026 13-Sep-2026	23-Jul-2026 13-Jan-2027

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

<sup>2</sup>Result is in the grayzone.

\*Individual replicates reported due to inability to determine an average value.

LGC= LGC SeraCare; RL = Reference Lab; NA = Not Available

The package insert for this panel can be found at [www.seracare.com](http://www.seracare.com).

A printed copy of the package insert or data sheet may be requested by email at [CDx-Info@LGCGroup.com](mailto:CDx-Info@LGCGroup.com) or by phone at 508.244.6400.