

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## OVERVIEW

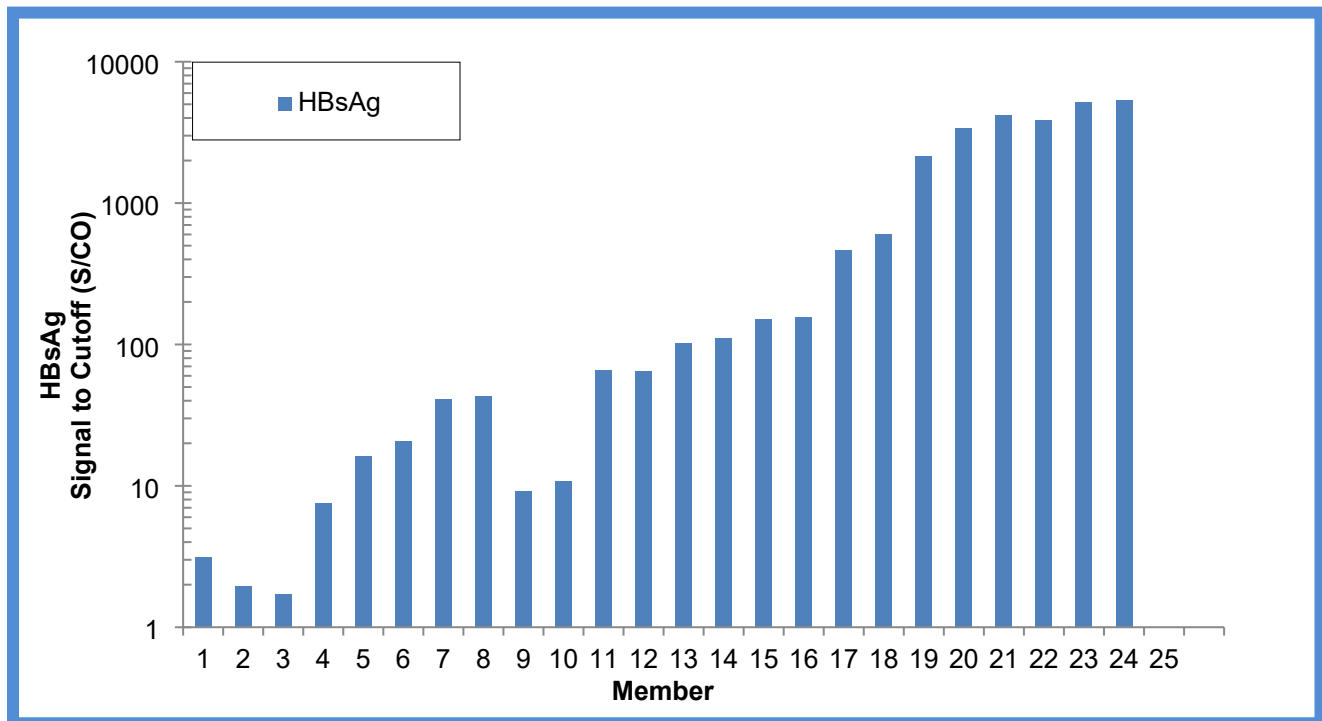
AccuSet™ HBsAg Mixed Titer Performance Panel 0805-0438 / Batch #10624502 is a 25-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HBsAg. Each sample represents a single 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.

AccuSet™ HBsAg Mixed Titer Performance Panel



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

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	BM217629	BD104785	13-Jun-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	9124953	NA	NA
08	9121493	BD110525	NA
09	10266961	BD328480	28-Oct-2015
10	10267024	BD328506	04-Jan-2017
11	9124990	NA	NA
12	10000632	BD226031	25-Jan-1996
13	BM217727	BD105187	18-Aug-2007
14	10000788	NA	22-Jan-1997
15	BM205270	BD102507	26-Apr-2006
16	10000624	NA	09-May-1998
17	9120182	BD110510	NA
18	9120447	BD110514	24-Aug-2000
19	9233770	HBA5373	29-May-1998
20	10000814	NA	18-Sep-1998
21	10267001	BD328495	18-Jan-2016
22	9233790	BD107200	09-Jul-2001
23	9253281	BD110945	18-Feb-2011
24	10266974	BD328486	20-Mar-2016
25	9252285	NA	NA

NA = Not Available

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## HBV DNA

Panel Member	Roche COBAS® Ampliprep / COBAS® Taqman® HBV Test, v2.0 (IU/mL) <sup>1</sup>
01	<b>3.24 x 10<sup>3</sup></b>
02	<b>1.14 x 10<sup>3</sup></b>
03	<b>7.44 x 10<sup>2</sup></b>
04	<b>1.16 x 10<sup>3</sup></b>
05	<b>4.10 x 10<sup>2</sup></b>
06	<b>1.60 x 10<sup>4</sup></b>
07	<b>1.94 x 10<sup>4</sup></b>
08	<b>2.99 x 10<sup>4</sup></b>
09	TND
10	TND
11	<b>6.38 x 10<sup>4</sup></b>
12	<b>1.97 x 10<sup>4</sup></b>
13	<b>1.93 x 10<sup>5</sup></b>
14	<b>4.29 x 10<sup>4</sup></b>
15	<b>2.61 x 10<sup>4</sup></b>
16	<b>4.27 x 10<sup>4</sup></b>
17	<b>3.35 x 10<sup>4</sup></b>
18	<b>1.30 x 10<sup>5</sup></b>
19	<b>2.03 x 10<sup>3</sup></b>
20	<b>7.05 x 10<sup>3</sup></b>
21	<b>2.92 x 10<sup>5</sup></b>
22	<b>1.90 x 10<sup>4</sup></b>
23	<b>1.52 x 10<sup>5</sup></b>
24	<b>1.08 x 10<sup>5</sup></b>
25	TND
Test Date	22-Jul-2022
Test Site	RL
Kit Part Code	NA
Kit Lot No.	J04292
Kit Exp. Date	31-Jul-2023

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

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## HBsAg

Panel Member	Abbott ARCHITECT HBsAg Qualitative (S/CO) <sup>1</sup>	Abbott Alinity s HBsAg (S/CO) <sup>2</sup>	Roche Elecsys HBsAg II (COI) <sup>1</sup>	Bio-Rad GS HBsAg EIA 3.0 (S/CO) <sup>1</sup>	Ortho VITROS HBsAg (S/CO) <sup>1</sup>
01	<b>3.11</b>	<b>3.03</b>	<b>2.12</b>	<b>2.76</b>	<b>1.90</b>
02	<b>1.95</b>	<b>1.95</b>	<b>1.49</b>	<b>1.54</b>	0.51
03	<b>1.72</b>	<b>1.83</b>	<b>1.27</b>	<b>1.44</b>	0.39
04	<b>7.50</b>	<b>7.68</b>	<b>4.28</b>	<b>5.97</b>	<b>2.87</b>
05	<b>16.13</b>	<b>15.16</b>	<b>10.15</b>	<b>13.05</b>	<b>8.41</b>
06	<b>20.57</b>	<b>19.59</b>	<b>15.73</b>	<b>16.50</b>	<b>12.40</b>
07	<b>40.93</b>	<b>41.27</b>	<b>25.75</b>	<b>26.69</b>	<b>18.55</b>
08	<b>43.24</b>	<b>41.91</b>	<b>25.94</b>	<b>13.94</b>	<b>11.30</b>
09	<b>9.19</b>	<b>9.54</b>	<b>6.35</b>	<b>7.12</b>	<b>3.71</b>
10	<b>10.83</b>	<b>11.11</b>	<b>6.88</b>	<b>4.86</b>	<b>2.09</b>
11	<b>66.13</b>	<b>66.00</b>	<b>36.00</b>	<b>32.31</b>	<b>34.05</b>
12	<b>64.68</b>	<b>62.44</b>	<b>34.83</b>	<b>31.71</b>	<b>25.60</b>
13	<b>102.05</b>	<b>104.14</b>	<b>50.47</b>	<b>38.69</b>	<b>77.35</b>
14	<b>110.59</b>	<b>111.27</b>	<b>58.18</b>	<b>37.30</b>	<b>45.60</b>
15	<b>151.95</b>	<b>154.88</b>	<b>91.22</b>	<b>40.90</b>	<b>69.35</b>
16	<b>155.16</b>	<b>163.95</b>	<b>78.52</b>	<b>40.31</b>	<b>66.35</b>
17	<b>460.99</b>	<b>452.91</b>	<b>257.15</b>	<b>&gt;42.55</b>	<b>222.50</b>
18	<b>602.34</b>	<b>589.35</b>	<b>405.25</b>	<b>&gt;42.55</b>	<b>338.50</b>
19	<b>2137.38</b>	<b>2097.11</b>	<b>2181.50</b>	<b>&gt;42.55</b>	<b>1220.00</b>
20	<b>3360.85</b>	<b>3082.80</b>	<b>2797.00</b>	<b>&gt;42.55</b>	<b>1970.00</b>
21	<b>4182.10</b>	<b>3687.13</b>	<b>3305.50</b>	<b>&gt;42.55</b>	<b>2825.00</b>
22	<b>3885.42</b>	<b>3659.19</b>	<b>5030.00</b>	<b>&gt;42.55</b>	<b>2290.00</b>
23	<b>5140.70</b>	<b>4741.58</b>	<b>4445.00</b>	<b>&gt;42.55</b>	<b>4025.00</b>
24	<b>5356.39</b>	<b>4998.29</b>	<b>3666.50</b>	<b>&gt;42.55</b>	<b>5080.00</b>
25	0.20	0.42	0.53	0.28	0.08
Test Date	07-Jul-2022	13-Jul-2022	18-Jul-2022	11-Jul-2022	15-Jul-2022
Test Site	SC	RL	RL	SC	RL
Kit Part Code	4P53	NA	NA	32591	NA
Kit Lot No.	37268FN00	36342FN00	608653	199RCC-05	9081
Kit Exp. Date	07-Oct-2022	26-Jan-2023	30-Nov-2022	31-Aug-2022	17-Mar-2023

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

<sup>2</sup>Results are reported as the mean result of 6 replicates for positive members noted in bold red. Negative member is the mean of duplicate testing. SC=SeraCare; RL = Reference Lab; NA = Not Available

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## HBeAg, Anti-HBe

Panel Member	DiaSorin LIAISON® XL Murex HBeAg (Index) <sup>1</sup>	Siemens ADVIA Centaur HBeAg (Index) <sup>1</sup>	Roche Elecsys Anti-HBe (COI) <sup>1</sup>
01	0.30	0.31	1.81
02	0.28	0.08	1.60
03	0.15	0.09	1.91
04	0.27	0.22	1.90
05	0.20	0.22	1.66
06	<b>0.77</b>	0.64	1.79
07	<b>1.53</b>	<b>1.17</b> , 0.83*	1.75
08	<b>1.63</b>	<b>1.36</b>	1.70
09	0.13	0.14	<b>0.18</b>
10	0.14	0.00	1.80
11	<b>2.17</b>	<b>1.64</b>	1.59
12	0.58	0.40	1.71
13	<b>32.85</b>	<b>2.20</b>	1.78
14	<b>1.58</b>	0.88	1.79
15	<b>4.72</b>	<b>9.73</b>	1.67
16	<b>4.41</b>	<b>2.86</b>	1.83
17	<b>4.49</b>	<b>4.52</b>	1.66
18	<b>10.20</b>	<b>10.89</b>	1.71
19	<0.10	0.10	<b>0.05</b>
20	0.47	0.62	1.22
21	<b>179.50</b>	<b>&gt;1000.00</b>	1.11
22	<0.10	0.12	<b>0.00</b>
23	<b>2.12</b>	<b>2.31</b>	<b>0.96</b>
24	<b>2.75</b>	<b>3.70</b>	<b>0.47</b>
25	0.13	0.26	1.82
Test Date	11-Jul-2022	15-Jul-2022	29-Jul-2022
Test Site	SC	RL	RL
Kit Part Code	318150	NA	NA
Kit Lot No.	267006	68931079 / 21646080	NA
Kit Exp. Date	02-Feb-2023	04-Aug-2023 / 19-Nov-2023	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.

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

# AccuSet™ HBsAg Mixed Titer Performance Panel

0805-0438 / Batch #10624502

## Anti-HBs, Anti-HBc

Panel Member	Roche Elecsys Anti-HBs (mIU/mL) <sup>1</sup>	Abbott Alinity i Anti-HBs (mIU/mL) <sup>1</sup>	DiaSorin LIAISON® XL Murex Anti-HBc (Index) <sup>1</sup>	DiaSorin LIAISON® XL Murex HBc IgM (Index) <sup>1</sup>
01	<3.50	0.09	>2.70	0.15
02	<3.50	0.33	>2.70	<0.10
03	<3.50	0.12	>2.70	<0.10
04	<3.50	0.31	2.09	<0.10
05	<3.50	0.23	2.55	<0.10
06	<3.50	0.14	>2.70	<0.10
07	<3.50	0.23	>2.70	<0.10
08	<3.50	0.00	>2.70	<0.10
09	<3.50	0.18	<b>&lt;0.10</b>	<0.10
10	<3.50	0.03	1.58	0.22
11	<3.50	0.08	>2.70	<0.10
12	<3.50	0.15	>2.70	<0.10
13	<3.50	0.41	2.33	0.10, <0.10*
14	<3.50	0.04	>2.70	<0.10
15	<3.50	0.88	<b>0.46</b>	<b>2.71</b>
16	<3.50	0.39	>2.70	<0.10
17	<3.50	0.25	>2.70	<0.10
18	4.46	0.28	>2.70	<0.10
19	<3.50	0.04	<b>&lt;0.10</b>	<b>1.24</b>
20	<3.50	0.29	<b>&lt;0.10</b>	<0.10
21	<3.50	0.21	<b>&lt;0.10</b>	0.50
22	<3.50	0.21	<b>&lt;0.10</b>	<b>1.70</b>
23	<3.50	0.21	<b>&lt;0.10</b>	<b>1.12</b>
24	<3.50	0.03	<b>&lt;0.10</b>	0.54
25	<3.50	0.13	>2.70	<0.10
Test Date	18-Jul-2022	18-Jul-2022	07-Jul-2022	18-Jul-2022
Test Site	RL	RL	SC	SC
Kit Part Code	NA	NA	318130	318140
Kit Lot No.	585568	31159FN00	263007	265008
Kit Exp. Date	31-Oct-2022	22-Oct-2022	23-Oct-2022	23-Oct-2022

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

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

SC=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.