

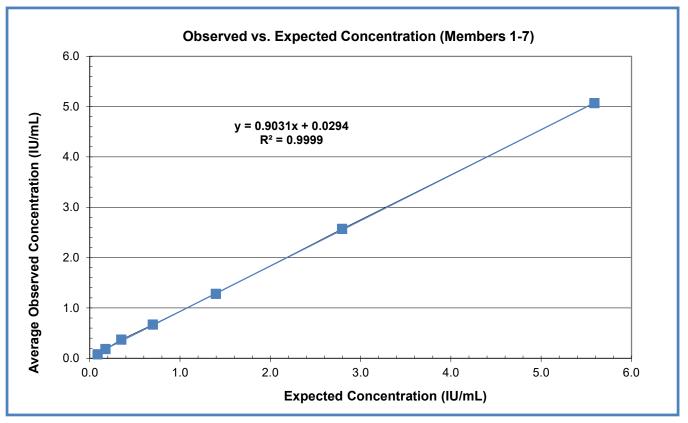
### OVERVIEW

The AccuSpan<sup>™</sup> HBsAg Sensitivity Panel 2410-0161 / Batch Number 10142649 is a 15-member panel composed of two sets of dilution series of HBsAg subtypes ad and ay. Each dilution series consists of seven members representing serial two-fold dilutions of positive serum, with established reactivity for each HBsAg subtype, diluted in negative diluent. The panel also includes a negative member prepared from the negative diluent. The diluent was prepared from pooled normal human serum non-reactive for HBsAg that was filtered through a 0.2 micron filter. Each member contains a preservative (0.1% ProClin 300).

Results are reported for each panel member on each specific test method. Linearity for each dilution series is shown graphically by plotting observed results against expected results. The WHO Reference Panel was tested in the same run as the AccuSpan HBsAg Sensitivity Panel members. Both expected and observed results for the standards are reported; expected results from the WHO standard are based upon application of a dilution factor to the WHO assigned value.

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

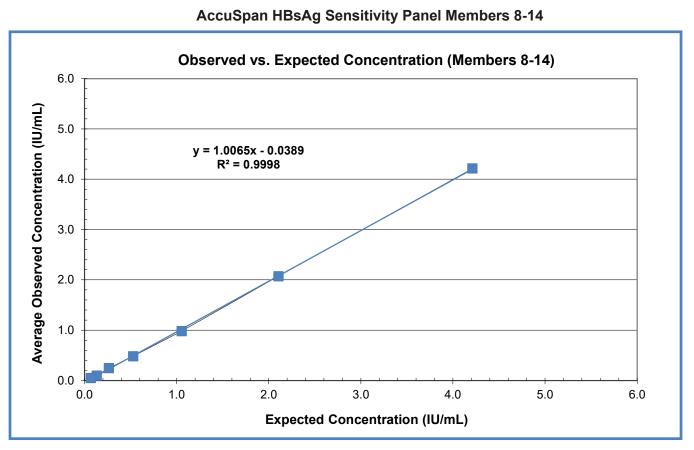
CAUTION: These materials have not been treated and should be considered biohazardous. Follow Universal Precautions.



### AccuSpan HBsAg Sensitivity Panel Members 1-7

HBsAg results were obtained using the Abbott ARCHITECT quantitative HBsAg test method. A line of best fit is shown.





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#### **HBsAg Assays**

|                    |               | Abbott ARCHITECT<br>Quantitative HBsAg | Abbott ARCHITECT<br>Qualitative HBsAg |  |
|--------------------|---------------|--|---------------------------------------|--|
| Panel Member       | HBsAg Subtype | (IU/mL) <sup>1</sup>                   | (S/CO) <sup>1</sup>                   |  |
| 01                 | ad            | 5.59                                   | 308.58                                |  |
| 02                 | ad            | 2.89                                   | 158.27                                |  |
| 03                 | ad            | 1.48                                   | 80.72                                 |  |
| 04                 | ad            | 0.77                                   | 39.76                                 |  |
| 05                 | ad            | 0.39                                   | 19.94                                 |  |
| 06                 | ad            | 0.21                                   | 10.32                                 |  |
| 07                 | ad            | 0.10                                   | 5.19                                  |  |
| 08                 | ау            | 4.58                                   | 246.58                                |  |
| 09                 | ау            | 2.33                                   | 127.99                                |  |
| 10                 | ау            | 1.19                                   | 61.65                                 |  |
| 11                 | ау            | 0.60                                   | 30.95                                 |  |
| 12                 | ау            | 0.32                                   | 16.51                                 |  |
| 13                 | ау            | 0.15                                   | 8.28                                  |  |
| 14                 | ау            | 0.06                                   | 4.23                                  |  |
| 15                 | N/A           | 0.00                                   | 0.24                                  |  |
| Test Date          |               | 22-Oct-2024                            | 07-Oct-2024                           |  |
| Test Site          |               | RL                                     | LGC                                   |  |
| Test Kit Cutoff    |               | 0.05                                   | 1.00                                  |  |
| Test Kit Part Code |               | N/A                                    | 4P53                                  |  |
| Test Kit Lot No.   |               | 65635FZ00                              | 65308FZ00                             |  |
| Test Kit Exp. Date |               | 18-Jun-2025                            | 18-Jan-2025                           |  |

<sup>1</sup>Results are reported as the mean result of triplicate testing. Results in red are considered positive.

RL = Reference Lab; LGC = LGC Clinical Diagnostics; N/A = Not Available



#### WHO HBsAg subtype adw2, genotype A Reference Panel (NIBSC code: 03/262)

|                    | Expected                              | Observed<br>Concentration<br>(IU/mL) <sup>1, 2</sup> |           |                           |  |
|--------------------|---------------------------------------|--|-----------|---------------------------|--|
| Sample ID          | Concentration<br>(IU/mL) <sup>2</sup> |  | Standard  |                           |  |
|                    |                                       |  | Deviation | % Difference <sup>3</sup> |  |
| Sample A           | 8.25                                  | 10.59  | 0.19      | 28%                       |  |
| Sample B           | 2.06                                  | 2.75   | 0.12      | 34%                       |  |
| Sample C           | 0.52                                  | 0.68   | 0.02      | 30%                       |  |
| Sample D           | 0.13                                  | 0.17   | 0.01      | 33%                       |  |
| Sample E           | 0.00                                  | 0.00   | 0.00      | N/A                       |  |
| Test Date          | 19-Nov-15                             |  |           |                           |  |
| Test Site          | RL                                    |  |           |                           |  |
| Test Kit Cutoff    | 0.05                                  |  |           |                           |  |
| Kit Part Code      | N/A                                   |  |           |                           |  |
| Kit Lot No.        | 57375LH00                             |  |           |                           |  |
| Test Kit Exp. Date | 30-Sep-2016                           |  |           |                           |  |
|                    |                                       |  |           |                           |  |

<sup>1</sup>Results are reported as the mean result of triplicate testing. Results in red are considered positive.

<sup>2</sup>WHO panel was tested in the same test run as the AccuSpan HBsAg Sensitivity Panel members.

<sup>3</sup>Percentage difference is how much the observed concentration differs from the expected concentration. Values calculated for

reference only. Some laboratories may use the data to apply a correction factor to the test results.

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The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at <u>CDx-Info@LGCGroup.com</u> or by phone at 508.244.6400.

www.seracare.com