

## AccuVert™ HBV Seroconversion Panel 0605-0038 / Batch # 10669238

#### **OVERVIEW**

AccuVert™ HBV Seroconversion Panel 0605-0038 / Batch #10669238 is an 8-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial) from a genotype A donor. Panel members represent serial bleeds from a single individual collected over 26 days in 2000. No preservatives were added.

Test results from commercially available HBV assays are included for characterization of the panel members. This panel converts from negative to positive for hepatitis B surface antigen (HBsAg). All panel members are positive for HBV DNA.

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. Panel members were found positive for HBV; all were found negative for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

#### 40 100.000 **HBsAg** 35 Positive cut-off (S/CO) **HBV DNA** 10,000 30 HBsAg Signal to Cutoff (S/CO) 25 HBV DNA (IU/mL) 20 1,000 15 10 100 5 0 10 20 10 12 14 18 22 24 26 **Days Since First Bleed**

AccuVert™ HBV Seroconversion Panel

This graph demonstrates the evolution of early HBV infection amongst panel members from the Roche cobas® 6800/8800 (HBV DNA) and Bio-Rad GS (HBsAg) test methods.

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### **Panel Member Information**

| Panel Member | SeraCare Batch # | Bleed Date  | Days Since 1st Bleed |
|--------------|------------------|-------------|----------------------|
| 01           | 9120174          | 19-May-2000 | 0                    |
| 02           | 9120173          | 24-May-2000 | 5                    |
| 03           | 9120172          | 26-May-2000 | 7                    |
| 04           | 9120171          | 31-May-2000 | 12                   |
| 05           | 9120170          | 05-Jun-2000 | 17                   |
| 06           | 9120169          | 07-Jun-2000 | 19                   |
| 07           | 9120168          | 12-Jun-2000 | 24                   |
| 08           | 9120167          | 14-Jun-2000 | 26                   |
|              |                  |             |                      |

### **HBV DNA**

|               | Abbott               | Roche                            |
|---------------|----------------------|----------------------------------|
|               | Alinity m HBV        | cobas <sup>®</sup> 6800/8800 HBV |
| Panel Member  | (IU/mL) <sup>1</sup> | (IU/mL) <sup>1</sup>             |
| 01            | 28.00                | 23.50                            |
| 02            | 120.50               | 100.00                           |
| 03            | 258.50               | 205.50                           |
| 04            | 416.00               | 374.00                           |
| 05            | 1949.00              | 1305.00                          |
| 06            | 2329.50              | 2565.00                          |
| 07            | 7677.50              | 7820.00                          |
| 08            | 10903.50             | 11000.00                         |
| Test Date     | 26-May-2023          | 26-May-2023                      |
| Test Site     | RL                   | RL                               |
| Kit Part Code | NA                   | NA                               |
| Kit Lot No.   | 380903               | NA                               |
| Kit Exp. Date | 15-July-2024         | NA                               |
|               |                      |                                  |

<sup>&</sup>lt;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

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| <b>HBsAg</b> |  |
|--------------|--|
|--------------|--|

|               | Abbott ARCHITECT    | Abbott Alinity s    | Bio-Rad GS          |
|---------------|---------------------|---------------------|---------------------|
|               | HBsAg Qualitative   | HBsAg               | HBsAg EIA 3.0       |
| Panel Member  | (S/CO) <sup>1</sup> | (S/CO) <sup>1</sup> | (S/CO) <sup>1</sup> |
| 01            | 3.41                | 3.75                | 2.13                |
| 02            | 9.59                | 10.54               | 5.15                |
| 03            | 12.94               | 14.39               | 6.67                |
| 04            | 53.47               | 57.27               | 22.02               |
| 05            | 181.21              | 193.29              | 37.04               |
| 06            | 261.83              | 292.88              | 38.95               |
| 07            | 822.33              | 921.87              | 40.00               |
| 08            | 1174.99             | 1243.22             | 40.00               |
| Test Date     | 25-May-2023         | 26-May-2023         | 30-May2023          |
| Test Site     | LGC                 | RL                  | LGC                 |
| Kit Part Code | 4P53                | NA                  | 32591               |
| Kit Lot No.   | 47521FN00           | 45312FN00           | 174TCC-05           |
| Kit Exp. Date | 30-July-2023        | 03-Oct-2023         | 31-July-2023        |
|               |                     |                     |                     |

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

## **HBV** antibody and other assays

| Panel Member  | Abbott ARCHITECT CORE<br>(S/CO) <sup>1</sup> | Abbott ARCHITECT CORE-M (S/CO) <sup>1</sup> | Abbott ARCHITECT<br>AUSAB (anti-HBs)<br>(mIU/mL) <sup>1</sup> |
|---------------|--|---|---|
| 01            | 0.32   | 0.06  | 0.29  |
| 02            | 0.33   | 0.06  | 0.00  |
| 03            | 0.50   | 0.05  | 0.00  |
| 04            | 0.29   | 0.06  | 0.00  |
| 05            | 0.30   | 0.07  | 0.00  |
| 06            | 0.28   | 0.06  | 0.00  |
| 07            | 0.33   | 0.05  | 0.00  |
| 08            | 0.33   | 0.06  | 0.00  |
| Test Date     | 30-May-2023                                  | 26-May-2023                                 | 30-May-2023   |
| Test Site     | LGC  | LGC   | LGC   |
| Kit Part Code | 6L22   | 6L23  | 1L82  |
| Kit Lot No.   | 49082BE00                                    | 48194BE00                                   | 48426FN00   |
| Kit Exp. Date | 17-Dec-2023                                  | 14-Mar-2024                                 | 09-Apr-2024   |

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

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HBeAg, Anti-HBe

| Panel Member  | DiaSorin LIAISON <sup>®</sup> XL<br>Murex HBeAg<br>(Index) <sup>1</sup> | DiaSorin LIAISON <sup>®</sup><br>Anti-HBe<br>(Index) <sup>1</sup> |
|---------------|---|---|
| 01            | <0.10   | 2.39, >2.40*  |
| 02            | 0.22  | >2.40   |
| 03            | 0.21  | 2.36, >2.40*  |
| 04            | 0.99  | 2.33, >2.40*  |
| 05            | 4.32  | 2.38, >2.40*  |
| 06            | 4.99  | >2.40   |
| 07            | 16.85   | >2.40   |
| 08            | 22.65   | >2.40   |
| Test Date     | 26-May-2023   | 26-May-2023   |
| Test Site     | LGC   | LGC   |
| Kit Part Code | 318150  | 318160  |
| Kit Lot No.   | 267007  | 269007  |
| Kit Exp. Date | 24-Sep-2023   | 14-Aug-2023   |

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

The package insert for this panel can be found at <a href="https://www.seracare.com">www.seracare.com</a>.

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

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<sup>\*</sup>Individual replicates reported.

LGC = LGC Clinical Diagnostics