

PRODUCT INFORMATION

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|----------------------------|-----------------------------------------------------|
| Product SKU | HBVP200 |
| Product Name | HBV Verification Panel 1.4mL |
| Kit Lot Number | 21060113 |
| Source Material | Inactivated HBV |
| Date of Expiration | 2023-05-31 |
| Base Matrix | True EDTA Plasma |
| Preservative | ProClin® 300 |
| Fill Volume | 1.4 mL |
| Storage Temperature | -20°C or Below |
| Regulatory Status | For In Vitro Diagnostic Use (IVD) |
| Traceability | 3 rd WHO International Standard (10/264) |
| Testing Platform | In-House HBV Assay |

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

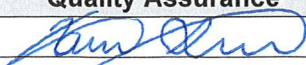
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

| Lot Number | Product Description | Target Concentrations | Results |
|------------|-------------------------------------|-----------------------|---------|
| 21060106 | HBV Panel Member 1: 1E2 IU/mL 1.4mL | 100 IU/mL | Pass |
| 21060107 | HBV Panel Member 2: 1E3 IU/mL 1.4mL | 1,000 IU/mL | Pass |
| 21060108 | HBV Panel Member 3: 1E4 IU/mL 1.4mL | 10,000 IU/mL | Pass |
| 21060109 | HBV Panel Member 4: 1E5 IU/mL 1.4mL | 100,000 IU/mL | Pass |
| 21060110 | HBV Panel Member 5: 1E6 IU/mL 1.4mL | 1,000,000 IU/mL | Pass |
| 21060111 | HBV Panel Member 6: 1E7 IU/mL 1.4mL | 10,000,000 IU/mL | Pass |
| 21060112 | HBV Panel Member 7: 1E8 IU/mL 1.4mL | 100,000,000 IU/mL | Pass |

| Bioburden Testing Results | |
|------------------------------------------|------|
| Acceptance Criteria: Less than 10 CFU/mL | Pass |

APPROVAL

| Quality Assurance | Date |
|-------------------------------------------------------------------------------------|-----------|
|  | 25 Jun 21 |