MONOLISA™ Anti-HBs EIA
Superior Hepatitis Testing from Bio-Rad
**MONOLISA™ Anti-HBs EIA**

Proven Performance and Quantification from a Single Test

- **Enzyme Immunoassay (EIA)** for the Qualitative and Quantitative Detection of Antibody to Hepatitis B Surface Antigen (anti-HBs) in Human Serum and EDTA or Citrated Plasma.
- **Excellent Percent Agreement with Other Anti-HBs FDA Approved Assays**

  The percent agreement between the MONOLISA™ Anti-HBs EIA and the reference anti-HBs assays was evaluated for each specimen classification.

  **Percent Agreement: MONOLISA™ Anti-HBs EIA versus Reference Anti-HBs EIA**

<table>
<thead>
<tr>
<th>HBV Classification</th>
<th>Total Number of Samples</th>
<th>Positive Percent Agreement</th>
<th>Negative Percent Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Infection</td>
<td>14</td>
<td>100.0% (1/1)</td>
<td>100.0% (13/13)</td>
</tr>
<tr>
<td>Chronic Infection</td>
<td>81</td>
<td>66.7% (4/6)</td>
<td>94.7% (71/75)</td>
</tr>
<tr>
<td>Early Recovery</td>
<td>107</td>
<td>75.0% (3/4)</td>
<td>85.4% (88/103)</td>
</tr>
<tr>
<td>Recovery</td>
<td>176</td>
<td>94.7% (163/169)</td>
<td>0.0% (0/3)</td>
</tr>
<tr>
<td>Recovered</td>
<td>12</td>
<td>0.0% (0/1)</td>
<td>0.0% (0/5)</td>
</tr>
<tr>
<td>Past Infection</td>
<td>96</td>
<td>94.8% (91/96)</td>
<td>NA (0/0)</td>
</tr>
<tr>
<td>HBV Vaccine Response</td>
<td>316</td>
<td>97.2% (307/316)</td>
<td>NA (0/0)</td>
</tr>
<tr>
<td>HBV Vaccine Response Status Indeterminate</td>
<td>32</td>
<td>0.0% (0/7)</td>
<td>5.9% (1/17)</td>
</tr>
<tr>
<td>Not Previously Infected</td>
<td>609</td>
<td>NA (0/0)</td>
<td>98.2% (598/609)</td>
</tr>
<tr>
<td>Uninterpretable</td>
<td>9</td>
<td>100.0% (1/1)</td>
<td>100.0% (8/8)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1452</strong></td>
<td><strong>94.3% (567/601)</strong></td>
<td><strong>93.5% (779/833)</strong></td>
</tr>
</tbody>
</table>

The positive percent agreement with the reference method is 94.3% (567/601) with a 95% confidence interval of 92.2 – 95.9%. The negative percent agreement with the reference method is 93.5% (779/833) with a 95% confidence interval of 91.6 – 95.0%.

The 18 specimens that were indeterminate by both assays were not included in the percent agreement calculations.

**Ease-of-Use**
- No sample predilution
- Ready-to-use calibrators
- Total incubation time = 2.5 hours
- Common reagents can be used with other Bio-Rad EIA assays
- Manual and automated use

**Advanced Safety Features**
- Bar coded reagents
- Color-coded reagent labels
- Microplate strip identification
- Color monitoring for sample and conjugate addition steps

**Excellent Correlation with the Official WHO Reference Standard Panel**

Dilutions of the WHO First International Reference Preparation for Antibody to HBsAg (1977) were run in the Bio-Rad MONOLISA™ Anti-HBs quantitative assay. A linear regression of the mean Anti-HBs EIA result versus the calculated concentration of each WHO dilution was used to determine the anti-HBs concentration.

**Quantification and Wide Calibration Range: MONOLISA™ Anti-HBs Calibrator Kit**

MONOLISA™ Anti-HBs Calibrator Kit allows measurement of a wide range of values in a calibration curve from 0 to 1000 mIU/mL without the need for dilution of high titer samples.

---

*This assay has not been FDA cleared or approved for the screening of blood or plasma donors. Performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic fluid, or pleural fluid.
**MONOLISA® Anti-HBs EIA Testing Procedure**

### Test Format

**Color of Well**

**BEFORE Dispensing**

- **1 HOUR**
  - Microplate coated with human HB antigen, subtypes ad and ay
  - 75 µL of control or sample and 25 µL of Specimen Diluent
  - Incubate for 1 hour at 37° C

**AFTER Dispensing**

**WASH**

- **1 HOUR**
  - 100 µL of Working Conjugate Solution
  - Incubate for 1 hour at 37° C

**WASH**

- **30 MINUTES**
  - 100 µL of Working TMB Solution
  - Incubate for 30 minutes in the dark at room temperature (18-30° C)
  - 100 µL of Stopping Solution
  - Cutoff = Mean OD of 10 mIU/mL
  - Cutoff Calibrator

**READ at dual wavelength 450/615-630 nm and 405/615-630 nm**

- Human HBs antigen
- HBs antigen labeled with Peroxidase
- Anti-HBs Ab from Sample

* Reactive samples after 30 minutes incubation

### Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>25220</td>
<td>MONOLISA® Anti-HBs EIA</td>
<td>192 tests</td>
</tr>
<tr>
<td>25219</td>
<td>MONOLISA® Anti-HBs Calibrator Kit</td>
<td>20 calibrations</td>
</tr>
</tbody>
</table>

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics.