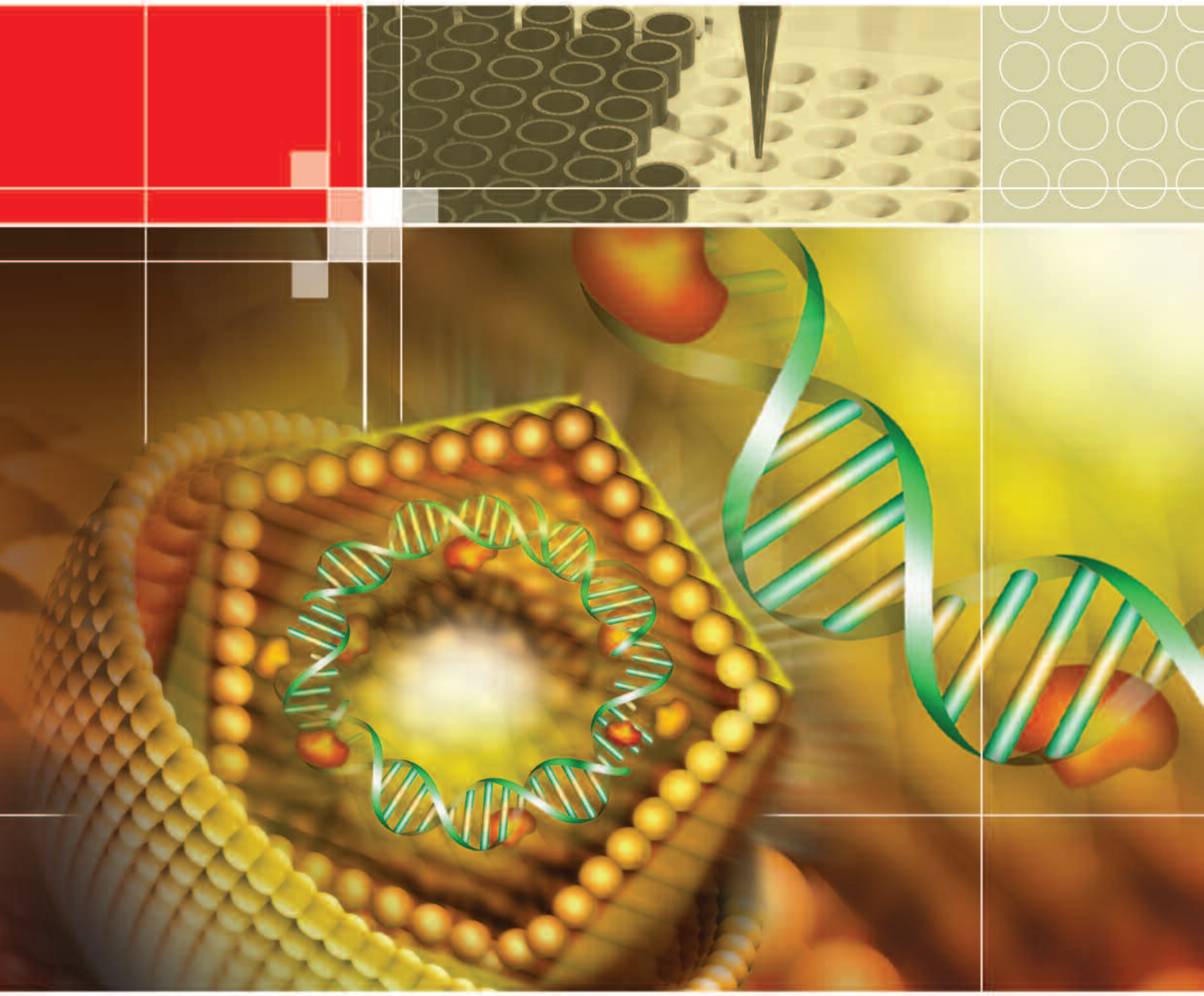
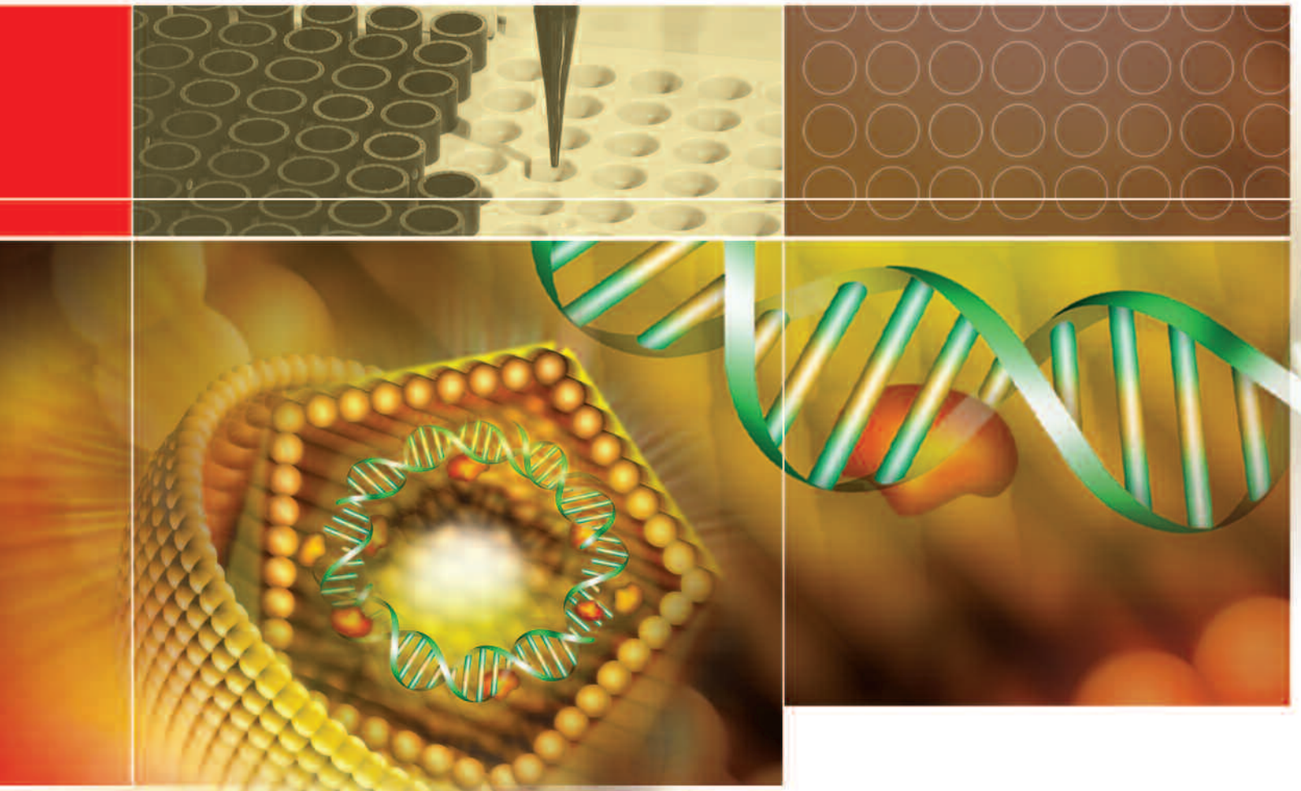


MONOLISA™ Anti-HBs EIA

Superior Hepatitis Testing from Bio-Rad

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.

* 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.

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 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*

HBV Classification	Total Number of Samples	Positive Percent Agreement	Negative Percent Agreement
Acute Infection	14	100.0% (1/1)	100.0% (13/13)
Chronic Infection	81	66.7% (4/6)	94.7% (71/75)
Early Recovery	107	75.0% (3/4)	85.4% (88/103)
Recovery	176	94.7% (160/169)	0.0% (0/3)
Recovered	12	0.0% (0/1)	0.0% (0/5)
Past Infection	96	94.8% (91/96)	NA (0/0)
HBV Vaccine Response	316	97.2% (307/316)	NA (0/0)
HBV Vaccine Response Status Indeterminate	32	0.0% (0/7)	5.9% (1/17)
Not Previously Infected	609	NA (0/0)	98.2% (598/609)
Uninterpretable	9	100.0% (1/1)	100.0% (8/8)
TOTAL	**1452**	**94.3% (567/601)**	**93.5% (779/833)**

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%.

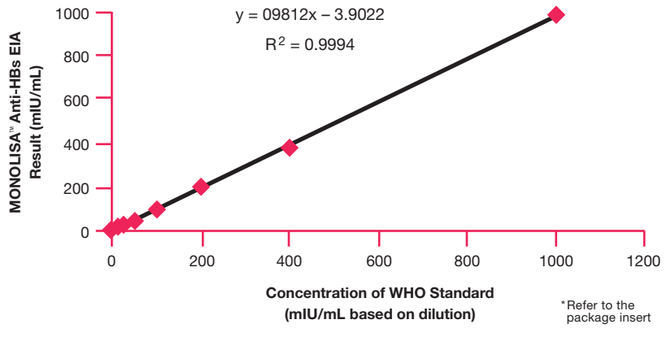
* Refer to the package insert

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

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.

Anti-HBs EIA: WHO Standard*



*Refer to the package insert

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.

MONOLISA™ Anti-HBs EIA Testing Procedure

Test Format

Color of Well BEFORE Dispensing | **Color of Well AFTER 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

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

Catalog No.	Description	
25220	MONOLISA™ Anti-HBs EIA	192 tests
25219	MONOLISA™ Anti-HBs Calibrator Kit	20 calibrations

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

Clinical Diagnostics Group

Website *www.bio-rad.com/diagnostics* ***U.S.*** *1-800-2BIO-RAD* ***Australia*** *61-2-9914-2800* ***Austria*** *43-1-877-8901* ***Belgium*** *32-9-385-5511* ***Brazil*** *5521-3237-9400* ***Canada*** *1-514-334-4372* ***China*** *86-21-64260808* ***Czech Republic*** *420-241-430-532* ***Denmark*** *+45-4452-1000* ***Finland*** *358-9-804-22-00* ***France*** *33-1-47-95-60-00* ***Germany*** *+49-(0)89-318-840* ***Greece*** *30-210-7774396* ***Hong Kong*** *852-2789-3300* ***Hungary*** *36-1-455-8800* ***India*** *91-124-4029300* ***Israel*** *972-3-9636050* ***Italy*** *+39-02-216091* ***Japan*** *81-3-6361-6902* ***Korea*** *82-2-3473-4460* ***Mexico*** *+52-(555)-488-7670* ***The Netherlands*** *+31-318-540666* ***New Zealand*** *64-9-415-2280* ***Norway*** *47-23-38-41-30* ***Poland*** *48-22-3319999* ***Portugal*** *351-21-472-7700* ***Russia*** *7-495-721-14-04* ***Singapore*** *65-6415-3188* ***South Africa*** *27-11-442-85-08* ***Spain*** *34-91-590-5200* ***Sweden*** *46-8-555-127-00* ***Switzerland*** *41-61-717-95-55* ***Thailand*** *662-651-8311* ***United Kingdom*** *+44-(0)20-8328-2000*

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