



Serological Disease Screening Tests for Blood Donation

Your Trusted Blood Safety Partner. For Life.

BIO-RAD

Bio-Rad at a Glance

Bio-Rad Laboratories, Inc. develops, manufactures, and markets a broad range of innovative products and solutions for the clinical diagnostic and life science research markets. The company is renowned for its commitment to quality and customer service among university and research institutions, hospitals, public health, commercial laboratories and blood banks, as well as the biotechnology, pharmaceutical, and food safety industries.

Founded in 1952, Bio-Rad is based in Hercules, California, and serves more than 100,000 research and healthcare industry customers through its global network of operations. The company employs more than 8,350 people worldwide with many facilities (sales offices, R&D sites, manufacturing sites, distribution centers, product training sites, etc.) located around the world.

Clinical Diagnostics

Products for hospitals and public/private laboratories and blood banks

- Infectious Disease (HIV, Hepatitis, Syphilis...)
- Microbiology (Mycology, Bacteriology)
- Immunohematology
- Quality Control
- Autoimmunity
- Diabetes Testing
- Hemoglobinopathy
- Newborn Screening
- Special Chemistry (Toxicology, Clinical HPLC)

Life Science

Products for universities, research institutions, and biotechnology, pharmaceutical, and applied laboratories.

- Food Science
- Life Science Education
- PCR Amplification
- Digital PCR
- Cell Analysis
- DNA/RNA Extraction and Analysis
- Protein Analysis
- Chromatographic Purification
- Biomarkers and Immunoassays
- Protein Sample Preparation



Advance Discovery. Improve Lives.

The Answer for Serological Screening

With an unprecedented level of transfusion safety

Screening for HIV, HCV, HBs Ag and syphilis is important for blood qualification in blood banks. Bio-Rad's four screening tests include early detection and exceptionally high specificity that allow you to report results confidently. The assays are easy to use with safety and fully-automatable features to help create a lab environment that is reliable and efficient.

Bio-Rad Screening Assays

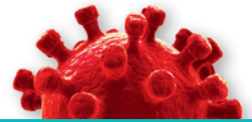
Each assay features early detection and high specificity for reduction of retesting and donor rejection rates along with reduced hands-on time with fully-automatable and secure processes.



HIV

Genscreen ULTRA HIV Ag-Ab Assay 4th Generation

Earlier detection with guaranteed
antigen sensitivity



HCV

Monolisa HCV Ag-Ab ULTRA V2 Assay 4th Generation

Improved detection due to dual antigen
and antibody detection



HBV

Monolisa HBs Ag ULTRA Assay

Earlier detection of hepatitis B infection including variant
detection



Syphilis

Syphilis Total Ab Assay

Earlier and continuous detection of syphilis infection
through IgA, IgM and IgG capture



Increase blood donation safety



Minimize blood unit rejection



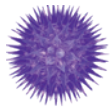
Streamline blood qualification

Specificity

High specificity increases lab efficiency by significantly reducing retest, blood unit, and donor rejection rates

The attention we put into our raw materials selection, manufacturing process and assay procedure allows us to deliver products with an excellent negative specimens distribution that provides high specificity.

Specificity of Non-Selected Blood Donors



Genscreen ULTRA HIV Ag-Ab Assay

99.95%*

Specificity in 3 blood bank sites
(6,035/6,038 specimens)



Monolisa HCV Ag-Ab ULTRA V2 Assay

99.94%*

Specificity in 2 blood bank sites
(5,174/5,177 specimens)



Monolisa HBs Ag ULTRA Assay

99.94%*

Specificity in 3 blood bank sites
(9,887/9,893 specimens)



Syphilis Total Ab Assay

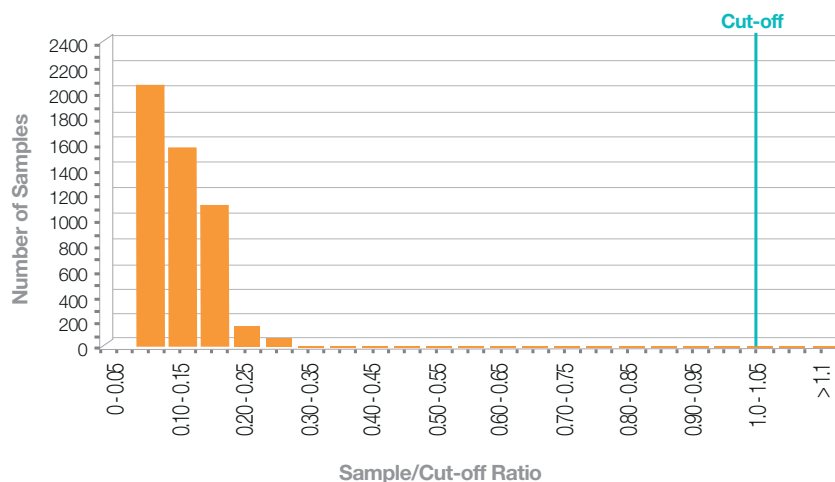
100%*

Specificity in 2 blood bank sites
(5,157/5157 specimens)

*Data from packaging insert

Negative Blood Bank Specimens Ratio Distribution Monolisa HCV Ag-Ab ULTRA V2 Assay

The excellent negative blood banks specimens ratio distribution contributes to obtaining high specificity.



Results from specificity* evaluation on 5,177 specimens from non-selected blood donors from two blood banks.

Sensitivity

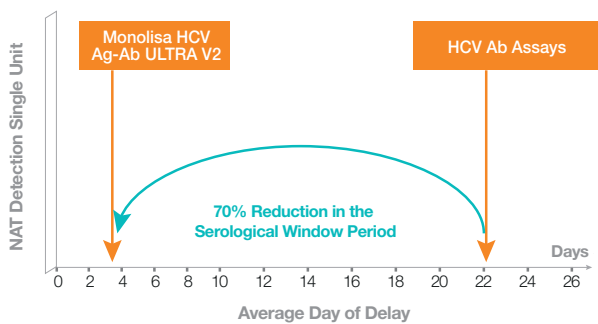
Excellent sensitivity allows earlier identification of seroconversion and reliable donation screening

Bio-Rad screening assays are designed to detect major viral genotypes and variants found worldwide. They provide early detection through a significant reduction in the serological window period. This is due to the addition of antigen detection for HIV and HCV. Especially for HCV, the decreased window period of 70% is relatively significant compared to tests detecting only antibodies.

Monolisa HCV Ag-Ab ULTRA V2 Assay - Performance Evaluation*

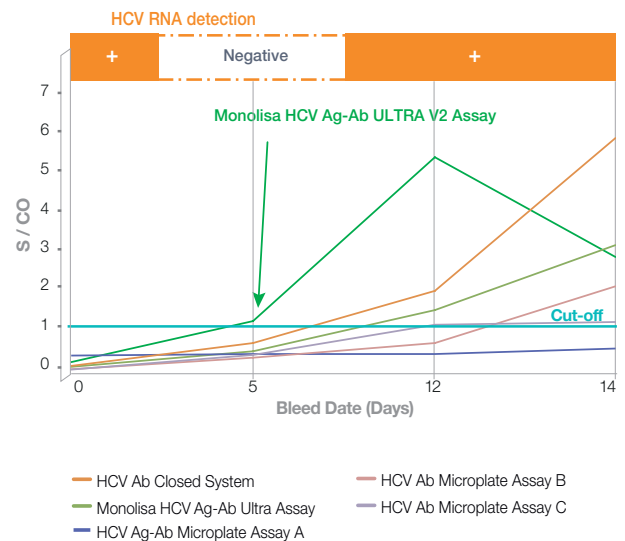
Sensitivity and specificity study evaluated on routine blood bank samples, hospitalized patient samples, known positive samples and seroconversion panels

Reduction in the Serological Window Period



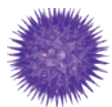
The delay between Monolisa HCV Ag-Ab ULTRA V2 and NAT is less than 4 days (3.8). The window period was reduced by 70% in comparison with anti-HCV assays which had an average delay of 22 days.

Antibody Detection



*N. Groleau, et al. (2014). Monolisa HCV Ag-Ab ULTRA V2 Assay - Performance Evaluation. Poster presented at: 33rd International Congress of ISBT. May 31 - June 5, 2014; Seoul, Korea.

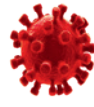
Seroconversion Panel 915 showed earlier detection with Monolisa HCV Ag-Ab ULTRA V2 while NAT and the other assays were negative, demonstrating an improvement in antibody detection.



Genscreen ULTRA HIV Ag-Ab Assay

Excellent antibody detection with guaranteed antigen sensitivity

Analytical sensitivity: 0.85 IU/mL by testing the 1st International WHO HIV P24 Antigen standard (90/636)



Monolisa HCV Ag-Ab ULTRA V2 Assay

Improved detection due to antigen and antibody combination



Monolisa HBs Ag ULTRA Assay

Earlier hepatitis B infection detection including variant

Analytical sensitivity: 0.025 IU/mL by testing the 2nd international WHO standard (00/588)



Syphilis Total Ab Assay

Earlier and continuous detection of syphilis infection through IgA, IgM and IgG capture

Analytical sensitivity: 0.83 mIU/mL by testing the 1st International WHO standard NIBSC 05/120

Automation

Fully automated solution allows for improved productivity, reliable results and cost savings

Bio-Rad's family of EVOLIS Systems are self-contained microplate processors designed to completely automate EIA techniques. The systems are designed for user-friendly and safe assay processing, as with our serological screening assays performed in today's transfusion centers and diagnostic labs.



Compliance with Regulatory Standards

- CE-IVD validated and FDA-approved assays



Safety

- Single-use tips that eliminate carryover
- Unique triple-detection technology
 - Liquid level detection
 - Aspiration pressure monitoring
 - Reagent addition verification
- Positive identification of samples, controls and reagents



Flexibility

- Multitasking priority setup
- Walk-away systems adapted to a wide range of activity
- Large onboard capacity



Efficiency

- Multiple systems consolidated with one LIS connection
- Online troubleshooting and training
- Accreditation tools for performance warranty



Bio-Rad and Blood Banks

Bio-Rad is one of the world's most respected suppliers of blood screening systems. We have been serving blood banks across the world for more than 40 years and are grateful for the confidence you place in us.

Our continued investments in innovation are driven by a commitment to delivering cost-effective, high performance, reliable systems, and services that meet the highest safety standards in blood donations throughout the world. We strive to develop high-performance screening assays, including supplemental and confirmatory assays for the detection of HIV, HCV, HBV and syphilis, and systems that ensure a reliable and comprehensive approach to testing.



Innovation

- Strong investment in research and development
- Internal development and manufacturing of key biological materials
- Continual releases of new generation assays for improved screening



Solutions You Can Trust

- Integration and validation of our assays on Bio-Rad platforms
- Compliance with the highest regulatory standards
- 4th generation assays for HIV, HCV and HBs screening assays
- Automation and assay integration designed to ensure safe and effective blood virus screening

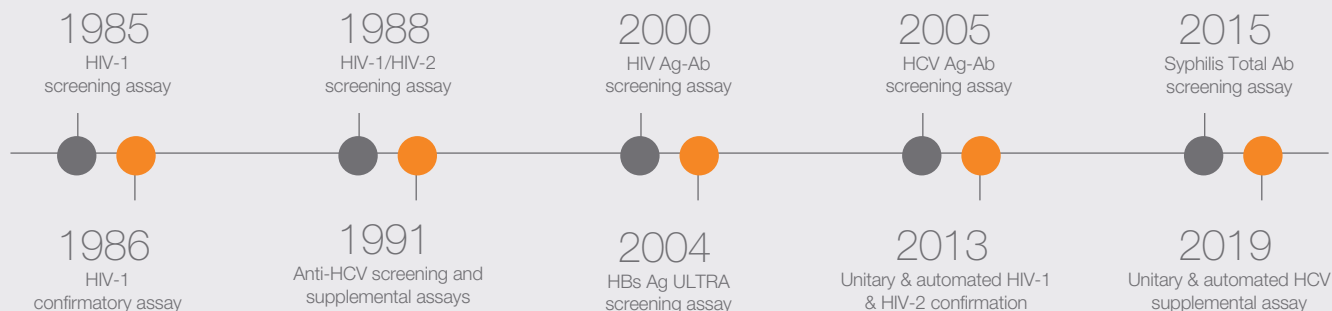


Services and Support

- A wide range of services – including hotlines, BriCare remote support software, metrology tools, onsite rapid response teams, training and training centers

Key Milestones

- 41 HIV assays launched since 1985
- More than 10 HCV assays supported by 20+ years of experience
- A complete range of HBV and syphilis assays developed since the late 1980s



Ordering Information

Catalog # Description

Blood Donation Screening Assays

72386	Genscreen ULTRA HIV Ag-Ab	96 tests
72388	Genscreen ULTRA HIV Ag-Ab	480 tests
72561	Monolisa HCV Ag-Ab ULTRA V2	96 tests
72562	Monolisa HCV Ag-Ab ULTRA V2	480 tests
72346	Monolisa HBs Ag ULTRA	96 tests
72348	Monolisa HBs Ag ULTRA	480 tests
72530	Syphilis Total Ab	96 tests
72531	Syphilis Total Ab	480 tests

Complementary Assays

72251	NEW LAV BLOT I	18 tests
72252	NEW LAV BLOT II	18 tests
72460	Geenius HIV 1/2 Confirmatory	20 tests
72329	Geenius HIV 1/2 Confirmatory controls (1 Pos. + 1 Neg.)	2 x 120 µL
92501	Geenius HCV supplemental	20 tests
92502	Geenius HCV supplemental controls (1 Pos. + 1 Neg.)	2 x 120 µL
72408	Monolisa HBs Ag ULTRA Confirmatory	25 tests

Other EIA Screening Assays

71120	Genscreen HIV-1 Ag	192 tests
71121	Genscreen HIV-1 Ag Confirmatory	25 tests
72566	Monolisa Anti-HBs PLUS	192 tests
72315	Monolisa Anti-HBc PLUS	96 tests
72316	Monolisa Anti-HBc PLUS	480 tests
72382	Monolisa Anti-HBc IgM	96 tests
72396	Monolisa HBe Ag-Ab PLUS	96 tests HBe Ag + 96 tests HBe Ab

Systems

89818B	EVOLIS System	1 system
93500B	EVOLIS Twin Plus System	1 system
85499B	PW40 Washer	1 unit
94196B	PR4100 Microplate reader	1 unit
87530B	IPS Microplate Incubator	1 unit
91600C	Autoblot Strip Processor	1 unit
92465	Geenius Reader	1 unit
12009704	Geenius Mini-PC (Dell 3380 Win10)	1 unit

BIO-RAD is a trademark of Bio-Rad Laboratories, Inc. in certain jurisdictions.

GENSCREEN, MONOLISA, GEENIUS and EVOLIS are trademarks of Bio-Rad Europe, GmbH in certain jurisdictions.



**Bio-Rad
Laboratories, Inc.**

*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.** 1-800-224-6723 **Australia** +61(2)9914-2800 **Austria** +43-1-877-8901 **Belgium** +32(3)710-53-00 **Brazil** +55(31)3689-6600
Canada 1-514-334-4372 **China** +86 21 6169 8500 **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** +36-1-459-6100 **India** +1800-180-1224 **Israel** +972-3-9636050 **Italy** +39-02-216091
Japan +81-3-6361-7070 **Korea** +82-2-3473-4460 **Mexico** +52(55)5488-7670 **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** +7-495-721-1404 **Singapore** +65-6415-3170 **South Africa** +27-11-442-85-08 **Spain** +34-91-590-5200
Sweden +46-8-555-127-00 **Switzerland** +41(0)26-674-55-05/06 **Taiwan** +886-2-2578-7189 **Thailand** +662-651-8311 **United Kingdom** +44(0)20-8328-2000