ULTRA Product Line

Safety is not a Matter of Chance
ULTRA Product Line

The best answer for HBV, HCV and HIV screening: a global automated solution for safe results.

ULTRA Line Assays

Design Suitable for:
- Variant detection
- Significant reduction of window periods
- Sensitivity close to those observed with Nucleic Acid Testing (NAT)
- Very high level of specificity

And with the highest level of safety and ease of use.

ULTRA Product Line:
- Monolisa™ HCV Ag-Ab ULTRA V2 Assay
- Monolisa™ HBs Ag ULTRA Assay
- Genscreen™ ULTRA HIV Ag-Ab Assay
Monolisa™ HCV Ag-Ab ULTRA V2 Assay  ▪ EIA for Detection of HCV

**Shorten the Anti-HCV Ab Negative Window Period**

70% reduction of the serologic HCV Ab negative window period. The Monolisa™ HCV Ag-Ab ULTRA V2 assay detects exposure to HCV on average 22 days before other anti-HCV Ab tested and before HCV combo assays. The delay between Monolisa™ HCV Ag-Ab ULTRA V2 and NAT is less than 4 days.

Ranking generated from Bio-Rad analysis on 23 commercial seroconversion panels from Seracare and Zeptometrix. Day zero represents the first positive day with Nucleic Acid Testing.

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Genscreen™ ULTRA HIV Ag-Ab Assay  ▪ EIA for Detection of HIV Antigen

**Early HIV Global (Antigen-Antibody) Detection**

The earliest detection among the HIV Ag-Ab combined tests to reduce the serological window period.

Ranking generated from Bio-Rad analysis on 85 commercial seroconversion panels (300 samples) from BBI, NABI and BCP. Day zero represents the first positive day with Nucleic Acid Testing.

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Monolisa™ HBs Ag ULTRA Assay  ▪ EIA for Detection of HBs Antigen

**Shorten the HBs Ag Negative Window Period after Hepatitis B Infection**

Average delay (days) for detection of Hepatitis B infection with Monolisa™ HBs Ag ULTRA assay and HBs Ag EIA competitors kits versus Nucleic Acid Testing (NAT).

Ranking generated from Bio-Rad analysis on 27 commercial seroconversion panels (104 samples) from Boston Biomedical Inc. Day zero represents the first positive day with Nucleic Acid Testing.
Antigen and HCV Antibodies

Antigen and Antibody Sensitivity
The highest antigen and global antigen-antibody detection sensitivity of all EIA tests. Particularly when NAT fails to detect infected blood donors.

![Graph showing HCV RNA detection and antibody testing](image)

<table>
<thead>
<tr>
<th>Monolisa HCV Ag-Ab ULTRA</th>
<th>Microplate Competitor M</th>
<th>Microplate Competitor D</th>
<th>Microplate Competitor O</th>
<th>Microplate Competitor B</th>
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A panel of 15 diluted recombinant HCV Ag proteins has been designed to represent a total of 30 single or multiple mutations located at 22 different amino acid positions in the “a” determinant of HCV Ag. All of these mutations based on the clinically relevant mutation reported by the literature are detected with Monolisa™ HCV Ag-Ab ULTRA.

Specificity
Very high level of specificity for Blood Banks: 99.94% and for hospitalized patients: 99.80%.

Variant Hepatitis B Virus Strain Detection
HBs Ag EIA competitor kit sensitivity on mutated HBs Ag recombinant protein samples from plasmidic construction.

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Outstanding Sensitivity
The analytical sensitivity has been estimated during clinical evaluations and was less than 0.06 ng/ml on the French SFTS 2001 HBs Ag panel and 0.025 IU/ml using the second international WHO standard (00/588).

Specificity
Very high level of specificity for Blood Banks and diagnostics labs: 99.94%.

Antigen and HIV-1 / HIV-2 Antibodies

Early HIV Antibody Detection
The Genscreen™ ULTRA HIV Ag-Ab assay shows the highest sensitivity for antibody detection of all HIV screening kits, taking into account the variability of seroconversion profiles (seroconversion with undetectable or low HIV antigen levels).

![Graph showing HIV Ag-Ab detection](image)

Early HIV Antigen Detection
The excellent antibody detection sensitivity is strengthened by the best HIV Ag detection: Genscreen™ ULTRA HIV Ag-Ab assay is a true Ag-Ab kit for the combined screening of HIV Ag and HIV Ab.

Analytical sensitivity:
0.85 IU/ml (1st International WHO HIV p24 Antigen Standard (90/636) 13.6 pg/ml (“Ag HIV SFTS 1998” panel) from external evaluations.

Specificity
Very high level of specificity for Blood Banks: 99.95% and for hospitalized patients: 99.75%.
Global Automated Solution

Highest Level of Safety
- Color-coded reagents
- Sample and reagent addition monitoring for all pipetting steps (sample, reagents and substrate) with Optical Density norms in the package insert
- Color-coded labels
- Color-coded control caps
- Barcode identification for reagents
- Clear identification of the product on microplate frame and strip

Easy to Use and Easily Automatable
- No sample pre-dilution
- Low sample and control volume requirements
- Generic reagents (wash solution, substrate, and stop solution)
- Validated protocol on Bio-Rad systems, fully automated systems (EVOLIS™ Family) and stand-alone systems (PR4100, PW40 etc.)
- Easily automatable: vials directly installed onboard with EVOLIS™ Systems
- All reagents included in the kit (microplate, controls, conjugates, wash solution, substrate and stop solution)
## Ordering Information

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Description</th>
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<tbody>
<tr>
<td>72561</td>
<td>Monolisa™ HCV Ag-Ab ULTRA V2 Assay, 96 tests</td>
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<tr>
<td>72662</td>
<td>Monolisa™ HCV Ag-Ab ULTRA V2 Assay, 480 tests</td>
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<tr>
<td>72346</td>
<td>Monolisa™ HBs Ag ULTRA Assay, 96 tests</td>
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<tr>
<td>72348</td>
<td>Monolisa™ HBs Ag ULTRA Assay, 480 tests</td>
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<tr>
<td>72408</td>
<td>Monolisa™ HBs Ag ULTRA Confirmatory Assay, 25 tests</td>
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<td>72386</td>
<td>Genscreen™ ULTRA HIV Ag-Ab Assay, 96 tests</td>
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<tr>
<td>72388</td>
<td>Genscreen™ ULTRA HIV Ag-Ab Assay, 480 tests</td>
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<thead>
<tr>
<th>Complete Systems</th>
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<tbody>
<tr>
<td>89700 EVOLIS™ Premium, 1 system</td>
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<tr>
<td>93500 EVOLIS™ Twin Plus, 1 system</td>
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<tr>
<th>Stand-Alone Systems</th>
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<tr>
<td>94196 PR 4100 Reader, 1 system</td>
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<tr>
<td>85499K PW40 Washer, 1 system</td>
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<tr>
<td>87530K IPS Incubator, 1 system</td>
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