Infectious Disease Testing

Geenius Solution

A Game Changer

BIO-RAD
Geenius HIV 1/2 Confirmatory

The Bio-Rad Geenius HIV 1/2 Confirmatory Assay is a single-use immunochromatographic test for the confirmation and differentiation of individual antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma samples.

- HIV-1 & HIV-2 confirmation and differentiation
- < 30 minutes
- Room temperature storage
- Automatic reading

1. Band 1 - gp36 (HIV-2, Envelope peptide) HIV-2 ENV
2. Band 2 - gp140 (HIV-2, Envelope peptide) HIV-2 ENV
3. Band 3 - p31 (HIV-1, Polymerase peptide) HIV-1 POL
4. Band 4 - gp160 (HIV-1, Envelope recombinant protein) HIV-1 ENV
5. Band 5 - p24 (HIV-1, Core recombinant protein) HIV-1 GAG
6. Band 6 - gp41 (Group M and O) HIV-1 ENV (HIV-1, Envelope peptide)

C Control Band - Protein A

- Listed on the following regulatory certifications: CE, FDA, TGA, ANVISA, Health Canada, CDSCO India, Thai FDA, Taiwan FDA
- Listed on the WHO prequalified IVD products list
Geenius HCV Supplemental Assay is a qualitative single-use immunochromatographic test for the confirmation of the presence of antibodies associated with infection caused by the Hepatitis C Virus (HCV) in human venous whole blood, serum or plasma specimens from blood donors or hospitalized patients.

- **Unitary HCV Supplemental Assay**: 20 minutes
- **Room temperature storage**: Automatic reading

<table>
<thead>
<tr>
<th>Band 1</th>
<th>Band 2</th>
<th>Band 3</th>
<th>Band 4</th>
<th>Control Band</th>
</tr>
</thead>
<tbody>
<tr>
<td>NS4 antigen peptides</td>
<td>NS5 recombinant protein</td>
<td>Core antigen peptides</td>
<td>NS3 recombinant protein</td>
<td>Protein A</td>
</tr>
</tbody>
</table>

- **CE-marked**
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A Game Changer

One Patient. One Cartridge. One Result.

Accurate Results
- Very high level of sensitivity and specificity
- Simple positivity criteria for easy overall interpretation
- Excellent differentiation rate

Automatic Reading & Interpretation
- A tiny system with mighty possibilities, that can find its place easily in every laboratory
- Automated interpretation of each individual band
- Automatic conclusion of patient status using expert software and proprietary algorithms
- Intuitive and user friendly interface
- Minimal training required

Full Traceability & Safety
- Unique datamatrix barcode on each cassette
- Automatic reader calibration
- Automatic checking of lot validation
- Positive identification of controls and patients
- Detailed report including cassette picture
- Secure data archiving
- Bidirectional interfacing with LIS

Visit www.bio-rad.com/diagnostics for more information.
Key Bio-Rad Milestones for Innovation in HIV and HCV Detection

2019 - 1st single use cassette for HCV confirmation with automated reading and interpretation in less than 30 minutes

2014 - BioPlex HIV Ag-Ab CE-marked

2013 - Improvement of the 4th generation HCV Ag-Ab Combo screening assay
       - 1st unitary and automated HIV-1 and HIV-2 confirmatory assay

2005 - 4th generation of HCV screening assay 1st HCV Combo assay

2001 - 3rd generation of HCV Ab screening assay

2000 - HIV Ag-Ab Combo screening assay

1996 - 2nd generation of HCV Ab screening assay and supplemental assay

1995 - HIV-1 & HIV-2 sandwich format with recombinant proteins and peptides screening assay

1992 - HIV-1 & HIV-2 IgG and IgM screening assay

1991 - 1st version of HCV screening assay and 1st HCV supplemental assay

1990 - 1st HIV-1 & HIV-2 differentiation assay

1987 - 1st HIV-2 screening and confirmatory assay

1985 - HIV-1 screening assay

HIV  HCV

Advance Discovery. Improve Lives.
Protocol Geenius HIV 1/2 Confirmatory

1. Dispense Controls or Samples into well 1
2. Buffer 2 Drops into well 1
3. Buffer 5 Drops into well 2

Whole Blood 15 µl

Controls/Serum/Plasma 5 µl
Wait 5-7 minutes

Read, interpret and report results

Protocol Geenius HCV Supplemental

1. Dispense Controls or Sample in “Sample + Buffer” Well
2. Buffer 4 Drops into “Sample + Buffer” Well

Venous whole blood 15 µl

Controls/Serum/Plasma 5 µl
Wait 20 minutes

Read, interpret and report results

Assays Ordering Information

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<thead>
<tr>
<th>Catalog #</th>
<th>Description</th>
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<tbody>
<tr>
<td>72460</td>
<td>Geenius HIV 1/2 Confirmatory Assay, 20 tests</td>
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<tr>
<td>72329</td>
<td>Geenius HIV 1/2 Confirmatory Controls (1 Positive + 1 Negative), 2 x 120 µl</td>
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<tr>
<td>92501</td>
<td>Geenius HCV Supplemental Assay, 20 tests</td>
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<tr>
<td>92502</td>
<td>Geenius HCV Supplemental Controls (1 Positive + 1 Negative), 2 x 150 µl</td>
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System Ordering Information

<table>
<thead>
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<th>Catalog #</th>
<th>Description</th>
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<tbody>
<tr>
<td>92465</td>
<td>Geenius Reader, 1 unit</td>
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<tr>
<td>12017081</td>
<td>Geenius PC + SW OUS (Dell 3510 Win10), 1 unit</td>
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<tr>
<td>92461</td>
<td>Geenius Software, 1 unit</td>
</tr>
<tr>
<td>94197</td>
<td>Anti-theft System, 1 unit</td>
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</tbody>
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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