Access® HCV Ab PLUS Assay

Detection of HCV Ab on Access® and UniCel® Immunoassay Systems.

Key Benefits

- Early detection of seroconversion
- Sensitivity: 100% (511 positive samples)
- Specificity: 99.9% (6,458 samples)
- Excellent discrimination between negative and positive samples

HCV Antibodies Screening Algorithm

Initial Reactivity

- Initial Result < 0.9 S/CO
  - Negative
- Initial Result ≥ 1.0 S/CO
  - Initial Reactive
- Initial Result > 0.9 to < 1.0 S/CO
  - Gray Zone

Reactivity

- Repeat in duplicate

2 of 3 Results

- ≥ 1.0 S/CO
  - Repeat Reactive
- < 1.0 S/CO
  - Negative

HCV Supplemental Testing

- RIBA for anti-HCV
- NAT for HCV RNA

2-Step Indirect CLIA Assay

- Paramagnetic particles coated with recombinant proteins (NS3 + NS4) and a capsid peptide
- Sample containing anti-HCV Ab
- Mix and Incubate at 36.5°C for 20 min
- Wash 3 times

- Add Anti-human IgG Ab (goat)/alkaline phosphatase conjugate
- Mix and Incubate at 36.5°C for 20 min
- Complex Formation
- Wash 3 times

- Add Substrate
- Incubate 5 min
- Read (RLU)

Signal production compared to cut-off for determination of HCV antibody status
Access® HCV Ab PLUS Assay

Performance: Sensitivity

Antibody 100% sensitivity based on 511 positive samples

Early detection of HCV Ab seroconversion when compared to other EIA

Performance: Specificity

<table>
<thead>
<tr>
<th>G-MED Registration data</th>
<th>Number of samples tested</th>
<th>Initial Reactive</th>
<th>IR Specificity (%)</th>
<th>Repeat Reactive</th>
<th>RR Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio-Rad</td>
<td>3,983</td>
<td>6</td>
<td>99.85</td>
<td>6</td>
<td>99.85</td>
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<tr>
<td>Blood Bank 1</td>
<td>1,000</td>
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<td>99.80</td>
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<tr>
<td>Blood Bank 2</td>
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<td>99.90</td>
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<td>Hospital</td>
<td>463</td>
<td>0</td>
<td>100.00</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>6,458</td>
<td>9</td>
<td>99.86</td>
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<td>99.86</td>
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</tbody>
</table>

(95% CI: 99.7-99.9%)

Characteristics

Sample Type/Size: Serum or plasma (EDTA, Heparin, Citrate)/25 μl

Time to First Result: 55 minutes

Open Pack Stability: 28 days

Calibration Stability: 28 days

Precision: Intra-assay < 5% Inter-assay < 10%

Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>34330</td>
<td>Access® HCV Ab PLUS</td>
<td>2 packs of 50 tests</td>
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<td>34335</td>
<td>Access® HCV Ab PLUS Calibrators</td>
<td>2 vials of 1 ml</td>
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<tr>
<td>34339</td>
<td>Access® HCV Ab PLUS QC</td>
<td>6 vials of 2.5 ml</td>
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