The ONLY Automated RPR Syphilis Test for Blood Donor Screening

- Full walk-away automation
- Accurate and reproducible results
- Lowest cost per automated test
- “Your Syphilis Authority,” over 30 years of manufacturing experience
- Performs 190 tests per hour
- CDC recommended testing algorithm

ASI Evolution
A Fully Automated Nontreponemal RPR Analyzer

FDA Cleared
For Blood Donor Screening
510(k) BK70114
Intended Use
The ASI Automated RPR (rapid plasma reagin) Test for syphilis is a qualitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis for use on the ASI Evolution analyzer. The test is intended for use in screening blood donors.

Evaluation of the ASI Evolution®
A total of 2861 specimens were evaluated to determine reactivity. Of the 2861 specimens, the ASI Evolution determined that 829 were reactive and 2032 specimens were nonreactive. Of those 2032 specimens, 4 discordant results were tested with a treponemal and a nontreponemal test and found to be nonreactive. A sensitivity >99.0% and a specificity >99.0% were determined.

<table>
<thead>
<tr>
<th>ASiManager-AT Results</th>
<th>ASI Evolution Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reactive</td>
</tr>
<tr>
<td>Reactive</td>
<td>829</td>
</tr>
<tr>
<td>Nonreactive</td>
<td>0</td>
</tr>
</tbody>
</table>

*Note: The 4 discordant results were tested with a treponemal and a nontreponemal tests and found to be nonreactive. The reactive samples ranged in reactivity from minimal 1:1 titters to 1:64 titters.

Image Analysis
The ASI Evolution’s HD camera, allows our proprietary algorithm to digitally analyze particle size and count to determine reactivity. Reaction images can then be stored with patient ID, archived, and retrieved.
The Nontreponemal Advantage

- A 2015 study by the CDC determined that nontreponemal tests can detect infection up to 14 days earlier than treponemal tests.
- CDC recommended testing algorithm.
- Preserve valuable blood resources.
- Reduce confusion among clinicians.

Performance Data

A long-term reproducibility study was performed by ASI at 5 different sites between July 2017 and January 2018. The study involved testing 4 different lots of RPR carbon antigen on panels of both known reactive and known nonreactive samples. Testing showed 100% concordance.

A summary of these tests is shown below.

<table>
<thead>
<tr>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>4384/4384</td>
<td>814/814</td>
</tr>
</tbody>
</table>

A repeatability study was performed by ASI at 5 different sites across the country. The study involved testing 2 different lots of carbon antigen on the same panel of known reactivity on 5 nonconsecutive days, testing twice a day. Testing showed 100% concordance.

Patient Value (Clinical)

- CDC recommended testing algorithm.
- Accurate and reproducible results.
- Reduce confusion among clinicians, laboratorians and health practitioners regarding testing.
- Monitor therapy.
- Fewer false positives (Reactives).
- Lower total healthcare costs.

Provider Value (Operational)

- Automated, walk-away system.
- Throughput of 190 test per hour.
- Eliminate subjectivity.
- Reduce labor cost.
- Reduce number of sample processing steps.
- Reduce biohazard exposure.
- Data Management (Analyze, Archive, Retrieve).

Payor Value (Reimbursement)

- Lower total healthcare cost.
- Lower cost of operation.
- Service and maintenance support available.
- USA “Syphilis Authority” manufacturing tens of millions of syphilis tests annually.
- Minimal consumables required.
- Superior quality and service.

<table>
<thead>
<tr>
<th>Day Since 1st Bleed</th>
<th>Non-treponemal Test</th>
<th>Treponemal Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASI RPR</td>
<td>BD RPR</td>
</tr>
<tr>
<td>Day 0</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>Day 5</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>Day 10</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>Day 13</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>Day 31</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>Day 45</td>
<td>POS</td>
<td>POS</td>
</tr>
<tr>
<td>Day 48</td>
<td>POS</td>
<td>POS</td>
</tr>
<tr>
<td>Day 52</td>
<td>POS</td>
<td>POS</td>
</tr>
<tr>
<td>Day 59</td>
<td>POS</td>
<td>POS</td>
</tr>
</tbody>
</table>

NEG= Negative, POS= Positive, IND= Indeterminate, Syphilis Seroconversion panel P5901

Courtesy of Centers for Disease Control and Prevention.
### System Specifications*

#### System Type
Bench top diagnostic analyzer

#### Physical Dimensions
- **Length**: 36.25" (92.1 cm)
- **Height**: 18.75" (47.6 cm)
- **Depth**: 21.5" (54.6 cm)
- **Weight**: 78 lbs. (35kg)

#### Performance Characteristics
- **Throughput**: 190/hour
- **Maximum number of specimens**: 192
- **Minimum Reaction Volume**: 110µl
- **Minimum Sample Requirement**: 300µl
- **Dual orbital shaker**

#### Reagent and Sample Dispensing
- **Capabilities**: Process qualitative syphilis RPR tests
- **Pump**: One syringe pump, 500µl
- **Probe**: 316 Stainless steel for maximum reagent compatibility, level sensing
- **Maximum Number of Reagents**: One carbon antigen reagent bottle
- **Reaction Vessel**: Four standard 48 well plates
- **Instrument bottles**: 1L Priming bottle

#### Reading
- **Detection Mode**: Image processing
- **Detector**: Built-in high resolution camera
- **Light Source**: LED light panel

#### Software/System Requirements
- **Format**: USB and Internet upgrades
- **Operating Systems**: Microsoft Windows® 10, 64-bit, Intel® Core™ i3, i5 or equivalent, 4 GB RAM, minimum 100MB free drive space, USB port
- **LIMS Integration**
- **Calculation Modes**: Proprietary Algorithm for particle analysis
- **QC Options**: Stores control data, patient results and reaction images
- **USB Port**: USB cable provided

#### Power
- **Voltage Range**: 100-240VAC
- **Frequency Range**: 50-60Hz
- **Power Maximum**: 160W
- **Installation Category**: CAT II

#### Recommended Environmental Conditions
- **Indoor use**
  - **Main supply voltage**: Fluctuations not to exceed ± 10% of the nominal voltage
  - **Operating temperature**: 18 - 35°C recommended
  - **Operating humidity**: Less than 85% recommended

#### Certifications
- **FDA Cleared**: For blood donor screening
- **CE Marked**
- **NRTL Intertek**

*Specifications subject to change without notice.

### Ordering Information

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>2800-000</td>
<td>ASI Evolution™ Automated Syphilis Analyzer</td>
<td>#2800-000</td>
</tr>
<tr>
<td>900480A</td>
<td>ASI Automated 480 Test Kit</td>
<td>#900480A</td>
</tr>
<tr>
<td>9004800A</td>
<td>ASI Automated 4800 Test Kit</td>
<td>#9004800A</td>
</tr>
<tr>
<td>905005A</td>
<td>ASI Automated RPR Control Set</td>
<td>#905005A</td>
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</tbody>
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