### Table 2
Sensitivity (reactive results/total samples tested) and Specificity (nonreactive results/total samples tested) of ASIManager-AT Readings and Visual Readings of ASI RPR Card Test Results with Serum Samples in Blood Banks and Diagnostic Settings.

<table>
<thead>
<tr>
<th></th>
<th>Blood Bank Setting</th>
<th>Diagnostic Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Visual Reading</td>
<td>ASIManager-AT</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>95% (95 CI)</td>
<td>95% (95 CI)</td>
</tr>
<tr>
<td>Specificity</td>
<td>95% (95 CI)</td>
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<td></td>
<td>95% (95 CI)</td>
<td>95% (95 CI)</td>
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</tbody>
</table>

### Table 3
Sensitivity and Specificity of ASIManager-AT and Visual Readings and Interpret ASI RPR Card Test Results in Tissue Bank Settings using Cadaveric Samples.

<table>
<thead>
<tr>
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<th>Tissue Bank Setting</th>
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<tbody>
<tr>
<td></td>
<td>Visual Reading</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>95% (95 CI)</td>
</tr>
<tr>
<td>Specificity</td>
<td>95% (95 CI)</td>
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<td></td>
<td>95% (95 CI)</td>
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</tbody>
</table>

### INTENDED USE
The ASI RPR (rapid plasma reagin) Card Test for syphilis is a qualitative and semiquantitative nontreponemal flocculation test for the detection of syphilis in human serum and plasma. It is a screening test for the serological evidence of syphilis. The test is intended for use in screening blood donors and cadaveric (heart beating) donor samples for tissue donation when the test is read and interpreted with the ASIManager-AT. The ASI RPR Card Test for Syphilis is for professional use only.

### PRINCIPLE OF THE PROCEDURE
The ASI RPR Card Test is an in vitro microscopic nontreponemal flocculation test to be used for the detection of syphilis. The nontreponemal cardiolipin reagent is a suspension of cardiolipin, lecithin, and cholesterol in distilled water. The result of this antigen-antibody reaction is macroscopic flocculation.

### REAGENTS
- **CARBON ANTIGEN**: 0.003% cardiolipin, 0.020–0.022% lecithin, 0.09% cholesterol; charcoal (activated) as visual enhancer.
- **RPR REAGENTS**: Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.
- **CONTROLS (REACTIVE, WEAK REACTIVE, NONREACTIVE)**: Human serum or defibrinated plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2, and HCV antibodies and found to be nonreactive.

### WARNINGS AND PRECAUTIONS
For in vitro diagnostic use.

1. **ASI RPR REAGENTS** contain sodium azide. Admix in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of mixtures containing azide, flush down the drain with large quantities of water to prevent azide buildup.

2. ASI RPR CONTROLS contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2, and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the reagents may contain infectious potential and universal precautions should be used. The CDC/HHS Health Manual “Guidelines for Microbiological and Biomedical Laboratories” describes how these materials should be handled in accordance with Good Laboratory Practice.

3. Do not pipet by mouth.

4. Do note smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.

5. Keep aseptic, plastic or other plastic skin coverings should be visibly protected.

### HANDLING AND PROCEDURAL NOTES
1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for syringes or samples.

2. **ASI RPR cards** are plastic coated and specifically designed to be used with the ASI RPR Reader. In handling take care not to touch the card areas, as this may result in an oily deposit and improper test result. When spreading specimens within the confines of the circle area, avoid scratching the card with the Denton pipet. If the specimen does not spread in the test area or spreads outside the test area, use another test circle.

3. The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. Do not wipe the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle top when using the needle assembly. Let the assembly air dry. Before next use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it.

4. The needle should deliver 60 ± 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy readings, follow the instructions in the package insert. To perform stability readings, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 ± 1 drops are obtained in 0.5 ml.

5. Do not use past the expiration date indicated on the label.

6. Disposal of RPR CARDS, the biological material from this kit with those of a different manufacturer. Discard the contaminated dressing and needle when the carbon antigen is exhausted.

### STORAGE INSTRUCTIONS
Store all reagents at 2–8°C as in storage position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration. Carbon Antigen may be stored for up to one month in the dropping bottle at 2–8°C. In this case, the needle must be cleaned at the end of each shift, using a Denton pipet.
**INDICATIONS OF DETERIORATION**

1. turbidity or precipitates in test tubes is indication of deterioration and the component should not be used.
2. Bacterial contamination of reagents or specimens may cause false positive results.

**SPECIMEN COLLECTION and STORAGE**

Specimens for visual and quantitative procedures are required to be handled carefully. Use heparin or EDTA anticoagulated serum samples, and specimens containing EDTA, CPD, CPDA-1, heparin or sodium citrate as an anticoagulant. Serum or plasma samples and whole blood, diluted preequilibrated units which have been collected with adequate volume to provide the appropriate proportions of specimen to anticoagulant.

Specimens for reading with the ASiManager AT use the Serotonin-AT, or for specimens that require long-term storage, for 1 day or more, use heparin or sodium citrate. Specimens with an LDH level above 10 times the normal upper limit (1000 units/L) are recommended for testing when printed matter cannot be read through it.

**USE of ASiManager AT for INTERPRETATION of RESULTS**

The ASiManager AT requires the RPR test sample to be diluted and then read and interpreted using the ASi RPR Card Test for ASi.

2. The positive titration factor is not used in blood donor screening.

3. See the ASiManager AT User Guide for complete instructions.

**SAMPLES WITH TITERS GREATER THAN 1:16**

1. Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum or plasma to 1.9 ml of saline. Mix thoroughly. Use 0.1 ml of this diluted sample onto circles 2 and 1. DO NOT SPREAD.

2. Place the card on the antigen and rotate gently under a high intensity light source. Continue the serial dilution through circle 5 and discard the remaining sample.

**PERFORMANCE of the TEST**

**Materials Provided:**

- Disposable syringe, 1 or 3 ml, accuracy of ± 5%
- Serum nonreactive to syphilis, in 0.9% saline, for diluting specimens reactive at the 1:16 dilution in the semiquantitative procedure
- Saline (0.9% NaCl Solution)
- Volumetric pipet to deliver 0.05 ml
- 3 ml Dropping bottle
- 20-ga Dispensing Needle (60 drops/ml)
- 0.05 ml Disposable Stirrer Pipets
- RPR Test card (10-well)

**Reactive Control**

- 0.5 ml
- 1.0 ml
- 2.0 ml
- 5 x 2.0 ml
- 5.0 ml

**Nonreactive Control**

- 0.05 ml
- 0.5 ml
- 1.0 ml
- 5 x 1.0 ml
- 5.0 ml

**Additional Material Required:**

- Volumes delivered by 3 ml dropper bottle (0.3 ml in 0.2 ml increments)
- 1:16 dilution of test sample
- Saline (0.9% NaCl Solution)
- Serum nonreactive to syphilis (in 0.9% saline), for diluting specimens reactive at the 1:16 dilution in the semiquantitative procedure
- Membrane test card, 125 mm long and 12 mm wide
- Membrane test card, 50 mm long and 12 mm wide
- Disposable syringes, 1 or 3 ml, accuracy of ± 5%

**Preparation of the TEST**

1. Allow all reagents and samples to warm to room temperature (20-30°C) before use. Remove reagents from their boxes before use. Do not freeze reagents in a water bath.

2. All reagents are ready to use as supplied. Gently mix the reagents before use, avoid foaming.

3. Vigorously agitate the CARBON ANTIGEN for 20-30 seconds before each use in order to ensure homogeneity.

**ASSAY PROCEDURE - QUALITATIVE**

1. Using a disposable pipet, dispense one free-falling drop (0.05 ml) of each serum or saline samples onto a separate circle on the test card. Use a fresh syringe for each sample. When using the sterile pipet, keep it in a vertical position to ensure accurate delivery. Metabolite by adding one free-falling drop of REACTING MATERIAL, in CONTACT with the surface of the antigen suspension.

2. Using the syringe, dispense the sample over the entire area of the test circle. Do not scratch the test circle.

3. Attach the needle to the dropper bottle. Mix the CARBON ANTIGEN suspension well. Squeeze the dropper bottle and draw a sufficient volume of the antigen suspension into the bottle. Dispense several drops into the dropper bottle cap to make sure the needle passage is clear.

4. Place the card on the antigen and rotate to maintain humidity. Rotate at 100 ± 5 rpm for 8 minutes (7 minutes 30 seconds). Following rotation, a brief hand rotation and tilting of the card (3–4 times) should be performed.

5. It is not necessary to perform the quantitative procedure on reactive donor samples.

**Permeability of the test**

1. Using a stirrer pipet (or other accurate volumetric pipet capable of delivering 0.05 ml), dispense one free-falling drop of saline onto the test circle. DO NOT SPREAD.

2. Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum or plasma to 1.9 ml of saline. Mix thoroughly. Use 0.1 ml of this diluted sample onto circles 2 and 1. DO NOT SPREAD.

3. Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum or plasma to 1.9 ml of saline. Mix thoroughly. Use 0.1 ml of this diluted sample onto circles 2 and 1. DO NOT SPREAD.

**In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of test results with other clinical findings.**

**PERFORMANCE CHARACTERISTICS**

**The following tables show the results of testing in the blood bank setting in comparison with the diagnostic setting.**

**Table 1**

<table>
<thead>
<tr>
<th>Specificity of ASiManager AT Readings and Visual Readings of ASi RPR Card Test Results with Plasma Samples from Blood Donors in Blood Banks (nonreactive results/total samples tested, with 95% confidence intervals in parentheses).</th>
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<tbody>
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<td><strong>Nonreactive</strong></td>
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