**Table 2**

<table>
<thead>
<tr>
<th>Blood Bank Setting</th>
<th>ASIManager-AT</th>
<th>Visual Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (95% CI)</td>
<td>0.87 - 0.96</td>
<td>0.87 - 0.96</td>
</tr>
<tr>
<td>Specificity (95% CI)</td>
<td>0.95</td>
<td>0.95</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnostic Setting</th>
<th>ASIManager-AT</th>
<th>Visual Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (95% CI)</td>
<td>0.87 - 0.96</td>
<td>0.87 - 0.96</td>
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<td>Specificity (95% CI)</td>
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<td>0.95</td>
</tr>
</tbody>
</table>

**Table 3**

<table>
<thead>
<tr>
<th>Table -2</th>
<th>Visual Reading</th>
<th>ASIManager-AT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of each shift, using a syringe or pipet.</td>
<td>0.87 - 0.96</td>
<td>0.95</td>
</tr>
</tbody>
</table>

**REFERENCES**

5. Data on file and available on request.

**BIOQUICKEN RPR Card Test for Syphilis**

**INDICATIONS**

BIOQUICKEN RPR Card Test for Syphilis is a qualitative and semiquantitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis. This test is intended for use in screening blood donors and cadaveric (non-heart beating) donor specimens 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.

**SUMMARY AND EXPLANATION**

Synonyms: quicken, the chemical agent of syphilis, inducing the production of at least two types of antibodies in human infection, anti- treponemal antibodies that can be detected by FTA-ABS antigen, and anti-nontreponemal antibodies (reagin) that can be detected by RPR antigen.

**PRINCIPLE OF THE PROCEDURE**

The ASI RPR Card Test is an immune macroscopic nontreponemal flocculation test to be used for the detection of reagin. The macroscopic nontreponemal RPR antigen enhances the visual discrimination between reactive and nonreactive results. The antigen-antibody reaction is macroscopic flocculation.

**REAGENTS**

CARBON ANTIGEN - 0.005% cardiolipin, 0.020–0.022% lecithin, 0.09% cholesterol, activated (as visual enhancer); 0.01% sodium azide as preservative and stabilizer.

CONTROLS (REACTIVE, WEAK REACTIVE, NONREACTIVE) - Human serum or defibrinated plasma (liquid), with 0.01% sodium azide as preservative.

**WARNINGS AND PRECAUTIONS**

For in-vitro diagnostic use.

1. ASI RPR REAGENTS contain sodium azide. Avoid in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents 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 in-vitro test offers complete assurance that infectious agents are absent, the CDC/NIH Health Manual “Guidelines for Microbiological and Biomedical Laboratories” describes how these materials should be handled in accordance with Good Laboratory Practices.

3. Do not pipe by mouth.

4. Do not smoke, eat, drink or apply cosmetics in areas where plasma/samples are handled.

5. Any cuts, abrasions or other skin lesions should be suitably 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 reagents or samples.

2. RPR test cards are plastic coated and specifically designed to be used with the RPR antigen. In handling, take care not to finger-touch 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 use. Do not wash the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle tip when inserting 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 expecting it.

4. The needle should deliver 60 ± 2 drops of antigen suspension per ml when held in a vertical position. To perform accuracy check, on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The number of drops is considered satisfactory if 30 ± 1 drops are obtained in 0.5 ml.

5. Do not reuse past the expiration date indicated on the kit.

6. Do not interchange components from this kit with those of a different manufacturer. Discard the disposable needle and dropping bottle when the carbon antigen is exhausted.

**STORAGE INSTRUCTIONS**

Store all reagents at 2–8°C in an upright position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration.

**PREFERENCES**

90001 100 Tests
900100 1000 Tests
900500 5000 Tests
900025 25 Tests
9001000 10000 Tests

**CPT Codes**

86592

**ASARI RPR CARD TEST FOR SYPHILIS**

**For in-vitro diagnostic use**

**Catalog Number**

90001 100 Tests
900100 1000 Tests
900500 5000 Tests
900025 25 Tests
9001000 10000 Tests

**CPT Code:** 86592
**SPECIMEN COLLECTION AND STORAGE**

- Use either serum or EDTA, heparin or sodium citrate plasma specimens for testing with the ASiManager-AT.
- 3. Samples should be free from heparin or micromembranes. A specimen is not recommended for testing when printed matter cannot be read through it.
- 6. Plasma samples stored longer than five (5) days at 2-8°C should not be used in the assay because of the potential for false reactive results.

**INDICATIONS OF DETERIORATION**

- Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
- 6. Continue with additional dilutions as required until an endpoint titer is reached.

**ASSAY PROCEDURE - QUANTITATIVE**

1. Using a stirrer pipet (or other accurate volumetric pipet capable of delivering 0.05 ml), dispense one free-falling drop of serum or saline onto circle 1 on the test card. DO NOT SPREAD.
2. Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum to 1.5 ml of saline. Mix thoroughly. Dispense 0.05 ml of this diluted sample onto circle 2.
3. Mix the solution on circle 2 by drawing the solution up and down 5 or 6 times into the tip of a volumetric pipet. Avoid bubble formation.
4. Transfer 0.05 ml of the mixture to circle 2 to circle 3 and mix. Repeat this serial dilution procedure to circle 4 and then circle 5, discarding 0.05 ml/mix each 3 seconds following rotation. A faint red hemolysis and thin hemolysis (1:16 to 1:1,000) result is normal.
5. Periodic testing and retesting is indicated to aid in differentiating nonreactive from minimally reactive results.

**ASSAY PROCEDURE - SEMIQUANTITATIVE**

1. The highest dilution in which visible aggregation occurs is considered the endpoint titer.
2. The final titer is not necessary to be used in the diagnostic reading.
3. Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test.
4. The nonreactive pattern is slightly granular or "rough" with specimens exhibiting a magnitude of reactivity of 1:16 to 1:400. A faint red hemolysis and thin hemolysis (1:16 to 1:1,000) result is normal.
5. In order to keep the test simple, the semiquantitative method is recommended.
6. The reagents and samples must be used as supplied until the test is completed.

**VISUAL INTERPRETATION OF RESULTS - QUALITATIVE**

- All reagents are ready to use as supplied. Gentle mix the reagents before use; avoid foaming.
- 4. It is not necessary to perform the quantitative procedure on reactive donor samples.
- 3. The nonreactive pattern is slightly granular or "rough" with specimens exhibiting a magnitude of reactivity of 1:16 to 1:400. A faint red hemolysis and thin hemolysis (1:16 to 1:1,000) result is normal.
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**ASO AND ASI RPM CARD TEST**

- The following data are the results of testing in the blood bank setting in comparison with the diagnostic setting.

**PERFORMANCE CHARACTERISTICS**

- The following data are the results of testing in the blood bank setting in comparison with the diagnostic setting.

**SPECIMEN STORAGE**

- Use either serum or EDTA, heparin or sodium citrate plasma specimens for testing with the ASiManager-AT.
- 3. Samples should be free from heparin or micromembranes. A specimen is not recommended for testing when printed matter cannot be read through it.
- 6. Plasma samples stored longer than five (5) days at 2-8°C should not be used in the assay because of the potential for false reactive results.

**LIMITATIONS OF THE PROCEDURE**

- Periodic testing and retesting is indicated to aid in differentiating nonreactive from minimally reactive results.
- 5. It is not necessary to perform the quantitative procedure on reactive donor samples.
- 6. Periodic testing and retesting is indicated to aid in differentiating nonreactive from minimally reactive results.

**ASO AND ASI RPM CARD TEST**

- The following data are the results of testing in the blood bank setting in comparison with the diagnostic setting.

**USING ASIMANAGER-AT FOR INTERPRETATION OF RESULTS**

- The ASiManager-AT should be used as a supportive tool to help in the evaluation of the results of the ASI RPM Test Card.
- The positive titer function is not used in blood donor screening.
- The following data are the results of testing in the blood bank setting in comparison with the diagnostic setting.

**SPECIAL CONSIDERATIONS**

- The following data are the results of testing in the blood bank setting in comparison with the diagnostic setting.

**TABLE 1**

<table>
<thead>
<tr>
<th>ASO/ASI RPM Card Test</th>
<th>Reagent</th>
<th>Nonreactive</th>
<th>Weak Reactive</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASO RPM Card Test</td>
<td>Reactive</td>
<td>462</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>ASO RPM Card Test</td>
<td>Nonreactive</td>
<td>1</td>
<td>737</td>
<td></td>
</tr>
<tr>
<td>ASO RPM Card Test</td>
<td>Weak Reactive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASO RPM Card Test</td>
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<td>9</td>
<td></td>
</tr>
<tr>
<td>ASO RPM Card Test</td>
<td>Nonreactive</td>
<td>1</td>
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**SAMPLES WITH TITERS GREATER THAN 1:16**

- Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum to 1.5 ml of saline. Mix thoroughly. Dispense 0.05 ml of this diluted sample onto circle 2 and 1:16.
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- Mix the solution on circle 2 and 1:16 by drawing the solution up and down 5 or 6 times into the tip of a volumetric pipet. Avoid bubble formation.
- Transfer 0.05 ml of the mixture to circle 2 and 1:16 and mix. Continue the serial dilution procedure from circle 5 and discard 0.05 ml/mix each 3 seconds following rotation. Circles 1 through 5 represent a dilution series as follows:

**VISUAL INTERPRETATION OF RESULTS - SEMIQUANTITATIVE**

- RPR CARBON ANTIGEN 0.5 ml 2.0 ml 9.0 ml 10 x 9.0 ml 20 x 9.0 ml
- RPR Test card (30-well) n/a n/a n/a 175 350

**VISUAL INTERPRETATION OF RESULTS - SEMIQUANTITATIVE**

- Timing device, minute and second capability
- 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)

<table>
<thead>
<tr>
<th>RPR CARBON ANTIGEN 0.5 ml</th>
<th>2.0 ml</th>
<th>9.0 ml</th>
<th>10 x 9.0 ml</th>
<th>20 x 9.0 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 ml</td>
<td>2.0 ml</td>
<td>9.0 ml</td>
<td>10 x 9.0 ml</td>
<td>20 x 9.0 ml</td>
</tr>
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</table>

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