Sensitivity (reactive results/total samples tested) and Specificity (nonreactive results/total samples tested) of ASiManager-AT

**Blood Bank Setting**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>98/100  =  98.0%</td>
<td>99/100 = 99.0%</td>
</tr>
</tbody>
</table>

**Diagnostic Setting**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>105/105 = 100%</td>
<td>105/105 = 100%</td>
</tr>
</tbody>
</table>

**REFERENCES**

5. Data on file and available on request.
9. Technical information (001) 489-0511 or (800) 654-0146.

**SUMMARY AND EXPLANATION**

Detection of antibodies against Treponema pallidum, the etiological agent of syphilis, induces the production of at least two types of antibodies in human infection: anti-treponemal antibodies that can be detected by FTA-ABS antigen2, and non-treponemal antibodies (reagin) that can be detected by RPR antigen2.

**PRINCIPLE OF THE PROCEDURE**

The ASI RPR Card Test is an in vitro microscopic nontreponemal fluorescent test used to be the detection of reagent. The microscopic card antigen enhances the visual discrimination between reactive and nonreactive results. The nontreponemal antibody binds to the antigen that is composed of a complex of antibodies, leukin and lecithin particles to form an arcuate structure. The result of the postantibody reaction is microscopic flocculation.

**REAGENTS**

CABOX ANTIGEN: 0.05% cardiolipin, 0.01-0.02% lecithin, 0.01% cholesterol, (activated as exalum, 0.01% sodium azide as a preservative and stabilizer).

**CONTROLS**

REACTIVE, WEAK REACTIVE, NONREACTIVE: Human serum or defibrinated plasma (liquid) with 0.1% sodium azide as a 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 sera or plasma which has been treated at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. No indigenous test offers complete assurance that infectious agents are absent. The CDC/NIH Health Manual ("Biosafety in 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 not smoke, eat, drink or apply cosmetics in areas where plasma/serum 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. All RPR test areas are plastic coated and specifically designed to be used with the RPR antigen. In handling take care not to finger mark the test card areas, as this may result in an oily deposit and improper test result. When spreading specimens within the confines of the circular area, avoid scratching the card with the dropper. If the specimens do 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 tip when washing the needle assembly. When spreading specimen within the confines of the circular area, avoid scratching the card with the dropper. If the specimens do not spread in the test area or spreads outside the test area, use another test circle.

4. A needle assembly should be thoroughly washed in distilled or deionized water and air dried. Do not wipe the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle tip when rinsing the needle assembly. Let dry as assembly dry. Before test use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it.

5. The needle should deliver 60 ± 2 drops of antigen suspension per milliliter 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 needle is considered satisfactory if 30 ± 1 drops are delivered.

6. Do not use past the expiration date indicated on the kit.

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

**STORAGE INSTRUCTIONS**

Store all reagents away from direct light and direct sunlight. Store in a cool, dry place. Do not store the test area, use another test circle.

**CPT CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>86592</td>
<td>For in vitro diagnostic use</td>
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</table>
4. Serum samples should be tested within five (5) days of collection. Optimum storage temperature for samples is 2-8°C. Samples stored at room temperature may show deterioration of antigen and should not be used for testing at the site.

3. Vigorously agitate the CARBON ANTIGEN for 20-30 seconds before each use in order to ensure homogeneity. Dispense one free-falling drop of the antigen suspension onto each sample while holding the bottle in a vertical position. DO NOT RESTIR the needle passage is clear.

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

1. Using a stirrer pipet, dispense one free-falling drop (0.05 ml) of each serum or plasma sample onto a separate circle on the test card. Use a fresh stirrer pipet for each sample. When using the stirrer pipet, keep in a vertical position to ensure accurate delivery. Adding one free-falling drop of REACTIVE, WEAK REACTIVE, NONREACTIVE, or CONTROL from the dropper vials supplied.

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