Title: **ASI AUTOMATED RPR CONTROL SET FOR USE ON THE ASI EVOLUTION**		Doc#: 6004-900A CLSI
Effective Date: 12/18	Supersedes Revision/Date: 05/18	Revision: 12/18

For in vitro diagnostic use

Catalog Number	**Kit Size**
905002.5A	**2.5 mL Control Set**
905005A	**5.0 mL Control Set**

CPT Code: 86592

1 INTENDED USE: The **ASI AUTOMATED RPR** (rapid plasma reagin) **CONTROL SET** consists of human serum reagents that are Reactive, Weak Reactive and Nonreactive in nontreponemal flocculation tests for the detection of reagin antibodies in human serum. These materials are intended to be acquired, possessed and used only by health professionals.

2 SUMMARY AND EXPLANATION: *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 antigen[1], and anti-nontreponemal antibodies (reagin) that can be detected by RPR antigen[2]. Control sera of known reactivity to reagin demonstrate the validity of the test.

3 PRINCIPLE OF THE PROCEDURE: The **ASI AUTOMATED RPR CONTROL SET** reagents provide graded reactivity (agglutination) for the detection of reagin. In the ASI automated RPR Test, nontreponemal antibodies present in the reactive control and weak reactive control combine with the lipid particles of the Carbon Antigen, causing them to agglutinate. The nonreactive control will not produce agglutination or flocculation in the test.

4 REAGENTS

4.1 Reactive Control – Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

4.2 Weak Reactive Control – Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

4.3 Nonreactive Control – Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative

5 WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

5.1 **ASI AUTOMATED RPR CONTROL SET** reagents contain sodium azide. Azides 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.

5.2 **ASI AUTOMATED RPR CONTROL SET** reagents 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 CONTROLS should be considered potentially infectious and universal precautions should be used. 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].

5.3 The cover of the ASI Evolution should be closed while tests are being performed to avoid glare from outside lighting sources.

5.4 Do not pipet by mouth.

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

5.6 Any cuts, abrasions or other skin lesions should be suitably protected.

6 HANDLING AND PROCEDURAL NOTES

6.1 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.

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

7 STORAGE INSTRUCTIONS: Store all reagents at 2-8°C in an upright position when not in use. Do not freeze reagents.

8 INDICATIONS OF DETERIORATION

8.1 Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.

8.2 Bacterial contamination of reagents or specimens may cause false positive results.

9 MATERIALS PROVIDED

Catalog Number:	905002.5	905005
REACTIVE CONTROL	2.5 ml	5.0 ml
WEAK REACTIVE CONTROL	2.5 ml	5.0 ml
NONREACTIVE CONTROL	2.5 ml	5.0 ml

10 TEST PROCEDURE

10.1 Follow procedures provided in the ASI Evolution Operator's Manual and the ASI RPR Test for Syphilis For Use on the ASI Evolution package insert.

10.2 For use in the ASI Evolution, allow the Control to warm to room temperature (20-30°C) before use. Do not heat in water bath.

10.3 Gently mix reagents before use. Avoid foaming.

11 QUALITY CONTROL

11.1 Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800-654-0146.

12 INTERPRETATION OF RESULTS

Results of the test should be interpreted according to instructions provided in the ASI Evolution Operator's Manual and the ASI RPR Test for Syphilis For Use on the ASI Evolution package insert.

13 LIMITATIONS OF THE PROCEDURE

13.1 When using the **ASI AUTOMATED RPR CONTROL SET**, temperature of reagents is crucial to test outcome; it should be between 20-30°C.

13.2 The results of a positive nontreponemal test must be confirmed by a treponemal test.

13.3 In accordance 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.

14 EXPECTED VALUES

Reactive controls weak reactive controls and nonreactive controls should provide reactive, weakly reactive and non-reactive results, respectively, when evaluated according to the directions provided in the ASI Evolution Operator's Manual and the ASI RPR Test for Syphilis For Use on the ASI Evolution package insert.

15 REFERENCES

1 Hunter EF, Deacon WE, Myer PE. 1964. *Public Health Reports*. 79:410-412.

2 Larsen SA, Pope V, Johnson RE, Kennedy EJ, Jr. (ed.), 9th ed. 1998 *Manual of Tests for Syphilis,* Public Health Service, Washington, D.C.

3 *Biosafety in Microbiological and Biochemical Laboratories,* 3rd ed. 1993. HHS Publication No. (CDC) 93-8395, Public Health Service, Washington, D. C.

TECHNICAL INFORMATION: (801) 489-8911 or (800) 654-0146