Subject/Title: **ASI SYPHILIS REFERENCE PANEL**		Doc#: 6004-908 CLSI
Effective Date: 11/10	Supersedes Revision/Date: 01/07	Revision: 11/10
Prepared by: ASI	QA Approval by:	Copy/Dept.:

FOR IN VITRO DIAGNOSTIC USE

Cat. No. 907000

1 **INTENDED USE:** The **ASI Syphilis Reference Sera** is provided as a qualitative and quantitative control serum to assist in establishing reactivity patterns for control serum samples either prepared by the user laboratory or purchased commercially for use in the nontreponemal tests for syphilis. In addition, the syphilis reference sera can be used in the evaluation of the reactivity of nontreponemal test antigens.

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 the RPR (rapid plasma reagin) card test or the VDRL test.[(2)]
Emphasis for many years on quality control procedures in syphilis serology has resulted in high uniformity of test performance within laboratories and among laboratories. One of the most important quality control procedures for assurance of reliable and reproducible test results is the use of stable control serum samples that have predetermined reactivity patterns. Such control serum usage is mandated by the Clinical Laboratory Improvement Act of 1988 (CLIA 88).[(3)] Control sera of known reactivity to reagin demonstrate the validity of the test.

3 **REAGENTS**
3.1 REFERENCE SERA - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

4 **WARNINGS AND PRECAUTIONS**
For *In Vitro* Diagnostic Use

4.1 **ASI REFERENCE SERA** contains 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 build-up.

4.2 **ASI REFERENCE SERA** 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 non-reactive. 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 Manual, "Biosafety in Microbiological and Biomedical Laboratories" describes how these materials should be handled in accordance with Good Laboratory Practice [(4)].

4.2.1 Do not pipet by mouth.

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

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

5 **HANDLING AND PROCEDURAL NOTES**
5.1 In order to obtain reliable and consistent results, the instructions provided by the supplier of the test kit must be strictly followed when using these reference sera. Do not modify the handling and storage conditions for reagents or samples.

5.2 Do not use past the expiration date indicated on the labels.

6 **STORAGE INSTRUCTIONS:** Store at 2-8°C in an upright position when not in use.

7 **INDICATIONS OF DETERIORATION**
7.1 Turbidity or precipitation in reference sera is indicative of deterioration and should not be used.

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

Title: ASI SYPHILIS REFERENCE PANEL		Doc#: 6004-908 CLSI
Effective Date: 11/10	Supersedes Revision/Date: 01/07	Revision: 11/10

8 SPECIMEN COLLECTION AND STORAGE

8.1 Follow the instructions of the Test Kit manufacturer. **ASI Syphilis Panel** is suitable for comparison with both serum and plasma specimens.

9 MATERIALS PROVIDED

REFERENCE SERA - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

10 ADDITIONAL MATERIALS REQUIRED

10.1 RPR Card Test Kit or VDRL Slide Test Kit

10.2 Additional materials as indicated by the test kit manufacturer

11 TEST PROCEDURE

11.1 Follow procedures provided by the manufacturer of the test kit.

11.2 For use in the VDRL Slide Test, Controls must be heat inactivated for 30 minutes at 56°C prior to testing. If heat-inactivation occurs more than four (4) hours prior to testing, reheat the Controls for an additional 10 minutes at 56°C before use.

11.3 For use in the RPR Card Test, Controls are ready for use as supplied. Allow the Controls to warm to room temperature (20-30°C) before use. Do not heat in a water bath.

11.4 Gently mix the reference sera before use. Avoid foaming.

12 INTERPRETATION OF RESULTS

Results of the test should be interpreted according to instructions provided by the manufacturer of the test kit.

13 LIMITATIONS OF THE PROCEDURE

13.1 Reaction times longer than specified in the test instructions may cause false positive results due to a drying effect.

13.2 Temperature of the reagents is crucial to test outcome; it should be between 20-30°C.

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

13.4 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.

14 EXPECTED VALUES

Reference Panel Serum should provide results as stated on the labels of each vial, when evaluated according to the instructions provided by the manufacturer of the test kit.

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. CDC Reference reactive and weakly reactive human control sera for nontreponemal tests users guide, October 1999, Atlanta, GA
4. *Biosafety in Microbiological and Biomedical Laboratories*, 3rd ed. 1993. HHS Publication No. (CDC) 93-8395, Public Health Service, Washington, D.C.