ARLINGTON SCIENTIFIC

ASI RPR/VDRL CONTROL SERUM SET

Cat. No. 905001	1.0 mL
Cat. No. 905002.5	2.5 mL
Cat. No. 905005	5.0 mL

INTENDED USE

The **ASI RPR/VDRL 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.

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]. Control sera of known reactivity to reagin demonstrate the validity of the test.

PRINCIPLE OF THE PROCEDURE

The **ASI RPR/VDRL CONTROL SET** reagents provide graded reactivity (agglutination) for the detection of reagin. In the RPR Card 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. In the VDRL Slide Test, nontreponemal antibodies present in the reactive control and weak reactive control combine with the lipoidal material in the VDRL Antigen, causing microflocculation. The nonreactive control will not produce agglutination or flocculation in either test.

REAGENTS

1. Reactive Control - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.
2. Weak Reactive Control - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.
3. Nonreactive Control - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative

WARNINGS AND PRECAUTIONS

This product should only be used by properly trained individuals. Precautions should be taken against microbial hazards. The toxicity of these reagents has not been determined. Do not pipet by mouth; do not ingest.

STABILITY OF THE REAGENTS

For *in vitro* diagnostic use

1. ASI RPR/VDRL 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 build-up.
2. ASI RPR/VDRL 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 Manual, "Biosafety in Microbiological and Biomedical Laboratories," describes how these materials should be handled in accordance with Good Laboratory Practice [3].
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 provided by the supplier of the Test Kit must be strictly followed when using these Controls. Do not modify the handling and storage conditions for reagents or samples.
2. Do not use past the expiration date indicated on the kit.

STORAGE INSTRUCTIONS

Store all reagents at 2–8°C in an upright position when not in use. Do not freeze reagents.

INDICATIONS OF DETERIORATION

1. Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
2. Bacterial contamination of reagents or specimens may cause false positive results.

9.0 MATERIALS PROVIDED			
Catalog Number	**905001**	**905002.5**	**905005**
Reactive Control	1 mL	2.5 mL	5 mL
Weak Reactive Control	1 mL	2.5 mL	5 mL
Nonreactive Control	1 mL	2.5 mL	5 mL

ADDITIONAL MATERIALS REQUIRED

1. RPR Card Test Kit or VDRL Slide Test Kit.
2. Additional materials as indicated by the Test Kit manufacturer

TEST PROCEDURE

1. Follow procedures provided by the manufacturer of the Test Kit.
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.
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.
4. Gently mix the reagents before use. Avoid foaming.
5. The dropper tips on the Control bottles dispense 0.05 ml per drop when the bottle is held vertically and squeezed gently.

QUALITY CONTROL

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 Arlington Scientific Technical Support at 800.654.0146.

INTERPRETATION OF RESULTS

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

LIMITATIONS OF THE PROCEDURE

1. When using the RPR Card Test, reaction times longer than specified in the test instructions may cause false positive results due to a drying effect.
2. Temperature of the reagents is crucial to test outcome; it should be between 20-30°C.
3. The results of a positive nontreponemal test must be confirmed by a treponemal test.
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.

EXPECTED VALUES

Reactive controls, weak reactive controls, and nonreactive controls should provide reactive, weakly reactive and nonreactive results, respectively, when evaluated according to the instructions provided by the manufacturer of the test kit.

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 Biomedical 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

ARLINGTON SCIENTIFIC

1840 North Technology Drive
Springville, UT 84663
801-489-8911
800-654-0146
www.arlingtonscientific.com

6004-900RC Rev. 03-2019