

## **LABORATORY PROCEDURE**

### **Macro-Vue™ RPR Card Test Liquid Controls**

#### **I. INTENDED USE**

The **Macro-Vue™** RPR (Rapid Plasma Reagin) Card Test Liquid Controls are designed as an unassayed control material to monitor, at three reaction levels, the precision of **Macro-Vue** RPR 18 mm Circle Card Test.

#### **II. SUMMARY AND EXPLANATION**

RPR Test Reagents should be routinely tested for patterns of graded reactivity against controls with established patterns of reactivity.

#### **III. PRINCIPLES OF THE PROCEDURE**

The **Macro-Vue** RPR Card Test Liquid Controls consist of three individually labeled vials of stabilized liquid RPR control serum; i.e., **Macro-Vue** RPR Card Test Reactive Control Serum (Control ++), **Macro-Vue** RPR Card Test Moderately Reactive Control Serum (Control +), and **Macro-Vue** RPR Card Test Negative Control Serum (Control –). Each lot of **Macro-Vue** RPR Card Test Liquid Controls is tested against reference antigen suspension and is a stable sample, containing reagin. When used properly and prior to the expiration date on the label, the controls will provide reproducible patterns of reactivity with the **Macro-Vue** RPR 18 mm Circle Card Test.

#### **IV. REAGENTS**

**Macro-Vue** RPR Card Test Liquid Controls contain pooled human serum with 0.1% sodium azide as a preservative.

**Control ++**, 1.5 mL **Macro-Vue** RPR Card Test Reactive Control Serum Positive.

**Control +**, 1.5 mL **Macro-Vue** RPR Card Test Moderately Reactive Control Serum Weakly Positive.

**Control –**, 1.5 mL **Macro-Vue** RPR Card Test Negative Control Serum Negative Control.

**Precautions:** For *in vitro* Diagnostic use.

**Reagents:** Do not use beyond the expiration date. Upon removal from refrigeration allow reagents to warm to room temperature (23 – 29°C) and gently invert to mix. Avoid microbial contamination of reagents.

The serum used for the Controls is derived from human blood tested by an FDA (U.S. Food and Drug Administration) approved method for the presence of the antibody to HIV (human immunodeficiency virus), HBsAg (Hepatitis B surface antigen) and HCsAg (Hepatitis C surface antigen) and found to be nonreactive.

**WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL.** Because no test method can offer complete assurance that HIV, hepatitis B virus, hepatitis C virus or other infectious agents are absent, SPECIMENS AND THESE REAGENTS SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING AN INFECTIOUS DISEASE. The FDA recommends such material be handled at a Biosafety Level 2. BSL2 is referenced in the Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) manual, *Biosafety in Microbiological and Biomedical Laboratories*.

Reagents contain sodium azide, which is very toxic by inhalation, in contact with skin, and if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

If the established reactivity patterns are not seen, delay routine testing until satisfactory reactivity is obtained by rechecking antigen suspension, test procedures, room temperature and equipment (including use of a rotator with humidifying cover). Non-acceptable results invalidate tests on individual specimens.

**Diagnostic Test Cards:** These are specially prepared cards designed for use with the RPR Card antigen. In handling, take care not to fingermark the card test areas, as this may result in an oily deposit and improper test results. When spreading specimens within the confines of test areas, avoid scratching the card with the **Dispenstirs**<sup>TM</sup> device or stirrer. If the specimen does not spread to the outer perimeter of the test area, use another test area of the card.

**Reading of Card Test Results:** Read immediately following rotation in the “wet” state under a high intensity incandescent lamp or strong daylight.

**Rotation:** The recommended speed for mechanical rotation is  $100 \pm 2$  rpm. The rotator should circumscribe a circle approximately two centimeters in diameter in the horizontal plane. A moistened humidifying cover should be used to prevent drying of control sera during rotation.

**Storage of Reagents:** Store as packaged at 2 – 8°C before initial use and after each use. Reagents should be recapped and returned to refrigeration when not in use. Once bottles are opened, reagents should be used within 10 months. Do not use beyond the expiration date printed on the label.

Any sign of microbial contamination warrants discontinuance of use.

## V. PROCEDURES

Before proceeding, review “Procedures” and “Precautions” in the package insert supplied with all **Macro-Vue** RPR Card Test kits.

**Material Provided:** **Macro-Vue** RPR Card Test Liquid Controls as listed under “Availability.”

**Materials Required But Not Provided:** One of the following **Macro-Vue** RPR 18 mm Circle Card Test kits:

Kit No. 104, 115, 110, 510, 532 (qualitative) or kit No. 112 (quantitative); a rotator,  $100 \pm 2$  rpm, 2 cm diameter, automatic timer, friction drive, with a humidifying cover containing a moistened blotter or sponge; a micropipettor which dispenses 0.05 mL (50  $\mu$ L) (see “Availability”). For availability of **Macro-Vue** RPR Card Test kits refer to the package insert supplied with all kits.

**IMPORTANT:** Read this entire procedure prior to performing any test. This procedure is **INTENDED TO SUPPLEMENT NOT REPLACE** the procedure outlined in the insert for **Macro-Vue** RPR 18 mm Circle Card Test. Before proceeding, review “Procedures” and “Precautions” in the package insert supplied with all **Macro-Vue** RPR 18 mm Circle Card Test.

REFER TO THE PACKAGE INSERT FOR THE **MACRO-VUE** RPR 18 mm CIRCLE CARD TEST KIT, **Qualitative Procedure:**

1. Dispense ONE (1) free falling drop (50  $\mu$ L) of **Macro-Vue** RPR Card Test Reactive Control Serum (Control ++) onto the appropriately identified circle of the test card. Repeat substituting **Macro-Vue** RPR Card Test Moderately Reactive Control Serum (Control +), and **Macro-Vue** RPR Card Test Negative Control Serum (Control -) each on its own test card.
2. Using a separate mixing device for each control, spread the contents of each circle over the entire surface area of the circle.
3. Add ONE (1) free falling drop of well mixed RPR Antigen Suspension to each of the control circles being used on the test card [refer to specific instructions in the package insert for the **Macro-Vue** RPR 18 mm Circle Card Test for more detailed information].
4. Immediately place the RPR Card on a mechanical rotator, cover with the humidifying cover and rotate for 8 min ( $\pm 30$  sec) at 100 rpm ( $\pm 2$  rpm).
5. Following rotation, a brief rotating and tilting of the card by hand (3 – 4 to and fro motions) must be made to aid in differentiating non-reactive from minimally reactive results. Read the card immediately in the wet state under a high intensity incandescent lamp.

### **Quantitative Procedure:**

Refer to the quantitative procedure outlined in the package insert of the **Macro-Vue** RPR 18 mm Circle Card Test kit.

## VI. RESULTS

Each laboratory must establish an acceptable reactivity pattern for each lot number of control material.

**Qualitative**

The Control ++ should show characteristic clumping; the Control – should show the smooth, grayish appearance of unclumped particles. The Control + should show minimal-to-moderate clumping which should be less than for the reactive control (Control ++). Any control exhibiting any deviation from these results should be rerun. Refer to the Reading Guide contained in the package insert provided in the **Macro-Vue** RPR 18 mm Circle Card Test.

**VII. LIMITATIONS OF THE PROCEDURE**

The **Macro-Vue** RPR Card Test Liquid Controls are matrix specific and are intended for use only when testing human serum. Only the presence or absence of Nontreponemal reagin using RPR Test kits has been evaluated with these controls.

Delay in reading test results after rotation, or performing the test procedure in an environment of low humidity (particularly without a humidifying cover on the rotator) may cause an undesirable reactivity pattern (a granular appearance in the Control –).

The intensity of clumping observed should not be used as a reading standard or guide in interpreting reactions observed with unknown specimens. The Reading Guide contained in the package insert provided with all **Macro-Vue** RPR Card Test kits is intended for this purpose.

For more information, refer to the “Limitations of the Procedure” section in the package insert for the **Macro-Vue** RPR 18 mm Circle Card Test kit.

**VIII. EXPECTED VALUES AND PERFORMANCE CHARACTERISTICS**

Each lot of **Macro-Vue™** RPR Card Test Liquid Controls is tested for established patterns of graded reactivity against reference antigen suspensions.

Example of results using dilutions of the enclosed controls:

Example:	1:1	1:2	1:4	1:8	1:16
Control ++	R	R	R	Rm	N
Control +	R	Rm	N	N	N
Control -	N	N	N	N	N

R=Reactive

Rm= Reactive minimal

N= Nonreactive

**IX. AVAILABILITY**

<b>Cat. No.</b>	<b>Description</b>
276909	<b>Macro-Vue™</b> RPR Card Test Liquid Controls, containing graded reactivity specimens, (Control ++, Control +, and Control –), Carton of 3 vials.
278051	<b>Macro-Vue™</b> RPR Card Test Rotator (with humidifying cover), 100 ± 2 rpm, automatic timer, friction drive, Model 51-II (110 V) Domestic.
277979	<b>Macro-Vue™</b> RPR Card Test Rotator Accessories Package, containing one 15 inch x 7 inch extension top and two humidifying covers.

**X. REFERENCES**

1. Portnoy, J., et al. 1972. Public Health Rep. 77: 645-652.
2. Manual of Tests for Syphilis, APHS Publication 8th ed. 1990.
3. Laboratory Procedures for Modern Syphilis Serology, PHS Publication No. 988. 1962.

**Technical Information:** In the United States, telephone BD Diagnostic Systems Technical Services, toll free (800) 638-8663

Approved By: \_\_\_\_\_

Date Effective: \_\_\_\_\_

Supervisor: \_\_\_\_\_ Date: \_\_\_\_\_

Director: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed:

PI Rev 07/99

Rev 06/02

