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Section: Serology Manual	Subject Title: Rapid Plasma Reagin Test for Syphilis Screening	
Issued by: LABORATORY MANAGER	Original Date: March 14, 2001	
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SYPHILIS SCREENING

I. Introduction

The NCS Rapid Plasma Reagin (RPR) Card test is a macroscopic non-treponemal flocculation test used to detect reagin antibodies.

II. Specimen Collection and Processing

Blood is collected (5 mL for adult and 1 mL for neonate) in a serum separator tube and separated by centrifugation. The serum is removed to a tube and refrigerated until testing. Specimens are stored in the refrigerator for 2 weeks after testing. A request for VDRL on spinal fluid (CSF) or neonate blood will be sent to PHL for testing.

III. Procedure

i) Reagents:

RPR reagent kit (NCS Diagnostics Inc.)

ii) Other Materials:

3 mL dropper bottle
 Dispensing needle (17 µL/drop)
 RPR test card
 0.05 mL disposable stirrer pipettes
 Serological rotator at 100 rpm
 dH₂O

iii) Precaution:

Refrigerate reagents until required. Warm to RT and mix well before use. To ensure stability, return the antigen suspension to the original glass bottle after testing. The dispenser and needle assembly must be thoroughly washed in dH₂O and air dried after use.

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iv) Needle Accuracy Check - When New Kit Opened:

This procedure is performed to check the needle delivering antigen each time before testing. Using a pipette, deliver 0.5 mL antigen to the dropper bottle. Attach the needle and, holding in a vertical position, count the number of drops delivered in 0.5 mL. The needle is considered satisfactory if 30 ± 1 drops are obtained. If the needle is unsatisfactory, repeat the check. Record the lot number of the newly opened kit in the reagent lot number binder.

v) Method:

1. Using the stirrer pipette held vertically, dispense one drop (50 μ L) of serum onto a circle on the test card. Use a fresh stirrer pipette for each sample. Repeat with the control sera.
2. Using the flat end of the stirrer pipette spread the sample over the entire area of the test circle.
3. Attach the needle to the dropper bottle. Mix the carbon antigen reagent well. Squeeze the dropper bottle and withdraw sufficient reagent into the bottle. Discard the first few drops into the reagent stock bottle and then dispense 1 drop into each circle in a vertical position. Do not mix the sample and the antigen. Rotate the card at 100 rpm for 8 minutes.
4. Observe for agglutination by two technologists independently.

vi) Interpretation of Results:

Positive Result: Any agglutination. Repeat test ---- see senior technologist for any discrepant results. Send all positive sera to PHL for VDRL and confirmatory tests. Write on PHL requisition: "RPR positive, please do confirmatory test"; DO NOT mark prenatal box for serum from prenatal patients.

Negative Result: No agglutination.

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IV. Reporting

Positive Result: Enter in LIS as "TO PHL". VDRL send-out test is ordered reflexively. Send to PHL next day.

Negative Result: Negative

V. Quality Control

Strongly reactive, weakly reactive and non-reactive control sera are included in each run. If controls are not working or the antigen is not falling cleanly from the needle, perform a needle check as outlined in the method.

Record control results and kit lot number on the task list. Run external control (Accurun 156) with each new lot. When opening a new kit, record the lot number, needle check and external control results in the reagent lot binder.

Refer to a senior technologist if control results are outside of limits or for any other problems with running or reporting the assay.

CAP provides external proficiency testing.

VI. Reference

Manufacturer's package insert (RPR Card Test, NCS Diagnostics Inc., 130 Matheson Blvd. E. Mississauga, Ontario L4X 1Y6).