RPR LIQUID CONTROLS

INTENDED USE
Remel RPR Liquid Controls contain human-based RPR control sera intended for use as unassayed controls with Remel RPR Card Test and other RPR tests to monitor the reactivity of RPR reagents.

SUMMARY AND PRINCIPLE
RPR test reagents should be routinely tested for patterns of graded reactivity against controls with established patterns of reactivity.

RPR Liquid Controls contains 1 bottle each of RPR Reactive, Minimally Reactive, and Nonreactive Controls. RPR Liquid Controls are stabilized liquid control sera designed for use with RPR reagents such as RPR Card Test. Each lot of RPR Liquid Controls is tested against a reference antigen suspension and Remel RPR Antigen.

PRECAUTIONS
This product is for In Vitro diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and test materials after use. Directions should be read and followed carefully.

1. Potential Biohazardous Material: The human serum used to manufacture the controls has been shown to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to HIV and HCV using FDA-licensed test methods. Because no test can ensure the absence of every infectious agent, all human specimens should be considered potentially infectious and handled accordingly. Refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories for information on handling human specimens.

2. These controls contain thimerosal as a preservative, which may be toxic if ingested.

3. Refer to Material Safety Data Sheet for additional information on reagent chemicals.

STORAGE
Store product in its original container at 2-8°C until used. Once bottles have been opened, reagents should be used within one year or by the expiration date, whichever occurs first. Do not freeze.

PRODUCT DETERIORATION
This product should not be used if (1) the appearance of the reagents has changed, (2) there is evidence of contamination, (3) the expiration date has passed, or (4) there are other signs of deterioration.

MATERIALS AND REAGENTS SUPPLIED
RPR Reactive Control: (1 ml) human serum containing 0.01% thimerosal as preservative.

RPR Minimally Reactive Control: (1 ml) human serum containing 0.01% thimerosal as preservative.

RPR Nonreactive Control: (1 ml) human serum containing 0.01% thimerosal as preservative.

Instructions for Use (IFU)

PROCEDURE
RPR Liquid Controls are ready for use and no further preparation is necessary. Allow controls to equilibrate to room temperature prior to use and return to indicated storage conditions immediately after each use. Return each cap/lid to its respective vial immediately after each use to avoid cross contamination and evaporation.

• Note: Read the entire procedure prior to performing the test. Refer to the IFU for the RPR test kit being used for additional information. This procedure is intended to supplement, not replace, the procedure outlined in the IFU for the RPR kit being used.

• Note: The controls contained in this kit should be tested using the same protocol followed for a patient specimen.

RESULTS
Each laboratory should establish the graded reactivity of the reactive and minimally reactive controls and use determined endpoints to monitor precision.

LIMITATIONS
RPR Liquid Controls have been validated for use only with RPR Antigen. The endpoint titers of these controls have not been determined for other RPR tests. For more information, refer to the RPR Card Test IFU.

EXPECTED VALUES
Each lot of RPR Liquid Controls is tested against a reference cardiolipin antigen suspension and RPR Antigen to ensure that the established patterns of graded reactivity are maintained from lot-to-lot.

This product was tested in a U.S. state public health laboratory and an urban general hospital in the southwestern U.S. Both sites reported reproducibility study endpoint titers of 1:1 to 1:2 of the Minimally Reactive Control and titers of 1:2 to 1:4 with the Reactive Control when using Remel RPR Card Test.

BIBLIOGRAPHY

PACKAGING
REF R16307, RPR Liquid Controls.................................................................1 Pk

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