Stanbio Syphilis Tri-Level Control Set, Procedure No. 1175

CE

For Use As Quality Control Material In The VDRL Slide Flocculation Test and For The Rapid Plasma Reagin (RPR) 18mm Circle Syphilis Card Test

Summary and Principle

Proper use of the VDRL/RPR flocculation test should include daily standardization of the antigen suspension prior to testing unknown specimens. This standardization is accomplished by use of serum controls of known activity in the VDRL/RPR test. When the antigen suspension is tested with controls showing Reactive, Weakly Reactive and Non-Reactive patterns, a standard reactivity pattern should be observed before the antigen is used for routine testing.

Standardization of the VDRL/RPR antigen suspensions as a daily routine control measure is recommended by the Center for Disease Control (CDC). Complete instructions for test performance and interpretation of results can be found in the Manual of Tests for Syphilis.[1-3]

Reagents

Reactive Syphilis Control, Cat. No. 1172
Prepared with syphilis positive human sera; preservative added.

Weakly-Reactive Syphilis Control, Cat. No. 1174
Prepared with syphilis positive human serum; preservative added.

Non-Reactive Syphilis Control, Cat. No. 1173
Prepared with human serum found to be non-reactive for syphilis; preservative added.

Precautions: For In Vitro Diagnostic Use.
These human serums has tested negative for hepatitis B surface (HBsAg) antigen and HIV.

Caution: Handle with same precautions as used for patients, since no known test can offer that products manufactured from human blood will not transmit disease.

Reagent Preparation: Tri-Level Syphilis Controls are supplied ready-to-use.

Reagent Storage and Stability: Tri-Level Serum Controls are stable until expiration dates on respective labels when properly stored at 2-8°C (refrigerated). If evidence of gross contamination is observed, sera should be discarded.

DO NOT FREEZE !

Procedure

Tri-level Syphilis Controls are used to test the VDRL antigen emulsion prior to its use with clinical specimens and to monitor the results of routine testing by inclusion of controls along with patient's samples.

All of the Syphilis controls should be used undiluted.

Aliquots of these sera should be **heat-inactivated** by incubation for 30 minutes at 56°C in a water bath prior to use in the VDRL slide test; controls are used **unheated** in the RPR card test.

Details of the procedures for daily testing of the VDRL antigen suspension and of the qualitative and quantitative VDRL slide tests and the qualitative RPR (18mm circle) card test can be found in the Manual of Tests for Syphilis.

Stanbio Syphilis Tri-Level Control Set, Procedure No. 1175

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For Use As Quality Control Material In The VDRL Slide Flocculation Test and For The Rapid Plasma Reagin (RPR) 18mm Circle Syphilis Card Test

Summary and Principle

Proper use of the VDRL/RPR flocculation test should include daily standardization of the antigen suspension prior to testing unknown specimens. This standardization is accomplished by use of serum controls of known activity in the VDRL/RPR test. When the antigen suspension is tested with controls showing Reactive, Weakly Reactive and Non-Reactive patterns, a standard reactivity pattern should be observed before the antigen is used for routine testing.

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Performance Characteristics

The reactivity of the Stanbio Tri-level Syphilis Control Set is established using VDRL antigen from the CDC and with current lots of Stanbio RPR antigen.

The reactivity of these controls with the RPR (18mm circle) card test is reported as Reactive, Reactive minimal to moderate and Non-Reactive.

Note: Control sera for nontreponemal tests are not to be used as reading standards.

References

1. Manual of Test for Syphilis, U.S. Public Health Service Publication No. 411 (1969).
2. Stanbio Laboratory, Inc., Package Insert- Cat. No. 1170; RPR Quicktest, (1994).
3. Portnoy, J., Brewer, J.H., and Harris, A., Publ. Health Reports 77, 645 (1962).

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