

**NON-REACTIVE SYPHILIS CONTROL**  
**for use with the**  
**SERODIA TP-PA GELATIN PARTICLE AGGLUTINATION TEST**

**INTENDED USE**

This separate liquid Non-Reactive Control Serum is intended exclusively for quality control assessment of the Serodia TP-PA Syphilis Test in conjunction with the Reactive Control included in the kit. The use of these controls is described in the Serodia TP-PA package insert.

**SUMMARY AND EXPLANATION**

The Non-Reactive Control is made from normal donor serum that is screened for non-reactivity to syphilis. The “neat” serum Control is diluted and treated like a patient sample each time the assay is run. Good laboratory Practice requires routine inclusion of Reactive and Non-Reactive Control Sera run with each batch of patient samples to ensure the proper and consistent performance of the assay. The Non-Reactive Control Serum is provided to aid in verification of performance.

**PRINCIPLE OF THE TEST**

The Serodia TP-PA test is based on the agglutination of colored gelatin particles sensitized with T. pallidum antigen. The Non-Reactive Control serum should yield a compact button formed by the settling of the non-agglutinated particles, characterizing a negative reaction.

**MATERIALS SUPPLIED**

Serodia TP-PA Non-Reactive Control – 1 Vial containing 0.5 mL human serum with 0.1% sodium azide as a preservative.

**MATERIALS REQUIRED BUT NOT PROVIDED**

Microplate  
Serodia TP-PA Gelatin Particle Agglutination Test Kit  
See the Serodia TP-PA Particle Agglutination Syphilis Test package insert for information.

**PRECAUTIONS**

1. For *in vitro diagnostic* use only.
2. **Caution:** All blood products should be treated as potentially infectious. Source materials from which this product was derived was found to be non-reactive for Hepatitis-B surface antigen (HBsAg) and Human Immunodeficiency Virus 1&2 (HIV) and HCV antibody when tested in accordance with current FDA required tests. No known test methods can offer total assurance products derived from human blood will not transmit HIV, Hepatitis or other potentially infectious agents. Therefore, this reagent and all patients’ specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual – “Biosafety in Microbiology and Biomedical Laboratories”, 1984 or latest edition<sup>1</sup>.
3. This Control contains sodium azide as a preservative. This substance may react with lead or copper plumbing to form potentially explosive metal azides. Flush sinks with large volumes of water to prevent azide buildup.

**STORAGE**

1. Store Serodia TP-PA Non-Reactive Control at 2 - 8 °C. DO NOT FREEZE.
2. The Serodia TP-PA Non-Reactive Control should not be used after the expiration date.
3. Visible signs of microbial growth or gross turbidity in the reagent may indicate degradation and warrant discontinuance of use.

**SPECIMEN COLLECTION AND PREPARATION**

Non-Reactive Control is a liquid ready to use human serum.

**DIRECTIONS FOR USE**

A single replicate of the Serodia TP-PA REACTIVE (included in the Serodia TP-PA kit) and NON-REACTIVE CONTROL must be tested with each batch of samples assayed. Additional QC testing may be performed by the user by including other well-characterized specimens or reference sera.

Perform the test as described under ASSAY PROCEDURE, in the Serodia TP-PA Syphilis Agglutination Test package insert using the REACTIVE (included in the kit) and this NON-REACTIVE CONTROL as the specimens. The Reactive and Non-Reactive Control should be diluted according to the Serodia TP-PA procedure and dispensed into the microplate for assay.

**INTERPRETATION OF RESULTS**

The REACTIVE CONTROL should produce a positive (+) reaction and the NON-REACTIVE CONTROL should produce a Negative ( - ) reaction as described in the Serodia TP-PA test package insert. If the appropriate results are not obtained with the controls, all assay results within that batch are invalid and must be re-tested.

**LIMITATIONS**

This Control has been tested for use with the Serodia TP-PA kit only. Performance in other tests has not been determined.

**QUALITY CONTROL**

A Non-Reactive Control should be run with each assay. Either this Non-Reactive Control Serum or an in-house specimen can be used. If the Non-Reactive Control is not with the kit or more is needed, the control can be obtained from the Technical Service Dept.

The Non-Reactive Control should yield a compact button of non-agglutinated particles in the assay. If the control does not perform as expected, re-run the assay. If the control continues to yield erroneous results, discard the vial and obtain a fresh control.

**PERFORMANCE CHARACTERISTICS**

Three lots of Non-Reactive Control were made using three different human sera and assayed in the Serodia TP-PA kit in triplicate over a five day period. A replicate results consistently demonstrated a negative reaction in the assay.

**REFERENCES**

1. US Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories, HHS Publication (NH) 88-8395, Washington U.S. Government Printing Office, May 1993.

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