

# Cenogenics

## VDRL Control Sera

### **INTENDED USE**

CENOGENICS' VDRL control sera are used to monitor the performance of nontreponemal antigens prepared for use in the VDRL slide test on serum.

### **SUMMARY AND EXPLANATION**

The Venereal Disease Research Laboratory of the Centers for Disease Control has recommended as part of a syphilis serology standardization program adherence to published test procedures and reagent control. Control sera with established reactivity patterns such as CENOGENICS' control sera, are intended to help laboratories achieve reliable and reproducible test results in syphilis serology and maintain a stable day-to-day consistency. It has been recommended that control sera be similar to test specimens and should include a Reactive, Weakly Reactive and a Nonreactive control.

### **PRINCIPLES OF THE PROCEDURE**

The principle of the test is an immunologic reaction between the *Treponema pallidum* antibodies (Reactive and Weakly Reactive) and a cardiolipin, lecithin, cholesterol antigen, and conversely a nonreaction using the Nonreactive serum.

### **REAGENTS**

**REACTIVE CONTROL SERUM** is a stabilized human syphilitic serum prepared to monitor nontreponemal test for syphilis reagents. It is to be used undiluted, and as such, will give a reproducible reactive pattern using standardized VDRL reagents.

**WEAKLY REACTIVE CONTROL SERUM** is a stabilized prediluted human syphilis serum prepared to monitor nontreponemal test for syphilis reagents. It is to be used undiluted, and as such, will give a reproducible weakly reactive pattern using standardized VDRL reagents.

**NONREACTIVE CONTROL SERUM** is a stabilized human non-syphilitic serum prepared to monitor nontreponemal test for syphilis reagents. It is to be used undiluted, and as such, will give a reproducible nonreaction using standardized VDRL reagents.

All plasma/serum used in the manufacture of Cenogenics' VDRL Control Sera have been found nonreactive for HIV-1 Ag. HIV 1/2 Ab. HCV and HbsAg.

**PRESERVATIVE:** Thimerosal, 0.02%

**WARNING**

For in vitro diagnostic use.

**STORAGE CONDITIONS**

Store at 2°-8° C. To insure expiration date, it is recommended that only sufficient sample for a day's testing be taken aseptically and remaining material be stopped and returned to refrigeration. An alternative to the above, is to aliquot into daily working amounts, refrigerate and use as needed.

**STABILITY**

The control sera should be examined before each use for any change in appearance, such as the occurrence of particulate matter or turbidity indicative of bacterial contamination. Such changes may prohibit achieving the desired reactivity.

**PRECAUTIONS**

Normal laboratory precautions should be observed with all sera of human origin. We do not recommend that the Weakly Reactive Serum be used as a point reading reference to differentiate between a weakly reactive and a negative specimen, but it be used only to judge the day-to-day performance of the VDRL reagents.

**PROCEDURE**

Use the same procedure as outlined in the VDRL test instruction.

**QUALITY CONTROL AND PERFORMANCE CHARACTERISTICS**

To eliminate the errors encountered in reconstitution of lyophilized control sera, CENOGENICS has provided the control sera in a stabilized liquid state. The reactivity patterns were established using CENOGENICS' VDRL reagents and standardized reference reagents available from the Centers for Disease Control. Each lot of serum has been tested by the Reagents Evaluation Unit of the U.S. Public Health Service Centers for Disease Control, and found to reproduce the reactivity of its standard reference reagent.

**BIBLIOGRAPHY**

Manual of Tests of Syphilis, U.S. Dept. of Health, Education and Welfare, U.S. Public Health Service Publication No. 411, revised 1969. U.S. Printing Office, Washington, D.C. 20402