

Status Mono Control Set

For *In Vitro* Diagnostic Use

Intended Use

Status Mono Control is intended for *in vitro* diagnostic use in quality control testing with the Status Mono test.

Summary

Status Mono Control Negative and Positive Control are external controls that are used to ensure proper kit and operator performance with the Status Mono Test.

Reagents

Status Mono Control Positive Control (1.0 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For *in vitro* diagnostic use only.

Status Mono Control Negative Control (1.0 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For *in vitro* diagnostic use only.

Test Procedure

Remove the cap. Dispense 1 drop (20–25 µl) of control into the sample well and follow procedure as indicated in package insert.

Storage

Store at 2–30°C. Stable until expiration date printed on label.

Warning Potential Biohazard Material

Each donor unit used in the preparation of this material has been tested by an FDA approved method for the presence of the antibody to Human Immunodeficiency Virus (HIV I/II) and Hepatitis C (HCV) as well as for HIV I and Hepatitis B Surface Antigens, and found to be non-reactive/negative (were not repeatedly reactive). However, as no test method can offer complete assurance that infectious agents are not present, this product as with any material of human origin should be considered potentially hazardous and handled as if capable of transmitting disease. Consult "Biosafety in Microbiological and Biomedical Laboratories," the Centers of Disease Control / National Institute of Health Manual, 1986, Atlanta, GA.

Procedural Precautions

Pipette and dispense reagents and specimens accurately since this will affect the results.

- Follow the directions for use of the IM test being employed.
- Discard if gross contamination or turbidity is observed.

Preparation For Use

Status Mono Control Positive and Negative Controls are ready to use. If stored at 2–8°C, controls need to be equilibrated to room temperature before use. Invert gently to mix prior to use.

Procedure

Use **Status Mono Control** Positive and Negative Controls in the same manner as patient samples according to the direction of the test kit being employed.

Expected Results

Even a very faint color band in the test region should be considered a positive result .

Negative Control results

Only one colored band appears in the control region. No apparent band in the test region.

Positive Control results

Color bands appear in the control and test regions. Even a very faint colored band in the test region should be considered a positive result.

Limitations

The **Status Mono Control** Controls are intended for supplementing laboratory quality control procedures and are not for validating test performance. The presence or absence of substances other than to IM has not been established for this product.