REF **200014**

StatusFirst Mono Control Set

For In Vitro Diagnostic Use

Intended Use

StatusFirst Mono Control Positive Control is intended for use as unassayed precision control material for in vitro serological tests that detect antibodies to Infectious Mononucleosis (IM). The use of these controls enable the laboratorian to monitor changes in calibration, along with any analytical error and imprecision. These are not intended to replace any controls furnished with a commercial kit. They are not intended for use as a standard.

Summary And Principle

Emphasis for many years on quality control procedures in serology has resulted in a high uniformity of test performance within and among laboratories. One of the most important quality control procedures for assurance of reliable and reproducible tests results is the use of stable control serum samples that have a predetermined reactivity potency and pattern. Routine use of controls enables laboratories to monitor day-to-day testing, operator and lot-to-lot performance of test kits variation, as well as identifying systematic errors. (1,2,3,4)
StatusFirst Mono Control Positive Control is developed for use as control material to monitor intra-laboratory system performance and estimate precision. These controls may also be used to control reactivity readings from day to day depending on the test system employed. Each lot of **StatusFirst Mono Control** Positive Control is tested in several different methodologies and assay systems to insure proper reactivity. Whenever possible, the controls are tested and compared with WHO, CDC or industrial standards.

Reagents

StatusFirst Mono Control Positive Control (0.5 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For in vitro diagnostic use only. Contents sterile until opened.
StatusFirst Mono Control Negative Control (0.5 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For in vitro diagnostic use only. Contents sterile until opened.

Test Procedure

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

Storage

Store at 2 – 8° C. Stable until expiration date printed on label if unopened, or 60 days after opening, whichever occurs first.

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

Preparation For Use

StatusFirst Mono Control Positive and Negative Controls are ready to use. Allow materials to equilibrate to room temperature and invert gently to mix prior to use.

Procedure

Use **StatusFirst Mono Control** Positive and Negative Controls in the same manner as patient samples according to the direction of the test kit being employed. Use any recognized method such as those described in the package insert of the product being used or the statistical rules described in NCCLS C24-A for assessing assay precision and to establish a target value and control limits. Other useful references include The Manual of Clinical Microbiology (5) and The Manual of Clinical Immunology (6).

Performance Characteristics And Expected Values

The **StatusFirst Mono Control** Positive Control should test positive unless it has been diluted beyond the sensitivity of the test being employed. For interpretation of endpoint / results refer to the "PERFORMANCE CHARACTERISTICS" of the kit being employed. The **StatusFirst Mono Control** Negative Control should test negative. Each laboratory must establish complete quality control testing in accordance with the requirements of regulatory and/or accrediting organizations and the laboratory's quality control goals. A trend log should be maintained for batch to batch consistency of the test. Large variations from the established mean may result from manufacturer's modifications to the test system or improper technique.

Limitations

The **StatusFirst 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.

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