AcroMetrix™ MSSA Positive Control

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 960025 AcroMetrix MSSA Positive Control

Intended Use
The AcroMetrix™ MSSA Positive Control is intended for use in assessing the performance of nucleic acid test procedures for the determination of the presence of MSSA DNA. Routine use of external run controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. This product is for *in-vitro* diagnostic use.

Summary and Explanation of the Test
The AcroMetrix MSSA Positive Control contains inactivated MSSA bacterial particles. The positive control was produced by diluting quantified MSSA stock into a proprietary enzyme compatible bacterial matrix.

Methicillin-sensitive Staphylococcus aureus (MSSA) is a type of bacteria that is sensitive to certain antibiotics. Staph infections, including MSSA, occur most frequently among persons in hospitals and healthcare facilities (such as nursing homes and dialysis centers) who have weakened immune systems. MSSA infections that occur in otherwise healthy people who have not been recently (within the past year) hospitalized or had a medical procedure (such as dialysis, surgery, catheters) are known as community-associated MSSA infections. These infections are usually skin infections, such as abscesses, boils, and other pus-filled lesions.[1]

The AcroMetrix MSSA Positive Control is designed as an unassayed control for use in qualitative molecular test procedures for the detection of MSSA DNA.

Principles of the Procedure
The AcroMetrix MSSA Positive Control has been formulated to mimic naturally occurring human specimens containing MSSA. Additionally, the intact bacteria format of the AcroMetrix MSSA Positive Control allows for the verification of effective bacterial DNA extraction and purification. The controls are designed to monitor all procedural steps in test procedures for determining the presence of MSSA DNA in human specimens. Because the AcroMetrix MSSA Positive Control contains intact bacteria, the test methodology must include an extraction step that releases the bacterial DNA for amplification and detection, as appropriate to the test.

The AcroMetrix MSSA Positive Control is designed to help ensure the quality of nucleic acid test results and to monitor assay performance. Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of these controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error.

Reagents

Catalog Number	Control Name	Quantity
960025	AcroMetrix MSSA Positive Control	5 x 0.2 mL

⚠ Precautions and Warning
WARNING: Although the AcroMetrix MSSA Positive Control contains inactivated MSSA, it should be considered potentially biohazardous. Contains ≤0.05% ProClin™ 300. Observe universal precautions for prevention of transmission of infectious agents when handling these materials.[2,3,4]

H412 - Harmful to aquatic life with long lasting effects.

Avoid release to the environment. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Do not pipette by mouth. Use personal protective equipment, including lab coats, gloves and safety glasses. Do not eat, drink or smoke in areas where panels and specimens are handled.

Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

This product contains 0.05% ProClin™ 300 as a preservative.

Storage Instructions
It is recommended that the AcroMetrix MSSA Positive Control be stored at 2°C to 8°C to ensure consistent results.

Do not use these products beyond the expiration date printed on the tube label.

Instructions for Use
The end user must determine the appropriate volume of AcroMetrix MSSA Positive Control to be utilized in their particular methodology because the volume requirements for extraction methods vary from method to method. The end user may alternatively use a sterile swab compatible with their assay technology to absorb the control material, and process the swab in a manner identical to that required for specimens run in the MSSA DNA test procedure being evaluated. Follow the manufacturer's instructions and recommendations for the handling and testing of specimens.

The AcroMetrix MSSA Positive Control is designed for single use and excess material in each vial is to be appropriately discarded.

Limitations
The AcroMetrix MSSA Positive Control is intended for *in vitro* diagnostic use. The AcroMetrix MSSA Positive Control is not intended for use as a substitute for the internal controls provided by *in vitro* diagnostic kit manufacturers.

References

1. Centers for Disease Control (CDC). Healthcare Associated Methicillin Resistant Staphylococcus aureus Infections. 2007.
2. Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
3. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
4. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

Glossary:
http://www.thermofisher.com/symbols-glossary

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