

NATtrol[™] MRSA/SA External Run Controls

Catalog #: NATMRSA-6MC Catalog #: NATMSSA-6MC Catalog #: NATMSSE-6MC

PRODUCT DESCRIPTION:

NATtrolTM MRSA/SA External Run Controls (NATMRSA-6MC, NATMSSA-6MC, and NATMSSE-6MC) are formulated with purified, intact bacterial particles that have been chemically modified to render them noninfectious and refrigerator stable*. Each control contains 6 x 0.5 mL vials of *S. aureus* NATtrolTM or *S. epidermidis* NATtrolTM. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*NATtrol[™] Patents Pending

INTENDED USE:

- NATtrol[™] MRSA/SA External Run Controls are full process controls designed to evaluate the performance of nucleic acid tests for determination of the presence of *S. aureus* DNA. These controls can also be used for quality control of clinical assays and training of laboratory personnel.
- NATMRSA-6MC, NATMSSA-6MC and NATMSSE-6MC contain intact organisms and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol[™] inactivation was carried out on each control. The inactivation was verified by the absence of bacterial growth in a validated growth protocol.
- The purified protein matrix was manufactured from materials that were screened and found to be negative for HIV 1&2 Ab, HBsAg, HTLV I&II Ab, HCV Ab, HIV RNA, HBV DNA and HCV RNA using FDA cleared kits at the single donor level.

PRECAUTIONS:

- Although NATtrol[™] MRSA/SA External Run Controls contain inactivated organisms, they should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

This product was manufactured in a facility which has a Quality Management System that is certified as being in compliance with ISO 13485

PINATMRSA-6MC PINATMSSA-6MC PINATMSSE-6MC Rev.: 06/2012 For Research Use Only

RECOMMENDED STORAGE:

• NATtrol[™] MRSA/SA External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

 Extract Nucleic Acids prior to use in downstream assays. Follow manufacturer instructions for integrated sample to result assays.

TABLE 1

Catalog Number	Description	Organism
NATMRSA-6MC	NATtrol MRSA Positive Control	S. aureus* (MRSA Hospital Strain)
NATMSSA-6MC	NATtrol SA Positive Control	S. aureus* (MSSA)
NATMSSE-6MC	NATtrol MRSA/SA Negative Control	S. epidermidis (MSSE HER 1292)

DO NOT USE IN HUMANS

These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

*EXPORT COMPLIANCE: This organism is currently included on the Commerce Control List (15 C.F.R. 774, Supplement 1). Export or re-export of such organism, certain genetic elements thereof and/or genetically modified organism is prohibited without the appropriate authorization or license from the Bureau of Industry and Security per the U.S. Export Administration Regulations (15 C.F.R. 730-774).

The foregoing is offered for general informational purposes only; ZeptoMetrix makes no representations or warranties as to its accuracy, omissions or completeness. Recipient of organism is solely responsible for assessing its obligations and complying with all relevant U.S. and foreign export control laws and regulations with regard to such organism.

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