NATtrol™ Strep A Verification Panel

Catalog Number: NATSAVP1-C

PRODUCT DESCRIPTION:

NATtrol™ Strep A Verification Panel (P/N NATSAVP1-C) is formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable*. NATSAVP1-C panel contains 24 x 0.1 mL vials each containing bacterial NATtrol™ targets listed in the Expected Results table. The panel members are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*Pat.:http://www.zeptometrix.com/patent-information/

INTENDED USE:

- NATtrol™ Strep A Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial nucleic acids. NATSAVP1-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATSAVP1-C contains 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 member in the panel. The inactivation was verified by the absence of bacterial growth in validated growth assays
- Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods. Heat inactivated bovine based source materials used in the manufacture of this product meet applicable USDA requirements for abattoir sourced animals, traceability and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and post mortem at the abattoir as required by the USDA.

PRECAUTIONS:

- Although NATSAVP1-C contains inactivated organisms, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ Strep A Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Use a clean, unused swab (not provided) for each panel member
- Shake NATtrol™ panel member vigorously for 10 seconds
- Dip the clean swab into the panel member tube for 10 seconds or until liquid is adsorbed and then transfer the swab to a transport tube.
- Follow the assay manufacturer's instructions for use to process the sample as a clinical sample.

EXPECTED RESULTS:

- Qualitative results are shown in Table 1.
- Each laboratory must evaluate the controls and establish their own acceptance criteria.
- The data shown below is for informational purposes only.

Table 1:

Panel Member	Strain	Expected Result
S. pyogenes	Z018	Strep A is detected
S. pyogenes	Z471	Strep A is detected
S. pyogenes	Z472	Strep A is detected
S. dysgalactiae	Z068	Strep A is not detected
S. mitis	clinical isolate	Strep A is not detected
S. anginosus	Z199	Strep A is not detected

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

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.

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
	Biological Risk		

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