

NATtrol™ CT/NG Panel

Catalog #: NATCT/NGP-C

PRODUCT DESCRIPTION:

NATtrol™ CT/NG Panel (NATCT/NGP-C) is formulated with purified, intact bacterial particles that have been chemically modified to render them non-infectious and refrigerator stable*. NATCT/NGP-C panel contains 17 x 1.2 mL vials each containing the bacterial NATtrol™ targets listed in the Expected Results. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.
*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ CT/NG Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence bacterial DNA. NATCT/NGP-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATCT/NGP-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 a validated growth protocol.
- 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.

PRECAUTIONS:

- Although NATCT/NGP-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[™] CT/NG Panel should be stored at 2-8°C

This product was manufactured in a facility which has a Quality

Management System that is ISO 13485 certified.

PINATCT/NGP-C Rev. No./Replaces: 1 / 02/2014 Research Use Only

EXPECTED RESULTS:

Panel Member	Strain	Expected Result
C.trachomatis-High	LGVII-434	CT Detected
		NG Not Detected
C.trachomatis-Medium	LGVII-434	CT Detected
		NG Not Detected
C.trachomatis-Low	LGVII-434	CT Detected
		NG Not Detected
C.trachomatis-High	D-UW3	CT Detected
		NG Not Detected
C.trachomatis-Me <mark>di</mark> um	D-UW3	CT Detected
		NG Not Detected
C.tracho <mark>m</mark> atis-Low	D-UW3	CT Detected
		NG Not Detected
C.trachomatis-High	HAR13	CT Detected
		NG Not Detected
C.trachomatis-Medium	HAR13	CT Detected
		NG Not Detected
C.trachomatis-Low	HAR13	CT Detected
		NG Not Detected
N.gonorrhoeae-High	Z017	CT Not Detected
		NG Detected
N.gonorrhoeae-Medium	Z017	CT Not Detected
		NG Detected
N.gonorrhoeae-Low	Z017	CT Not Detected
		NG Detected
N.gonorrhoeae-High	Z001	CT Not Detected
		NG Detected
N.gonorrhoeae-Medium	Z001	CT Not Detected
		NG Detected
N.gonorrhoeae-Low	Z001	CT Not Detected
		NG Detected
N.cinerea	Z104	CT Not Detected
		NG Not Detected
N.flavescens	Z061	CT Not Detected
		NG Not Detected

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.

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