NATtrol™ BC/GN Panel

Catalog Number:
NATBCGN-NNS

PRODUCT DESCRIPTION:

NATtrol™ BC/GN Panel (NATBCGN-NNS)* is formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATBCGN-NNS contains 12 x 0.75 mL vials of bacterial NATtrol™ targets listed in Table 1. These panels 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™ BC/GN Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial nucleic acids. NATBCGN-NNS can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATBCGN-NNS 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 the bacterial stock used to formulate panel members. 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. 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 NATBCGN-NNS 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™ BC/GN Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- This panel has been tested with the Verigene® BC-GN assay and provides all expected results for the panel members listed in Table 1.
- Panel members should be tested individually (700ul per test), but the *Providencia* member must be mixed in equal volumes with one additional panel member for NDM detection on the BC-GN assay (375µL of each member).
- Vortex NATtrol™ sample for 5-10s prior to direct use for testing and also prior to mixing with any other panel member.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

SUGGESTED MIXTURES: Although it is recommended to run the panel members individually, the panel can be run following the suggested mixture combinations.

- Each laboratory must evaluate the mixes and establish performance criteria.

1. *A.baumannii, Providencia sp* (375µl each; Mix well and use 700µl per test)
2. *P.mirabilis, P.aeruginosa, K.oxytoca* (250µl each; Mix well and use 700µl per test)
3. *E.coli, K.pneumoniae (*KPC2*)* (375 µl each; Mix well and use 700µl per test)
4. *K.pneumoniae* (Z135)*, K.pneumoniae* (Z138) (375 µl each; Mix well and use 700µl per test)
5. *C.freundii, E.cloacae* (375µl each; Mix well and use 700µl per test)

TABLE 1. EXPECTED RESULTS:

Panel Member	Strain	Verigene® BC-GN Summary Result
K. oxytoca	Z115	*K. oxytoca* Detected
P. aeruginosa	Z139, VIM1	*P. aeruginosa* Detected VIM Detected
E.coli	ETEC	*E. coli* Detected
A. baumannii	307-0294	*Acinetobacter* Detected
P. mirabilis	Z050	*Proteus* Detected
C. freundii	Z064	*Citrobacter* Detected
E. cloacae	Z101	*Enterobacter* Detected
Providencia sp.	Z137, NDM1	NDM Detected**
K. pneumoniae	KPC2	*K. pneumoniae* Detected KPC Detected
K. pneumoniae	Z135	*K. pneumoniae* Detected CTX-M Detected IMP Detected
K. pneumoniae	Z138, OXA 48, CTX-M	*K.pneumoniae* Detected CTX-M Detected OXA Detected
Negative	N/A	Not Detected

****Providencia* will only result in NDM being detected when it is pooled with an additional panel member that detects a BC-GN panel bacterial target.**

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.

REF	Catalog Number		Temperature Limitation
LOT	Batch Code		Expiration Date
RUO	For Research Use Only		Biological Risk
	Manufacturer		

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