NATtrol™ BC/GP Panel

Catalog #: NATBC/GP-NNS

PRODUCT DESCRIPTION:

NATtrol™ BC/GP Panel (NATBC/GP-NNS) is formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable*. NATBC/GP-NNS contains 10 x 0.75 mL vials of bacterial NATtrol™ targets listed in Table 1 except *S.pneumoniae*. The *S.pneumoniae* member is sold separately (NATSPN-NNS) as 1 X 0.75 mL vial. The panel and the *S.pneumoniae* control are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.
*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ BC/GP Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial nucleic acids. NATBC/GP-NNS can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATBC/GP-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.

PRECAUTIONS:

- Although NATBC/GP-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/GP Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Verigene® BC-GP:

- Prepare cartridge and sample reagents following manufacturer's instructions.
- Vortex NATtrol™ sample for 5-10s.
- Testing single panel member: Add 350µl of sample into Extraction Tray Sample Loading Well.
- Testing Mixtures: Mix equal proportions of single vial samples into sterile container. Vortex thoroughly. Add 350µl of sample to Extraction Tray Sample Well.
- Follow manufacturer's instructions

RECOMMENDED MIXTURES:

1. *S. aureus* (MRSA), *E. faecalis, S. pneumoniae* (120µl each; Mix well and use 350 ul per test)
2. *S. pyogenes, S. agalactiae, S. anginosus* (120 µl each; Mix well and use 350µl per test)
3. *S. epidermidis* (MSSE), *S. lugdenensis, E. faecium, L. monocytogenes* (90 µl each; Mix well and use 350µl per test)

For other assays follow manufacturer's instructions.

EXPECTED RESULTS:

Panel Member	Strain	Verigene® BC-GP Summary Result
S. aureus (MRSA)	COL	*Staphylococcus* Detected *S. aureus* Detected *mecA* Detected
S. epidermidis (MSSE)	HER1292	*Staphylococcus* Detected *S. epidermidis* Detected
S. lugdunensis	Z097	*Staphylococcus* Detected *S. lugdunensis* Detected
S. pneumoniae	Z022	*Streptococcus* Detected *S. pneumoniae* Detected
S. aginosus/intermedius	CL-CS 56	*Streptococcus* Detected *S. anginosus gp*. Detected
S. agalactiae	Z019	*Streptococcus* Detected *S. agalactiae* Detected
S. pyogenes	Z018	*Streptococcus* Detected *S. pyogenes* Detected
E. faecalis	VRE	*E. faecalis* Detected *vanB* Detected
E. faecium	Van A MCW-CS - 166	*E. faecium* Detected *vanA* Detected
L. monocytogenes	N/A	*Listeria* Detected
Negative	N/A	-

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.

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

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