

NATtrol™ Blood Culture Identification Panel

Catalog Number: NATBCP-BIO

PRODUCT DESCRIPTION:

NATtrol™ Blood Culture Identification Panel (NATBCP-BIO)* is formulated with purified, intact bacterial and fungal cells that have been chemically modified to render them non-infectious and refrigerator stable. NATBCP-BIO panel contains 23 x 0.2 mL vials each containing bacterial and fungal NATtrol™ targets listed in Table 1. The panel is 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™ Blood Culture Identification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial, and fungal nucleic acids. NATBCP-BIO can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATBCP-BIO 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 tissue culture based infectivity 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 NATBCP-BIO 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™ Blood Culture Identification Panel should be stored at 2-8°C. INSTRUCTIONS FOR USE: • This panel has been tested with the BioFire Diagnostics FilmArray® Blood Culture Identification (BCID) assay and provides all expected results for the panel members listed in Table 1. Follow Assay manufacturer recommendations for use of this panel.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

Table 1: PANEL MEMBERS

Panel Member	Strain
Acinetobacter baumannii	307-0294
Candida albicans	Z006
Candida glabrata	Z007
Candida krusei	Z009
Candida parapsilosis	Z011
Candida tropicalis	Z012
Enterobacter cloacae	Z101
Enterococcus faecalis	VRE; Z345; vanB
Escherichia coli	ETEC, ST+, LT+
Haemophilus influenzae	MinnA
Klebsiella oxytoca	Z115
Klebsiella pneumoniae	KPC-2
Listeria monocytogenes	Serotype 1/2b
Neisseria meningitidis	Serogroup A
Proteus mirabilis	Z050
Pseudomonas aeruginosa	Z139, VIM-1
Serratia marcescens	Z053
Staphylococcus aureus	MRSA; COL
Staphylococcus epidermidis	MSSE; HER 1292
Streptococcus agalactiae	Z053
Streptococcus pneumoniae	Z022
Streptococcus pyogenes	Z018
Negative	NA

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.