

## NATtrol™ Blood Culture Identification 2 (BCID2) Panel

### PRODUCT DESCRIPTION:

**NATtrol™ Blood Culture Identification 2 (BCID2) Panel\*** is formulated with purified, intact bacterial and fungal cells. The cells have been chemically modified to render them non-infectious and refrigerator stable. NATBCP2-BIO contains 34 x 0.2 mL vials of bacterial and fungal NATtrol™ and 1 x 0.2mL of negative (matrix only) as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

### INTENDED USE:

- NATtrol™ BCID2 Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and fungal nucleic acids (from organisms listed in Table 1). NATtrol™ Blood Culture Identification 2 Panel can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

### WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated microorganisms and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that has been tested and found to be non-reactive at the donor level for HIV1/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 Fetal Bovine Serum used in the manufacture of this product meets 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

### RECOMMENDED STORAGE:

- NATtrol™ BCID2 Panel should be stored at 2-8°C.

### INSTRUCTIONS FOR USE:

- Mix vial vigorously for at least 5 seconds.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

### LIMITATION:

### FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

**TABLE 1: PANEL MEMBERS:**

Panel Member	Strain	Panel Member	Strain
A. baumannii	307-0294	K. pneumoniae	Z460** (CTX-M/NDM)
B. fragilis	Z029	K. pneumoniae	KPC-2
C. albicans	Z006	K. pneumoniae	Z138, OXA-48
C. auris	Z485	L. monocytogenes	serotype 1/2b
C. gattii	Z156	N. meningitidis	serogroup A
C. glabrata	Z007	P. aeruginosa	Z139, VIM-1
C. krusei	Z009	P. mirabilis	Z050
C. neoformans	serotype A	S. agalactiae	Z019
C. parapsilosis	Z011	S. aureus	MRSA; COL
C. tropicalis	Z012	S. enterica typhimurium	Z005
E. cloacae	Z101	S. epidermidis	MSSE; HER 1292
E. coli	Z297; IMP**	S. lugdunensis	Z097
E. coli	Z521; mcr-1**	S. maltophilia	Z074
E. faecalis	VRE, Z345, vanB	S. marcescens	Z053
E. faecium	VRE, Z347, vanA	S. pneumoniae	Z022
H. influenzae	MinnA	S. pyogenes	Z018
K. aerogenes	Z052	Negative	N/A
K. oxytoca	Z115		

\*\*This strain is sourced and used under license from the National Collection of Type Cultures (NCTC®), Public Health England.