NATtrol™ Vaginal Panel

Catalog Number: NATVP-BD

PRODUCT DESCRIPTION:
NATtrol™ Vaginal Panel (NATVP-BD)* is formulated with purified, intact bacterial and fungal cells that have been chemically modified to render them non-infectious and refrigerator stable. NATVP-BD panel contains 24 (4 of each panel member) x 0.5mL vials each containing NATtrol™ bacterial vaginosis markers, either Positive or Negative marker combination, and/or *Candida* species, and/or *Trichomonas vaginalis*. These controls 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™ Vaginal Panel is designed to evaluate the performance of nucleic acid tests for the determination of the presence of BV DNA markers that represent Positive or Negative BV depending on marker combination used, *Candida* species, and *Trichomonas vaginalis* DNA. NATVP-BD can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATVP-BD 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 and fungal stocks used to formulate each control. The inactivation was verified by the absence of bacterial/fungal 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 NATtrol™ Vaginal Panel contains inactivated organisms, they 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™ Vaginal Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH BD MAX™ Vaginal Panel Assay:
- Pipet 150µL from the NATtrol™ Vaginal Panel Member vial and dispense into one BD MAX UVE Sample Buffer Tube. Recap the tube with a blue septum cap provided in the BD MAX™ Vaginal Panel kit.
- Process the Panel Member as if it is a patient sample according to the procedure indicated in the BD MAX System Operation section of the BD MAX™ Vaginal Panel Assay Package Insert.

EXPECTED RESULTS:

Panel Member	Organism	Strain	BD MAX™ Vaginal Panel Assay Expected Result
1	*L. crispatus*	Z246	BV NEG C group NEG Ckru NEG Cgla NEG TV NEG
2	*C. albicans*	Z006	BV POS C group POS Ckru NEG Cgla NEG TV NEG
	G. vaginalis	Z247	
	A. vaginae	Z242	
	BVAB2	recombinant	
3	*T. vaginalis*	Z070	BV POS C group NEG Ckru NEG Cgla NEG TV POS
	G. vaginalis	Z247	
	A. vaginae	Z242	
	BVAB2	recombinant	
4	*C. glabrata*	Z007	BV POS C group NEG Ckru NEG Cgla POS TV NEG
	L. crispatus	Z246	
	G. vaginalis	Z247	
	A. vaginae	Z242	
5	*L. crispatus*	Z246	BV NEG C group NEG Ckru NEG Cgla NEG TV NEG
	G. vaginalis	Z247	
6	*C. krusei*	Z009	BV POS C group NEG Ckru POS Cgla NEG TV NEG
	L. crispatus	Z246	
	G. vaginalis	Z247	
	A. vaginae	Z242	

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 further manufacturing use. These products are NOT intended for use in the manufacturing 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.

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

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