

PRODUCT DESCRIPTION:

NATtrol™ *Candida*/TV (*Candida*/*T. vaginalis*) Positive Control* is formulated with purified, intact parasite and fungal cells that have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 x 0.15 mL of the control in a purified protein matrix that mimics the composition of a true clinical specimen.

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

INTENDED USE:

- NATtrol™ *Candida*/TV Positive Control is a full process control designed to evaluate the performance of nucleic acid tests for determination of the presence of *Candida* and *T. vaginalis* DNA. NATCTVPOS-BD can also be used for quality control of clinical assays and training of laboratory personnel.
- NATCTVPOS-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 parasite and fungal stocks used to formulate each control. The inactivation was verified by the absence of 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 this control contains inactivated organisms, it should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ *Candida*/TV Positive Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH BD MAX™ Vaginal Panel Assay:

- Pipet 150µL from the control 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 Control 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:

Catalog Number	Organism	Strain	BD MAX™ Vaginal Panel Assay Expected Result
NATCTVPOS-BD	<i>C. albicans</i>	Z006	BV NEG Cgroup POS Ckru POS Cgla POS TV POS
	<i>C. krusei</i>	Z009	
	<i>C. glabrata</i>	Z007	
	<i>T. vaginalis</i>	Z070	

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.

PINATCTVPOS-BD
Revision: 03
Effective Date: 07/07/2021

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

PCA# 21-112
Page 1 of 1