Catalog Number: NATBRD-6L

NATtrol™ *B. pertussis/B. parapertussis* Positive Control

PRODUCT DESCRIPTION:

NATtrol™ *Bordetella pertussis/parapertussis* Positive Control (NATBRD-6L)* is formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 x 0.25 mL vials of NATtrol™ *B.pertussis/parapertussis*. 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™ *Bordetella pertussis/parapertussis* Positive Control is a full process control designed to evaluate the performance of nucleic acid tests for determination of the presence of *Bordetella pertussis* and *Bordetella parapertussis* DNA. NATBRD-6L can also be used for quality control of clinical assays and training of laboratory personnel.

- NATBRD-6L 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 each control pack. 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. 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™ *Bordetella pertussis/parapertussis* Positive Control contains inactivated bacterial cells, 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™ *Bordetella pertussis/parapertussis* Positive Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH ARIES BORDETELLA ASSAY:

- Vortex NATtrol™ sample for 5-10 seconds.
- Pipet 200 µL of sample into cassette.
- Run cassette per manufacturer's instructions.

EXPECTED RESULTS:

Catalog Number	Organism	ARIES Bordetella Assay Expected Result
NATBRD-6L	*B. pertussis*; *B. parapertussis*	*B. pertussis* Positive; *B. parapertussis* Positive

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.

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
	Biological Risk	RUO	For Research Use Only

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