

INTENDED USE:

NATtrol™ Vaginal Positive Control (NATVPOS-6C) is a qualitative *in vitro* diagnostic control intended to be used with molecular assays for the detection of *Atopobium vaginae*, BVAB2, *Candida albicans*, *Candida glabrata*, and *Trichomonas vaginalis* for the evaluation of test performance.

SUMMARY AND EXPLANATION:

Control should be used according to an assay manufacturer's instructions. The routine use of external controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, the effect of adverse environmental conditions, and can aid in the identification of random or systematic error.

PRINCIPLE:

NATtrol Vaginal Positive Control contains purified, intact *Atopobium vaginae*, *Escherichia coli* containing BVAB2 (recombinant), *Candida albicans*, *Candida glabrata*, and *Trichomonas vaginalis* that have been chemically modified to render them non-infectious and refrigerator stable. The control is formulated in a proprietary matrix.

MATERIALS SUPPLIED:

6 x 0.9 mL vials

ADDITIONAL NATtrol VAGINAL EXTERNAL CONTROLS (sold separately):

NATVNEG-6C (6 X 0.9 mL) NATtrol Vaginal Negative Control.

WARNINGS AND PRECAUTIONS:

- NATtrol inactivation was carried out on microorganism stocks used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This control contains inactivated microorganisms. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Disposal must follow the established procedures of the laboratory, federal, state, and local regulations.
- Do not decontaminate the control using bleach; matrix is incompatible with bleach.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol Vaginal Positive Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix each vial vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- Each vial is intended for single use.

LIMITATIONS:

- For In Vitro Diagnostic Use.
- Intended for professional use only.
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the device.



EXPECTED RESULTS:

The table below is for informational purposes, each laboratory must evaluate the control and establish their own performance criteria. NATtrol Vaginal Positive Control is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Organism present	Result
NATVPOS-6C	<i>Atopobium vaginae</i>	<i>Atopobium vaginae</i> Detected
	BVAB2 ¹	BVAB2 (recombinant) Detected
	<i>Candida albicans</i>	<i>Candida albicans</i> Detected
	<i>Candida glabrata</i>	<i>Candida glabrata</i> Detected
	<i>Trichomonas vaginalis</i>	<i>Trichomonas vaginalis</i> Detected

¹ NATtrol Vaginal Positive Control contains *Escherichia coli* harboring a plasmid containing a short sequence of the BVAB2 bacterial genome; therefore, each laboratory must evaluate performance in their assay.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	In vitro Diagnostic Use		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		Consult Instructions for Use