

NATtrol™ CT/NG/TV External Run Control Kit



INTENDED USE:

NATtrol™ CT/NG/TV External Run Control Kit (NATCTNGTV-ERCK-IVD) is a qualitative *in vitro* diagnostic external control intended to evaluate test performance of molecular assays which detect *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* nucleic acids.

SUMMARY AND EXPLANATION:

The control should be used according to the 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 errors.

PRINCIPLE:

NATtrol™ CT/NG/TV External Run Control Kit contains NATtrol™ CT/NG/TV Positive Control 2.0 and NATtrol™ CT/NG/TV Negative Control. NATtrol™ CT/NG/TV Positive Control 2.0 contains purified, intact *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* that have been chemically modified to render them non-infectious and refrigerator stable and is formulated in a proprietary matrix. NATtrol™ CT/NG/TV Negative Control is formulated in the absence of any microorganisms and contains proprietary matrix only. NATtrol™ CT/NG/TV External Run Control Kit is a full process control designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

MATERIALS SUPPLIED:

- 2 x 1.0 mL vials NATtrol™ CT/NG/TV Positive Control 2.0
- 2 x 1.0 mL vials NATtrol™ CT/NG/TV 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 product contains inactivated microorganisms. 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 proprietary diluent used in the manufacture of this product contains buffers and preservative.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ CT/NG/TV External Run Control Kit 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.

NATtrol™ CT/NG/TV External Run Control Kit











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:

NATtrol™ CT/NG/TV External Run Control Kit is an unassayed qualitative control and does not have assigned analyte values or ranges. Each laboratory must evaluate the control and establish their own performance criteria.

Symbols used in the labeling of this product:

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