

**PRODUCT DESCRIPTION:**

**NATtrol™ BK Virus Linearity Panel (NATBK-LIN)** is formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable\*. NATBK-LIN contains 6 x 0.25 mL vials of BK Virus NATtrol™ at concentrations listed in Table 1. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

\*NATtrol™ Patents Pending

**INTENDED USE:**

- NATtrol™ BK Virus Linearity Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of human BK Virus DNA. NATBK-LIN can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATBK-LIN contains intact virus 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 BK Virus stock used to formulate panel members. The inactivation was verified by the absence of viral growth in validated tissue culture based infectivity assays.
- The purified protein matrix was manufactured from materials that were screened and found to be negative for HIV 1&2 Ab, HBsAg, HTLV I&II Ab, HCV Ab, HIV RNA, HBV DNA and HCV RNA using FDA cleared kits at the single donor level.

**PRECAUTIONS:**

- Although NATBK-LIN contains inactivated virus, it 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.

This product was manufactured in a facility which has a Quality Management System that is certified as being in compliance with ISO 13485.

**RECOMMENDED STORAGE:**

- NATtrol™ BK Virus Linearity Panel should be stored at 2-8°C.

**INSTRUCTIONS FOR USE:**

- Extract BK Virus DNA prior to use in downstream assays.

**Table 1: NATBK-LIN PANEL MEMBERS**

Panel Member	BK Virus DNA Target Concentration (copies/mL)
BKV 1E8	100,000,000
BKV 1E7	10,000,000
BKV 1E6	1,000,000
BKV 1E5	100,000
BKV 1E4	10,000
Negative	0

**DO NOT USE IN HUMANS**

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.

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