

NATtrol™ HIV-1 Linearity Panel

Strain: IIIB

Catalog #: NATHIV1-LIN

PRODUCT DESCRIPTION:

NATtrol[™] HIV-1 Linearity Panel (NATHIV1-LIN) is formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable*. NATHIV1-LIN contains 6 x 0.25 mL vials of HIV-1 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[™] HIV-1 Linearity Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of HIV-1 RNA. NATHIV1-LIN can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATHIV1-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 the HIV-1 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 NATHIV1-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[™] HIV-1 Linearity Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

• Extract HIV-1 RNA prior to use in downstream assays.

Table 1: NATHIV1-LIN PANEL MEMBERS

Panel Member	HIV-1 RNA Concentration (IU/mL)
HIV1 1E6	1,000,000
HIV1 1E5	100,000
HIV1 1E4	10,000
HIV1 1E3	1,000
HIV1 4E2	400
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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