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NATtrol™ HIV-1 Virus Linearity Panel

ZMC Catalog #: NATHIV1-Lin

FOR RESEARCH USE ONLY
Not for *in vitro* Diagnostic Use

Product Description

NATtrol™ HIV1 Linearity Panel (NATHIV1-Lin) is formulated with intact HIV1 virus particles that have been chemically modified to render them non-infectious and refrigerator stable*. Each linearity panel contains 6 x 0.25 mL of each member with concentrations spanning the clinically significant range for HIV-1 infected individuals. These controls are supplied in a purified serum protein matrix that mimics the composition of a true clinical specimen. Panel members are quantitated using an in-house real-time PCR assay targeting the HIV1 *gag* gene. International Units were calibrated against the WHO International Standard (2nd International Standard) for HIV1 RNA.

*NATtrol™ Patents Pending.

Intended Use

- The NATtrol™ HIV1 Linearity Panel (NATHIV1-Lin) is designed to evaluate the recovery, accuracy and sensitivity of nucleic acid tests (NAT) for the determination of HIV1 RNA. NATHIV1-Lin can also be used for assay validation, training of laboratory personnel, QA/QC and educational purposes.
- The NATHIV1-Lin panel contains intact organisms and should be run in a manner identical to that used for clinical specimens.
- **All panel members must be extracted prior to amplification.**

The table below lists the targeted IU / ml concentrations for each member in the linearity panel.

Panel Member	HIV1 Virus RNA IU/ml
1 M	10 ⁶
100 K	10 ⁵
10 K	10 ⁴
1K	10 ³
400	400
Negative	0

- The purified serum protein matrix was sourced from licensed U.S. blood banks and screened 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 individual donor level.

DO NOT USE IN HUMANS OR AS A CLINICAL DIAGNOSTIC.

These products are intended for research, product development or manufacturing use only. 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.

Precautions

- Use Universal Precautions when handling NATHIV1-Lin.

To avoid cross-contamination, use separate pipette tips for all reagents.



This product was manufactured in a facility whose Quality Management System is certified as being in compliance with ISO 9001:2008 and ISO 13485:2003 standards

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