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NATtrol™ Cytomegalovirus Virus Linearity Panel

Strain: AD-169



ZMC Catalog #: NATCMV-LIN

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

Product Description

NATtrol™ **CMV Linearity Panel (NATCMV-LIN)** is formulated with intact CMV particles that have been chemically modified to render them non-infectious and refrigerator stable*. Each linearity panel contains 6 x 0.25 mL vials of each member with concentrations spanning the clinically significant range for CMV 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 CMV *pol* gene. Copies/mL were calibrated against commercially available quantitated CMV DNA.

*NATtrol™ Patents Pending.

Intended Use

- The NATtrol™ CMV Linearity Panel (NATCMV-LIN) is designed to evaluate the recovery, accuracy and sensitivity of nucleic acid tests (NAT) for the determination of CMV virus DNA. NATCMV-LIN can also be used for assay validation, training of laboratory personnel, QA/QC and educational purposes.
- The NATCMV-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.**
- NATtrol™ inactivation was carried out on the CMV in each control. The inactivation was measured by following the absence of viral growth in validated tissue culture based infectivity assays.

The table below lists the targeted copies / ml Concentrations for each member in the linearity panel.

Panel Member	CMV Virus DNA copies/ml
5M	5×10^6
500k	5×10^5
50K	5×10^4
5k	5×10^3
500	5×10^2
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 NATCMV-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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