

NRL In-House HTLV-1 Proviral Load (PVL) Assay

Class 3 In-Vitro Diagnostic (IVD) for monitoring HTLV-1 infection

Overview

The **NRL In-House HTLV-1 PVL Assay** is a qPCR-based test that quantifies HTLV-1 viral DNA integrated within genomic DNA from blood cells of patients previously confirmed HTLV-1 positive by serology.

For monitoring purposes only. Not for diagnostic or confirmatory use.

Specimen Requirements

- 4mL or 8mL of Whole Blood collected in EDTA and transported at ambient temperature (15 - 25°C) within 7 days post collection.
- 4mL or 8 mL Whole Blood collected in BD Vacutainer® CPT™ Mononuclear Cell Preparation Tube - Sodium Citrate centrifuged according to tube manufacturer's IFU. Centrifuged tubes should be stored and transported chilled and on their sides, to be received within 7 days of collection.
- A minimum of 200uL of Buffy Coat, PMBC (resuspended in 100µL of PBS per 1mL of whole blood processed), cerebrospinal fluid (CSF) and Bronchoalveolar Lavage (BAL) samples transported frozen on dry ice post collection.

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Turnaround Time (TAT)

5 working days from specimen receipt.

Assay Details

- **Limit of Detection:** 5.8 copies/reaction
- **Limit of Quantification:** 12.5 copies/reaction
- **Reporting Units:** HTLV-1 copies/10⁵ cells (% PVL)