

| EDX HIV-1 LOD Summary   |  |
|-------------------------|--|
| Catalog Number          | HIVLOD                                     |
| Analyte                 | Inactivated HIV-1                          |
| Matrix                  | True EDTA Plasma                           |
| Preservative            | ProClin® 300                               |
| Storage                 | -70°C or Below                             |
| Fill Volume             | 1.0mL                                      |
| Number of Vials Per Kit | 10 Vials                                   |
| Number of Uses          | Single Use                                 |
| Shelf Life              | 24 Months from Date of Manufacture         |
| Traceability            | 3 <sup>rd</sup> WHO International Standard |
| Precautions             | Biological Risks                           |
| Regulatory Status       | For In Vitro Diagnostic Use                |

**INTENDED USE:**

The EDX HIV-1 LOD is calibrated against the 3<sup>rd</sup> WHO International Standard for HIV-1 (10/152)<sup>1</sup>. EDX HIV-1 LOD is used to determine the analytical sensitivity of the assay for Human Immunodeficiency Virus (HIV-1) RNA. EDX HIV-1 LOD allows laboratories to evaluate their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

The EDX HIV-1 LOD contains whole, intact virus that has been heat inactivated. The control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HIV-1 LOD is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, HBsAg and antibodies for HIV-1/2, and HCV.

**PROCEDURE:**

The EDX HIV-1 LOD requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX HIV-1 LOD is an unassayed control and does not have assigned values. The control is not a substitute for the manufacturer’s kit controls provided with the assay. EDX HIV-1 LOD is to be tested according to the assay manufacturer’s or testing laboratory’s instructions and recommendations. Expected results utilizing EDX HIV-1 LOD must be established by the end user for their specific assay.

**STORAGE AND HANDLING:**

The EDX HIV-1 LOD should be stored at -70°C or below.

Thaw EDX HIV-1 LOD at room temperature and vortex briefly prior to use.

Once thawed, EDX HIV-1 LOD is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX HIV-1 LOD beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX HIV-1 LOD contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced<sup>2</sup>. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contain pathogenic agents.

**REFERENCES:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for HIV-1 (10/152) IFU.  
<http://www.nibsc.org/documents/ifu/10-152.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

**SYMBOL REFERENCES:**



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Do not re-use



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Positive Control



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