

EDX HIV-1 1E3 cp/mL Precision Summary	
Catalog Number	HIVL201
Analyte	Inactivated HIV-1
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	9 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 1E3 cp/mL Precision is calibrated against the 3<sup>rd</sup> WHO International Standard for HIV-1 (10/152)<sup>1</sup>. EDX HIV-1 1E3 cp/mL Precision is used to determine the accuracy of the assay for the presence of Human Immunodeficiency Virus (HIV-1) RNA at the target concentration of 1E3 cp/mL. Routine use of EDX HIV-1 1E3 cp/mL Precision allows laboratories to evaluate their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

The EDX HIV-1 1E3 cp/mL Precision contains whole, intact virus that has been heat inactivated. EDX HIV-1 1E3 cp/mL Precision is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HIV-1 1E3 cp/mL Precision is reported in copies per milliliter (cp/mL). EDX HIV-1 1E3 cp/mL Precision 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 1E3 cp/mL Precision requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX HIV-1 1E3 cp/mL Precision is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

**STORAGE AND HANDLING:**

The EDX HIV-1 1E3 cp/mL Precision should be stored at -20°C or below.

Thaw EDX HIV-1 1E3 cp/mL Precision at room temperature and vortex briefly prior to use.

Once thawed, EDX HIV-1 1E3 cp/mL Precision 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 1E3 cp/mL Precision beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX HIV-1 1E3 cp/mL Precision 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:**

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Do not re-use
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use

  
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