

EDX HIV-1 High Run Control	
Catalog Number	HIVH102
Analyte	Inactivated HIV-1
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Single Use
Shelf Life	36 Months from Date of Manufacture
Traceability	3 rd WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX HIV-1 High Run Control is an external quality control, intended to be used with HIV-1 assays to monitor the performance of that given assay. EDX HIV-1 High Run Control is calibrated against the 3rd WHO International Standard for HIV-1 (10/152)¹. EDX HIV-1 High Run Control is used to monitor the presence of Human Immunodeficiency Virus (HIV-1) RNA. Routine use of EDX HIV-1 High Run Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

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

The EDX HIV-1 High Run Control 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 High Run Control 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 High Run Control 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 High Run Control is to be tested according to the assay manufacturer’s or testing laboratory’s instructions and recommendations. Expected results utilizing EDX HIV-1 High Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX HIV-1 High Run Control should be stored at -20°C or below.

Thaw EDX HIV-1 High Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX HIV-1 High Run Control 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 High Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostics use.

WARNINGS AND PRECAUTIONS:

The EDX HIV-1 High Run Control contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced². 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:

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

²Siegel 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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