

EDX HHV-6 Low Run Control	
Catalog Number	HV6L101
Analyte	Inactivated HHV-6B
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	Multiple Use
Shelf Life	24 Months from Date of Manufacture
Traceability	1 st WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX HHV-6 Low Run Control is an external quality control, intended to be used with HHV-6 assays to monitor the performance of that given assay. EDX HHV-6 Low Run Control is calibrated against the 1st WHO International Standard for HHV-6B virus (15/266)¹. The control is used to monitor the presence of Human Herpesvirus-6 (HHV-6) DNA. Routine use of EDX HHV-6 Low 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 HHV-6 Low Run Control contains whole, intact virus that has been heat inactivated. EDX HHV-6 Low Run Control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HHV-6 Low Run Control is internally value assigned using Bio-Rad Droplet Digital PCR (ddPCR). EDX HHV-6B Low Run Control is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, HHV-6A DNA, HHV-6B DNA, HBsAg and antibodies for HIV-1/2 and HCV.

PROCEDURE:

The EDX HHV-6 Low 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 HHV-6 Low 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 HHV-6 Low Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX HHV-6 Low Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX HHV-6 Low Run Control should be stored at -20°C or below.

Thaw EDX HHV-6 Low Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX HHV-6 Low Run Control is stable for 24 hours when stored at 2-8°C. Product can be frozen and reused a maximum of four (4) times. After the fourth freeze thaw, any remaining materials must be disposed of properly. Do not dilute.

Do not use EDX HHV-6 Low Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HHV-6 Low 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.












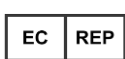
REFERENCES:

¹The 1st WHO International Standard for HHV-6B (15/266) IFU.
<https://www.nibsc.org/documents/ifu/15-266.pdf>

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

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SYMBOL REFERENCES:

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use
-  CONTROL + Positive Control
-  European Mark of Conformity
-  EC REP Authorized Representative



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