

EDX HBV High Run Control	
Catalog Number	HBVH102
Number of uses	Single Use
Number of Vials Per Kit	5 Vials
Fill Volume	1.0mL
Analyte	Inactivated HBV Virus
Traceability	3 rd WHO International Standard
Matrix	True EDTA Plasma
Precautions	Biological Risks
Storage	-20°C or Below
Shelf Life	18 Months from date of manufacture
Regulatory Status	For In Vitro Diagnostic Use
Preservatives	ProClin® 300

INTENDED USE:

EDX HBV High Run Controls are run controls for various molecular assays, calibrated against the 3rd WHO International Standard for Hepatitis B (10/264) ¹. The controls are used to monitor the presence of Hepatitis B virus "HBV" DNA. The materials are whole, intact virus allowing operators to test the entire process of a molecular assay, train operators and test for proficiency.

PRODUCT DESCRIPTION:

EDX HBV High Run Controls are intact whole virus that has been heat inactivated. The control is intended to test the entire process of a variety of molecular assays from extraction, detection, and amplification.

EDX HBV Low Run Controls are reported in International Units per milliliter (IU/mL). The controls were developed using a heat inactivated HBV virus containing the HBV Target. The EDX HBV High Run Controls are formulated in True EDTA plasma that was not found to be reactive for HBV DNA, HCV RNA, HIV-1 RNA, HBsAg and antibodies for HIV-1/2, and HCV.

PROCEDURE:

EDX HBV High Run Controls are whole, intact virus and should be treated similarly as all other samples going through an extraction step, allowing the operator to assess their extraction technique. Test the EDX HBV High Run Controls according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

EDX HBV High Run Controls should be stored at -20°C or below.

Thaw material at room temperature and vortex briefly prior to use.

Once thawed, material 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.

LIMITATIONS:

For In Vitro Diagnostic Use

WARNINGS AND PRECAUTIONS:

EDX HBV High Run Controls contain heat inactivated virus, but should be considered biohazardous and 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.

REFERENCES:

¹The 3rd WHO International Standard for Hepatitis B (10/264) IFU.
<http://www.nibsc.org/documents/ifu/10-264.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



Positive Control