

EDX HBV Low Run Control Summary

Catalog Number	HBVL101
Analyte	Inactivated HBV
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	36 Months from Date of Manufacture
Traceability	3 rd WHO International Standard
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX HBV Low Run Control is an external quality control, intended to be used with HBV assays to monitor the performance of that given assay. EDX HBV Low Run Control is calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)¹. The control is used to monitor the presence of Hepatitis B Virus (HBV) DNA. Routine use of EDX HBV 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 HBV Low Run Control contains whole, intact virus that has been heat inactivated. EDX HBV Low Run Control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

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

STORAGE AND HANDLING:

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

Thaw EDX HBV Low Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX HBV Low Run Control is stable for 5 days 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. Do not dilute.

Do not use EDX HBV Low Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use

WARNINGS AND PRECAUTIONS:

The EDX HBV 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 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



Expiration Date



Do not re-use



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Positive Control



European Mark of Conformity



Authorized Representative



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



Exact Diagnostics
100 South Jones Street, Suite 100,
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