

EDX HBV Verification Panel 1.4mL Summary	
Catalog Number	HBVP200
Analyte	Inactivated HBV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	7 Vials
Number of Uses	Single Use
Shelf Life	24 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 HBV Verification Panel 1.4mL is a standard for various molecular assays. EDX HBV Verification Panel 1.4mL is calibrated against the 3rd WHO International Standard for Hepatitis B (10/264)¹. EDX HBV Verification Panel 1.4mL is used to establish points of reference (qualitative and quantitative) for the measurement of Hepatitis B Virus (HBV) DNA. EDX HBV Verification Panel 1.4mL allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX HBV Verification Panel 1.4mL contains whole, intact virus that has been heat inactivated. EDX HBV Verification Panel 1.4mL is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HBV Verification Panel 1.4mL is reported in International Units per milliliter (IU/mL). EDX HBV Verification Panel 1.4mL is manufactured according to ISO 17511:2003. EDX HBV Verification Panel 1.4mL 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.

EDX HBV Components	Concentration
EDX HBV Panel Member 1	100 IU/mL
EDX HBV Panel Member 2	1,000 IU/mL
EDX HBV Panel Member 3	10,000 IU/mL
EDX HBV Panel Member 4	100,000 IU/mL
EDX HBV Panel Member 5	1,000,000 IU/mL
EDX HBV Panel Member 6	10,000,000 IU/mL
EDX HBV Panel Member 7	100,000,000 IU/mL

PROCEDURE:

The EDX HBV Verification Panel 1.4mL requires an extraction step. The panel must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX HBV Verification Panel 1.4mL is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX HBV Verification Panel 1.4mL should be stored at -20°C or below.

Thaw EDX HBV Verification Panel 1.4mL at room temperature and vortex briefly prior to use.

Once thawed, EDX HBV Verification Panel 1.4mL 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 HBV Verification Panel 1.4mL beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HBV Verification Panel 1.4mL 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:

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

² 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:

	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


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