

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 <sup>rd</sup> WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

**INTENDED USE:**

EDX HBV Verification Panel 1.4mL is a standard for various molecular assays. The verification panel is calibrated against the 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264)<sup>1</sup>. The EDX HBV Verification Panel 1.4mL is used to establish points of reference (qualitative and quantitative) that are used in the determination of values in the measurement 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 Verification Panel 1.4mL is formulated from intact whole virus that has been heat inactivated. The verification panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

EDX HBV Verification Panel 1.4mL is reported in International Units per milliliter (IU/mL). The verification panel members are developed using heat inactivated HBV. 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:**

EDX HBV Verification Panel 1.4mL contains 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 EDX HBV Verification Panel 1.4mL according to the assay manufacturer’s or testing laboratory’s instructions and recommendations.

**STORAGE AND HANDLING:**

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

Thaw material at room temperature and mix for 10 seconds before placing on instrument.

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 Verification Panel 1.4mL contains heat inactivated virus, but should be considered biohazardous and universal precautions and proper disposal should be practiced<sup>2</sup>. 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:**

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

<sup>2</sup>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