

EDX HBV 1E3 IU/mL Precision Summary	
Catalog Number	HBVL201
Analyte	Inactivated HBV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	9 Vials
Number of Uses	Single Use
Shelf Life	24 Months from Date of Manufacture
Traceability	2 <sup>nd</sup> WHO International Standard
Precautions	Biological Risks
Regulatory Status	In Vitro Diagnostic Use

**INTENDED USE:**

The EDX HBV 1E3 IU/mL Precision is calibrated against the 2<sup>nd</sup> WHO International Standard for Hepatitis B (97/750)<sup>1</sup>. EDX HBV 1E3 IU/mL Precision is used to determine the accuracy of the assay for the presence of Hepatitis B Virus (HBV) DNA at the target concentration of 1E3 IU/mL. Routine use of EDX HBV 1E3 IU/mL Precision allows laboratories to evaluate their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

The EDX HBV 1E3 IU/mL Precision contains whole, intact virus that has been heat inactivated. EDX HBV 1E3 IU/mL Precision is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HBV 1E3 IU/mL Precision is reported in International Units per milliliter (IU/mL). EDX HBV 1E3 IU/mL Precision 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 1E3 IU/mL Precision requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX HBV 1E3 IU/mL Precision is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

**STORAGE AND HANDLING:**

The EDX HBV 1E3 IU/mL Precision should be stored at -20°C or below.

Thaw EDX HBV 1E3 IU/mL Precision at room temperature and vortex briefly prior to use.

Once thawed, EDX HBV 1E3 IU/mL Precision 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 1E3 IU/mL Precision beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX HBV 1E3 IU/mL Precision contains heat inactivated virus but should be considered biohazardous. 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>The 2<sup>nd</sup> WHO International Standard for Hepatitis B (97/750) IFU.

<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



Consult Instructions for Use



Exact Diagnostics LLC  
100 South Jones Street, Suite 100,  
Fort Worth, Texas 76104  
United States



**Bio-Rad  
Laboratories**

**Clinical  
Diagnostics Group**

9500 Jeronimo Road  
Irvine, California 92618  
(800) 854-6737  
FAX (949) 598-1550  
bio-rad.com/qualitycontrol

**Technical Service:**  
(800) 854-6737

**United States Customer Service:** 4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373  
**Also in:** **Gladesville, Australia,** Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888 **Vienna, Austria,** Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29 **Temse, Belgium,** Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01 **São Paulo, Brazil,** Phone +55 11 3065-7550 **Montréal, Canada,** Phone +1 514 334 4372 • Fax +1 514 334 0872 **Shanghai, China,** Phone +86 21 6169 8500 • Fax +86 21 6169 8599 **Prague, Czech Republic,** Phone +420 241 431 660 **Symbion Science Park, Denmark,** Phone +45 44 52 10 00 • Fax +45 44 52 10 01 **Helsinki, Finland,** Phone +358 9 804 22 00 **Marnes-la-Coquette, France,** Phone +33 (0)1 47 95 60 00 • Fax +33 (0)1 47 41 91 33 **Munich, Germany,** Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136 **Athens, Greece,** Phone +30 210 7774396 • Fax +30 210 7774376 **Quarry Bay, Hong Kong,** Phone +85 2 2789 3300 • Fax +85 2 2789 1257 **Budapest, Hungary,** Phone +36 1 459 6190 • Fax +36 1 459 6101 **Haryana, India,** Phone +91 124 4029300 • Fax +91 124 2398115 **Rishon Le Zion, Israel,** Phone +972 03 963 6025 • Fax +972 03 951 4129 **Milan, Italy,** Phone +39 024 94 86 600 • Fax +39 02 21609399 **Tokyo, Japan,** Phone +81 3 6361 7070 • Fax +81 3 5463 8481 **Seoul, Korea,** Phone +82 080 007 7373 • Fax +82 (2) 3472 7003 **Mexico D.F., Mexico,** Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246 **Veenendaal, The Netherlands,** Phone +31 (0)318 540 666 • Fax +31 (0)318 542 216 **Auckland, New Zealand,** Phone +64 (9)415 2280 • Fax +64 (9)415 2284 **Oslo, Norway,** Phone +47 23 38 41 30 • Fax +47 23 38 41 39 **Warsaw, Poland,** Phone +48 22 331 99 99 • Fax +48 22 331 99 88 **Amadora, Portugal,** Phone +351 21 47 27 700 • Fax +351 21 472 7777 **Moscow, Russia,** Phone +7 495 721 1404 • Fax +7 495 721 1412 **Singapore,** Phone +65 6415 3170 • Fax +65 6415 3189 **Johannesburg, South Africa,** Phone +27 11 442 8508 • Fax +27 11 442 8525 **Madrid, Spain,** Phone +34 91 490 6580 • Fax +34 91 590 5211 **Sundbyberg, Sweden,** Phone +46 844 98053 • Fax +46 8 55 51 27 80 **Cressier, Switzerland,** Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550 **Taipei, Taiwan,** Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-6890 **Bangkok, Thailand,** Phone (662) 651 8311 • Fax (662) 651 8312 **Hertfordshire, United Kingdom,** Phone +44 (0)1923 471301 • Fax +44 (0)1923 471340