

EDX HBV AMR Panel Summary	
Catalog Number	HBVAMR
Analyte	Inactivated HBV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	3 Vials
Number of Uses	Single Use
Shelf Life	36 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:**

The EDX HBV Analytical Measurement Range (AMR) Panel is a standard for various molecular assays. EDX HBV AMR Panel is calibrated against the 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264)<sup>1</sup>. EDX HBV AMR Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Hepatitis B Virus (HBV) DNA. EDX HBV AMR Panel allows laboratories to evaluate the analytical measurement range of their molecular assay, test for operator proficiency, and perform calibration verification.

**PRODUCT DESCRIPTION:**

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

The EDX HBV AMR Panel is reported in International Units per milliliter (IU/mL). EDX HBV AMR Panel is manufactured according to ISO 17511:2003. EDX HBV AMR Panel 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 AMR Components	Concentration
EDX HBV AMR Panel Member 1	100 IU/mL
EDX HBV AMR Panel Member 2	100,000 IU/mL
EDX HBV AMR Panel Member 3	10,000,000 IU/mL

**PROCEDURE:**

The EDX HBV AMR Panel 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 AMR Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

**STORAGE AND HANDLING:**

The EDX HBV AMR Panel should be stored at -20°C or below.

Thaw EDX HBV AMR Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX HBV AMR Panel 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 AMR Panel beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

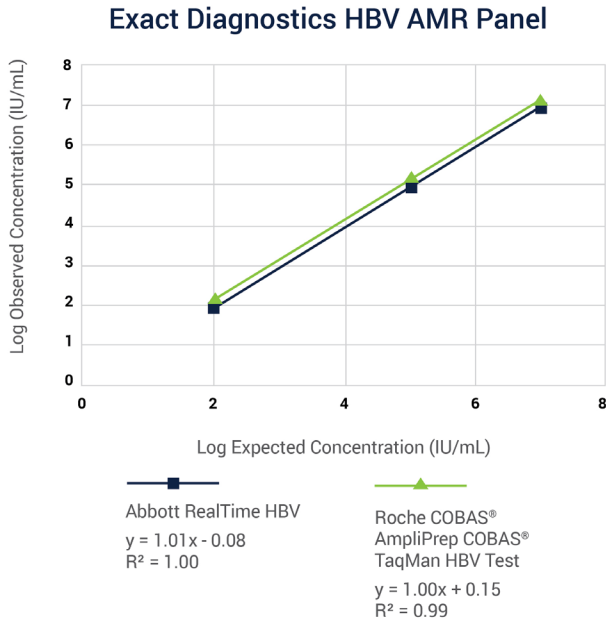
**WARNINGS AND PRECAUTIONS:**

The EDX HBV AMR Panel 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.











**PERFORMANCE CHARACTERISTICS:**

Three unique lots of EDX HBV AMR Panel were tested in triplicate across the assays identified in the graph below.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**SYMBOL REFERENCES:**

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Do not re-use
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use

**REFERENCES:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <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



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](http://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