

EDX HCV AMR Panel Summary	
Catalog Number	HCVAMR
Analyte	Recombinant HCV
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	4 <sup>th</sup> WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

**INTENDED USE:**

The EDX HCV Analytical Measurement Range (AMR) Panel is a standard for various molecular assays. EDX HCV AMR Panel is calibrated against the 4<sup>th</sup> WHO International Standard for Hepatitis C (06/102)<sup>1</sup>. EDX HCV AMR Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Hepatitis C Virus (HCV) RNA. EDX HCV 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 HCV AMR Panel contains whole, intact virus. EDX HCV AMR Panel is developed using recombinant, non-infectious virus which contains the HCV 5' UTR insertion. EDX HCV AMR Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HCV AMR Panel is reported in International Units per milliliter (IU/mL). EDX HCV AMR Panel is manufactured according to ISO 17511:2003. EDX HCV 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 HCV AMR Components	Concentration
EDX HCV AMR Panel Member 1	500 IU/mL
EDX HCV AMR Panel Member 2	50,000 IU/mL
EDX HCV AMR Panel Member 3	5,000,000 IU/mL

**PROCEDURE:**

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

**STORAGE AND HANDLING:**

The EDX HCV AMR Panel should be stored at -20°C or below. Thaw EDX HCV AMR Panel at room temperature and vortex briefly prior to use.

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

**LIMITATIONS:**

For In Vitro Diagnostic Use.

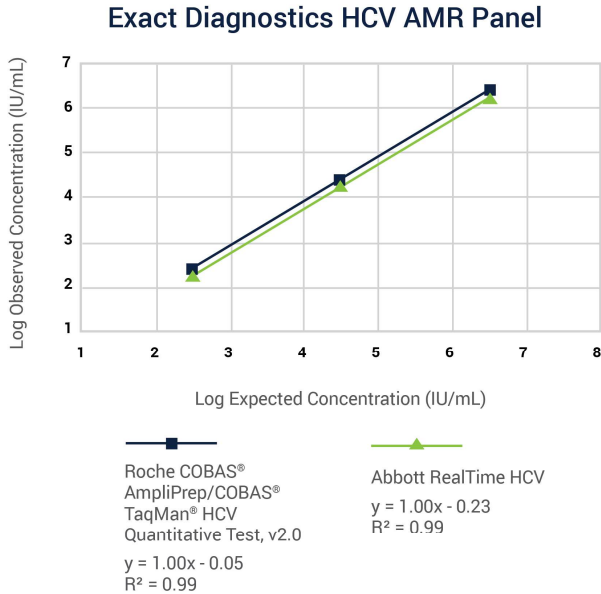
**WARNINGS AND PRECAUTIONS:**

The EDX HCV AMR Panel contains recombinant, non-infectious 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 HCV 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 4<sup>th</sup> WHO International Standard for Hepatitis C (06/102) IFU. <http://www.nibsc.org/documents/ifu/06-102.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



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