

EDX HIV-1 AMR Panel Summary	
Catalog Number	HIVAMR
Analyte	Inactivated HIV-1
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 rd WHO International Standard
Precautions	Biological Risks
Regulatory Status	In Vitro Diagnostic Use

INTENDED USE:

The EDX HIV-1 Analytical Measurement Range (AMR) Panel is a standard for various molecular assays. EDX HIV-1 AMR Panel is calibrated against the 3rd WHO International Standard for HIV-1 (10/152)¹. EDX HIV-1 AMR Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Human Immunodeficiency Virus (HIV-1) RNA. EDX HIV-1 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 HIV-1 AMR Panel contains whole, intact virus that has been heat inactivated. EDX HIV-1 AMR Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HIV-1 AMR Panel is reported in copies per milliliter (cp/mL). EDX HIV-1 AMR Panel is manufactured according to ISO 17511:2003. EDX HIV-1 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 HIV-1 AMR Components	Concentration
EDX HIV-1 AMR Panel Member 1	600 cp/mL
EDX HIV-1 AMR Panel Member 2	60,000 cp/mL
EDX HIV-1 AMR Panel Member 3	6,000,000 cp/mL

PROCEDURE:

The EDX HIV-1 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 HIV-1 AMR Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX HIV-1 AMR Panel should be stored at -20°C or below.

Thaw EDX HIV-1 AMR Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX HIV-1 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 HIV-1 AMR Panel beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

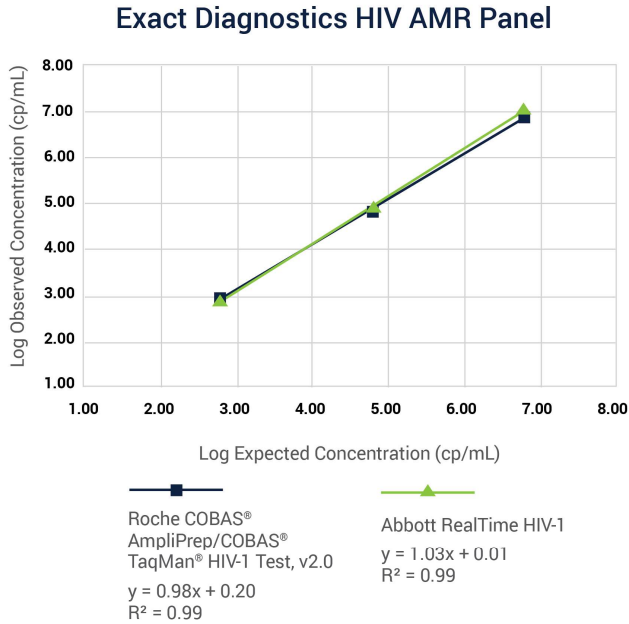
WARNINGS AND PRECAUTIONS:

The EDX HIV-1 AMR Panel 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.











PERFORMANCE CHARACTERISTICS:

Three unique lots of EDX HIV-1 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:

¹The 3rd WHO International Standard for HIV-1 (10/152) IFU.
<http://www.nibsc.org/documents/ifu/10-152.pdf>

²Siegel 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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