

EDX EBV Verification Panel Summary	
Catalog Number	EBVP100
Analyte	Inactivated EBV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Single Use
Shelf Life	36 Months from Date of Manufacture
Traceability	1 st WHO International Standard
Precautions	Biological Risks
Regulatory Status	In Vitro Diagnostic Use

INTENDED USE:

The EDX EBV Verification Panel is a standard for various molecular assays. EDX EBV Verification Panel is calibrated against the 1st WHO International Standard for Epstein-Barr virus (09/260)¹. EDX EBV Verification Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Epstein-Barr Virus (EBV) DNA. EDX EBV Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

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

The EDX EBV Verification Panel is reported in International Units per milliliter (IU/mL). EDX EBV Verification Panel is value assigned by digital droplet PCR and manufactured according to ISO 17511:2003. EDX EBV Verification Panel is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, EBV DNA, HBsAg and antibodies for HIV-1/2 and HCV.

EDX EBV Components	Concentration
EDX EBV Panel Member 1	500 IU/mL
EDX EBV Panel Member 2	5,000 IU/mL
EDX EBV Panel Member 3	50,000 IU/mL
EDX EBV Panel Member 4	500,000 IU/mL
EDX EBV Panel Member 5	5,000,000 IU/mL

PROCEDURE:

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

STORAGE AND HANDLING:

The EDX EBV Verification Panel should be stored at -20°C or below.

Thaw EDX EBV Verification Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX EBV Verification 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 EBV Verification Panel beyond the expiration date.

LIMITATIONS:

In Vitro Diagnostic Use.

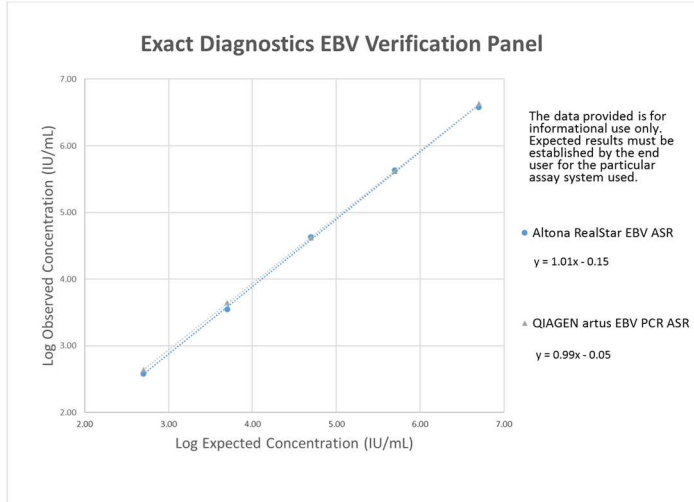
WARNINGS AND PRECAUTIONS:

The EDX EBV Verification 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 EBV Verification Panel were tested in triplicate across the assays identified in the graph below.



REFERENCES:

¹The 1st WHO International Standard for Epstein-Barr virus (09/260) IFU. <http://www.nibsc.org/documents/ifu/09-260.pdf>

²Siegel 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



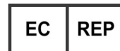
Caution



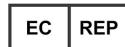
Consult Instructions for Use



European Mark of Conformity



Authorized Representative



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