

EDX EBV High Run Control	
Catalog Number	EBVH102
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	Multiple Use
Shelf Life	36 Months from Date of Manufacture
Traceability	1 <sup>st</sup> WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

**INTENDED USE:**

The EDX EBV High Run Control is an external quality control, intended to be used with EBV assays to monitor the performance of that given assay. EDX EBV High Run Control is calibrated against the 1<sup>st</sup> WHO International Standard for Epstein-Barr virus (09/260)<sup>1</sup>. The control is used to monitor the presence of Epstein-Barr Virus (EBV) DNA. Routine use of EDX EBV High Run Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

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

The EDX EBV High Run Control is value assigned using digital droplet PCR. EDX EBV High Run Control 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.

**PROCEDURE:**

The EDX EBV High Run Control requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX EBV High Run Control is an unassayed control and does not have assigned values. The control is not a substitute for the manufacturer’s kit controls provided with the assay. EDX EBV High Run Control is to be tested according to the assay manufacturer’s or testing laboratory’s instructions and recommendations. Expected results utilizing EDX EBV High Run Control must be established by the end user for their specific assay.

**STORAGE AND HANDLING:**

The EDX EBV High Run Control should be stored at -20°C or below.

Thaw EDX EBV High Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX EBV High Run Control is stable for 24 hours when stored at 2-8°C. Product can be frozen and reused a maximum of four (4) times. After the fourth freeze thaw, any remaining materials must be disposed of. Do not dilute.

Do not use EDX EBV High Run Control beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX EBV High Run Control 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 contained pathogenic agents.

**REFERENCES:**

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

**SYMBOL REFERENCES:**



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Positive Control



European Mark of Conformity



Authorized Representative



Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands



Exact Diagnostics LLC  
3400 Camp Bowie Blvd CBH-214  
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