

EDX BKV High Run Control	
Catalog Number	BKVH102
Analyte	Heat Inactivated BK Virus
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	18 months from date of manufacture
Traceability	1st WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

EDX BKV High Run Controls are external quality controls, intended to be used with BKV assays to monitor the performance of that given assay. EDX BKV High Run Controls are calibrated against the 1st WHO International Standard for BK Virus (BKV) (14/212)¹. The controls are used to monitor the presence of Polyomavirus BK virus "BKV" DNA. The control materials are whole, intact virus allowing operators to test the entire process of a molecular assay, train operators and test for proficiency.

PRODUCT DESCRIPTION:

EDX BKV High Run Controls are intact whole virus that has been heat inactivated. The control is intended to test the entire process of a variety of molecular assays from extraction, detection, and amplification.

The EDX BKV High Run Controls are reported in copies per milliliter (cp/mL) or International Units per milliliter (IU/mL). The controls are developed using heat inactivated BK Virus. EDX BKV High Run Controls are formulated in True EDTA plasma that was found to be non-reactive for BKV DNA, HBV DNA, HCV RNA, HIV-1 RNA, HBsAg and antibodies for HIV-1/2, and HCV.

PROCEDURE:

EDX BKV High Run Controls are whole, intact virus and should be treated similarly as all other samples going through an extraction step, allowing the operator to assess their extraction technique. EDX BKV High Run Controls are unassayed controls. These controls must not be used as a substitute for the manufacturer's kit controls provided with the assay. Operators should test EDX BKV High Run Controls according to the assay manufacturer's or testing laboratory's instructions and recommendations. The expected results utilizing EDX BKV High Run Controls must be established by the end user for the specific assay.

STORAGE AND HANDLING:

EDX BKV High Run Controls should be stored at -20°C or below.

Thaw material at room temperature and vortex briefly prior to use.

Once thawed, material 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.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

EDX BKV High Run Controls contain heat inactivated virus, but should be considered biohazardous and 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 contained pathogenic agents.

REFERENCES:

¹ 1st WHO International Standard for BK virus (BKV) (14/212)
IFU. <http://www.nibsc.org/documents/ifu/14-212.pdf>

² 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



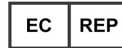
Biological Risks



Expiration Date



Upper Limit of Temperature



Manufacturer

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Caution



Positive Control



European Mark of Conformity

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Fort Worth, Texas 76107
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Authorized Representative