

| EDX BKV Verification Panel 1.4mL Summary | |
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| Catalog Number | BKVP200 |
| Analyte | Inactivated BKV |
| Matrix | True EDTA Plasma |
| Preservative | ProClin® 300 |
| Storage | -20°C or Below |
| Fill Volume | 1.4mL |
| Number of Vials Per Kit | 6 Vials |
| Number of Uses | Single Use |
| Shelf Life | 24 Months from Date of Manufacture |
| Traceability | 1 st WHO International Standard |
| Precautions | Biological Risks |
| Regulatory Status | For In Vitro Diagnostic Use |

INTENDED USE:

The EDX BKV Verification Panel 1.4mL is a standard for various molecular assays. EDX BKV Verification Panel 1.4mL is calibrated against the 1st WHO International Standard for BK Virus (BKV) (14/212)¹. EDX BKV Verification Panel 1.4mL is used to establish points of reference (qualitative and quantitative) for the measurement of Polyomavirus BK Virus (BKV) DNA. EDX BKV Verification Panel 1.4mL allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX BKV Verification Panel 1.4mL contains whole, intact virus that has been heat inactivated. EDX BKV Verification Panel 1.4mL is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX BKV Verification Panel 1.4mL is reported in International Units per milliliter (IU/mL). EDX BKV Verification Panel 1.4mL is manufactured according to ISO 17511:2003. EDX BKV Verification Panel 1.4mL is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, BKV DNA, HBsAg and antibodies for HIV-1/2 and HCV.

| EDX BKV Components | Concentration |
|------------------------|------------------|
| EDX BKV Panel Member 1 | 100 IU/mL |
| EDX BKV Panel Member 2 | 2,000 IU/mL |
| EDX BKV Panel Member 3 | 20,000 IU/mL |
| EDX BKV Panel Member 4 | 200,000 IU/mL |
| EDX BKV Panel Member 5 | 2,000,000 IU/mL |
| EDX BKV Panel Member 6 | 20,000,000 IU/mL |

PROCEDURE:

The EDX BKV Verification Panel 1.4mL 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 BKV Verification Panel 1.4mL is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX BKV Verification Panel 1.4mL should be stored at -20°C or below.

Thaw EDX BKV Verification Panel 1.4mL at room temperature and vortex briefly prior to use.

Once thawed, EDX BKV Verification Panel 1.4mL 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 BKV Verification Panel 1.4mL beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX BKV Verification Panel 1.4mL 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.

REFERENCES:

¹The 1st WHO International Standard for BK Virus DNA (14/212).
<https://nibsc.org/documents/ifu/14-212.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:

-  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


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