

REF BKVULOD

IVD

Exact Diagnostics BKV Urine LOD Summary	
Catalog Number	BKVULOD
Target Analyte	Inactivated BKV
Source Material	Whole Virus
Matrix	Stabilized Human Urine
Storage	-70°C or Below
Shelf Life	24 Months from Date of Manufacture
Fill Volume	1.4 mL per Vial
Number of Uses	Single Use
Number of Vials Per Kit	10 Vials
Traceability	1 st WHO International Standard
Precautions	Biological Risks
Regulatory Status	In Vitro Diagnostic Use

INTENDED USE:

The Exact Diagnostics BKV Urine LOD is calibrated against the 1st WHO International Standard for BK Virus (BKV) (14/212)¹. This product is used to determine the analytical sensitivity of the assay for Polyomavirus BK Virus (BKV) DNA in human urine and allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The Exact Diagnostics BKV Urine LOD contains whole, intact virus that has been heat inactivated. The control is intended to test the entire process of a molecular assay including extraction, amplification, and detection.

This product is formulated in stabilized human urine. Human urine is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, HBsAg and antibodies for HIV-1/2, and HCV.

PROCEDURE:

This product requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction procedure.

This product is an unassayed control and does not have assigned values. This product is not a substitute for the manufacturer's kit controls provided with the assay. This product is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing this product must be established by the end user for their specific assay.

If during the use of this device or as a result of its use, a serious incident occurs, please report it to Bio-Rad Laboratories and to your national health authority, as required.

STORAGE AND STABILITY:

This product will be stable until the expiration date when stored at -70°C or below.

Thaw this product at room temperature and vortex briefly prior to use.

Once thawed, this product is stable for 24 hours when stored at 2-8°C. Do not dilute.

LIMITATIONS:

1. Do not use this product beyond the expiration date.
2. This product is for Laboratory/Professional use only.
3. All remaining materials must be disposed of after one use. Do not reuse.

SAFETY PRECAUTIONS:

1. **This material contains guanidine hydrochloride. Do not allow direct contact between guanidine hydrochloride and sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures can release a noxious gas.**
2. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.
3. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
4. Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with water and then 0.5% sodium hypochlorite solution.
5. Dispose of any discarded materials in accordance with the requirements of the local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Service.



WARNINGS AND PRECAUTIONS:

Biological source material. Treat as potentially infectious.

Source materials used to produce these products have been treated to inactivate infectious agents. Universal precautions and proper disposal should be practiced². It is recommended that this product be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)³, Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.^{4,5}

Hazard (H) and Precautionary (P) statements

Contains: Guanidine, hydrochloride (1:1)

H302 Harmful if swallowed. **H315** Causes skin irritation. **H319** Causes serious eye irritation. **P264** Wash face, hands and any exposed skin thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P337 + P313** If eye irritation persists: Get medical advice/attention. **P501** Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. **P280** Wear protective gloves/protective clothing/eye protection/face protection.

A Safety Data Sheet (SDS) is available for professional users on www.bio-rad.com.

REFERENCES:

1. The 1st WHO International Standard for BK Virus DNA (14/212). <https://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.
3. U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories- Sixth Edition HHS Publication (CDC) 300859: June 2020.
4. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from Occupational Acquired infections; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4), Clinical and Laboratory Standards Institute Wayne, Pennsylvania 19087-1898, USA 2005.
5. Clinical and Laboratory Standards Institute (CLSI) Clinical Laboratory Waste Management; Approved Guideline – Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8), CLSI Wayne, Pennsylvania 19087, USA 2011.



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