

**PRODUCT INFORMATION**

<b>Product SKU</b>	BKVULOD
<b>Product Name</b>	BKV Urine LOD
<b>Kit Lot Number</b>	21072602
<b>Source Material</b>	Inactivated BKV
<b>Date of Expiration</b>	2023-06-30
<b>Base Matrix</b>	Stabilized Human Urine
<b>Fill Volume</b>	1.4 mL
<b>Storage Temperature</b>	-70°C or Below
<b>Regulatory Status</b>	For In vitro Diagnostics
<b>Traceability</b>	1 <sup>st</sup> WHO International Standard (14/212)
<b>Testing Platform</b>	Roche Cobas® 6800/8800 BKV Assay

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

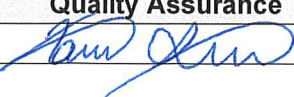
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

**TESTING DATA**

Lot Number	Product Description	Target Concentration	Testing Results	Quantity
21072602	BKV Urine LOD	12 IU/mL	Pass (≥ 95% detection rate)	10 Vials

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

**APPROVAL**

Quality Assurance	Date
	11 Aug 21