

**PRODUCT INFORMATION**

|                     |   |
|---------------------|---|
| Product SKU         | BKVL101   |
| Product Name        | BKV Low Run Control                                 |
| Kit Lot Number      | 21111101  |
| Source Material     | Inactivated BKV                                     |
| Date of Expiration  | 2024-10-31  |
| Base Matrix         | True EDTA Plasma                                    |
| Preservative        | ProClin® 300  |
| Fill Volume         | 1.0 mL  |
| Storage Temperature | -20°C or Below                                      |
| Regulatory Status   | CE-IVD  |
| Traceability        | 1 <sup>st</sup> WHO International Standard (14/212) |
| Testing Platform    | In-House BKV Assay                                  |

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. 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<br>(Comparison of Target Value<br>Against Reference Standard) | Quantity |
|------------|---------------------|----------------------|---|----------|
| 21111101   | BKV Low Run Control | 2,000 IU/mL          | Pass  | 5 Vials  |

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

**APPROVAL**

| Quality Assurance   | Date      |
|---|-----------|
|  | 13 Dec 21 |