Intended Use

Analyte Specific Reagent (ASR). Analytical and performance characteristics are not established. This ASR is intended to be used as a component of a laboratory developed test (LDT) used exclusively by laboratories. Laboratories may develop their own LDTs using one or more ASRs and/or general laboratory reagents for in vitro diagnostic purposes.

Product Description

The BK virus (BKV) Probe ASR contains an oligonucleotide designed to detect the VP2 gene of BKV. The oligonucleotide contains a 5’ CAL Fluor Red 610 label and a 3’ BHQ-2 label.

Materials Provided

BKV Probe (Cat. No. PRD-04992)

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Tubes</td>
<td>1 x 0.53 mL</td>
<td>25 µmol/L</td>
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</table>

Warnings and Precautions

A. Analytical and performance characteristics are not established.

B. Use routine laboratory precautions. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling reagents.

C. Dispose of all materials that have come in contact with reagents according to local, state, and federal regulations.

Quality Control

This analyte specific reagent was manufactured and released in accordance with the Hologic quality control and quality assurance procedures.

Storage and Handling

Upon receipt, store material at -15 to -85 ºC. Multiple freeze/thaw cycles should be minimized by appropriate aliquoting and should not exceed 3 freeze/thaw cycles.