

RealStar® ASR BKV Probe – Product Information Sheet

Product number: 031093-11

Analyte Specific Reagent

Analytical performance characteristics have not been established.

Product description

The RealStar® ASR BKV Probe is an analyte specific reagent (ASR) for the *in vitro* detection of BK virus (BKV) specific DNA by real-time polymerase chain reaction (PCR).

The RealStar® ASR BKV Probe is FAM™ labeled and intended for laboratory use.

Material provided

| Cap color | Number of vials | Content | Concentration |
|-----------|-----------------|---------|---------------|
| Brown | 8 | 12 µl | 1 µM |

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to support@altona-diagnostics.com for the Safety Data Sheet.

Binding Affinity

Nucleic acid sequence databases indicate that the RealStar® ASR BKV Probe does not show any binding affinity and significant homology with the following human pathogens:

| | |
|------------------------------|-------------------------|
| Herpes simplex virus (HSV) | Cytomegalovirus (CMV) |
| Varicella-zoster virus (VZV) | JC virus (JCV) |
| Epstein-Barr virus (EBV) | Human adenovirus (HAdV) |
| Human herpesvirus 6 (HHV-6) | Parvovirus B19 |

Storage and handling

- All components should be stored between -25 and -15 °C upon arrival.
- Before use all components should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly.
- Repeated thawing and freezing of component (more than twice) should be avoided, as this might affect the performance of the product. The component should be frozen in aliquots, if to be used intermittently.
- Storage between +2 and +8 °C should not exceed a period of two hours.

Note: The RealStar® ASR BKV Probe is shipped on dry ice. The product should arrive frozen. If product is not frozen upon receipt, or if tubes have been compromised during shipment, contact altona Diagnostics USA, Inc. for assistance.

Warnings and precautions

Before first use check the product for:













- Integrity
- Completeness with respect to number, type and filling
- Correct labelling
- Frozenness upon arrival
- Specimens should always be treated as infectious and/or biohazardous in accordance with safe laboratory procedures.
- Always handle samples and product components with caution to avoid contamination.

- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling specimens or product components.
- Use separated and segregated working areas for (i) sample preparation, (ii) reaction setup and (iii) amplification/detection activities. The workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering a different area.
- Seal reaction tubes/plate thoroughly and do not open post amplification to avoid contamination.
- Do not autoclave reaction tubes/plate after the PCR, since this bears the risk to contaminate the laboratory area.
- Do not use product components that have passed their expiration date.
- Discard sample and product waste according to your local safety regulations.

Instructions for use

Each laboratory should establish its own standard operating procedures and instructions for using the RealStar® ASR BKV Probe in a molecular assay.

Symbols

| | |
|---|-----------------------------------|
|  | Batch code |
|  | Cap color |
|  | Product number |
|  | Content |
|  | Number |
|  | Component |
|  | Global Trade Item Number |
|  | Analyte Specific Reagent |
|  | Consult Product Information Sheet |
|  | Temperature limitation |
|  | Use until |
|  | Manufacturer |

Limitations

The reagent is not intended for use as a donor screening test. The product is for professional use only.

Technical assistance

For technical advice, please contact our Technical Support:

| | |
|------------------------------------|---------------------------------------|
| e-mail: | support@altona-diagnostics.com |
| phone USA: | +1 415 777 1712 |
| phone headquarters Hamburg: | +49 40 548 0676 0 |