

AcroMetrix™ BKV Low and High Controls

IVD For In Vitro Diagnostic Use

Rx Only

REF 960050 AcroMetrix BKV Low Control
960051 AcroMetrix BKV High Control

Intended Use

The AcroMetrix™ BKV Low and High Controls are intended for use in assessing the performance of nucleic acid test procedures for the determination of the presence of BKV DNA. Routine use of external run controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, operator variation, and can assist in identifying increases in random or systematic error. This product is for *in vitro* diagnostic use.

Summary and Explanation

The AcroMetrix BKV Low and High Controls contain the human BKV. The controls were produced by diluting quantified BKV stock material into normal human EDTA plasma. The normal human EDTA plasma was tested and found to be non-reactive for HCV RNA, HBV DNA, and HIV-1 RNA, as well as non-reactive for antibodies to HIV-1 and HIV-2, and HBsAg.

The AcroMetrix BKV Low and High Controls contain intact, encapsidated viral particles which allows for verification of an effective viral DNA extraction procedure. The AcroMetrix BKV Low and High Controls are designed as unassayed controls for use in molecular test procedures for the detection of BKV DNA.

Reagents

Catalog Number	Control Name	Quantity
960050	AcroMetrix BKV Low Control	5 x 0.5 mL
960051	AcroMetrix BKV High Control	5 x 0.5 mL

Precautions and Warning

WARNING: The AcroMetrix BKV Low and High Controls contain active BK virus and should be considered biohazardous. Contains ≤0.05% Sodium azide. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials^{1,2}.

Do not pipette by mouth. Do not eat, drink or smoke in areas where controls and specimens are handled.

Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents according to state and federal regulations.

Storage Instructions

The AcroMetrix BKV Low and High Controls must be stored at -20°C or below to ensure highest quality. Controls may be refrozen after first use, thawed and used a second time with minimal loss of activity. Discard any unused material after the second use.

Instructions for Use

Thaw the AcroMetrix BKV Low and High Controls at room temperature, vortex briefly, and immediately place on ice after thawing.

The AcroMetrix BKV Low and High Controls should be handled and tested in a manner identical to that required for clinical specimens run in the BKV DNA test procedure being evaluated.

References

- Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
- Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.

Glossary:

<http://www.thermofisher.com/symbols-glossary>


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 For insert updates go to:
www.thermofisher.com/Acrometrix

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