

ACCURUN® 420

BK Virus Reference Material

2410-0254

Package Insert

PLEASE NOTE:

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

ACCURUN® products are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN 420 BK Virus Reference Material is formulated for use with amplified nucleic acid test methods that detect and quantitate BK Virus (BKV) DNA. *For Research Use Only. Not for use in diagnostic procedures.*

SUMMARY

A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent reference material may provide valuable information concerning laboratory proficiency and kit lot variation.

PRINCIPLES OF THE PROCEDURE

ACCURUN 420 BKV Reference Material is designed for use with assay procedures for the purpose of monitoring test performance. ACCURUN 420 is manufactured from whole inactivated BKV strain type 1b-2 diluted in normal human plasma and formulated for positive and negative reactivity with BKV DNA assays. The kit contains 4 vials of reference material with varying concentrations of BKV: 1 vial of high positive material, 1 vial of medium positive material, 1 vial of low positive material, and 1 vial of negative material.

REAGENTS

Item No. 2410-0254

4 vials
1.0 mL vial each of:

BKV High Positive Material
BKV Medium Positive Material
BKV Low Positive Material
BKV Negative Material

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle ACCURUN Reference Materials as though capable of transmitting infectious agents.

Safety Precautions

Use Center for Disease Control (CDC) recommended universal precautions for handling reference materials and human specimens¹. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use ACCURUN 420 BKV Reference Material beyond the expiration date. Each vial should be thawed and used one time.

STORAGE INSTRUCTIONS

Store ACCURUN 420 BKV Reference Material at -70 °C or colder until use. Once opened, an individual vial of ACCURUN 420 should not be reused. Store vials upright to prevent leakage.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN 420. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 420 BKV Reference Material is manufactured from whole inactivated BKV strain type 1b-2 and normal human plasma.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Allow the reference material to come to room temperature and mix the contents of the vials by gentle inversion before use. Process ACCURUN 420 according to the laboratory's procedure for unknown samples. ACCURUN 420 must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control

Since ACCURUN 420 BKV Reference Material does not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN 420 with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 420 BKV Reference Material may vary with different manufacturers' tests and different test kit lots. Since the material does not have assigned values, the laboratory must establish acceptable results for each concentration level of BKV. When results for ACCURUN 420 are outside of the established acceptance range for any of the 4 levels of material, it may indicate unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE

ACCURUN REFERENCE MATERIALS MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN Reference Materials are not calibrators and should not be used for assay calibration. Performance characteristics for ACCURUN 420 reference material have been established only for amplified nucleic acid tests that detect BKV DNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN 420 BKV Reference Material DOES NOT HAVE ASSIGNED VALUES. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories. ACCURUN 420 BKV Reference Material contains high positive material, medium positive material, low positive material, and negative material. Each concentration level is formulated to produce different results. Each laboratory should establish its own range of acceptable values for each individual concentration level. Refer to Table 1 for target values for each concentration level in ACCURUN 420 BKV Reference Material.



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SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN Reference Materials do not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

Table 1: Typical Data for ACCURUN 420 BK Virus Reference Material

ACCURUN 420 BK Virus Reference Material	Analyte	Target Values (Log copies/mL)
ACCURUN 420 High Positive Material	BKV DNA	5.00
ACCURUN 420 Medium Positive Material	BKV DNA	4.00
ACCURUN 420 Low Positive Material	BKV DNA	3.00
ACCURUN 420 Negative Material	BKV DNA	BLD



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