

LABORATORY REPORT

QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 46 Y

Molecular

Collected: 08/13/2024 15:41 Received: 08/13/2024 15:41

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

BK Virus DNA PCR, Quantitative, Plasma

BK Virus DNA, Qualitative, Plasma

Not detected

Not detected

Not detected

WMRL

BK Virus DNA, Quantitative, Plasma

<250

<250

Copies/mL

WMRL

Log BK Virus DNA, Plasma

<2.40

Copies/mL

WMRL

Copies/mL

This test utilizes a polymerase chain reaction to amplify sequences from the VP1 regions of the BK virus genome. Real-time detection and quantification are used to determine the viral copy number. The analytical measurement range is 125 to 5 million copies/mL (2.10 to 6.70 $\log(10)$ copies/mL). The qualitative limit of detection is 100 $\log(1.78 \log(10))$ copies/mL).

Specimens reported as "DETECTED" but <125 copies/mL contain detectable levels of BK virus DNA but the viral load is below the limit of quantitation. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

Reported Date: 08/13/2024 15:41 PBKQN

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108