VCU Health™

Department of Pathology Laboratories

Notification Date: March 19th, 2025
Effective Date: April 1st, 2025

CMV, EBV and BKV DNA Quantitative Tests – Method Change

Please be informed that the assay method for CMV, EBV and BKV DNA quantification will change from Arpil 1, 2025.

The current laboratory developed tests (LDT) will be replaced by the FDA-approved Roche cobas® CMV, cobas® EBV, and cobas® BKV tests, respectively. These tests are performed on the Roche cobas® 6800 and cobas® 5800 systems.

Performance evaluation of the LDT and the FDA-approved methods showed no clinically significant differences in the results.

Orderable tests (remain the same):

CMV DNA QUANTITATIVE [LAB913]

EBV DNA QUANTITATIVE [LAB1373]

BKV PLASMA DNA QUANTITATIVE [LAB1374]

Specimen type: plasma.

Test Performance specifications and comparison with the LDT:

	CMV DNA Quant		**EBV DNA Quant**		**BKV DNA Quant**	
Method:	**cobas® CMV**	**LDT**	**cobas® EBV**	**LDT**	**cobas® BKV**	**LDT**
Linear Measurement Range:	**34.5 to 1.0E+07 IU/mL**	150 to 3.0E+06 IU/mL	**35 to 1.0E+08 IU/mL**	100 to 1.0E+06 IU/mL	**21.5 to 1.0E+08 IU/mL**	1,000 to 4.5E+06 IU/mL
Lower limit of quantitation (LOQ):	**34.5 IU/mL**	150 IU/mL	**35.0 IU/mL**	100 IU/mL	**21.5 IU/mL**	1,000 IU/mL
Lower limit of detection (LOD):	**34.5 IU/mL**	150 IU/mL	**18.8 IU/mL**	100 IU/mL	**21.5 IU/mL**	1,000 IU/mL
PPA	100% (positive results by the LDT were also positive by the cobas)		82% (the cobas did not detect a small number of low positives with the LDT)		100% (positive results by the LDT were also positive by the cobas)	
NPA	78% (the cobas is more sensitive, detecting more positives than the LDT)		89% (2 not detected by the LDT were detected by the cobas)		94% (1 not detected by the LDT was low positive by the cobas)	

The cobas tests with a lower detection limit, will generally detect more positives than the LDTs.

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Results interpretation and reportable:

CMV	EBV	BKV	Interpretation
“CMV not detected.”	"EBV not detected"	"BKV not detected"	Target DNA not detected
“CMV detected, less than 34.5 IU/mL”	"EBV detected, less than 35.0 IU/mL"	"BKV detected, less than 21.5 IU/mL"	Target Detected, below the lower limit of quantitation or LOQ
“[Titer] of CMV detected”.	"[Titer] of EBV detected"	"[Titer] of BKV detected"	Calculated titer is within the Linear Range of the assay
“CMV detected, greater than 1.0E+07 IU/mL”	"EBV detected, greater than 1.0E+08 IU/mL"	"BKV detected, greater than 1.0E+08 IU/mL"	Calculated titer is above the Upper Limit of Quantitation of the assay

Intended Use:

CMV is intended for use as an aid in the management of solid-organ transplant and hematopoietic stem-cell transplant patients who are undergoing anti-CMV therapy.

EBV is intended for use as an aid in the management of EBV in transplant patients.

BKV is intended for use as an aid in the management of BKV in transplant patients.

For questions, please contact Pathology Client Services at (804) 828-7284 or the Molecular Diagnostics Laboratory at (804) 828-9564.