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Viral load assays on Roche Cobas® 6800 for HIV, HBV, HCV and CMV

TECHNICAL BULLETIN

Colleagues:

Effective March 26, 2024, DMC University Laboratories will transition from the current platform to the Roche cobas® 6800 for HIV, HBV, HCV and CMV viral load assays. This change will increase specimen throughput and improve the quality of the assays.

The cobas® 6800 HIV, HBV, HCV and CMV quantitative PCR assays are based on real time nucleic acid amplification. There is no change to the assays' names, specimen collection or specimen transportation, however, there are changes to the lower and upper limit of quantification of these assays as follows:

Assay name	Current lower and upper limit	New lower and upper limit
HIV	20 - 10,000,000 cp/mL	20 - 10,000,000 cp/mL
HBV	20 - 10,000,000 IU/mL	10 - 1,000,000,000 IU/mL
HCV	15 - 100,000,000 IU/mL	15 - 100,000,000 IU/mL
CMV	137 - 9,100,000 IU/mL	34 - 10,000,000 IU/mL

Based on correlation studies, the viral load value from the current platform (Amplicor) and Roche cobas® 6800 are very close and comparable. However, due to changes in the CMV assay design, the viral load values from Roche cobas® 6800 are higher than the Amplicor results. This increase in viral load is known as *fragmentation effect* and is due to the use of new primers in the Roche cobas® 6800 CMV assay that target smaller segments of DNA.

Thank you,

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