Clinical Pathology Laboratories

Cytomegalovirus (CMV) by PCR testing changes

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective December 18th, 2017, Clinical Pathology Laboratories will change the current instrumentation and reagents for CMV testing in EDTA plasma from the Roche AmpliPrep/TaqMan 2.0 to the new Roche cobas® CMV quantitative nucleic acid test on the cobas 8800.

The intended use of both assays is as an aid in the management of CMV in solid organ transplant (SOT) patients and in hematopoietic stem cell transplant (HSCT) patients, specifically including serial DNA measurements to assess viral response to treatment.

Both assays are traceable to WHO International Standards and demonstrate strong quantitative correlation to one another.

Due to assay design changes there could be differences in quantitation for individual patients.

- The lower limit of quantitation has decreased from 137 IU/mL to 35 IU/mL. With higher sensitivity, this assay will result in more samples with low quantifiable results.
- More samples will show a "detected" result below the limit of quantitation when previously a result of "not detected" may have been reported.
- In clinical specimens for both SOT and HSCT, Roche found a slight positive bias in new CMV assay relative to the TaqMan CMV (approximately 0.2 log IU/mL).
- Rare samples showed discrepant viral loads between the two assays due to polymorphisms within CMV target sequences.

Retesting and verification of CMV results may be necessary if a result with the new assay is clinically unexpected. Please contact a CPL Pathologist if there are any questions regarding this testing.

Order Unit Code/Test Name:	4019, 4187 CMV BY PCR QUAL/QUANT and QUANT
Test Method:	Polymerase chain reaction (PCR) by Roche Cobas 8800
Specimen Requirements:	3 mL EDTA plasma
Specimen Rejection Criteria:	Samples received in frozen BD PPT tube, serum, heparin plasma
Transport Temperature:	Frozen or Refrigerated*
Stability (collection to initiation of testing):	6 Days Refrigerated; 12 Weeks Frozen
Performed:	Monday, Wednesday, Friday
Specimen Retention:	2 Weeks
Range of quantitation:	35 – 1.0E+07 IU/mL (1.54 – 7.00 log IU/mL)**
CPT Code:	87497

* Previous transport temperature was frozen only
**Previous range of quantitation: 137 – 9.1E+06 IU/mL (2.14 – 6.96 log IU/mL)
Order Unit Code 4045 CMV by PCR, Qual/Quant, Whole Blood is unaffected by this change.

Thank you for supporting

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