An international multicenter performance analysis of cytomegalovirus load tests

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BACKGROUND: Quantification of cytomegalovirus (CMV) load is central to the management of CMV infections in immunocompromised patients, but quantitative results currently differ significantly across methods and laboratories. METHODS: The COBAS AmpliPrep/COBAS TaqMan CMV Test (CAP/CTM CMV test), developed using the first World Health Organization CMV standard in the calibration process, was compared to local assays used by 5 laboratories at transplant centers in the United States and Europe. Blinded plasma panels (n = 90) spiked with 2.18-6.7 log(10) copies/mL and clinical plasma samples from immunocompromised patients (n = 660) were tested. RESULTS: Observed mean panel member concentrations by site and 95% confidence intervals (CIs) of the data combined across sites were narrower for CAP/CTM CMV test compared with local assays. The 95% CI in log(10) copies/mL of the combined data per panel member for CAP/CTM CMV test vs comparator assays was .17 vs 1.5 at 2.18 log(10) copies/mL; .14 vs .52 at 2.74 log(10) copies/mL; .16 vs .6 at 3.3 log(10) copies/mL; .2 vs 1.11 at 4.3 log(10) copies/mL; .21 vs 1.13 at 4.7 log(10) copies/mL; and .18 vs 1.4 at 6.7 log(10) copies/mL. In clinical specimens, constant and variable quantification differences between the CAP/CTM CMV test and comparator assays were observed. CONCLUSIONS: High interlaboratory agreement and precision of CAP/CTM CMV test results across 5 different laboratories over 4 orders of magnitude suggest that this assay could be valuable in prospective studies identifying clinical viral load thresholds for CMV treatment.
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