Recently, the first FDA-approved CMV DNA Viral Load monitor test (the Roche COBAS® AmpliPrep/COBAS TaqMan® CMV Test) became available for use in the clinical laboratory. This test is calibrated using the 1st WHO International Standard allowing test results to be reported in IU/mL for the first time. The UCDHS Molecular Laboratory will implement this new IVD assay effective March 27, 2013. The dynamic range of the Roche monitor test is 137 – 9,100,000 IU/mL. Based on this broad dynamic range, one real-time PCR test using the Roche COBAS TaqMan CMV Test will be offered for CMV DNA detection and quantitation. Separate qualitative and quantitative assays will no longer be available. (The current LightCycler assays using the Qiagen ASR test system will be discontinued.) All CMV DNA testing should be ordered with one test: CMV Quantitative, Blood.

**Sample Requirements:**

**Collect:** One sterile 4 mL EDTA tube (lavender) mixed adequately according to the manufacturer's instructions.

**Storage/Transport:** Store whole blood at 2°C to 25°C for no longer than 6 hours. Centrifuge and aliquot plasma to sterile transport tube within 6 hours of collection. Freeze plasma at -20°C to -70°C.

**Minimum Specimen:** 0.6 mL frozen plasma

**Remarks:** DO NOT freeze whole blood specimen

**TAT:** Assay performed once per week (Thursday)

**Results:** Test results will be electronically reported in EMR

**Reference Intervals:**

- **137 – 9,100,000 IU/mL** (reportable range of the assay)
- **< 137 IU/mL** (below the limit of quantitation of the assay)
- **> 9,100,000 IU/mL** (above the upper range of the assay)

If you have questions or need additional information please contact Laboratory Client Services at 734-7373 or email pathologyclientservices@ucdmc.ucdavis.edu.

**LIS mnemonic: CMVLD**