HOLOGIC®

Aptima® CMV Quant Assay

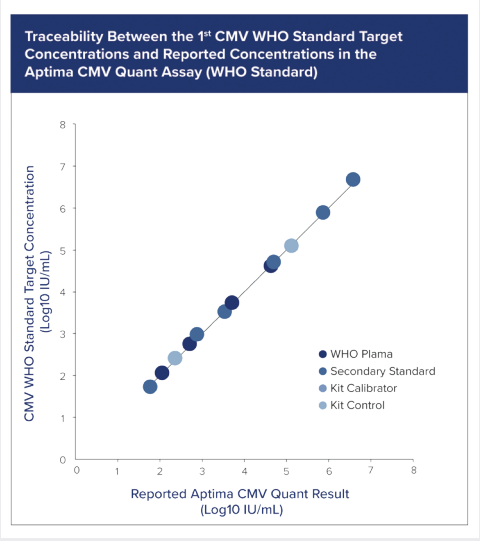
■ Detect and monitor active CMV infections.

Fast and reliable. Streamline laboratory workflows and quickly deliver accurate and actionable viral load insights to post-transplant patients and their care teams with the Aptima CMV Quant assay on the fully automated Panther® system.

Excellent Performance

Our FDA-approved solution for CMV testing completely aligns with the WHO 1st international standard for CMV, ensuring the highest degree of standardization necessary to reliably monitor viral load trends over time.

LoD	40.7 IU/mL plasma (WHO 1st international standard)
Specificity	99.7% Plasma
LLoQ	53 IU/mL plasma



Product Details

Intended Use	Aid in the management of solid-organ and hematopoietic stem cell transplant patients	**Genotypes**	Genotypes 1-4 and drug resistant mutants: UL54, UL97 & UL56*
Technology	Real-time transcription-mediated amplification (RT-TMA)	**Sample Type**	Plasma (EDTA, PPT)
Target Region	UL56 gene	**Assay Input Volume**	Primary tube: 500µL Secondary tube: 700µL

* UL54 gene mutations can lead to cross resistance to several antivirals for treatment of CMV infection such as ganciclovir (GCV), cidofovir (CDV), and foscarnet (PFA). UL97 gene mutations also lead to GCV resistance. UL56 gene mutations lead to letermovir (LET) resistance.

Aptima®

Aptima CMV Quant assay runs on our highly efficient sample-to-result platform.

Efficient Workflow

Attain same day results with our fully-automated, fully-integrated, and high-throughput CMV assay run on the Panther® system.

Labor Savings	
Full Automation	Samples may be loaded at the end of the day and run labor-free after hours Generates specialized reports to automate tracking and trending of QC and results: Levey-Jennings Provides Prevalence Reports, Sample History Report, Sample Curve Report and Maintenance Checklist
Platform Efficiencies	Broad assay menu on a single platform allows consolidation and the ability to run more tests per full-time employee Ability to run multiple test orders from a single patient sample at the same time expedites results
Primary Tube Processing	No need for aliquoting or manual sample transfer Tube flexibility: PPT and EDTA tubes validated
Time Savings	
Random Access	No more batching; new test orders can be added to the instrument as samples arrive Run CMV with other assays at the same time
Rapid Turnaround Time with Stat Result Option	First results in 2 hours, 40 minutes Stat result option: ability to prioritize results
Flexible Sample and Reagent Loading	No manual sample prep or barcode clips Automated barcode scanning allows for positive sample identification and tracking
Cost Savings	
Small Footprint	Gives labs the ability to run more tests per square foot and options for scalability and redundancy
Consolidated Platform	Consolidation of platforms helps reduce LIS connection costs and streamline tech training and competencies

Ordering Information

Item	Quantity	Catalog #
Aptima CMV Quant assay kit (1 assay box, 1 target enhancer reagent box, 1 calibrator box, and 1 controls box)	100 Tests	PRD-05074

RUN ON

Primary Tube Sampling

✓ Plasma: EDTA, PPT

For more information, visit **hologic.com/CMVQuant**

Reference 1. Aptima CMV Quant Assay. US package insert AW-22600-001. Hologic, Inc.; 2021.