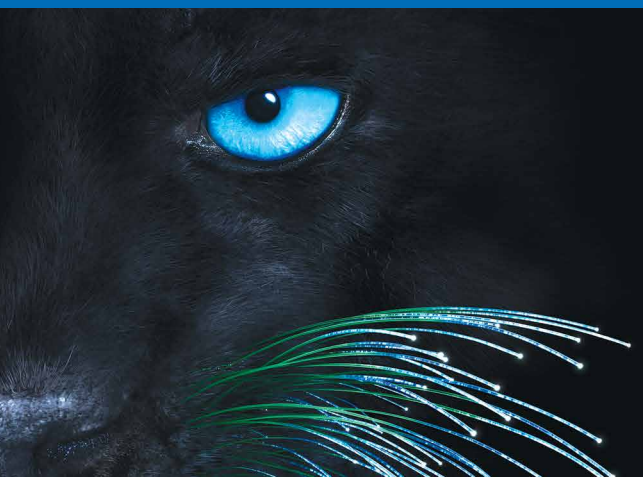
HOLOGIC



Aptima CMV Quant Assay

Confident CMV results for viral load testing in plasma and whole blood.

Accurate, highly reproducible quantitation. Enhance patient management with the preferred method of monitoring CMV infection.[1]

High reproducibility with full automation[2]

Performance

LoD	Plasma: 40.7 IU/mL Whole blood: 131.0 IU/mL (1st WHO International Standard)
LLoQ	Plasma: 53 IU/mL Whole blood: 176 IU/mL (1st WHO International Standard)
Linear range	Demonstrated linearity across panels ranging from 1.62 log IU/mL to 7.30 log IU/mL
Method correlation	Plasma: assessed against the Roche cobas® CMV on the cobas® 6800 System Whole blood: assessed against the Abbott CMV RealTi*m*e assay on the *m2000* platform

Reproducibility			
Mean concentration IU/mL	Plasma total SD	Mean concentration IU/mL	Whole blood total SD
2.28	0.18	2.78	0.17
2.82	0.14	3.38	0.14
3.49	0.15	3.95	0.18
4.53	0.11	4.76	0.16
5.57	0.12	5.64	0.13
6.67	0.12	6.74	0.12

SD = standard deviation.

The high reproducibility of the assay provides confidence that results are accurate regardless of where they are performed.[2]

Demand more from your CMV assay

Product design			
Intended use	CMV viral load monitoring	**Genotypes**	1-4
Technology	Real-time transcription-mediated amplification	**Sample types**	Plasma and whole blood
Target region	*UL56* gene	**Sample input volume**	Primary tube (EDTA, PPT): 1.2 mL plasma Secondary tube: 700 µL plasma Whole blood: 500 µL with automated dilution factor

Aptima® CMV Quant Assay

The Aptima CMV Quant assay on the Panther® system combines assay performance and excellent automation for viral load monitoring.

Sample-to-result within a single integrated instrument

Key automation characteristics	
Random access	No more batching; load samples with different test orders as they arrive
Plasma primary tube processing	No need for aliquoting or manual sample transfer Tube flexibility: PPT and EDTA tubes validated
Whole blood processing	Use pre-filled tubes for whole blood dilution, which can be loaded directly onto the Panther system Specified dilution factor automatically applied versus manual calculation
Flexible sample and reagent loading	No manual sample prep or barcode clips for primary tube processing Automated barcode scanning of tubes allows positive sample identification Run multiple assays from a single specimen tube at the same time
Rapid turnaround time with stat result option	First results in 2 hours, 41 minutes Stat result option: ability to prioritise results
Automated QC analysis	Levey-Jennings plots to track and trend controls

Ordering information

Aptima® Transplant assay	Items	Quantity	Catalogue number
Aptima® CMV Quant Assay	Aptima CMV Quant assay kit (1 assay box, 1 calibrator kit, 1 controls kit)	100 tests	PRD-05074
	Aptima whole blood diluent tubes (pre-filled tubes containing whole blood diluent)	100 tubes	PRD-06783

Validated sample types

✓ Plasma: EDTA, PPT
✓ Whole blood

RUN ON PANTHER®

References: 1. Kotton CN, Kumar D, Caliendo AM, et al. The third international consensus guidelines on the management of cytomegalovirus in solid-organ transplantation. *Transplantation.* 2018;102(6):900-931.
2. Aptima CMV Quant Dx assay [package insert]. AW-21334-001. San Diego, CA: Hologic, Inc.; 2021.

Diagnostic Solutions | Hologic.com | euinfo@hologic.com