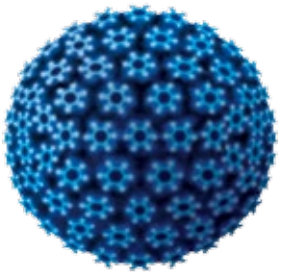
cobas® CMV

Setting the standard in monitoring CMV infection

Cytomegalovirus (CMV) is a leading cause of morbidity and mortality in transplant recipients. Severe CMV infection in high risk patients may occur soon after transplantation. Without effective treatment, patients may develop CMV syndrome, tissue invasive disease, and potential rejection or loss of the graft. The **cobas**® CMV quantitative nucleic acid test for use on the **cobas**® 6800/8800 Systems reliably monitors infection in patients receiving antiviral therapy.



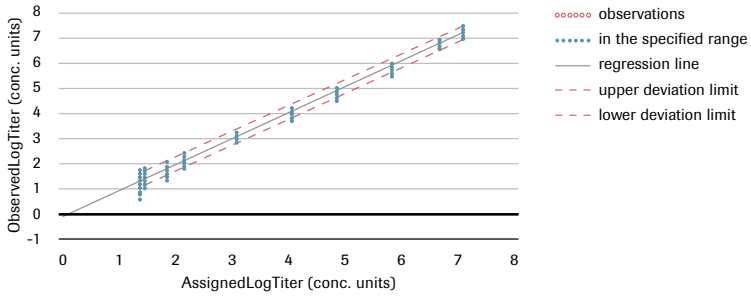
Assay Benefits

Traceability to the WHO Standard – cobas® CMV is traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162) providing consistent, reliable results across the dynamic range of the assay and across institutions.

Proven advantages over Lab Developed Tests – cobas® CMV eliminates the need to perform complex LDTs, providing quality control and quality assurance of reagents and validated results.

Reassurance in clinical decision making – cobas® CMV standardized viral load testing enables a common strategy to be developed in the management of CMV infection in transplant patients.

Linearity for cobas® CMV (EDTA plasma)



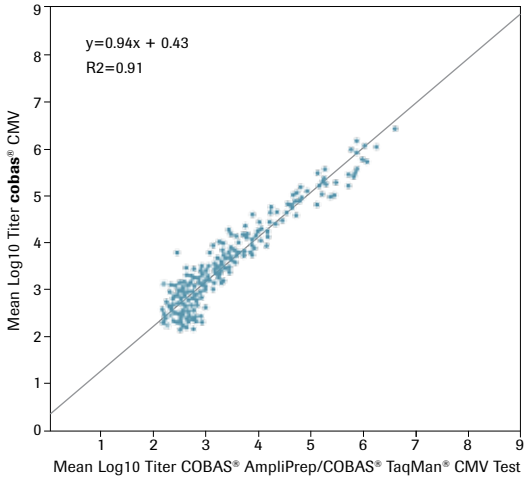
Roche

cobas®

Life needs answers

Not available in all markets, including the U.S.

Correlation (EDTA plasma)



Standardized for improved results

cobas® CMV is standardized to an international higher order standard and provides accurate, reproducible, sensitive and reliable results, particularly at clinically relevant titers. The tight precision of the assay minimizes variability in results. Correlation to other methods (e.g. COBAS® AmpliPrep/ COBAS® TaqMan® CMV Test) demonstrates similar quantitation throughout the linear dynamic range. **cobas**® CMV is an in vitro nucleic acid amplification test for the quantitation of cytomegalovirus DNA in EDTA human plasma. The test can quantitate CMV DNA over the range of 34.5 - 1E+07 IU/mL.

cobas® CMV performance summary

Parameter	Performance
Sample type	EDTA plasma
Minimum amount of sample required	500 µL
Sample processing volume	350 µL
Analytical sensitivity	34.5 IU/mL
Linear range	34.5 IU/mL to 1E+07 IU/mL
Specificity	100%
Genotypes detected	CMV Glycoprotein B Genotype 1-4
Drug resistant CMV specimens detected	CMV specimens resistant against Ganciclovir, Valganciclovir, Cidofovir and Foscamet

cobas® CMV ordering information

Material number	Product name	Tests per unit (cassette/bottle)
07001029190	cobas® CMV	96
07001037190	cobas® CMV control kit	8 runs
07002220190	cobas® NHP negative control kit	16 runs

Comprehensive menu for viral load testing

- cobas® HIV-1*
- cobas® HBV*
- cobas® HCV*
- cobas® CMV*

*For use with the **cobas**® 6800/8800 Systems

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