

Cytomegalovirus (CMV) DNA Quantitation, PCR

Introduction

Cytomegalovirus is a DNA virus and a member of the Herpesviridae family. This group includes HSV, VZV, EBV, and HHV types 6, 7, and 8. Characteristically, most of the members of this family are known for establishing latency, possessing a high prevalence rate, and causing disease in immunologically compromised hosts. Consequently, transplant, cancer, or AIDS patients,^{1,6} and newborns are the individuals at highest risk for severe disease.² Since CMV infections are acquired throughout life, most infections usually develop as a result of CMV reactivation. Primary infections may lead to severe consequences, especially in the neonate, as well as in the transfused, transplanted, or older adult. Disease syndromes caused by CMV may include interstitial pneumonia, gastrointestinal infection, CNS disease, hepatitis, retinitis, and encephalitis. In transplant patients, CMV is also linked with acute and chronic graft rejection and associated with bacterial and fungal superinfection.⁸ For this reason, the use of sensitive, specific, and rapid testing to support a diagnosis of CMV infection is critical to proper patient management.

CMV Assay

Sensitive and reproducible assays for detecting and monitoring viral DNA levels are essential tools for managing patient populations at risk for CMV disease. Clinically, quantitative PCR assays have largely replaced standard diagnostic methods, such as culture and antigenemia. Cultures lack sensitivity, do not allow for quantitation of viral load, and do not produce a high degree of reproducibility while antigenemia assays have a limited use due to the lack of standardization and their subjective interpretation.⁸ Preemptive therapy has become the standard method for CMV disease prevention in high-risk patients, and quantitative assays are now being used to identify patients at risk for developing CMV disease,

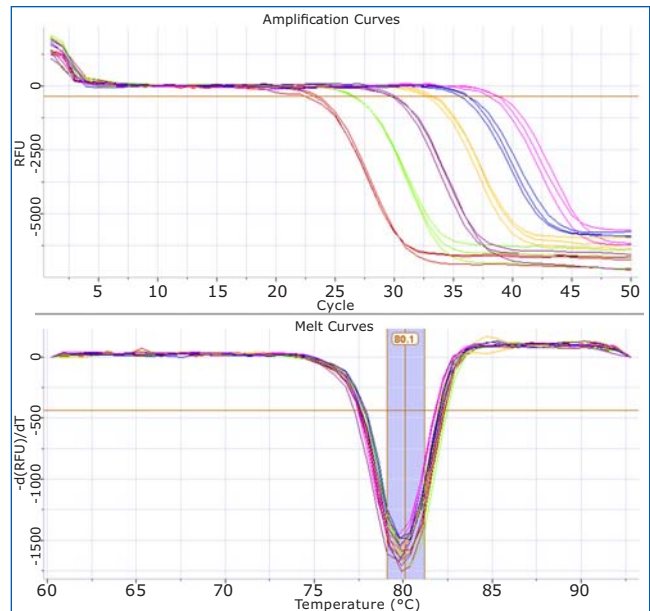


Figure 1—Target Quantitation.⁷ Representative demonstration of reproducible signal generation over a 6-log range of input target concentration.


provide rapid diagnosis of established CMV disease, monitor response to antiviral therapy, predict the risk of virological and clinical relapse, and serve as an early indicator of antiviral resistance.⁸

The quantitative PCR assay for CMV (qCMV-PCR) employs MultiCode[®]-RTx technology for detecting PCR products in real time.

Test characteristics and performance⁷:

- Use of tagged primers rather than probes for improved precision of target quantitation.
- Enables multiplexed detection of CMV and an extractable internal control target.
- Quantitation is accomplished via interpolation of results into externally-generated, lot specific, calibration curves (Figure 1).
- Capable of highly reproducible quantitation of CMV DNA in clinical samples over a range of at least 5 logs, resulting in

an upper limit of quantitation of at least 1 million copies/mL (Figure 2).

- Generates results that are concordant with currently available reference methods for assessing CMV viral loads.
- Limits of detection (LOD) of approximately 50 cp/mL (plasma) and 100 cp/mL (urine) with a lower limits of quantitation (LLOQ) of approximately 250 cp/mL for both samples types (SD < 0.2 logs).
- Negative cross-reactivity for HSV-1, HSV-2, HHV-6 (A), HHV-6 (B), EBV, HIV-1, HBV, HCV, WNV, BKV, JCV, Adenovirus, *Staphylococcus aureus*, *E coli*, *K pneumoniae*, *Candida albicans*.
- Storage of samples for up to seven days under either refrigerated or frozen conditions. 

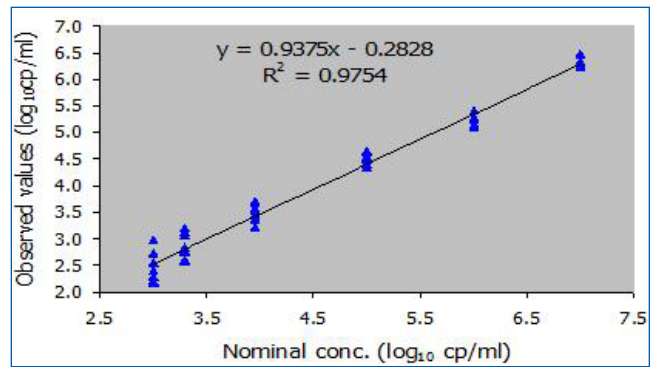


Figure 2—Target Quantitation.⁷ Demonstration of linearity and repeatability of qCMV-PCR assay for plasma samples. Plasma sample panel consisted of members of a CMV linearity panel obtained from SeraCare Diagnostics.⁷

Cytomegalovirus (CMV) DNA Quantitation, PCR . . . 139149

CPT 87497

Synonym CMV Quantitation, PCR

Specimen Plasma

Volume 4 mL

Minimum Volume 1 mL

Container Lavender-top (EDTA) tube

Collection Plasma must be separated within 24 hours. To avoid delays in turnaround time when requesting multiple tests on frozen samples, please submit separate frozen specimens for each test requested.

Storage Instructions Refrigerate or freeze.

Causes for Rejection Quantity not sufficient for analysis; specimen grossly contaminated; specimen too old; leaking or broken tube

Use Detect cytomegalovirus DNA in clinical specimen; management of CMV infections

Methodology Polymerase chain reaction (PCR)

Cytomegalovirus (CMV) DNA Quantitation, PCR, Urine . . .

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CPT 87497

Synonym CMV Quantitation, PCR, Urine

Specimen Urine

Volume 4 mL

Minimum Volume 1 mL

Container Sterile urine container without preservatives

Storage Instructions Refrigerate or freeze.

Causes for Rejection Quantity not sufficient for analysis; specimen grossly contaminated; specimen too old; leaking or broken tube

Use Detect cytomegalovirus DNA in clinical specimen; management of CMV infections

Methodology Polymerase chain reaction (PCR)

References

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