

# Evaluation of an automated extraction system in combination with Affigene<sup>®</sup> CMV Trender for CMV DNA quantitative determination: Comparison with nested PCR and pp65 antigen test

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## Abstract

CMV viral load quantitation is a powerful tool to assist clinicians in making accurate diagnoses, managing post-transplant CMV disease and monitoring antiviral therapy. The aim of this study was to evaluate the performance of Affigene<sup>®</sup> CMV Trender for CMV viral load determination used in combination with a non-dedicated nucleic acid extraction system (BioRobot MDx) for high-throughput routine. Linearity, reproducibility and sensitivity were examined. Clinical samples were used to compare results obtained with the Affigene<sup>®</sup> CMV Trender, with an "in house" nested PCR used for routine diagnosis and with pp65 antigenemia. The results indicated that the test is linear in the range of 1.81-5.18 Logcopies/ml and that sensitivity is 77 copies/ml. The concordance of the Affigene<sup>®</sup> CMV Trender with nested PCR was high, ( $k=0.91$ , IC 95%=0.82-1.00), whereas a substantial concordance with pp65 antigenemia was observed ( $k=0.64$ , IC 95%=0.54-0.73). In conclusion, combined use of a non-dedicated automated nucleic acid extraction method with the Affigene<sup>®</sup> CMV Trender results in an accurate high throughput system, suitable for routine laboratory monitoring of CMV infection.

**Keywords:** CMV; Viral load; Nucleic acid extraction

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