

Product specification affigene® CMV trender

Technical specification

Code No	71000940 (48 tests)
Intended use	Monitoring of Cytomegalovirus (CMV) DNA in clinical samples
Regulatory status	CE labelled according to IVD Directive 98/79/EC Annex II List B for the complete process from sample preparation to result
Total kit size	48 determinations
Flexible run size	8-48 determinations per run (5-45 clinical samples)
Ready to use	All reagents provided in a ready-to-use format
Compatible profiles	Compatible profiles with other affigene trender assays enabling multitarget runs
Contamination prevention	UDG technology, Single-use reagents
Prev. of false neg. results	Internal Control introduced during sample preparation
Software provided	Results reported by the affigene® analysis software
Sample	Plasma (ACD, EDTA) and whole blood
PCR instrument compatibility	Validated according to CE/IVD standards for: Mx3000P/Mx3005P (Agilent/Stratagene) iCycler iQ/iQ5 (BioRad) Rotor-Gene 3000/6000 (Qiagen/Corbett Research) ABI 7300 (Applied Biosystems)
Sample preparation compatibility	Validated according to CE/IVD-standards for: affigene® DNA extraction (Cepheid AB) NucliSens easyMAG (bioMérieux)

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Performance characteristics

Dynamic range Plasma: ~100-1x10⁷ copies/ml
Whole blood: ~600-1x10⁷ copies/ml

Limit of Detection (LOD) Using affigene® DNA extraction:

Plasma 200µl protocol:
88 copies/ml (95% confidence interval: 61-234 copies/ml)

Whole blood 50 µl protocol:
590 copies/ml (95% confidence interval: 376-1240 copies/ml)

Using easyMAG:

Plasma 500 µl protocol:
57 copies/ml (95% confidence interval: 36-134 copies/ml)

Whole blood 100 µl protocol:
1300 copies/ml (95% confidence interval: 808-3244 copies/ml)

Quantitative range Using affigene® DNA extraction:
Plasma: 500 - 1.0x10⁷ copies/ml
Whole blood: 1000 - 1.0x10⁷ copies/ml

Using easyMAG:
Plasma: 100 - 2.0x10⁷ copies/ml
Whole blood: 1300 - 3.0x10⁶ copies/ml

Precision ≤ 0.19 log₁₀ throughout the quantitative range. Determined with different lots, different operators at different test occasions.

Subtype Inclusivity Equal sensitivity, specificity and amplification efficiency for Davies, AD169 and Towne.

Exclusivity and Microorganism Interference No cross-reactivity with HBV, EBV, VZV, HSV-1, and -2, HHV-6 A and B, HHV-7, HHV-8, other DNA and RNA viruses, human DNA, bacterial or fungal DNA.