

Product specification affigene® HSV 1/2 tracer

Technical specification

Code No	71001063 (48 tests)
Intended use	Separate detection of Herpes simplex virus-1 (HSV-1) and Herpes simplex virus-2 (HSV-2) DNA in clinical samples
Regulatory status	CE labelled according to IVD Directive 98/79/EC for the complete process from sample preparation to result
Total kit size	48 determinations
Flexible run size	8-48 determinations per run (6-46 clinical samples)
Ready to use	All reagents provided in a ready-to-use format
Compatible profiles	Compatible profiles with other affigene® tender/ tracer 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	CSF and vesicle swabs
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

Limit of Detection (LOD)	Using affigene® DNA extraction:
	Vesicle swabs 200µl protocol: 219 copies/ml (95% confidence interval: 150-389 copies/ml)
	CSF 200µl protocol: 178 copies/ml (95% confidence interval: 127-299 copies/ml)
	Using easyMAG:
	Vesicle swabs 500 µl protocol: 101 copies/ml (95% confidence interval: 69-194 copies/ml)
	CSF 200µl protocol: 133 copies/ml (95% confidence interval: 94-217 copies/ml)
Separate detection	HSV-1 and HSV-2 separately detected without cross-reactivity
Subtype Inclusivity	All known variants of HSV-1 and HSV-2 detected.
Exclusivity and Microorganism Interference	No cross-reactivity with relevant pathogens: CMV, EBV, VZV, HHV-6, HHV-7, HHV-8, Adenovirus, human DNA, bacterial or fungal DNA.
Robustness	200/200 replicates of a sample at a concentration of 650 copies/ml (approximately threefold concentration of LOD) were determined positive for either HSV-1 or HSV-2 DNA as well as for Internal Control.