

## Product specification affigene® VZV tracer

### Technical specification

<b>Code No</b>	71001053 (48 tests)
<b>Intended use</b>	Detection of Varicella Zoster virus (VZV) DNA in clinical samples
<b>Regulatory status</b>	CE labelled according to IVD Directive 98/79/EC for the complete process from sample preparation to result
<b>Total kit size</b>	48 determinations
<b>Flexible run size</b>	8-48 determinations per run (6-46 clinical samples)
<b>Ready to use</b>	All reagents provided in a ready-to-use format
<b>Compatible profiles</b>	Compatible profiles with other affigene® tender/ tracer assays enabling multitarget runs
<b>Contamination prevention</b>	UDG technology, Single-use reagents
<b>Prev. of false neg. results</b>	Internal Control introduced during sample preparation
<b>Software provided</b>	Results reported by the affigene® analysis software
<b>Sample</b>	CSF and vesicle swabs
<b>PCR instrument compatibility</b>	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)
<b>Sample preparation compatibility</b>	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:

328 copies/ml (95% confidence interval: 228-689 copies/ml)

CSF 200µl protocol:

168 copies/ml (95% confidence interval: 110-399 copies/ml)

Using easyMAG:

Vesicle swabs 500 µl protocol:

72 copies/ml (95% confidence interval: 47-167 copies/ml)

CSF 200 µl protocol:

110 copies/ml (95% confidence interval: 74-217 copies/ml)

**Subtype Inclusivity**

All known variants detected.

**Exclusivity and  
Microorganism  
Interference**

No cross-reactivity with EBV, CMV, Adeno, HHV-6 (U1102), HSV-1, HSV-2, HHV-6 (Z-29), HHV-7 and HHV-8, human DNA, bacterial or fungal DNA.

**Robustness**

108/108 replicates of a sample at a concentration of 900 copies/ml (approximately threefold concentration of LOD) were determined positive for VZV DNA as well as for Internal Control.