

## Product specification affigene® Aspergillus tracer

### Technical specification

<b>Code No</b>	71000935 (48 tests) 71900935 (16 tests)
<b>Intended use</b>	Detection of Aspergillus DNA in clinical samples
<b>Regulatory status</b>	CE labelled according to IVD Directive 98/79/EC
<b>Total kit size</b>	48 determinations / 16 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® treader/ 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>	Whole blood, serum and plasma (ACD, EDTA)
<b>PCR instrument compatibility</b>	Validated according to CE/IVD standards for: Mx (Stratagene): Mx3000P and Mx3005P iCycler (BioRad): iQ and iQ5 Rotor-Gene (Corbett Research): Rotor-Gene 3000



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### Performance characteristics

- Limit of Detection (LOD)** 0.54 genome equivalents/  $\mu$ L (95% confidence interval 0.42-0.80 genome equivalents/  $\mu$ L).
- Subtype Inclusivity** All clinically relevant variants detected:  
*Aspergillus (A) fumigatus, A. flavus, A. niger, A. clavatus, A. versicolor, A. terreus, A. nidulans, A. oryzae, A. ustus.*
- Exclusivity and Microorganism Interference** No cross-reactivity (verified by In-silico analysis):  
Fungus: *Exophiala dermatitidis, Acremonium reefeii, Cryptococcus neoformans, Scedosporium inflatum, Fusarium solani, Alternaria alternate, Blastomyces dermatitidis, Coccidioides immitis, Histoplasma capsulatum, Saccaromyces cervisiae, Candida albicans, Candida glabrata, Malassezia furfur, Trichosporon beigeli*  
Reacts with *Penicillium marneffeii*  
Virus: HBV, CMV, EBV, VZV, HSV-1, -2, HHV-6 A, B, HHV-7, HHV-8.  
Other DNA and RNA viruses: human DNA, bacterial DNA
- Robustness** 400/400 replicates of a sample at a concentration of 1.44 geq/  $\mu$ L (approximately threefold concentration of LOD) were determined positive for Aspergillus DNA as well as for Internal Control.

