

Product specification affigene® Aspergillus tracer

Technical specification

Code No	71000935 (48 tests)
Intended use	Detection of Aspergillus DNA in clinical samples
Regulatory status	CE labelled according to IVD Directive 98/79/EC
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® trender/ 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	Whole blood, serum and plasma (ACD, EDTA)
PCR instrument compatibility	Validated according to CE/IVD standards for: Mx3000P/Mx3005P (Agilent/Stratagene) iCycler iQ/iQ5 (BioRad) Rotor-Gene 3000 (Qiagen/Corbett Research) ABI 7300 (Applied Biosystems)

Product specification affigene® Aspergillus tracer

Performance characteristics

- Limit of Detection (LOD)** 0.54 genome equivalents/ μ L (95% confidence interval 0.42-0.80 genome equivalents/ μ 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, Saccharomyces cerevisiae, Candida albicans, Candida glabrata, Malassezia furfur, Trichosporon beigelii*
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/ μ L (approximately threefold concentration of LOD) were determined positive for Aspergillus DNA as well as for Internal Control.