

Aspergillus

Fungal Infections

Key Facts

- / Roughly 300 species of *Aspergillus* have been identified
 - *A. fumigatus* responsible for approx. 90 % cases of aspergillosis
 - *A. terreus*, *A. flavus*, *A. niger*, *A. nidulans* – the rest of approx. 10 % cases of aspergillosis
 - *A. terreus* – resistant to amphotericin B and to commonly used antifungal agents, associated with high mortality
- / Individuals with compromised immune system show development of aspergillosis

Aspergillosis

/ Invasive aspergillosis

Invasive Pulmonary Aspergillosis (IPA) affects respiratory system, lung parenchyma or distant organs via hematogenous pathway

- immunodeficient patients
- immunosuppressed patients

/ Semi-invasive aspergillosis

Aspergilloma, Chronic Pulmonary Aspergillosis (CPA)

- patients with heavy pulmonary tissue damage (TBC, chronic obstructive pulmonary disease, bronchiectasis, etc.)

/ Noninvasive aspergillosis

SAFS asthma, Allergic Bronchopulmonary Aspergillosis (ABPA)

- immunocompetent patients in contact with high infection dose of *Aspergillus*

CDC Statistics



/ ABPA

- 15 % patients with cystic fibrosis
- 2.5 % adults suffering from asthma, i.e. 4.8 mil. people worldwide
- 400 thousand people with ABPA at the same time suffer from chronic pulmonary aspergillosis

/ CPA

- 1.2 mil. people suffer from chronic pulmonary aspergillosis as a result of tuberculosis
- 70 thousand people suffer from CPA resulting from lung sarcoidosis complication

Diagnostics

/ Cultivation diagnostics methods – time consuming, not sensitive enough

/ Serology

/ Metabolites detection

/ Molecular detection of fungal DNA

/ The PCR kit is designed for the detection of the clinically significant representatives of the *Aspergillus* species (*A. fumigatus*, *A. flavus*, *A. niger*, *A. terreus*) causing serious infectious diseases especially in immunodeficient patients by the real-time Polymerase Chain Reaction (PCR) method.

The *Aspergillus* detection is based on the amplification of a specific sequence of ribosomal DNA and measuring the amplification product concentration growth using PCR process and fluorophore labelled probes. *Aspergillus spp.* presence is indicated by FAM fluorophore fluorescence growth and the presence of *Aspergillus terreus* is indicated by Cy5 fluorophore fluorescence growth. An Internal Standard (IS) is included in the reaction mix, controlling the possible inhibition of the PCR reaction (ISIN version) and possibly also the DNA extraction process quality (ISEX version). IS positive amplification is detected in the HEX fluorophore fluorescence channel. The detection kit utilizes the "hot start" technology, minimizing non-specific reactions and assuring maximum sensitivity. Ready to Use MasterMix contains uracil-DNA-glycosylase (UDG), eliminating possible contamination of the PCR reaction by amplification products. The kit performs very sensitive *Aspergillus* detection in clinical material (blood, plasma, serum, CSF, sputum, BAL). The kit is designed for *in vitro* diagnostics and provides qualitative detection.

technical specification

Technology	real-time PCR		
Target sequence	interface ITS2/28S rDNA		
Specificity	<i>Aspergillus spp.</i> (<i>Aspergillus fumigatus</i> , <i>Aspergillus flavus</i> , <i>Aspergillus niger</i> , <i>Aspergillus clavatus</i> , <i>Aspergillus nidulans</i> , <i>Aspergillus oryzae</i> , <i>Aspergillus ustus</i> , <i>Aspergillus versicolor</i> , <i>Aspergillus niveus</i> , <i>Aspergillus candidus</i> , <i>Aspergillus wentii</i> , <i>Aspergillus foetidus</i>) with <i>Aspergillus terreus</i> differentiation		
Clinical Sensitivity (LOD)	reaches 48.837 genomes/ml		
Analytical Sensitivity (LOD)	for <i>Aspergillus</i> species reaches 1.568 copies/μl with the probability of 95 % for <i>A. terreus</i> species reaches 1.724 copies/μl with the probability of 95 %		
Extraction / Inhibition Controls Included	control of PCR inhibition (ISIN version) control of PCR inhibition and quality of DNA Extraction (ISEX version)		
Sample Material	blood, plasma, serum, CSF, sputum, BAL		
Kit Storage	-85 °C to -10 °C		
Validated Isolations	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit		
Validated Real-Time PCR Devices	croBEE Real-Time PCR System LineGene 9600	Applied Biosystems 7500 Real-Time PCR System Rotor-Gene 3000/Q CFX96™/Dx Real-Time PCR Detection System	LightCycler® 480 SLAN® Real-Time PCR System
Quality Control	regularly tested by QCMD External Quality Assessment panels – results at www.geneproof.com		
Certification	CE IVD for <i>in vitro</i> Diagnostics Use		

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/ The Sample Pretreatment Set is designed for use in diagnostic laboratories dealing with routine PCR diagnostics of clinically significant representatives of the *Aspergillus* species.

The sample pretreatment step allows disintegration of the fungal cell wall, which subsequently increases the efficiency of DNA extraction. The set is designed for fungal DNA extraction from many types of clinical materials (blood, plasma, serum, CSF, sputum and BAL).

order

Product name	Technology	Cat. No.			
		10 preps.	25 reactions	50 reactions	100 reactions
GeneProof Aspergillus PCR Kit	real-time PCR	–	ASP/ISIN/025	ASP/ISIN/050	ASP/ISIN/100
GeneProof Aspergillus PCR Kit	real-time PCR	–	ASP/ISEX/025	ASP/ISEX/050	ASP/ISEX/100
GeneProof Aspergillus Sample Pretreatment Set	Pretreatment Set	ASP/010	–	–	–