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

Guaranteed control over the complete process of development, manufacturing and distribution of all the offered GeneProof products.
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 mitochondrial 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

<table>
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<tr>
<th>Technology</th>
<th>real-time PCR</th>
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<tr>
<td>Target sequence</td>
<td>interface ITS2/28S rDNA</td>
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### Specificity


### Clinical Sensitivity (LOD)

- Reaches 48.837 genomes/ml

### Analytical Sensitivity (LOD)

- For Aspergillus species reaches 1.568 copies/μl with the probability of 95%
- For A. terreus 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
- CFX96™/Dx Real-Time PCR Detection System SLAN® Real-Time PCR System

### Quality Control

- Regularly tested by QCMD External Quality Assessment panels — results at www.geneproof.com

### Certification

CE IVD for in vitro 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).

### Product Overview

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Technology</th>
<th>10 Preps.</th>
<th>25 Reactions</th>
<th>50 Reactions</th>
<th>100 Reactions</th>
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<td>ASP/ISIN/025</td>
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