

GeneProof Aspergillus Sample Pretreatment Set

In vitro diagnostic medical device

The kit has been manufactured according to EC Directive 98/79/EC as an *in vitro* diagnostic medical device and it has been designed for professional use in specialized clinical and research laboratories.

KIT CONTENT

| REF | Component | Preparations |
|----------------|--|--------------|
| ASP/010 | GeneProof Aspergillus Sample Pretreatment Set | 10 |
| 40040250 | MS1 | 1x400 µl |
| 40040249 | MS2 | 1x1500 µl |
| 40040251 | Sample pretreatment vial | 10 pcs |

STORAGE AND TRANSPORTATION CONDITIONS

The kit can be transported at temperature below -20 °C and after transport can be stored at temperatures between +15 °C and +25 °C. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept.

TECHNICAL SPECIFICATIONS

| | |
|------------------------------|--|
| Technology | preisolation step |
| Isolation principle | sample treatment before DNA isolation |
| Specificity | <i>Aspergillus</i> spp. |
| Sample volume | 1000 µl |
| Processing time | 15 min |
| Validated specimens | whole blood, plasma, serum, BAL, CSF, sputum |
| Storage | +15 °C to +25 °C |
| Validated extraction methods | croBEE NA16 Nucleic Acid DNA Extraction System GeneProof PathogenFree DNA Isolation Kit |
| External Quality Control | regularly tested by QCMD e.V. External Quality Assessment Panels |

METHOD PRINCIPLES

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 wall, which will subsequently increase the efficiency of DNA extraction. The set is designed for fungal DNA extraction from many types of clinical materials.

SAFETY INSTRUCTIONS

It is recommended that the GeneProof Aspergillus Sample Pretreatment Set is only used by demonstrably trained person with a focus on working with molecular biology techniques and the handling of potentially infectious biological material.

1. Before use

Read the Package insert carefully before operating with GeneProof Aspergillus Sample Pretreatment Set.

2. Handling requirements

Do not use kits after expiration date.

Avoid contact with skin, eyes and mucous membranes.

When contact with eyes, immediately rinse the affected area with plenty of water.

When outpouring of reagents, dilute spilled part with water and then wipe.

3. Laboratory procedures

Do not drink, eat and smoke in laboratory working area.

Wear protective disposable gloves, laboratory coats and goggles when handling reagents.


Avoid contamination with bacteria, viruses or nuclease.

Wash hands thoroughly after handling samples and test reagents..

4. Waste handling

Discard all unused reagents and waste complied with country, federal, state and local regulations.

The following components of the GeneProof Aspergillus Sample Pretreatment Set contain hazardous contents.

| Component | Hazard Contents | Hazard Symbols | Hazard Phrases |
|-----------|-----------------------------|--|----------------|
| MS1 | N-LAUROYLSARCOSINE (1 %) |  Warning | H319 |

Hazard Phrases

H319 Causes serious eye irritation

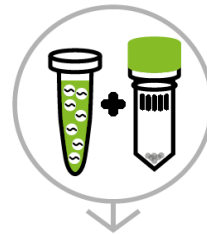
SAMPLE PREPARATION FOR ISOLATION

The protocol for isolation of *Aspergillus* spp. is based on 15min long preisolation processing of material with following utilization of croBEE NA16 Nucleic Acid Extraction System or/and GeneProof PathogenFree DNA Isolation Kit. In case of storing MS2 at temperatures lower than +20 °C a precipitate may be formed in the tube. In this case incubate the tube for several minutes at temperatures +30 °C to +40 °C and vortex well until the precipitate dissolve.

1 Material preparation

Add 1 ml of sample into a 2 ml Sample pretreatment vial.

Plasma, serum and blood dilute before isolation with Nuclease-free water in ratio 1:1. Sputum must be liquified by 0,1% dithiotreitol in ratio 1:1, incubated in 37 °C for 15 min and continuously vortexed

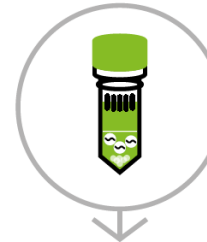


+ 1 ml of sample

2 Centrifugation

Centrifuge Sample pretreatment vial with 1 ml of sample for 1 min/11 000 g. Remove 850 µl of supernatant.

Leads to concentration of sample

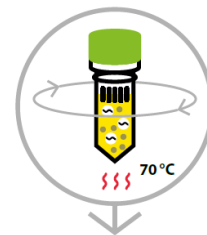


1 min
11 000 × g
- 850 µl of
supernatant

3 Sample lysis

To 150 µl of sediment add 25 µl MS1. Than add 100 µl MS2.

It is important to follow described order of added components!



+ 25 µl MS1
+ 100 µl MS2

4 Incubation

Incubate at 70 °C for 15 min, vortex repeatedly.

70 °C;
15 min

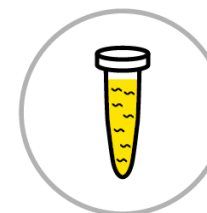
5 DNA isolation

When using GeneProof PathogenFree DNA Isolation Kit

- In step 5: remove 200 µl of incubated sample and transfer to new 1.5-2ml tube and continue isolation following instructions in the package insert

When using croBEE NA16 Nucleic Acid Extraction System

- In step 2: after centrifugation remove 700 µl of supernatant
- in step 3: to 300 µl of sediment add 25 µl MS1 and 100 µl MS2
- follow step 4 incubation
- in step 5: remove 400 µl of incubated sample and transfer to new sample tube, a part of package, and continue isolation following instructions in the package insert



WARNING

A single valid package insert for a specific kit is included in the package or to be requested for the particular lot from the manufacturer. The kit should be disposed of after use according to the current legal regulations considering the fact that the kit doesn't contain any dangerous, infectious or toxic components that would be subject to special safety regulations, and the packaging materials are made of paper and polypropylene. If you have any questions please contact our Customer Service.

Support and customer care

Phone: +420 543 211 679
Fax: +420 516 770 824
E-mail: support@geneproof.com

Orders

Phone: +420 543 211 679
Fax: +420 516 770 824
E-mail: sales@geneproof.com

