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Microbiological Assay

REF MSA05

120 tests

Filamentous Fungi Pretreatment Reagent

This is a reagent which used for pretreatment of Filamentous Fungi in the identification of measurand for using with AUTOF MS.

Key to Graphical Symbols Used

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	*in vitro* diagnostic medical device		temperature limitation
REF	catalogue number		consult instructions for use
EC REP	authorized representative in the European Community		date of manufacture

EC REP

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CE IVD

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Contact your local dealers for all product-related questions in your local language

Introduction

In the clinical microbiology laboratories, microbial identification is conventionally done by phenotypic and biochemical analysis mostly using automated systems. They are required time ranging from a few hours to several days depending on microbial species. MALDI-TOF MS technology makes generation of unique mass spectral fingerprints of microorganisms possible, which are mostly a snapshot of ribosomal proteins ideal for an accurate microbial identification at the species level.[1] MALDI-TOF MS can rapidly and accurately identify a wide range of microorganisms at a reasonable cost using only a portion or the entire colony and a drop of matrix solution.[2,3] This is a reagent which used for pretreatment of Filamentous Fungi in the identification of measurand for using with AUTOF MS.

Measurement Principle

The Filamentous Fungi Pretreatment Reagent is a reagent which used for pretreatment of filamentous fungi in the identification of measurand for using with AUTOF MS. The reagent breaks down the cell walls of filamentous fungi to release proteins for analysis using AUTOF MS. Perform the identification in accordance with the instruction of AUTOF MS.

Components

1. Filamentous Fungi Pretreatment Reagent

4 vials each containing solution with formic acid.
Reagent provided ready to use.

Σ	120 Tests
Filamentous Fungi Pretreatment Reagent	1.0 mL *4 vials

Note: The volume of the reagent indicated is the minimum dispensing volume.

Materials Required but not Provided

1. Micropipette
2. Centrifuge
3. 1.5mL Centrifuge tube
4. 75% ethanol
5. CHCA Matrix for use with AUTOF MS

Assay analyzers on which the reagent can be used

- AUTOF MS

The Filamentous Fungi Pretreatment Reagent is intended for use on Autof ms.

Warnings and Precautions

Health and safety information

For this reagent, which contains formic acid, the following statements apply.

GHS 05
Danger

H314 Causes severe skin burns and eye damage.
P260 Do not breathe dusts or mists.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

1. For professional use only. For *In Vitro* Diagnostic Use.
2. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this instruction for use.
3. When any damage to the protective packaging or any change of dissolubility or usage characteristic is observed, do not use the kit.
4. Avoid cross-contamination when using the micropipette.
5. Be aware of biosafety risks and operate in a biosafety cabinet.
6. Avoid vigorously shaking from formation of bubbles.
7. Consider the samples and reagents as potentially infectious material and deal them in accordance with local requirement.
8. Do not use reagent beyond the labeled expiry date. Store the remaining reagent at 2-8 ℃, and be certain the lid is securely sealed.
9. Handle the potentially contaminated materials and wastes safely according to local requirement.
10. Do not smoke, drink, eat or use cosmetics in the working area. Keep the reagents away from fire.
11. Wear protective clothing and disposable gloves when dealing with the Lysate. Wash hands after operations.
12. Conduct the dilution procedure away from bad ambient conditions. e. g. ambient air containing high concentration corrosive gas such as sodium hypochlorite acid, alkaline, acetaldehyde and so on, or containing dust.
13. The reagents have chemical hazard, avoid contact to skin or mucosa. If happened as follows:
    Skin or mucosa contact: Take off contaminated clothes, wash the area extensively with water, and seek for medical treatment if necessary.
14. Refer to the material safety data sheet and product labeling for any chemical hazards that may be present in this assay.

Storage

1. Store all components at 2-8 ℃. Avoid strong light. When stored as direction, the component is stable until the expiration date.
2. Store and seal the reagent at 2-8 ℃ after opening, under which conditions the stability will be retained for 30 days.

Sample

1. The product applies for the pretreatment of filamentous fungus samples.
2. The samples should be pure colony of Fresh filamentous fungus
3. After pretreatment, the sample shall be tested within 2 hours.

Pretreatment Procedure

1. Check the consumable materials
- Verify adequate volume of consumable materials is present prior to running the test.
- Refer to the AUTOF MS's operation manual.

2. Pretreatment tests
- Add 1.0mL of 75% ethanol into 1.5mL Centrifuge tube.
- Add a small amount of mycelium or/and spores to the centrifuge tube in a biosafety cabinet, and fully mixed. Culture medium should be avoided when collecting mycelium or/and spores.
- Centrifuge with 10000-13000 rpm for 2 minutes. Remove the

supernatant, but avoid removing any sample.
- Add 30 μL this reagent, mix sufficiently by pipetting or vortex.
- Add the mixture to the target slide and dry the sample spot without obvious water mark.
- Add 1μL CHCA Matrix for use with AUTOF MS, dry the sample spot and identify the sample with the instrument according to the AUTOF MS's operation manual.

Measurement Results

1. For identification of microorganisms, please analyze the results according to the methods of AUTOF MS system.

Limitations of the Procedure

1. This reagent cannot be used alone, it should be used together with CHCA Matrix for use with AUTOF MS and AUTOF MS system.
2. Mixed with the culture medium during pretreatment procedure may affect the test results.
3. If the amount of the samples is too little or insufficient (below the sensitivity of the AUTOF MS system), it may result in failure to report test results.
4. The test results cannot be effectively improved by using this kit because of the limitations of the MALDI-TOF MS.

Control Procedure

The recommended control procedure for this assay is to identify *Aspergillus fumigatus* ATCC®16903 and *Rhizopus oryzae* ATCC®56536 separately. Conduct the same operations as in **Pretreatment tests** procedure on two strains. The result should be species/genus identification, and also should be identified correctly to Aspergillus fumigatus and Rhizopus oryzae.

Performance Characteristics

Use Filamentous Fungi Pretreatment Reagent for pretreatment of 2 microorganisms (*Aspergillus fumigatus* ATCC®16903 and *Rhizopus oryzae* ATCC®56536) follow the instruction of **Pretreatment tests** section. The results were correctly identified to *Aspergillus fumigatus* and *Rhizopus oryzae*.

Literature References

1. A. Croxatto, G. Prod'hom, and G. Greub, "Applications of MALDI-TOF mass spectrometry in clinical diagnostic microbiology," *FEMS Microbiology Reviews*, vol. 36, no. 2, pp. 380-407, 2012.
2. M.A. Claydon, S.N. Davey, V. Edwards-Jines, and D. B. Gordon, "The rapid identification of intact microorganisms using mass spectrometry," *Nature Biotechnology*, vol. 14, no. 11, pp. 1584-1586, 1996.
3. R. D. Holland, J. G. Wilkes, F. Rafii et al., "Rapid identification of intact whole bacteria based on spectral patterns using matrix-assisted laser desorption/ionization with time-of-flight mass spectrometry," *Rapid Communications in Mass Spectrometry*, vol. 10, no. 10, pp. 1227-1232, 1996.