

Microbiological Assay

REF MSA03

0.5ml*4 Bottles

CHCA Matrix for use with AUTOF MS

CHCA Matrix for use with AUTOF MS is used in conjunction with AUTOF MS for pretreatment of bacteria and fungi (except for filamentous fungi) in clinical identification.

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Key to Graphical Symbols Used

LOT

batch code



use by



manufacturer



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

EC REP

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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] The ability of MALDI-TOF MS to directly identify bacteria in positive blood cultures is also important for the effective management of bloodstream infections.^[4,5]

Measurement Principle

The CHCA Matrix for use with AUTOF MS is used in the identification of bacteria and fungi (except for filamentous fungi) for use with MALDI-TOF MS. The CHCA Matrix can adsorb laser energy and transfer the energy to the microbial protein to create ions. Then the ions can be detected by the detector of MALDI-TOF MS. Perform the identification in accordance with the instruction of MALDI-TOF MS.

Components

1. CHCA Matrix

4 vials each containing 0.5ml of α -cyano-4-hydroxycinnamic acid.

Materials Required but not Provided

- 60% formic acid
- Micropipette

Assay Analyzers on which the reagent can be used

- Autof ms

The CHCA Matrix is intended for use on MALDI-TOF MS which is Autof ms.

Warnings and Precautions

Health and safety information

For CHCA Matrix, the following statements apply.



GHS 02
Danger

H225 Highly flammable liquid and vapour.
H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.
H319 Causes serious eye irritation.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P240 Ground/bond container and receiving equipment.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
H332 Harmful if inhaled.
H412 Harmful to aquatic life with long lasting effects.



GHS 05
Danger



GHS 07
Warning

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340+P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.

- For professional use only.
- 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.
- Handle the potentially contaminated materials and wastes safely according to local requirement.
- Do not smoke, drink, eat or use cosmetics in the working area. Keep the reagents away from fire.
- Wear protective clothing and disposable gloves when dealing with the reagent. Wash hands after operations.
- Do not use reagent beyond the labeled expiry date. Store the remaining solution at 2-8 °C, and be certain the lid is securely sealed.
- Do not mix or substitute reagent from other manufacturers.
- The presence of a small amount of yellow precipitation is normal, mix gently before use. If there is a large amount of precipitation, incubate the reagent at 37°C to make the crystal dissolved before use.
- Consider the samples and reagents as potentially infectious material and deal them in accordance with local requirement.
- 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.
- Refer to the material safety data sheet and product labeling for any chemical hazards that may be present in this assay.
- When any damage to the protective packaging or any change of dissolubility or usage characteristic is observed, do not use the kit.
- Avoid the culture medium when picking out the colony.
- Avoid cross-contamination when using the micropipette.
- The reagent is volatile, seal and return unused reagent to 2-8 °C in time.
- Calibrate the MALDI-TOF MS according to the instructions of the analyzer before the identification to avoid the deviation of the result due to the analyzer.

Storage

- Store the component at 2-8 °C. Avoid strong light.
- Do not freeze. When stored as direction, the component is stable until the expiration date.
- Seal and return opened reagent to 2-8 °C, under which conditions the stability will be retained for 30 days.

Sample

- Select fresh isolated colonies from patient sample source. For bacteria, culture the sample at appropriate temperature for 24 hours to obtain isolated colonies; for fungi, culture the sample at appropriate temperature for 36-48 hours to obtain isolated colonies.
- After pretreatment, the sample shall be identified within 2 hours.

Measurement Procedure

1. Check the consumable materials

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

2. Measurement tests

For measurement of bacteria:

- Smear some fresh colonies to the target slide uniformly.
- Overlay each sample spot with 1 μ l CHCA Matrix respectively, dry the sample spot without obvious water mark. Then identify the sample with MALDI-TOF MS.

For measurement of fungi:

- Smear some fresh colonies to the target slide uniformly.
- Overlay each sample spot with 1 μ l 60% formic acid respectively, dry the sample spot without obvious water mark.
- Overlay each sample spot with 1 μ l CHCA Matrix respectively, dry the sample spot without obvious water mark. Then identify the sample with MALDI-TOF MS.

Measurement Results

1. Analyse the identification results of microorganism according to the analysis method of microbial mass spectrometry.

Limitations of the Procedure

1. The product can't be used alone and should be used together with MALDI-TOF MS.
2. If the sample count is too little (less than the sensitivity of the MALDI-TOF MS), the result is unavailable.
3. When picking out the colony, avoid the culture medium, which may affect the identification results.
4. This reagent cannot be used for identification of filamentous fungi directly. Filamentous fungi can only be identified with this reagent after proper pretreatment.
5. The test results cannot be effectively improved by using this kit because of the limitations of the MALDI-TOF MS.

Performance Characteristics

1. Positive test

Identify the reference strains *E. Coli* ATCC®PTA-1977 and *Candida albicans* ATCC®10231 separately. Conduct the same operations as in **Measurement Procedure** on the two strains. The result is valid if the results are *E. Coli* and *Candida albicans*, and confirmed to the species level.

2. Negative test

Identify the CHCA Matrix directly, the result shall be negative.

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.
4. M. Drancourt, "Detection of microorganisms in blood specimens

using matrix-assisted laser desorption ionization time-of-flight mass spectrometry: a review," *Clinical Microbiology and Infection*, vol. 16, no. 11, pp. 1620-1625, 2010.

5. Y. Hoyos-Mallecot, C. Riazzo, C. Miranda-Casas, M. Rojo Martín, J. Gutiérrez-Fernández, and J. Navarro-Marí, "Rapid detection and identification of strains carrying carbapenemases directly from positive blood culture using MALDI-TOF MS," *Journal of Microbiological Method*, vol. 105, pp. 98-101, 2014.