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Microbiological Assay

REF MSA02

80 tests

Calibrator for use with AUTOF MS

Calibrator for use with AUTOF MS is used in conjunction with AUTOF MS for calibration of assay runs.

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		

EC REP

OBELIS S.A.
Bd. Général Wahis, 53
1030 Brussels
Belgium

AUTOBIO DIAGNOSTICS CO., LTD.
No.87 Jingbei Yi Road
National Eco & Tech Development Area
Zhengzhou
China
450016

CE IVD

For any technical assistance please contact us in English at:
Email: customerservice@autobio.com.cn
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] 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

Calibrator for use with AUTOF MS is a reagent which used for calibration of AUTOF MS. The Calibrator contains ribonuclease, myoglobin and protein extracted from *E. coli*, which shows typical peptide and protein peaks in MALDI-TOF MS.

Components

1. Calibrator

4 vials containing lyophilized purified protein mixture.

Materials Required but not Provided

1. Sample Pretreatment Reagent
2. Centrifuge
3. 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

1. For professional use only.
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. Handle the potentially contaminated materials and wastes safely according to local requirement.
4. Do not smoke, drink, eat or use cosmetics in the working area. Keep the reagents away from fire.
5. Wear protective clothing and disposable gloves when dealing with the Sample Pretreatment Reagent. Wash hands after operations.
6. 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.
7. Do not use reagent beyond the labeled expiry date. Store the remaining reagent at -20 ℃, and be certain the lid is securely sealed.
8. Do not mix or substitute reagent from other manufacturers.
9. The presence of a small amount of yellow precipitation in prepared matrix solution is normal, mix gently before use.
10. Consider the samples and reagents as potentially infectious material and deal them in accordance with local requirement.
11. 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.
12. When any damage to the protective packaging or any change of dissolubility or usage characteristic is observed, do not use the kit.
13. Mix the sample sufficiently with the reagents during the pretreatment process.
14. Avoid cross-contamination when using the micropipette.

Storage

1. Store all components at ≤ -20 ℃. When stored as direction, all components are stable until the expiration date.
2. Seal the calibrator after pretreatment at ≤ -20 ℃, under which conditions the stability will be retained for 30 days.
3. The Calibrator can be multiple frozen and thawed after dissolution.

Measurement Procedure

1. Check the consumable materials

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

2. Measurement

- Add 15 μL Lysate 1 to the Calibrator. Shake completely and mix well.
- Add 15 μL Lysate 2 to the Calibrator. Shake completely and mix well.
- Centrifuge the prepared Calibrator with 13000 rpm for 2 minutes.
- Inoculate 1 μL supernatant to the target slide and dry it.
- Overlay the sample spot with 1 μL matrix solution and dry it. Place the target slide into the analyzer.
- Calibrate the AUTOF MS according to the AUTOTOF MS's operation manual. If the calibration is successful, identify the sample with AUTOF MS. If the calibration fails, terminate the identification and repeat the above mentioned steps until the calibration is successful.

Measurement Results

1. Construct the database 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 AUTOF MS.
2. For calibration of AUTOF MS only.
3. The test results cannot be effectively improved by using this kit because of the limitations of the MALDI-TOF MS.

Performance Characteristics

1. Homogeneity

This Calibrator is designed to have a between-vial homogeneity of ≤ 0.2%.

This Calibrator is designed to have a within-vial homogeneity of ≤ 0.1%.

2. Magnitude accuracy

Identify the Calibrator with the MALDI-TOF MS, which was calibrated with the manufacturer's working calibrator, the bias shall be ≤ 0.1%.

3. Calibration accuracy

The calibration error range of the protein shall be within ±300ppm. The calibration information is listed in the following table:

Protein name	Molecular weight	Calibration error range (± 300ppm)
E.PM $3K^+$	3637.772 Da	3638.863 Da-3636.681 Da
E.PM $4K^+$	4365.343 Da	4366.653 Da-4364.033 Da
E.PM $5K^+$	5096.776 Da	5098.305 Da-5095.247 Da
E.PM $5.3K^+$	5381.446 Da	5383.060 Da-5379.832 Da
E.PM $6K^+$	6255.444 Da	6257.321 Da-6253.567 Da
E.PM $7K^+$	7274.467 Da	7276.649 Da-7272.285 Da
E.PM $10K^+$	10300.032 Da	10303.122 Da-10296.942 Da
R.PM $13K^+$	13683.173 Da	13687.278 Da-13679.068 Da
M.PM $16K^+$	16952.332 Da	16957.418 Da-16947.246 Da

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 carbapenemasses directly from positive blood culture using MALDI-TOF MS," *Journal of Microbiological Method*, vol. 105, pp. 98-101, 2014.