

## Certificate of Analysis

Product Name: MBT Sepsityper IVD Kit

Part No.: 1834338 LOT No.: 6010525007 Use by<sup>1)</sup>: 2027-04-30

Date of Production: 2025-06-13

Storage Conditions: All kit components must be stored at room temperature (15–25 °C).

## <u>Test</u> <u>Specification</u> <u>LOT Results</u>

Identification of Candida glabrata from a blood culture using the MALDI Biotyper and the MBT Sepsityper IVD Kit following the kit sample preparation procedure.

Classification Result Report Passed lists "Candida glabrata" as

the best match.

log(score) Value ≥ 2.00 of

Passed

Passed

the best match.

Identification of blank test samples using the MALDI Biotyper and the MBT Sepsityper IVD Kit following the kit sample preparation procedure. Classification Result Report lists "no peaks found" or "No Organism Identification Possible" as

the best match.

log(score) Value < 1.60 of

Passed

the best match.

## Remarks:

1) Kit components should be handled carefully to avoid contaminations.

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Quality Management