

Certificate of Analysis

Product Name: MBT Sepsityper IVD Kit

Part No.: 1834338 LOT No.: 6010524010 Use by¹⁾: 2026-07-31 Date of Production: 2024-09-27

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

Test Specification LOT Results

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 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.

Passed

Remarks:

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

Bruker Daltonics GmbH & Co. KG Fahrenheitstr. 4 28359 Bremen Germany Phone +49-421-2205-0

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Quality Management