

• Certificate of Analysis

Product Name : MBT Sepsityper IVD Kit

Part No.: 1834338

LOT No.: 6010525006

Use by¹⁾: 2027-04-30

Date of Production: 2025-06-18

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 <i>Candida glabrata</i> from a blood culture using the MALDI Biotyper and the MBT Sepsityper IVD Kit following the kit sample preparation procedure.	Classification Result Report lists „ <i>Candida glabrata</i> ” as the best match.	Passed
	log(score) Value ≥ 2.00 of the best match.	Passed
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.	Passed
	log(score) Value < 1.60 of 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

QC release date: 2025-06-20


Quality Management