

• Certificate of Analysis

Product Name : MBT Sepsityper IVD Kit

Part No. 1834338

LOT No.: 7010520007

Use by¹⁾: 2021-07-31

Date of Production: 2020-10-29

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. log(score) Value ≥ 2.0 of the best match.	Passed Passed
Identification of blank test samples based on one millilitre washing buffer using the MALDI Biotyper and the MBT Sepsityper IVD Kit sample preparation procedure.	Classification Result Report lists „no peaks found” or “no reliable identification” as the best match. log(score) Value < 1.6 of the best match.	Passed

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

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For In Vitro Diagnostic Use.