

• Certificate of Analysis

Product Name : MBT Sepsityper IVD Kit
Part No.: 1834338
LOT No.: 6010523006
Use by¹⁾: 2025-04-30
Date of Production: 2023-06-20
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.

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QC release date: 2023-06-20



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