

## • Certificate of Analysis

**Product Name :** MBT Sepsityper IVD Kit  
**Part No.:** 1834338  
**LOT No.:** 6010524012  
**Use by<sup>1)</sup>:** 2026-09-30  
**Date of Production:** 2024-12-17  
**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.<br><br>log(score) Value $\geq 2.00$ of the best match.                            | Passed<br><br>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.<br><br>log(score) Value $< 1.60$ of the best match. | Passed<br><br>Passed |

### Remarks:

<sup>1)</sup> Kit components should be handled carefully to avoid contaminations.

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 Quality Management