Certificate of Analysis

Product Name :	**MBT Sepsityper IVD Kit**
Part No.:	1834338
LOT No.:	6010526007
Use by[1]:	2028-07-30
Date of Production:	2026-07-30
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 lists „*Candida glabrata*" 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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Quality Management

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