

## Certificate of Analysis

Product Name:

MBT Sepsityper IVD Kit

Part No.

1834338

LOT No.:

7010521001

Use by1):

2022-08-31

**Date of Production:** 

2021-01-21

**Storage Conditions:** 

All kit components must be stored at room temperature (15-25 °C).

## Test:

## Identification of Candida glabrata from a blood culture using the MALDI Biotyper and the MBT Sepsityper IVD Kit following the kit sample preparation procedure.

## **Specification**

Classification Result Report lists "Candida glabrata" as the best

log(score) Value  $\geq 2.0$  of

the best match.

Passed

Passed

Passed

LOT Results

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.

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

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Dr. Markus Kostrzewa, SAFETY OFFICER

For In Vitro Diagnostic Use.