

Certificate of Analysis

Product Name:

MBT Sepsityper IVD Kit

Part No.:

1834338

LOT No.:

6010522007

Use bv1):

2024-03-31

Date of Production:

2022-06-30

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 Passed

lists "Candida glabrata" as

the best match.

log(score) Value ≥ 2.000 of

Passed

the best match.

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 Organism Identification Possible" as the best match.

Passed

log(score) Value < ≤ 1.699 of the best match.

Passed

Remarks:

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

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