

Certificate of Analysis

Product Name:

MBT STAR-Carba IVD Kit

Part No.:

1848467

LOT No.:

0000415053

Use by 1):

2023-11-30

Date of Production:

2023-01-06

Storage Conditions:

The MBT STAR-Carba IVD Kit is shipped at ambient temperature

but must be stored at -18 to -25°C immediately on arrival.

Test

Specification

LOT Results

1. Instrument calibration for MBT STAR-BL assay mass range using MBT STAR-BL IVD Module.

Successfull automated MBT STAR
Calibrator based instrument calibration.

Passed

2. MBT STAR-BL assay functional performance test using MBT STAR-Carba IVD Kit in accordance with the IFU.

MBT STAR-BL IVD Module results:

negative control (- ctrl) as
 non-hydrolyzed

Passed

positive control (+ ctrl; KPC) as hydrolyzed

Passed

3. negative QC Sample (- QC) as non-hydrolyzed

Passed

positive QC Sample (+ QC; NDM-1) as hydrolyzed

Passed

Remarks:

Kit components have to be handled carefully to avoid contaminations.

1) If stored unopened at -18 to -25°C the product is stable until expiration date.

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