

Certificate of Analysis

Product Name: MBT STAR-Cepha IVD Kit

 Part No.
 1858555

 LOT No.:
 6000396824

 Use by:
 2023-01

 Date of Production:
 2022-04-01

 QC release date:
 2022-04-08

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

Instrument calibration for MBT STAR-BL Assay mass range using MBT Compass IVD and MBT STAR-BL IVD Module.

Successfully automated MBT STAR Calibrator based instrument calibration.

Passed

Passed

Passed

Passed

MBT STAR-BL Assay Performance Test using MBT STAR-Cepha IVD Kit according to the IFU

MBT STAR-BL IVD Module Results:

1. negative control (- ctrl) as

non-hydrolyzed

2. positive control (+ ctrl) as

hydrolyzed

3. negative QC Sample (- QC) as

non-hydrolyzed

4. positive QC Sample (+ QC) as

hydrolyzed

Passed

Remarks:

Kit components have to be handled carefully to avoid contaminations.

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

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For In Vitro Diagnostic Use.