

● Certificate of Analysis

Product Name : MBT STAR-Cepha IVD Kit

Part No. 1858555
 LOT No.: 0000350333
 Use by: 2021-04
 Date of Production: 2020-06-09
 QC release date: 2020-06-05

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.**

<u>Test</u>	<u>Specification</u>	<u>LOT Results</u>
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
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 Passed Passed 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.