

• Certificate of Analysis

Product Name : MBT STAR-Carba IVD Kit

Part No. 1848467
 LOT No.: 0000351107
 Use by: 2021-04
 Date of Production: 2020-06-19

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:	
	Sample 1	Passed
	Sample 2	Passed
	Sample 3	Passed
	Sample 4	Passed
	Sample 5	Passed

MBT STAR-BL Assay Performance Test using MBT STAR-Carba IVD Kit according to the IFU	MBT STAR-BL IVD Module Results:	
	1. negative control (- ctrl) as non-hydrolyzed	Passed
	2. positive control (+ ctrl; KPC) as hydrolyzed	Passed
	3. negative QC Sample (- QC) as non-hydrolyzed	Passed
	4. positive QC Sample (+ QC; NDM-1) 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.