

• Certificate of Analysis

Product Name : **MBT STAR-Carba IVD Kit**

Part No. **1848467**
 LOT No.: **6000380016**
 Use by: **2022-05**
 Date of Production: **2021-08-16**

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 | 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.

Bruker Daltonics GmbH & Co. KG, Germany
 Fahrenheitstr. 4 – 28359 Bremen
 phone +49-421-2205-0



BRUKER
 Bruker Daltonics GmbH & Co. KG
 Fahrenheitstr. 4
 D-28359 Bremen
 Phone +49 (0)421 - 2205-370
Dr. Markus Kostrzewa, SAFETY OFFICER

For In Vitro Diagnostic Use.