

Certificate of Analysis

Product Name:

IVD Bacterial Test Standard

Part No.

8290190

LOT No.:

0000320877

Use by¹⁾:

2020-06-30

Date of Production:

2019-07-08

QC release date:

2019-08-19

Storage Conditions:

Store at -18 °C or below immediately on arrival.

| <u>Test</u> | Specification | LOT Results |
|--|---|-------------|
| Verification of the calibration points by MALDI-TOF MS | Within a mass range of ± 900ppm | Passed |
| Relative intensity of reference proteins No. 3 by MALDI-TOF MS | 0.20 ± 0.05 | Passed |
| Relative intensity of reference proteins No. 4 by MALDI-TOF MS | 0.22 ± 0.05 | Passed |
| MALDI Biotyper identification | Classification Result Report lists "Escherichia coli" as best match. | Passed |
| | log(score) Value ≥ 2.2 of the best match | Passed |

Remarks:

1) IVD BTS is shipped at ambient temperature but must be stored at -18°C or below immediately on arrival. The expiry date on the package is valid for the enclosed IVD BTS when stored at -18°C or below on arrival. Frozen, dissolved Bruker IVD BTS can be stored for up to 5 months at -18°C or below. See instruction for use at www.bruker.com/qare.

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