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Instructions for Use

IVD Bacterial Test Standard

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CE IVD

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Regulatory notices

Read the Instructions for Use before use and follow the directions that are described in it.

Note If any serious incident occurs in relation to the device, this shall be reported to the manufacturer and to the competent authority of your localization. Use the following e-mail address: complaints.bdal@bruker.com

Bruker Daltonics GmbH & Co. KG makes no warranty or guarantee of any kind with respect to the performance of this product, when not used in accordance with this IFU, and/or if used for purposes outside the claimed Intended Use.

Document history

Title:	Instructions for Use IVD Bacterial Test Standard
Revision:	Revision L1 (February 2022)
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The following table describes important changes from the previous revision of this document.

Section	Changes
-	Chapters added to comply with IVDR requirements

Table of contents

1 Intended purpose

IVD Bacterial Test Standard is an *in vitro* diagnostic device for control and optimization of the Bruker IVD MALDI Biotyper System.

It is used in conjunction with the semi-automated Bruker IVD MALDI-TOF mass spectrometer, software, reference libraries, and reagents of the MALDI Biotyper workflow for qualitative identification of microorganisms cultured from clinical samples from human specimens.

This product is intended for Professional Use only.

2 Precautions and warnings

The following safety information apply to the use of this product.

2.1 General precautions

Check the IVD Bacterial Test Standard, referred to as IVD BTS, package on arrival. If it is damaged, check the tubes. If the tubes are damaged, the IVD BTS must not be used.

You are obliged to consult all relevant Safety Data Sheets that are available at www.bruker.com/msds. In case further reagents or reagent mixtures are used to perform IVD MBT workflows, you are also obliged to read the reagents' Safety Data Sheets that are provided by the supplier.

2.2 Precautions for handling the product

Make sure that you wear appropriate personal protective equipment at all times:

- lab coat
- protective gloves
- safety glasses

Observe federal, state, and local regulations. Make sure that personal protective equipment is in good condition.

IVD BTS should be handled with the care that is necessary when dealing with chemicals. Further hazardous properties cannot be excluded.

2.3 Precautions for handling specimens

The Bruker IVD MALDI Biotyper System may deal with potentially dangerous biological material. Every person that works with this system is responsible for reading and following all necessary health and safety precautions.

All samples and microbial cultures or associated materials and equipment must be considered potentially infectious. Only qualified and trained laboratory staff are allowed to work with the IVD BTS in combination with the Bruker IVD MALDI Biotyper System, and they are responsible for taking and following all necessary safety precautions for handling potentially infective material.

2.4 Disposing of product, samples, and packaging

Dispose of the IVD BTS tubes and package following community waste disposal authority guidelines. During sample preparation onto MALDI target plates, some reagents are mixed with microorganisms and consequently with potentially dangerous biological material.

Some of the accessories and consumables that are used will come into contact with microorganisms. It is the operator's responsibility to carefully handle, correctly dispose of, and decontaminate the relevant substances, accessories, and consumables according to national or local safety regulations.

3 Product description

The IVD BTS contains an extract of *Escherichia coli* DH5 alpha that shows a characteristic peptide and protein profile in MALDI-TOF mass spectra. The extract is spiked with two additional proteins that extend the upper boundary of the mass range covered by IVD BTS. The overall mass range covered by IVD BTS is m/z 3,600 to m/z 17,000.

3.1 Fields of application

The IVD BTS is designed to be used as a system performance check for a Bruker IVD MALDI Biotyper System. It is prepared on MALDI target plates, for example, MBT Biotarget 96, MSP 48 target polished steel BC, MSP 96 target polished steel BC, which are used as a tool for IVD MBT mass spectra acquisition and identification. Microorganisms or IVD BTS to be identified, either an individual colony from a culture plate or a cell extract, are transferred to a selected position on a MALDI target plate. The MALDI target plate is dried and matrix is added.

When the matrix has crystallized and is completely dry, the prepared MALDI target plate is ready to be analyzed using the MBT Compass IVD or MBT Compass HT IVD software.

For more information on processing samples and on the test principle, see the User Manual of the MBT Compass IVD or MBT Compass HT IVD software.

3.2 Product content

IVD BTS is provided in 0.5 mL screw cap tubes. One (1) package unit contains five (5) IVD BTS tubes. The product is lyophilized. After reconstitution, one (1) IVD BTS tube contains enough material for the preparation at least thirty-five (35) MALDI target plate spots.

3.3 Materials required

The IVD BTS is to be used in conjunction with any Bruker IVD MALDI Biotyper System.

The following hardware, consumables, reagents, solvents, and software are required in order to use the product as intended, and can be ordered separately:

Note Prepare the IVD Matrix HCCA-portioned solution as described in the relevant Instructions for Use.

Product	Part number
Screw cap micro tubes, Sarstedt	72.730.003
Screw caps, Sarstedt	65.716.002
IVD Matrix HCCA-portioned	8290200

A standard solvent containing acetonitrile 50%, water 47.5%, and trifluoroacetic acid 2.5% is required to use the product as intended:

Note Bruker has tested the standard solvents and recommends these for the dissolution of IVD BTS. Any of the solvents in the list may be used.

Note As an alternative to using the recommended commercially available standard solvent, you can mix 475 µL HPLC-grade water, 25 µL trifluoroacetic acid, and 500 µL acetonitrile in a 1.5 mL Eppendorf tube to produce 1 mL standard solvent.

Product	Provider	Part number
Bruker standard solvent	Sigma Aldrich https://www.sigmaaldrich.com	900666
Acetonitrile 50%, Water 47.5% and Trifluoroacetic acid 2.5%	Honeywell Riedel-de Haen https://www.lab-honeywell.com	19182
SOLUTION OS	VWR International https://de.vwr.com	PRLS89449.230

Depending on your workflow, the following MALDI target plates are compatible:

Product	Part number
MBT Biotarget 96 IVD	1839298
MSP Biotarget Adapter	8267615
MSP 48 target polished steel BC	8281817
MSP 96 target polished steel BC	8280800

Depending on your configuration, your Bruker IVD MALDI Biotyper System uses the following MALDI Biotyper software:

Product	Part number
MBT Compass IVD	1832771
MBT Compass HT IVD	1877017

Equipment and tools

- Centrifuge
- Pipette tips
- Pipettes

Further Bruker IVD consumables and kits may be used depending on the desired application. Refer to the corresponding Instructions for Use. Contact you local Bruker representative for availability in your country.

3.4 Storage and stability

The following conditions apply for the storage of the product.

3.4.1 Storage on arrival

	–18°C	IVD BTS is shipped at ambient temperature but must be stored at –18°C or below immediately on arrival. The use-by date on the package is valid for the enclosed IVD BTS when stored at –18°C or below on arrival. Do not use beyond the use-by date noted on the package.

3.4.2 Storage after dissolution and aliquoting

IVD BTS must be dissolved before use. We strongly recommend to aliquot IVD BTS solution in 0.5 mL Sarstedt screw cap micro tubes with Sarstedt screw caps and to store the aliquots frozen at –18°C or below.

	–18°C	Frozen IVD BTS solution can be stored for up to 5 months at –18°C or below.

4 Test procedure

The test procedure of the IVD Bacterial Test Standard includes the preparation of IVD BTS samples.

For more details on sample preparation methods, refer to the User Manuals MBT Compass IVD and MBT Compass HT IVD.

4.1 Preparing the IVD BTS sample

The generation of ions through MALDI depends on the presence of an optimal ratio of matrix substance to analyte.

For best results, use freshly prepared solutions and chemicals of HPLC or MALDI-compatible grade, for example, LC-MS grade, solvents. Consider the use-by date of the solvent provider.

Note Make sure that the storage container of the standard solvent is tightly closed after use to minimize solvent evaporation.

4.1.1 Preparing the IVD BTS aliquots

1. Remove IVD BTS containing screw cap tube from the freezer and equilibrate for at least 5 minutes at room temperature.
2. Add 50 µL of standard solvent to the IVD BTS pellet and dissolve by pipetting up and down at least 20 times at room temperature. Close the tube tightly.

   Avoid foaming of the solution.
3. Incubate the IVD BTS solution for at least 5 minutes at room temperature and then mix by pipetting up and down at least 20 times. Close the tube tightly.
4. Centrifuge briefly, about 10 seconds; full speed; room temperature.
5. Pipette 5.0 µL aliquots of the IVD BTS solution into Sarstedt screw cap micro tubes and close tubes tightly.
6. Store the aliquots at –18°C or below.

4.1.2 Preparing the IVD BTS sample on a MALDI target plate

Note Frozen IVD BTS solution must be thawed at room temperature for at least 5 minutes and mixed by flicking the screw cap micro tube with a finger. Centrifuge briefly, about 10 seconds; full speed; room temperature. Screw cap micro tubes must be closed tightly and stored at –18°C or below immediately after preparation of IVD BTS spot(s). Each 5 µL aliquot contains enough material for at least four (4) spots. IVD BTS must be prepared onto each MALDI target plate before processing.

Note Prepared MALDI target plates must be measured within 24 hours of preparation. If more than 24 hours have elapsed since preparation, sample prepared MALDI target plate cannot be tested and sample preparation procedure must be repeated.

1. Pipette 1 µL IVD BTS solution onto at least one (1) unoccupied MALDI target plate position.

Note Make sure that the screw cap tube containing IVD BTS solution is tightly closed after use to minimize solvent evaporation.

2. Allow the IVD BTS spot(s) to dry at room temperature.

Note If IVD HCCA solution is not added to IVD BTS spot(s) within 30 minutes after they have dried, these positions cannot be tested.

3. Overlay the IVD BTS spot(s) with 1 µL IVD HCCA solution.

Note Make sure that the screw cap tube containing IVD HCCA solution is tightly closed after use to minimize solvent evaporation.

4. Dry again at room temperature.

A homogeneous preparation should be observed.

5 Troubleshooting

This section describes potential sources of user application failures that may happen during IVD BTS sample preparation and suggests measures for their minimization.

Dissolution of IVD BTS

Scenario	Potential cause	Recommended action
Calibration or validation failed	Target cleaning incomplete (additional peaks from previous sample spot detected)	Follow the instructions on cleaning and storing reusable MALDI target plates in the User Manual MBT Compass IVD or MBT Compass HT IVD. Make sure that all required steps were performed. Repeat target cleaning procedure and repeat IVD BTS sample preparation.
	Problematic reagents used for dissolution of IVD BTS (contamination leads to poor sample preparation)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that recommended chemicals or chemicals of the highest purity available were used.
	Erroneous dissolution procedure of IVD BTS (wrong volume of standard solvent added)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the correct volume of standard solvent was added.
	Incomplete mixing or incubation procedure for reconstitution of IVD BTS (less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the correct number of pipetting steps and the correct incubation time were applied.
	Reconstituted IVD BTS screw cap micro tube not immediately closed after sample preparation (ACN evaporated or less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the reconstituted IVD BTS screw cap micro tube was tightly closed after sample preparation.
	Reconstituted IVD BTS screw cap micro tube not immediately stored at ≤-18°C after sample preparation (oxidation of IVD BTS or less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the dissolved IVD BTS screw cap micro tube was immediately stored at ≤- 18°C after sample preparation.
	IVD BTS screw cap micro tube used after expiry date (less than eight calibration peaks found)	Refer to IVD BTS Storage and stability, section 3.4. Make sure that the IVD BTS screw cap micro tube was not used after expiry date.

Preparation of IVD BTS aliquots

Scenario	Potential cause	Recommended action
Calibration or validation failed	Target cleaning incomplete (additional peaks from previous sample spot detected)	Follow the instructions on cleaning and storing reusable MALDI target plates in the User Manual MBT Compass IVD or MBT Compass HT IVD. Make sure that all required steps were performed. Repeat target cleaning procedure and repeat IVD BTS sample preparation.
	Problematic plastic ware used for generation of aliquots (polymer leached from plastics or cap does not close tightly)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that plastic ware used for preparation of IVD BTS aliquots has been qualified , see section 3.3. Do not use plastic ware that has not been validated. Repeat preparation of IVD BTS aliquots using validated plastic ware.
	Erroneous preparation of IVD BTS aliquots (wrong aliquots pipetted or less than 4 sample spots possible)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the correct aliquots were pipetted.
	Incomplete thawing or mixing procedure for reconstitution of IVD BTS aliquots (less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the thawing process had been completed and that mixing was performed by flicking the tube with a finger.
	Final centrifuge step of thawed IVD BTS screw cap micro tube missing (less than eight calibration spots)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the final centrifuge step was carried out.
	Reconstituted IVD BTS aliquot not immediately closed after sample preparation (acetonitrile evaporated / less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the reconstituted IVD BTS aliquot was tightly closed after sample preparation.
	Reconstituted IVD BTS aliquot not immediately stored at ≤- 18°C after sample preparation (oxidation of BTS / less than eight calibration peaks found)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the reconstituted IVD BTS aliquot was immediately stored at ≤-18°C after sample preparation.
	IVD BTS aliquot used after expiry date (less than eight calibration peaks found)	Refer to IVD BTS Storage and stability, section 3.4. Make sure that the IVD BTS aliquot was not used after expiry date.

Scenario	Potential cause	Recommended action
Less than 4 calibration or validation spots	Erroneous preparation of IVD BTS aliquot (wrong aliquots pipetted / less than 4 sample spots possible)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the correct aliquot was pipetted.
	Final centrifuge step of thawed IVD BTS aliquot was missing (less than 4 sample spots possible)	Refer to the IVD BTS sample preparation procedure described in section 4.1. Make sure that the final centrifuge step was carried out.

Preparation of IVD BTS Sample on a MALDI target plate

Scenario	Potential Cause	Recommended Action
Calibration or validation failed	Target cleaning incomplete (additional peaks from previous sample spot detected)	Follow the instructions on cleaning and storing reusable MALDI target plates in the User Manual MBT Compass IVD or MBT Compass HT IVD. Make sure that all required steps were performed. Repeat target cleaning procedure and repeat testing.
	Incomplete sample preparation (forgot to add sample and/or matrix to the MALDI target plate)	Follow the suitable procedure for Direct Transfer sample preparation, extended Direct Transfer sample preparation, or Extraction sample preparation in the User Manual MBT Compass IVD or MBT Compass HT IVD. Make sure that all required steps were performed. Repeat preparation.
	Incorrect sample preparation (excessive or insufficient amount of inoculum)	Follow the suitable procedure for Direct Transfer sample preparation, extended Direct Transfer sample preparation, or Extraction sample preparation in the User Manual MBT Compass IVD or MBT Compass HT IVD. Check inoculum size. Repeat testing.
	Incorrect sample preparation (sample spot not completely dried)	Follow the suitable procedure for Direct Transfer sample preparation, extended Direct Transfer sample preparation, or Extraction sample preparation in the User Manual MBT Compass IVD or MBT Compass HT IVD. Check, whether sample spot was completely dried before matrix addition. Repeat testing.
	Delayed Matrix overlay (oxidation of BTS)	Follow the suitable procedure for Direct Transfer sample preparation, extended Direct Transfer sample preparation, or Extraction sample preparation in the User Manual MBT Compass IVD or MBT Compass HT IVD. Make sure that IVD BTS was overlaid - after drying - with reconstituted matrix solution.
	Application of excessive amounts of oxidative disinfectants to disinfect laboratory and equipment at customer's site. This could lead to a high concentration of oxidative disinfectant in the gas phase in the laboratory air, which may lead to condensation of aerosols on the MALDI target plate surface.	Follow the instructions on cleaning and storing reusable MALDI target plates in the User Manual MBT Compass IVD or MBT Compass HT IVD. Store MALDI target plates in a dry place at room temperaturein in a transport box or any suitable box other than the one in which the MALDI target plates are shipped. Avoid exposing IVD BTS to potential sources of contamination, for example, dust, or corrosive atmospheres, for example, high amounts of oxidative disinfectants. If possible, store the MALDI target plates outside of the laboratory during the disinfection of the laboratory.

6 Limitations of the method

You may use the IVD BTS only in combination with a Bruker IVD MALDI Biotyper System, dedicated software, and further consumables of the Bruker IVD MALDI Biotyper System portfolio, see section 3.3.

For specific limitations of the method, refer to the User Manual of MBT Compass IVD or MBT Compass HT IVD.

Use of the IVD BTS is limited to users that are trained in the procedure. Bruker provides training during the commissioning of a Bruker IVD MALDI Biotyper System.

7 Performance characteristics

As the IVD BTS is to be used in combination with further Bruker IVD devices, performance characteristics were obtained for the entire workflow.

You can find details on the performance of the entire workflow in the User Manuals of MBT Compass IVD or MBT Compass HT IVD.

8 Abbreviations

BTS	Bacterial Test Standard
HCCA	α-Cyano-4-hydroxycinnamic acid
HT	High throughput
IFU	Instructions for Use
IVD	*In vitro* diagnostic
MALDI-TOF	Matrix-Assisted Laser-Desorption Ionization – Time of Flight
MBT	MALDI Biotyper
MSP	microScout plate

9 Symbols

The following symbols are used in the labeling:

	Catalog number
	CE mark
	*In vitro* diagnostic medical device
	Temperature limit
	Manufacturer
	Batch code
	Use-by date
	Consult Instructions for Use

10 Manufacturer

Bruker Daltonics GmbH & Co. KG
Fahrenheitstraße 4
28359 Bremen
Germany

Support

Email: biotyper.support@bruker.com
Phone: +49 (421) 2205-1401
Fax: +49 (421) 2205-106

Sales information

Email: care@bruker.com
Phone: +49 (421) 2205-0
Web: www.bruker.com/care

Ordering information

Product	Part number
IVD Bacterial Test Standard, 5 tubes	8290190

For Australian customers:

Bruker Pty. Ltd.
1/28a Albert Street
Preston
Victoria 3072
Australia

Support (hardware and software)
Email: biotyper.anz@bruker.com
Phone: +61 (1800) 171-247

Sales
Email: sales.anz@bruker.com
Phone: +61 (1800) 278-537
Fax: +61 (03) 9474-7070

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