



Instructions for Use

IVD Matrix HCCA-portioned

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Language: en

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 Matrix HCCA-portioned
Revision:	Revision M (February 2022)
First revision:	July 2014

The following table describes important changes from the previous revision of this document.

Section	Changes
-	Chapters added to comply with IVDR requirements
4	Removed sample preparation procedures

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1 Intended purpose

IVD Matrix HCCA-portioned is an *in vitro* diagnostic device that serves as matrix for measurements with 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 Matrix HCCA-portioned, referred to as IVD HCCA, package on arrival. If it is damaged, check the tubes. If the tubes are damaged, the IVD HCCA must not be used.

	<p>CAUTION</p> <p>Risk of skin, eye, and respiratory irritation</p> <p>This product contains α-Cyano-4-hydroxycinnamic acid. If swallowed, inhaled, or getting in contact with skin, it may cause severe skin, eye, and respiratory irritations.</p> <p>Do not inhale vapors and aerosols. Use protective gloves, clothing, and eye protection.</p>
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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 HCCA should be handled with the care that is necessary when dealing with chemicals. Further hazardous properties cannot be excluded.

2.3 Precautions for handling the specimens

The IVD HCCA as consumable of 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 HCCA and 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

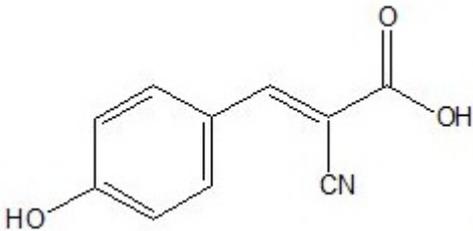
Dispose of the IVD HCCA tubes and package following community waste disposal authority guidelines. During sample preparation onto MALDI target plates, some reagents are mixed with microorganisms and consequently with potentially dangerous biological material.

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

IVD HCCA is a consumable within the IVD MALDI Biotyper workflow for identification of microorganisms by IVD MALDI-TOF mass spectrometry. In this IVD MALDI Biotyper workflow, the IVD HCCA is used in combination with a mass spectrometer, software and reference libraries, a MALDI target plate, and a calibration standard for identification of unknown microorganisms in samples that are sub-cultured from human specimens.

IVD HCCA enables the preparation of MALDI matrix solution for IVD MALDI-TOF-MS measurement of peptides and proteins.

Synonyms	2-Cyano-3-(4-hydroxyphenyl) acrylic acid
Molecular formula	C ₁₀ H ₇ NO ₃
Structural formula	
Molecular weight	189.17 g/mol
CAS number	28166-41-8
EC number	248-879-1
Melting point	245-250°C

3.1 Fields of application

The IVD HCCA is designed to overlay dried test organisms or IVD BTS which are prepared on MALDI target plates, for example, MBT Biotarget 96 IVD, MSP 48 target polished steel BC, MSP 96 target polished steel BC, with a defined amount of matrix material for optimal analyte/matrix ionization process in an Bruker IVD MALDI Biotyper System.

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 HCCA is provided in 2.0 mL screw cap tubes with 2.5 (± 0.3) mg of lyophilized IVD HCCA matrix. One (1) package unit contains ten (10) IVD HCCA tubes.

3.3 Materials required

The IVD HCCA 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 Bruker IVD Bacterial Test Standard solution as described in the relevant Instructions for Use.

Product	Part number
Bruker IVD Bacterial Test Standard, 5 tubes	8290190

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 HCCA. 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

- Vortex mixer
- 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 your 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

+2°C		+8°C	<p>IVD HCCA is shipped at ambient temperature.</p> <p>The use-by date on the package is valid for the product when stored in a refrigerator at 2°C to 8°C immediately on arrival. Do not use beyond use-by date noted on the package.</p>
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3.4.2 Storage after dissolution

+20°C		+25°C	<p>IVD HCCA solution is stable at controlled room temperature (20°C to 25°C) for up to one (1) week after first opening.</p>
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4 Test procedure

To be able to use the matrix, IVD HCCA must be dissolved first.

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

4.1 Dissolving IVD HCCA

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.

After the samples have dried, test organisms and IVD BTS must be overlaid with IVD HCCA within 30 minutes.

1. Add 250 μL standard solvent to the screw cap tube containing IVD HCCA and close the tube tightly. The final concentration will be 10 mg IVD HCCA/mL accordingly.
2. Dissolve IVD HCCA at room temperature by using a vortex mixer. Make sure all crystals are completely dissolved.
3. Shake the contents down.

The IVD HCCA is ready for use.

5 Troubleshooting

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

Scenario	Potential cause	Recommended action
No IVD MBT ID of test organisms (reduced log (scores))	Erroneous dissolution procedure of IVD HCCA (wrong volume of standard solvent added)	Refer to the IVD HCCA test procedure as described in section 4. Make sure that you add the correct volume of standard solvent.
	Problematic reagents used for dissolution of IVD HCCA (contamination leads to poor sample preparation)	Refer to the IVD HCCA test procedure as described in section 4. Make sure that you use the recommended chemicals or chemicals of the highest purity available.
	IVD HCCA screw cap micro tube used after use-by date	Refer to Storage and stability, section 3.4. Make sure that you do not use the IVD HCCA screw cap micro tube after use-by date.
	Reconstituted IVD HCCA solution used after use-by date	Refer to Storage and stability, section 3.4. Make sure that you do not use the reconstituted IVD HCCA solution after use-by date.
	Tube containing reconstituted IVD HCCA solution not immediately closed after sample preparation (acetonitrile evaporated → precipitation of IVD HCCA)	Refer to Storage and stability, section 3.4. Make sure that you close the reconstituted IVD HCCA solution tightly after sample preparation.
	Tube containing reconstituted IVD HCCA solution stored in the fridge → precipitation of IVD HCCA	Refer to Storage and stability, section 3.4. Make sure that you do not store the reconstituted IVD HCCA solution in the fridge after sample preparation.
	Test organisms or IVD BTS not overlaid with IVD HCCA within 30 minutes → side chain reactions	Refer to the IVD HCCA test procedure as described in section 4. Make sure that - after drying - you overlay the test organisms or IVD BTS with reconstituted IVD HCCA solution.
IVD MBT System not started or no peaks found	Test organisms or IVD BTS not overlaid with IVD HCCA → IVD MBT System not started or test organisms not identified	Refer to the IVD HCCA test procedure as described in section 4. Make sure that you overlay the test organisms or IVD BTS with reconstituted IVD HCCA solution.

6 Limitations of the method

You may use the IVD Matrix HCCA-portioned 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 Matrix HCCA-portioned 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 Matrix HCCA-portioned 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	<i>In vitro</i> 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:

	Warning
	Catalog number
	CE mark
	<i>In vitro</i> 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 Matrix HCCA-portioned, 10 tubes	8290200

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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