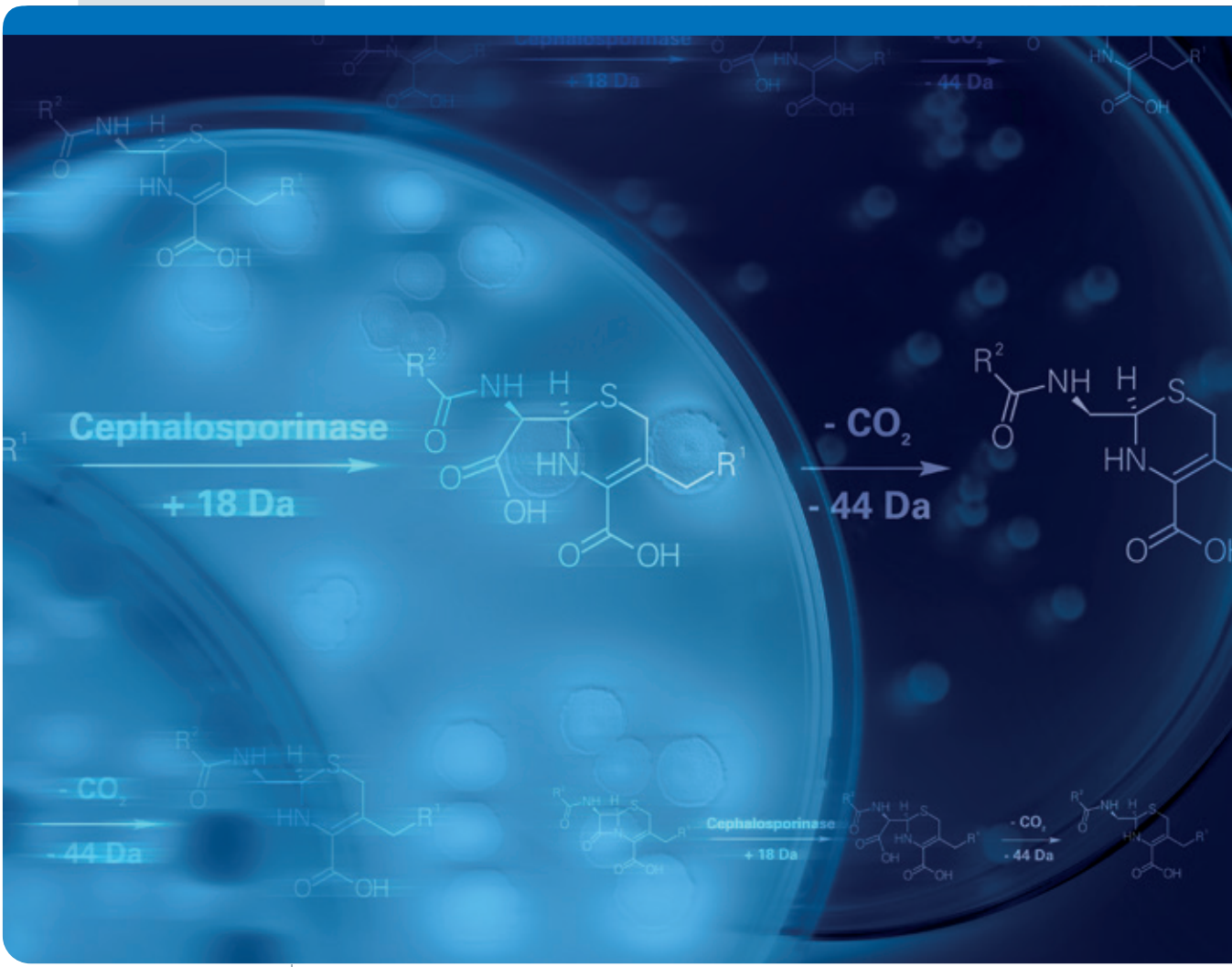
IVD



MBT STAR®-Cepha IVD Assay

- Rapid cephalosporinase detection within 60 minutes from a positive blood culture

MALDI Biotyper®

Enabling rapid detection of cephalosporinase activity

Effective patient care and infection control relies on rapid detection methods.

The rise of multi-resistant bacteria is an ever increasing healthcare threat directly linked to an increase in morbidity, mortality, and healthcare costs, demanding reliable, rapid and cost-effective assays for detection of antibiotic resistance. Amongst the different resistance mechanisms used by bacteria, an important one is the enzymatic deactivation of 3rd generation cephalosporin antibiotics by cephalosporinase producing Enterobacterales.

MALDI-TOF beyond microorganism identification

The easy to use MBT STAR-Cepha IVD Kit, in combination with the MBT STAR-BL IVD Module, allows rapid detection of cephalosporinase activity towards 3rd generation cephalosporins. Starting from a positive blood culture or a culture plate, cephalosporinase producing Enterobacterales are detected within one hour.

This mass spectrometric resistance assay expands the MBT STAR product family and further broadens the application of the MALDI Biotyper in clinical microbiology beyond microorganism identification.

The MBT STAR-Cepha Assay Principle

The MBT STAR-Cepha IVD Kit utilizes a 3rd generation cephalosporin benchmark antibiotic, provided in convenient 96 well plates. Incubation of cephalosporinase producing bacteria with the antibiotic reagent results in cleavage (hydrolysation) of the antibiotic's ß-lactam ring, hence converting the antibiotic into an inactive metabolite.

The detection of cephalosporinase activity covers most ESBL and AmpC harboring strains, offering sensitive and selective detection of a wide range of possible cephalosporinases, irrespective of their genetic (pre-)characterization or prevalence:

ESBL:

- E.g. plasmidic TEM, SHV and CTX-M

AmpC:

- Chromosomal and plasmidic;
- Inducible or de-repressed resistance genes;
- E.g. AmpC, FOX, LAT, DHA and CMY

The incubation time is only 30 minutes for Enterobacterales. After incubation, cleavage of the benchmark antibiotic is monitored by detection of a specific mass shift in the MALDI-TOF mass spectrum (Figure 1).

This fully automated monitoring is performed by the MBT STAR-BL IVD Module – an addition to the regular MBT Compass IVD software. Based on acquired mass spectra of aliquots of the incubated solution, an automatic calculation of the intensity of the antibiotic peaks and corresponding ratio hydrolyzed / non-hydrolyzed is performed. The resulting report is easy to interpret by means of color codes, as shown in Figure 2.

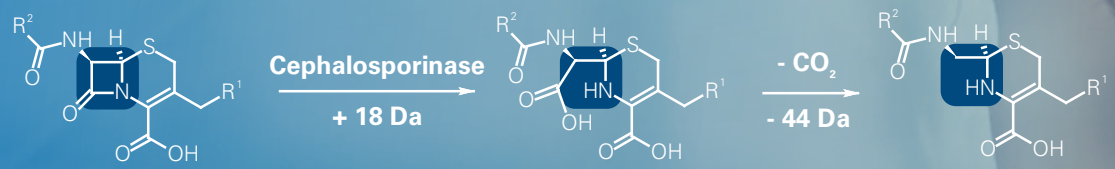


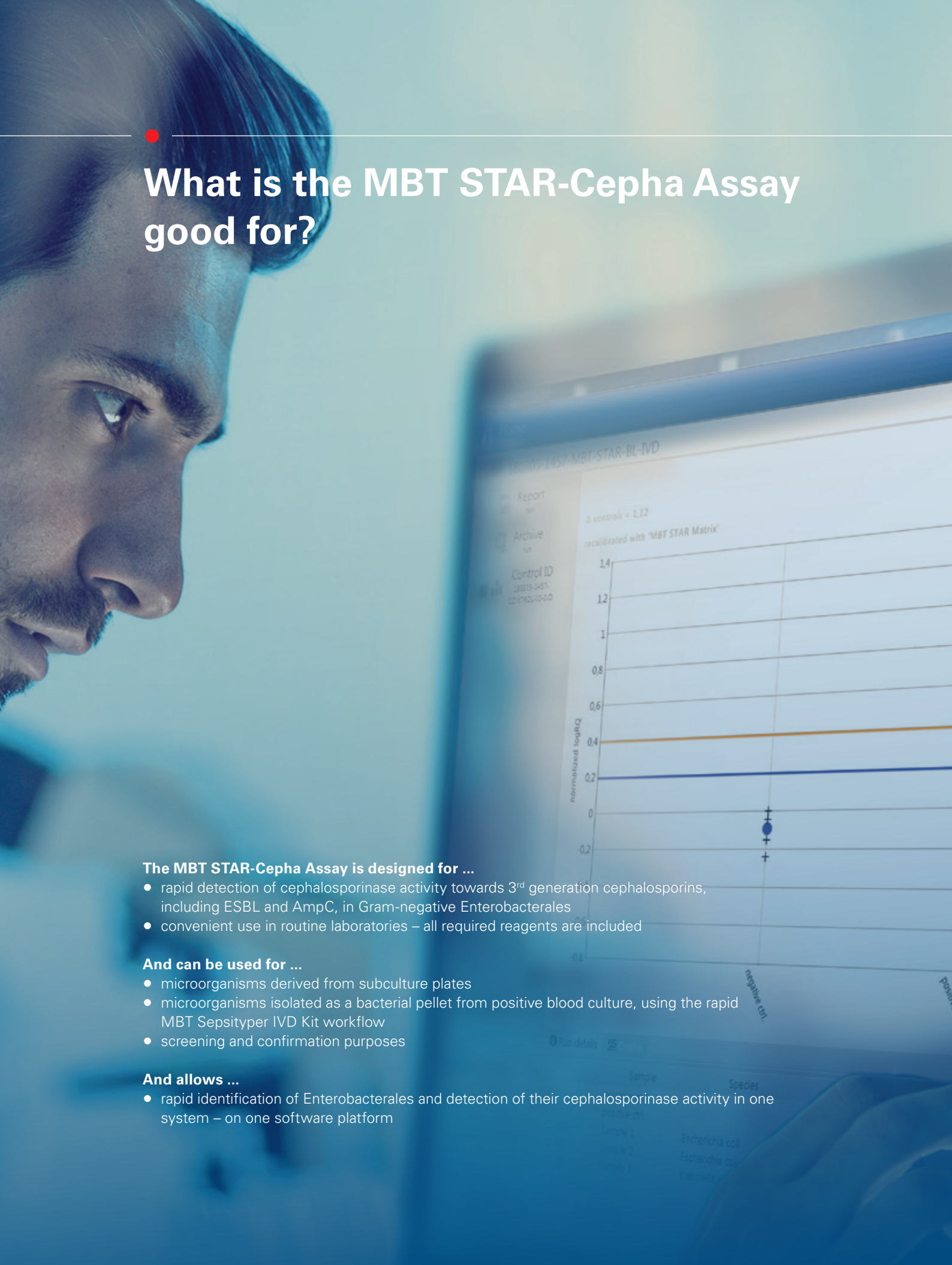
Figure 1: Hydrolysis of an antibiotic's β-lactam ring leads to mass shifts that can easily be detected by MALDI-TOF mass spectrometry

Sample	Species	Control ID	Cepha	
Sample 1	Escherichia coli	confirmed	1.28	H
Sample 2	Escherichia coli	confirmed	1.14	H
Sample 3	Klebsiella variicola	confirmed	-0.55	NH
neg.control		not performed	-0.10	NH
pos.control		not performed	1.04	H
Δcontrols			1.12	

H	Hydrolyzed[1]
NH	Non-hydrolyzed[2]

Figure 2 : Result report allowing easy and objective interpretation of the detection of cephalosporinase activity
[1] cephalosporinase activity detected; [2] no cephalosporinase activity detected

What is the MBT STAR-Cepha Assay good for?



The MBT STAR-Cepha Assay is designed for ...

- rapid detection of cephalosporinase activity towards 3rd generation cephalosporins, including ESBL and AmpC, in Gram-negative Enterobacterales
- convenient use in routine laboratories – all required reagents are included

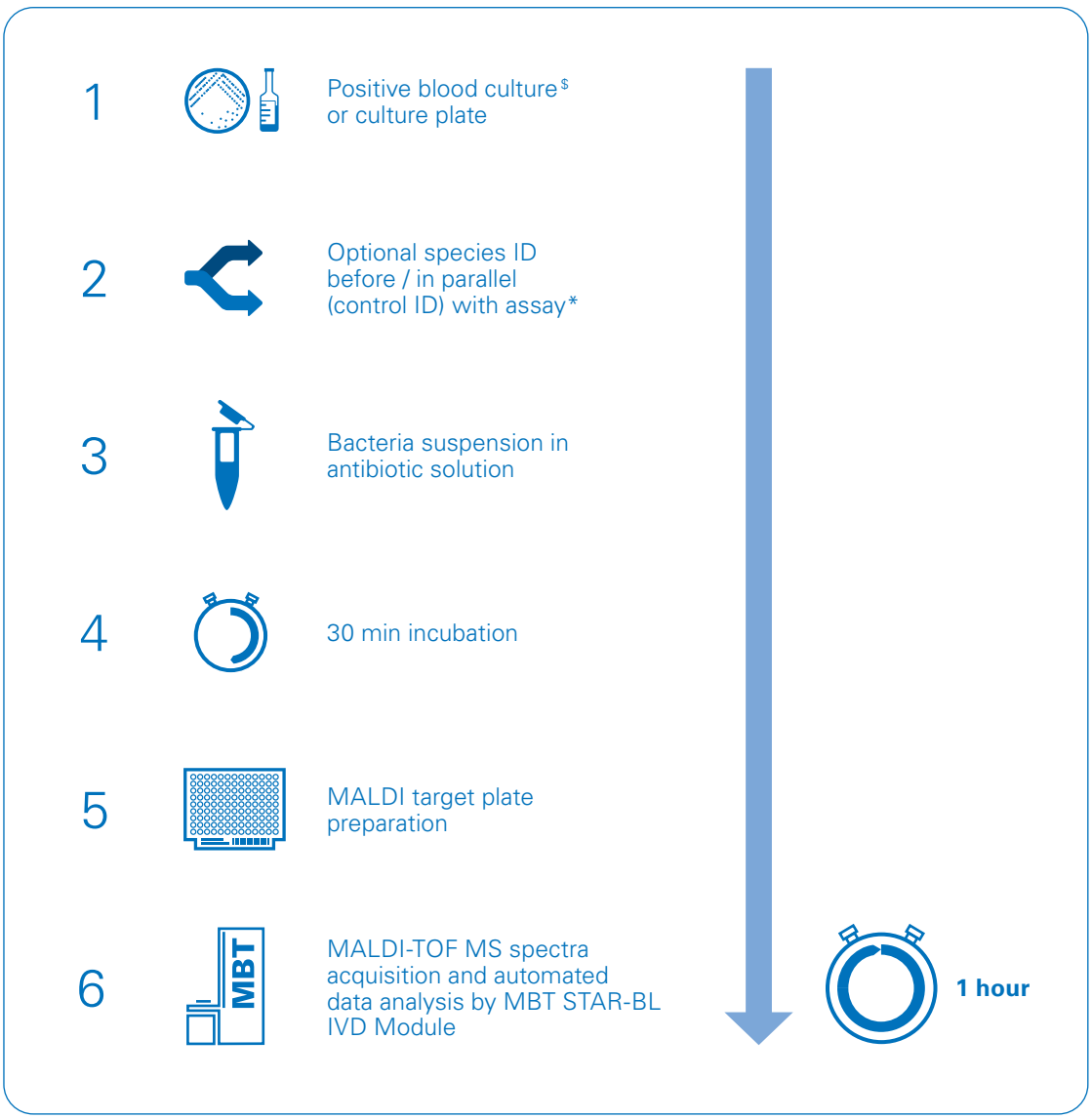
And can be used for ...

- microorganisms derived from subculture plates
- microorganisms isolated as a bacterial pellet from positive blood culture, using the rapid MBT Sepsityper IVD Kit workflow
- screening and confirmation purposes

And allows ...

- rapid identification of Enterobacterales and detection of their cephalosporinase activity in one system – on one software platform

Identification of Microorganisms and Detection of their Cephalosporinase Activity on one System



$ Use pellet sample based on direct transfer procedure as per IFU of the MBT Sepsityper IVD Kit.

* The regular MBT microorganism identification workflow may be performed as an additional test. Identification of bacteria can be conducted as an initial identification run, allowing relevant samples to be selected for subsequent cephalosporinase activity testing. A parallel *control* identification run allows fast and simple identification verification during cephalosporinase activity testing.

Order Information

Pre-requisite for the MBT STAR-Cepha IVD Assay is the MBT Compass IVD software (Part-No. 1832771).

Part-No. 1858555
MBT STAR-Cepha IVD Kit

The MBT STAR-Cepha IVD Kit provides all necessary reagents and components to conduct the cephalosporinase assay.

Part-No. 1850907
MBT STAR-BL IVD Module

Software for analysis of co-incubation assays for detection of carbapenemase and cephalosporinase activity in bacteria. Incl. 2 licenses to install MBT STAR-BL IVD Module on the acquisition system and on one additional client PC.

Part-No. 1834338
MBT Sepsityper IVD Kit

For the isolation of microorganisms from positive blood culture. Please refer to the specific product information.

Quality control strains:
Possible commercial control strains recommended for the performance control of the MBT STAR-Cepha IVD Assay include e.g. CCUG62975 (positive control) and ATCC® 25922™ (negative control).
The strain ATCC® 700603™, also recommended for ESBL QC in several guidelines, is known to exhibit a variable enzymatic activity and should not be used for control strain purposes.

Please contact your local representative for availability in your country.
Not for sale in the USA.

CE IVD

As of May 2021, Bruker Daltonik GmbH is now Bruker Daltonics GmbH & Co. KG.

Bruker Daltonics GmbH & Co. KG

Bremen · Germany
Phone +49 (0) 421-2205-0

info.md@bruker.com - www.bruker.com/microbiology