



REF E2-333-020

Instructions for Use Iron-depleted CAMHB



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: micronaut.support@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 Iron-depleted CAMHB |
| Revision: | Revision A (May 2022) |
| First revision: | May 2022 |

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

| Section | Changes |
|---------|----------------------------|
| – | No changes: first revision |

Table of contents

| | |
|--|-----------|
| Regulatory notices | 2 |
| Document history | 3 |
| Table of contents | 4 |
| 1 Intended purpose | 5 |
| 2 Precautions and warnings | 6 |
| 2.1 General precautions | 6 |
| 2.2 Precautions for handling the product | 6 |
| 2.3 Precautions for handling specimens | 6 |
| 2.4 Disposing of product, samples, and packaging | 6 |
| 3 Product description | 7 |
| 3.1 Test principle | 7 |
| 3.2 Product content | 7 |
| 3.3 Materials required but not included | 7 |
| 3.4 Storage and stability | 8 |
| 4 Quality control | 9 |
| 5 Test procedure | 10 |
| 6 Limitations of the method | 11 |
| 7 Performance characteristics | 12 |
| 8 References | 13 |
| 9 Symbols | 13 |
| 10 Manufacturer | 14 |

1 Intended purpose

Iron-depleted CAMHB (Iron-depleted Mueller Hinton Broth, cation-adjusted) is an *in vitro* diagnostic medical device for the quantitative detection of bacterial growth of members of the Enterobacterales, *Pseudomonas aeruginosa*, *Acinetobacter baumannii* and *Stenotrophomonas maltophilia* in the presence of cefiderocol. Only pure cultures obtained from human test material can be used. The device must be used in combination with UMIC Cefiderocol. The test is based on the broth microdilution method and is not automated. The results are intended solely as an aid to diagnosis for targeted antibacterial therapy and must not be used as single source for diagnosis, treatment, or patient management decision. The device is intended for professional laboratory use only.

2 Precautions and warnings

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

2.1 General precautions

Iron-depleted CAMHB tubes are for single use only.

Inspect the product on arrival and do not use in case of damage. Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass.

Wear protective clothing and observe federal, state, and local regulations.

2.2 Precautions for handling the product

Do not use tubes if evidence of microbial contamination, evaporation, precipitation, or other signs of deterioration are present.

For additional information, refer to the Safety Data Sheet(s) that can be downloaded from www.bruker.com/msds

2.3 Precautions for handling specimens

Samples, bacterial cultures, inoculated Iron-depleted CAMHB, and other materials used must be considered as potentially infectious and must be treated properly and with respect to the corresponding precautionary measures by qualified specialist staff. It is important to work aseptically during the whole test procedure. For further information, refer to "BioSafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 99-8395, 4th Edition (April 1999)", and to the corresponding federal, state, and local regulations and requirements. Apply established precautions against microbiological hazards throughout all procedures.

This medium is not suitable for direct use with specimens or other materials that contain mixed microbial cultures. It may be used as a supplementary enrichment broth in addition to primary cultivation media. Refer to respective reference literature and guidelines for further information.

2.4 Disposing of product, samples, and packaging

After use, tubes, specimen containers and other contaminated materials must be sterilized by suitable procedures, for example, autoclaving, before discarding in accordance with federal, state, and local regulations.

3 Product description

In accordance with ISO 20776-1, *in vitro* antimicrobial susceptibility tests are performed on microorganisms that are suspected of causing disease, particularly if the organism is thought to belong to a species that may exhibit resistance to frequently used antimicrobial agents. The tests are also important in resistance surveillance, epidemiological studies of susceptibility and in comparisons of new and existing agents.

3.1 Test principle

Iron-depleted CAMHB for broth microdilution in accordance with ISO 20776-1 contains:

- Beef Extract
- Acid Hydrolysate of Casein
- Starch
- Iron ions ≤ 0.03 mg/l

and is used to measure quantitatively and qualitatively the *in vitro* activity of cefiderocol against a given bacterial isolate. The concentration of iron ions has been reduced to ≤ 0.03 mg/l, the concentrations of Ca^{2+} , Mg^{2+} and Zn^{2+} have been adjusted to 20-25 mg/l, 10-12.5 mg/l and 0.5-1 mg/l, respectively.

Acid hydrolysate of casein and beef extract supply amino acids and other nitrogenous substances, minerals, some vitamins and other nutrients support the growth of microorganisms. Starch acts as a protective colloid against toxic substances that may be present in the medium. Hydrolysis of the starch during autoclaving provides a small amount of dextrose, which is a source of energy.

Iron-depleted CAMHB must be used with UMIC Cefiderocol for antimicrobial susceptibility testing of non-fastidious aerobic, Gram negative bacteria based on broth microdilution as mentioned in the respective EUCAST and CLSI standards. Refer to the respective IFUs for further information that can be downloaded from www.bruker.com/IFU

3.2 Product content

- 20 glass tubes (E2-333-020), containing 5.0 ± 0.3 ml Iron-depleted CAMHB, each
- Ready for use

3.3 Materials required but not included

For antimicrobial susceptibility testing, for example, in accordance with ISO 20776-1, additional culture media, reagents, consumables, quality control organisms and laboratory equipment are required. Refer to the respective procedures.

For performance of the antimicrobial susceptibility testing with UMIC Cefiderocol, refer to the respective IFU that can be downloaded from www.bruker.com/IFU

3.4 Storage and stability

On receipt, Iron-depleted CAMHB must be stored at 2-25 °C in the dark. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light.

Iron-depleted CAMHB broth tubes are for single use only.

For shelf life of the media stored as labeled please follow the expiration date printed on the product.

4 Quality control

Iron-depleted CAMHB is subject to quality controls that are carried out systematically at different stages of the production.

The bacteriological quality control can be carried out with the following strains:

| Strain | ATCC No¹ | DSMZ No² | Growth |
|-------------------------------|----------------------------|----------------------------|----------------------------|
| <i>Staphylococcus aureus</i> | ATCC 29213 | DSM 2569 | good, pronounced turbidity |
| <i>Escherichia coli</i> | ATCC 25922 | DSM 1103 | good, pronounced turbidity |
| <i>Pseudomonas aeruginosa</i> | ATCC 27853 | DSM 1117 | good, pronounced turbidity |
| <i>Enterococcus faecalis</i> | ATCC 29212 | DSM 2570 | good, pronounced turbidity |

Inoculum for productivity: ≤10-100 CFU/tube

Incubation Conditions: 20-24 h at 36 ± 1 °C

¹ATCC = American Type Culture Collection

²DSMZ = Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (German Collection of Microorganisms and Cell Cultures Ltd.)

5 Test procedure

Microorganisms to be subcultured or incubated using Iron-depleted CAMHB must first be isolated in pure culture on blood agar plates without additives.

Generally, transfer isolates and materials using standard bacteriologic techniques under conditions that are appropriate for the respective organism that is being cultured.

For susceptibility testing that uses the UMIC Cefiderocol broth microdilution assays, typically a certain number of microorganisms is required. Refer to the respective Instruction for Use for preparation of standardized suspensions, further sample processing, and evaluation and interpretation of results.

6 Limitations of the method

You may use the Iron-depleted CAMHB only in combination with the UMIC Cefiderocol.

7 Performance characteristics

The general requirements apply to ISO 20776-1. For monitoring the accuracy for minimal inhibitory concentrations (MICs), refer to the acceptable limits for quality control strains according to the relevant version of "Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST" (<http://www.eucast.org>) or the relevant version of "Performance Standards for Antimicrobial Susceptibility Testing; CLSI Document M100" (<http://www.clsi.org>).













The performance of Iron-depleted CAMHB can only be assessed in combination with UMIC Cefiderocol. For performance data, refer to the corresponding Instructions for Use of UMIC Cefiderocol.

8 References

- The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST in the currently valid version. <http://www.eucast.org>.
- Performance Standards for Antimicrobial Susceptibility Testing; CLSI Document M100 in the currently valid version. <http://www.clsi.org>
- ISO 20776-1: Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases in the currently valid version
- BioSafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 99-8395, 4th Edition (April 1999)

9 Symbols

The following symbols are used in the labeling:

| | |
|---|---|
|  | Do not re-use |
|  | Contains sufficient for <n> tests |
|  | Temperature limit |
|  | Keep away from sunlight |
|  | Consult instructions for use |
|  | Use-by date |
|  | CE mark |
|  | <i>In vitro</i> diagnostic medical device |
|  | Batch code |
|  | Catalog number |
|  | Global Trade Item Number |
|  | Manufacturer |

10 Manufacturer



Bruker Daltonics GmbH & Co. KG

Fahrenheitstraße 4
28359 Bremen
Germany

Support

Email: micronaut.support@bruker.com

Phone: +49 421 2205-0

Sales Information

Email: ms.sales.bdal@bruker.com

Phone: +49 421 2205-0

Web: www.bruker.com/microbiology

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

Descriptions and specifications supersede all previous information.

© Copyright 2022 Bruker Daltonics GmbH & Co. KG