Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
email: sales@mast-group.com
Web: www.mast-group.com

Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com

MASTDISCS® *AST* Antibiotic Susceptibility Test Cartridges Discs Aztreonam 30 µg/ Avibactam 20 µg (AZA50C) UKCA

Introduction

MASTDISCS® *AST* Cartridge Discs are for determination of the susceptibility of common, rapidly growing bacterial pathogens isolated from clinical specimens to antimicrobial chemotherapeutic agents by the agar diffusion test procedure. The diameter of the zone of inhibition formed around a disc is used to indicate the susceptibility category of the bacterial strain tested: for example; resistant, intermediate or susceptible.

Susceptibility of the pathogen indicates there is a probability of therapeutic success if the patient is treated with that antimicrobial agent, while resistance indicates a probability of therapeutic failure.

Results of susceptibility testing are utilised alongside consideration of current antimicrobial stewardship policies, clinical efficacy, and indications for usage to aid in the selection of an appropriate antimicrobial agent for treatment of a clinical condition.

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Intended Use

MASTDISCS® *AST* Cartridge Discs are qualitative, non-automated, agar diffusion tests for the determination susceptibility to antimicrobial agents of aerobic, some fastidious, and microaerophilic bacteria previously isolated from clinical specimens.

The function of the device is to provide the antimicrobial source, of a specified content, in an agar diffusion test for the prediction of likelihood of treatment response to a particular antimicrobial agent for individuals with an identified microbial infection.

The test methods used follow a standardised agar diffusion susceptibility test protocol, principally from those issued by The European Committee on Antimicrobial Susceptibility Testing (EUCAST) and The Clinical and Laboratory Standards Institute (CLSI).

MASTDISCS® *AST* Cartridge Discs are placed on the surface of an appropriate agar medium previously inoculated with a calibrated suspension of a pure, actively growing culture of the bacterial strain to be tested. After incubation at a defined time and temperature, zones of growth inhibition form around the discs, which are measured and compared to published critical values for the various antimicrobial agents tested in order to determine the clinical category of susceptibility. Typically these categories are; susceptible [S], resistant [R], or intermediate [I] (alternatively “Susceptible, increased exposure” or “Susceptible - dose dependant” depending on the method employed by the end-user) to the antimicrobial agent tested.

Results of testing can assist the clinician in the choice of antimicrobial agent for therapeutic or prophylactic use in the treatment of infectious disease. Results can be used to predict treatment response but should not be used as the sole basis for treatment or case management decision. The test is performed on pure, previously isolated bacteria from clinical samples; hence, there is no direct link to the testing population. The device is intended to be used by professional trained clinical laboratory users. The device is intended to be used with aerobic and some fastidious, and microaerophilic bacteria only, and should not be used for the determination of susceptibility of anaerobic bacteria isolates.

Principle of Test

Disc diffusion testing is a method used to determine antimicrobial susceptibility to clinically relevant bacteria. This method is used extensively in the majority of routine microbiology laboratories, due to its low cost, ease of use and the high reproducibility of the method. In this technique, antibiotic impregnated paper discs are placed onto the surface of an agar medium, which has been evenly inoculated with the test organism. During incubation, the antibiotic diffuses radially from the disc to produce a concentration gradient in the medium. Susceptibility of the test organism is visualised as a circular zone of growth inhibition around a disc. Zones of inhibition are measured to the nearest millimetre and compared to recognised zone size ranges for the antimicrobial agent being tested, in order to categorise the organism as susceptible [S], resistant [R], or intermediate [I]. Various global organisations (principally EUCAST and CLSI) publish methodological guidelines and interpretative criteria. The end-user must perform the test in accordance to the current guidance provided by the chosen organisation.

The size of the zone relates to the degree of sensitivity of the organism to the antibiotic but is influenced by other modifying factors inherent to the method. These include the potency, and rate of diffusion of the antibiotic, the growth rate of the organism, the medium used, incubation temperature and atmosphere, and the density of the inoculum. To ensure that susceptibility test results are as accurate and reproducible as possible it is essential that these and other variables be controlled by following standardised susceptibility test methods.

Components

MASTDISCS® *AST* Cartridge Discs are supplied in cartridges, and packaged into outer containers incorporating desiccant. Each 6 mm diameter paper disc is printed on each face with a 1 to 3 letter identification code and a number indicating the nominal antibiotic content of the disc in µg or International Units.

Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
email: sales@mast-group.com
Web: www.mast-group.com

Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com

Stability and storage

The expiry date applies to discs contained in intact and unopened outer containers and stored according to the manufacturer's instructions.
The expiry date and batch number is indicated on both the cartridge and container.

- Store packs in the containers provided at the recommended storage temperature and until the expiry date shown on the pack label.
- Allow containers and contents to equilibrate to ambient temperature before opening.
- **MAST**DISCS® *AST* Cartridge Discs are used in conjunction with the **MAST**® DiscMaster Dispenser. Remove one cartridge from its outer container and insert it into the appropriate position in the **MAST**® DiscMaster Dispenser.
- Discs may be stored in dispensers in the airtight storage canisters for up to 4 weeks at 2°C to 8°C, provided the desiccant is sufficiently charged.
- Once opened, return the original outer container and remaining cartridge tubes to storage at 2°C to 8°C for no more 4 weeks.
- Do not return used cartridges to the outer container.
- Do not use discs after the expiry date.
- Do not use any cartridge of discs left at room temperature for more than 8 hours without verifying an acceptable level of performance before continuing to use this cartridge.

Warnings and precautions

1. **MAST**DISCS® *AST* Cartridge Discs are for *in vitro* diagnostic use only,
2. **MAST**DISCS® *AST* Cartridge Discs should only be used by trained laboratory staff.
3. All microbiological cultures and equipment used to transfer and manipulate them should be treated as infectious.
4. Autoclave sterilise all biohazard waste before disposal.
5. On receipt, store discs at the temperature stated on the pack.
6. Do not store **MAST**DISCS® *AST* Cartridge Discs at temperatures colder than minus 25°C.
7. Do not store or transport **MAST**DISCS® *AST* Cartridge Discs in or over dry ice (solid form of carbon dioxide).
8. Allow **MAST**DISCS® *AST* Cartridge Discs and **MAST**® DiscMaster Dispenser storage containers to come to room temperature before opening to minimise condensation.
9. Replace **MAST®** DiscMaster Dispensers in their airtight storage canisters and store at 2°C to 8°C.
10. The expiration date applies only to discs in intact and unopened containers, stored as directed.
11. Do not use discs after their expiry date.
12. Always discard expired discs appropriately.
13. The current version of the standardised method used must be consulted to ensure correct test procedures and interpretive criteria are applied. Any deviation from the method, including the use of out of date versions, may produce incorrect results.
14. When incubating, inoculated plates should not be placed in high stacks this will result in an uneven distribution of heat, this delay could cause overly large zones.

Materials required but not provided

Standard microbiological supplies and equipment such as loops, suitable AST culture media, additives such as defibrinated blood, swabs, incubator, McFarland standards, densitometer, **MAST**® DiscMaster Dispenser, suitable control strains of microorganisms, callipers or other measuring device, and use of the latest version of a standardised reference method such as CLSI, EUCAST, and CA-SFM, for method and interpretive criteria.

Procedure

1. **MAST**DISCS® *AST* Cartridge Discs are compatible to be used according to appropriate standardised susceptibility test methodologies.
2. Remove **MAST**DISCS® *AST* Cartridge Discs container from the refrigerator and allow to equilibrate to room temperature before opening.
3. Using the **MAST**® DiscMaster Dispenser with appropriate capacity for the method followed e.g. 6 place MDD6 series, load each **MAST**DISCS® *AST* Cartridge Disc cartridge required into the dispenser. Ensure cartridges are locked in position according to the instructions provided with the dispenser (see **MAST®** DiscMaster Dispenser instructions for full details).
4. Place the dispenser over the pre-inoculated plate of susceptibility test medium. Confirm placement of the dispenser is correct and then fully depress the handle of the dispenser in a smooth, continuous, downward movement and release. Do not exert undue pressure on the handle. (See **MAST®** DiscMaster Dispenser instructions for full details).
5. Incubate plates as described in the chosen reference methodology. For example, aerobically, at 35°C to 37°C for 18 to 24 hours.

Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
email: sales@mast-group.com
Web: www.mast-group.com

Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com

6. After incubation is complete, measure the diameter of zones of inhibition that are observed around the antibiotic impregnated discs to the nearest whole millimetre (or alternative measurement protocol, e.g. radius measurement, specified in the methodology followed).

Interpretation of results

Interpret measured zones of inhibition by reference to published tables of critical zone diameter breakpoints specified in the methodology followed and classify test isolate as [S], resistant [R], or intermediate [I] (alternatively "Susceptible, increased exposure" or "Susceptible - dose dependant" depending on the method employed by the end-user).

Limitations of use

1. This product is for diagnostic use only within England, Scotland and Wales as per UKCA marking. Use outside these territories is not supported.
2. Discs must not be used for tests performed directly on clinical samples. Testing should be performed on isolated, pure colonies.
3. The disc diffusion susceptibility test is appropriate primarily for rapidly growing aerobic pathogens. Ensure the correct methodology is consulted when testing fastidious or microaerophilic pathogens, which requires alternative procedures.
4. Observation of variation in zone sizes may be due to a number of factors within the test system including organism inoculation density, preparation or depth of medium, and fluctuation in incubation temperature. Accuracy of results is dependent on correct storage of discs and maintenance of quality control organisms, and adherence to the method followed. Any deviation of zone sizes from the acceptance range with quality control organisms must be investigated and these factors taken into account.
5. **MAST**DISCS® *AST* Cartridge Discs cannot be used in susceptibility testing of *Neisseria* spp.
6. **MAST**DISCS® *AST* Cartridge Discs cannot be used in susceptibility testing of anaerobic organisms.
7. Results should not be used as the sole basis for treatment or case management decision.

Quality control

Check for signs of product degradation. Quality control must be performed with at least one organism to demonstrate a correct susceptibility pattern. Consult the current version of the standardised method used for details of additional quality control requirements.

Record results obtained with quality control reference strains according to laboratory quality management system requirements. Any zone sizes produced by quality control reference strains that deviate from the acceptance range should be investigated.

The list below illustrates a range of performance control strains which the end user can easily obtain. Do not use the product if the reactions with the control organisms are incorrect.

Table 1: reference strains

Test Organism	
Escherichia coli ATCC® 25922	Correct susceptibility pattern*
Pseudomonas aeruginosa ATCC® 27853	Correct susceptibility pattern*
Escherichia coli ATCC® 35218	Correct susceptibility pattern*
Klebsiella pneumoniae ATCC® 700603	Correct susceptibility pattern*

*See appropriate quality control table

Full bibliography available on request.

Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
email: sales@mast-group.com
Web: www.mast-group.com

Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com

Analytical Performance

A lot of **MAST**DISCS® *AST* Cartridge Discs Aztreonam 30 µg / Avibactam 20 µg (AZA50C); 338586 was tested against four ATCC® reference strains (See Table 1) with QC limits following CLSI guidelines.

Table 2: Organisms tested in evaluations of Aztreonam 30 µg / Avibactam 20 µg discs.

Organism	Quality Control Range (mm) CLSI[1]	Average Zone of Inhibition diameter (mm) *n* = 240	Mode (mm) *n* = 240	% zone of inhibition within QC limit *n* = 240
Escherichia coli ATCC® 25922	32 to 38[2]	35	36	99.17
Pseudomonas aeruginosa ATCC® 27853	24 to 30	27	26	100
Escherichia coli ATCC® 35218	31 to 38	35	35	97.92
Klebsiella pneumoniae ATCC® 700603	26 to 32[2]	29	28	100

1. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 34th ed. CLSI supplement M100; 2024.
2. Quality control range also applies to EUCAST. European Committee on Antimicrobial Susceptibility Breakpoints for aztreonam-avibactam. Addendum (May 2024) to EUCAST breakpoint tables v. 14.0

IFU 489 GB 09/24 V1