Manufacturer's Quality Control Procedures

The concentration of antibiotic on the AST disc is analysed for every batch and is controlled using internal and external specifications (e.g. FDA[3]). The actual concentration is detailed on the Certificate of Analysis. The performance of AST discs (zone diameter) is analysed for every batch using internal quality control organisms and specific organisms detailed by CLSI[1bc] and/or EUCAST[2]. Users are advised to check the Certificate of Analysis (www.thermoscientific.com) for all QC organisms used and results obtained.

Limitations

This product is for *in vitro* diagnostic use. Test results, when compared to standards from International bodies (e.g. CLSI / EUCAST), may provide an indication of *in vivo* susceptibility of the test organism. The selection of antimicrobial agents to test and report is a decision that must be made by each clinical laboratory. The decision to use an antimicrobial agent for therapy against the test organism is the responsibility of the clinician who will consider other factors which may influence the *in vivo* activity of the compound. Reported test results should form part of a holistic approach to treatment and the reported test results will be assessed by the clinician in conjunction with the patient's history, clinical presentations and results of other clinical tests.

Atypical isolates may present false resistance or sensitivity towards various antimicrobial agents. Reports of false resistance are not uncommon, although failures of QC tests can be wrongly reported as such. QC failures are typically associated with degradation of the drugs, caused by incorrect handling (including storage and transport) described in this IFU. Reports of false sensitivity are uncommon but again can be linked to incorrect handling.

Failure to observe instructions for use may lead to erroneous results.

Please note, when using ampicillin 10µg discs to test the susceptibility of Escherichia coli ATCC® 25922™ with Oxoid Mueller Hinton medium, please read the outer zone edge and ignore any inner growth/colonies.

Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

Contact Information:

International Telephone: +44 (0) 1256 841144
Email: microbiology@thermofisher.com
Website: www.thermofisher.com

References

1. Clinical Laboratory Standards Institute (CLSI).
   a. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – M02 - Latest Edition.
   b. Performance Standards for Antimicrobial Susceptibility Testing – M100 – Latest Edition.
   c. Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline – M45 – Latest Edition.
2. European Committee on Antimicrobial Susceptibility Testing (EUCAST).
   a. Antimicrobial Susceptibility Testing, EUCAST disk diffusion method – Latest version.
   b. Reading guide, EUCAST disk diffusion method for antimicrobial susceptibility testing – Latest version.
3. Food and Drug Administration (FDA). CFR Title 21, Volume 5, Part 460 (2005).

Glossary of Symbols

Symbol/Label	Meaning
	Manufacturer
	In Vitro Diagnostic Medical Device
	Temperature limit
	Batch Code
	Catalog Number
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Contains sufficient for <n> tests
	Use-by date
	Do not use if package is damaged and Consult instructions for use
	Authorized representative in the European Community/ European Union
	Unique device identifier
	USA: Caution: Federal law restricts this device to sale by or on order of a Physician
	European Conformity Mark
	UK Conformity Mark

Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, UK

https://www.thermofisher.com

EU +800 135 79 135
US 1 855 236 0910
CA 1 855 805 8539
ROW +31 20 794 7071

EN – Oxoid™ Antimicrobial Susceptibility Test Discs

NOTE: This IFU should be read in combination with the relevant drug-specific supplementary electronic instructions for use document (IFU). Please refer to our websites or alternatively call one of the above numbers to request a copy of the IFU.

Intended Use

Thermo Scientific™ Oxoid™ Antimicrobial Susceptibility Test Discs are used in the semi-quantitative agar diffusion test method for *in vitro* susceptibility testing. Used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection, these discs are intended to determine susceptibility against microorganisms for which specific drugs have been shown to be active both clinically and *in vitro*. To be used with a pure, agar grown culture, Oxoid Antimicrobial Susceptibility Test Discs are for professional use only.

A drug specific intended use for each product within the AST disc range can be found in the relevant drug supplementary electronic instructions for use document.

Principle of the Test

A suitable therapeutic agent for *in vivo* use can be determined using filter paper discs impregnated with specified concentrations of antimicrobial agents placed on the surface of a suitable test medium. Pure cultures of clinical isolates are inoculated onto the test medium and the AST disc placed on the surface. The antibiotic within the disc diffuses into the agar. After incubation, the zones of inhibition around the discs are measured and compared against recognised zone diameter ranges for the specific antimicrobial agents/organisms combination under test.

Components

Oxoid AST Discs consist of 6mm diameter paper discs impregnated with a specific antimicrobial concentration. The discs are marked on both sides with an alpha-numeric code identifying the antimicrobial agent and concentration. Oxoid AST discs are supplied in cartridges of 50 discs. There are 5 cartridges in each pack. Cartridges are individually packed in a foil-sealed blister pack with a desiccant. Each individual disc is single use only.

Materials required but not supplied

Agar plates with appropriate media, inoculum suspension medium, sterile loops and swabs, sterile forceps, McFarland turbidity standards, incubator, modified atmosphere environments, antibiotic disc dispensers, quality control strains, apparatus to measure zone sizes and interpretative criteria for local standard methods.

Warnings and Precautions

- For in vitro diagnostic use only.
- Follow instructions for use.
- Observe aseptic techniques and established precautions against all microbiological hazards throughout all procedures.
- Cultures, containers and other contaminated materials must be sterilised after use in accordance with guidelines for the handling and disposal of biohazardous waste.
- Refer to the Material Safety Data Sheet (MSDS) for safe handling and disposal of the product (found on www.thermofisher.com).
- Inspect the product packaging before first use. Do not use the product if there is any visible damage to the foil seal.
- Do not use the product beyond the stated expiry date.
- Once the cartridge is open ensure it is stored in an opaque desiccated environment to prevent degradation of the antimicrobial.
- If the discs do not produce the expected inhibition zone diameters with recommended control organisms, review the entire procedure.
- In the event of malfunction do not use device.
- The device does not contain any carcinogenic, mutagenic or toxic to reproduction (CMR), endocrine disrupting substances or materials likely to cause sensitisation or an allergic reaction, under normal use.

Storage and Handling

Unopened cartridges must be stored at -20°C to 8°C until required. Allow cartridges to reach room temperature before removing them from the packaging to minimize condensation as this may reduce the potency of the antimicrobial agent. The expiry date is valid only for unopened blister packs stored under correct conditions. Once opened, cartridges should be stored within a dispenser (sold separately) in the container provided (with an unsaturated (orange) desiccant), or other suitable opaque airtight container with a desiccant to protect the discs from moisture. Dispensers should be stored within the container at 2 - 8°C and be allowed to come to room temperature before opening to prevent the formation of condensation.

Please refer to the carton or drug supplementary electronic IFU for the validated opened use period. Once the product has been opened, customers should carry out their own validation/verification of the product's performance if it is to be used beyond the stated period.

Procedure

Oxoid AST discs may be used with a variety of standardised testing methodologies such as those described by CLSI[1ac] and EUCAST[2].

Method

1. Remove the discs from storage and allow to equilibrate to room temperature before use (approximately 1 hour).
2. Organisms under test should be fresh and pure clinical isolates from culture media. If possible, specimens should be taken from patients before antimicrobial therapy is initiated.
3. Appropriate growth media (e.g. Mueller-Hinton agar) and inoculum levels should be used according to the chosen standard susceptibility test method.
4. Allow agar plates to equilibrate to room temperature before use. If plates are moist, dry them appropriately before use.
5. Inoculate media according to chosen method.
6. Using either sterile forceps, single disc ejector or disc dispenser; apply the disc(s) to the surface of the pre-inoculated agar.
7. Discs should be applied to the plate within 15 minutes of inoculation. Ensure the disc is in full contact with the surface of the agar and incubate within 15 minutes.
8. Incubate plate in accordance with the chosen methodology (for example: incubate in air at 35°C +/- 2° for 16 – 24 hours (CLSI method) or at 35°C +/- 1° for 18 +/-2 hours (EUCAST method) for non-fastidious organisms.

Interpretation

For full instructions relating to the interpretation of the results according to CLSI[1bc]/EUCAST[2ab] methodology please refer to the relevant current standards. Tables showing CLSI[1bc]/EUCAST[2] compound/concentrations can be found in their documentation referenced below. Additional compounds and concentrations are available from Thermo Fisher Scientific for use with other local methods.

User Quality Control Procedures

It is recommended that control strains are tested at appropriate intervals under local conditions; this should be when each test is performed or as recommended by the guidance from the reference groups for antibiotic susceptibility testing. If the result obtained for a quality control organism against an antimicrobial compound is outside of the range specified, patient results should not be reported and the discs should not be used for testing clinical isolates until the reason for the discrepancy is determined (e.g. media, fill volume, inoculum, incubation conditions, control strain or incorrect storage or application of the disc).

Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, UK