


INTENDED USE

Biolab Antibacterial and Antifungal Antimicrobial Susceptibility Test Discs (ASTD) are designed for *in vitro* diagnostic use, intended for manual application with the semi-quantitative agar disk diffusion test method. They are used to assist clinicians in determining treatment options for infected patients and may be applied in both fastidious and/or non-fastidious bacterial and fungal infections. The discs are used on culture media prepared with pure isolates or standard strains. The test provides information to classify organisms as resistant, intermediate, or susceptible to antimicrobial agents. The device is non-automated and must be used exclusively by laboratory professionals. It is not a companion diagnostic device.

COMPONENTS

Biolab ASTDs are prepared by impregnating high-absorption capacity absorbent paper with antimicrobial agents. Each disc has a diameter of 6 mm. A product-specific code indicating the antimicrobial agent and its concentration is printed on both sides of each disc. ASTDs are packaged with 50 discs per cartridge and 5 cartridges per box. Each cartridge is sealed in a blister pack containing one silica gel capsule, and the blister is divided into five individual foil-wrapped blocks. Each disc is for single use only.

DESCRIPTION & TEST PRINCIPLE

Antimicrobial Susceptibility Test Discs are used to support the selection of appropriate therapeutic agents for potential *in vivo* use by measuring the zone of inhibition formed around the disc by an effective antimicrobial agent against an organism inoculated on a suitable culture medium. Interpretation is performed by laboratory professionals to assist clinicians in determining treatment options. These discs are prepared by impregnating absorbent paper with antimicrobial agents at various concentrations and are applied by placing them onto the surface of the appropriate culture medium.

The device is intended for manual use with the disk diffusion method. For proper and evenly spaced placement of discs on Petri dishes, Biolab disc dispensers may be used as optional supporting equipment, although their use is not mandatory.

MATERIALS REQUIRED BUT NOT PROVIDED

Petri dishes containing appropriate culture media, dehydrated media, sterile loops, swabs and forceps, incubator, modified atmospheric conditions (*e.g.*, anaerobic jar and CO₂ incubators), disc dispensers, microscope slides, and quality control strains.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions for use (IFU).
- Sterile conditions and laboratory techniques must be observed throughout the procedure. Appropriate protective measures must be taken against microbiological contamination.
- Used cultures, containers, and other contaminated materials must be disposed of as biological/medical waste in accordance with the Medical Waste Regulation.
- For safe transport and disposal of the product, refer to the Material Safety Data Sheet (MSDS). (*See: www.biolab.hu*)
- Inspect the product packaging before use. Do not use and dispose of the product if there is any visible damage to the packaging or if the foil is open.
- Do not use products that are past their expiry date.
- Once the cartridge has been opened, the discs must be stored in a tightly closed, airtight tube under recommended storage conditions to prevent deterioration.
- If the discs do not produce the expected inhibition zone diameters with the recommended control organisms for the respective product, the entire procedure should be reviewed.
- Do not use the product if it shows invalid or inappropriate result values.
- Under normal use, the device does not contain carcinogenic, mutagenic or reproductive toxic (CMR) substances, endocrine disruptors, or materials that could cause sensitization or allergic reactions.
- If any problem is suspected with the product, the end user must immediately inform Biolab via the specified contact methods (*phone, email*).

STORAGE AND TRANSPORTATION

Unopened cartridges should be stored between -20 °C and 8 °C until use. To prevent any moisture/condensation on the discs, which could negatively affect product performance, they should be allowed to reach room temperature before use. The expiration date applies only to unopened blister packages stored under proper conditions. After opening, cartridges must be stored in a tightly closed, airtight tube or in a lidded dispenser (*sold separately*) containing silica gel to protect the discs from moisture and under recommended storage conditions. Dispensers should be stored at 2–8 °C in their own lidded box and should be allowed to reach room temperature before opening to prevent condensation. The period of use after opening is indicated in the pictograms. For products used beyond this period, users must perform internal quality control verifications regarding product performance. Once removed from their silica gel-containing packaging, discs must be used within 7 days and only if stored as described in these Instructions for Use.

PROCEDURE

Biolab Antimicrobial Susceptibility Test Discs can be used in accordance with methodologies established by international organizations such as CLSI, EUCAST, and/or SFM.

METHOD

1. Discs should be removed from storage and allowed to reach room temperature (approximately 30 minutes) before use.
2. Test organisms must be fresh, pure clinical isolates obtained from culture media. Samples should ideally be collected from patients prior to the initiation of antimicrobial therapy.
3. An appropriate culture medium (*e.g.*, Mueller-Hinton agar) and McFarland standard should be selected based on the chosen standard susceptibility testing method.
4. Petri dishes should be brought to room temperature before use. If the plates are moist, allow them to dry in a sterile environment before proceeding.

5. The culture medium should be inoculated according to the appropriate McFarland standard for the organism.
6. Using sterile forceps, a trigger, or a dispenser, apply the disc(s) to the surface of the pre-inoculated agar medium.
7. Discs should be applied within 15 minutes after inoculation. Ensure the discs are properly placed on the surface of the medium and transfer the plates to the incubator within 15 minutes.
8. Incubate the Petri dishes according to the selected methodology. (*For bacterial products: Non-fastidious organisms: 35°C ± 2°C for 16–24 hours, Fastidious organisms: 35°C ± 1°C for 48–72 hours (CLSI method) or 35°C ± 1°C for 18 ± 2 hours (EUCAST method). For fungal products: 35°C ± 1°C for 24 hours or longer (48–72 hours) following CLSI guidelines.*)

INTERPRETATION

For complete instructions on interpreting results according to CLSI, EUCAST, or SFM methodologies, please refer to the relevant current standards. Tables showing the composition and concentrations of the products can be found in the documents referenced below. For additional compounds or alternative concentrations intended for use with other local methods, please contact Biolab.

USER QUALITY CONTROL PROCEDURES

Biolab ASTDs have been tested using standard quality control organisms and found to be acceptable. It is also recommended that quality control strains be tested at regular intervals. If the result obtained for a quality control organism falls outside the specified range for a given antimicrobial susceptibility disc, patient results should not be reported, and the discs should not be used for testing clinical isolates until the cause of the discrepancy is identified (*e.g.*, culture medium, plate volume, inoculum, incubation conditions, control strain, or improper storage or application of the disc).

MANUFACTURER'S QUALITY CONTROL PROCEDURES

Each batch of ASTDs is analyzed after production. The performance of the ASTDs (*zone diameter*) is evaluated for every batch using standard ATCC quality control strains and the specific organisms recommended by CLSI and/or EUCAST. Users are encouraged to obtain the Certificate of Analysis, which includes information on all quality control strains used and the results obtained, by contacting biolab@biolab.hu

LIMITATIONS

This product is intended for *in vitro* diagnostic use. When compared with the standards of international organizations (*e.g.*, CLSI/EUCAST), test results may provide an indication of the *in vivo* susceptibility of the test organism. The selection of ASTDs to be tested and reported is determined by the clinical laboratory. The responsibility for selecting the antimicrobial agent to be used for treatment against the tested organism lies with the clinician. Reported results should be considered as part of overall patient management and evaluated by the clinician in conjunction with the patient's history, clinical findings, and results from other supportive tests.

Atypical isolates may exhibit falsely resistant or susceptible results to antimicrobial agents. Poor performance in quality controls may be attributed to degradation of the active substance due to misuse (including storage and transport) as described in this IFU. Failure to follow the instructions for use may lead to incorrect results.

Certain ASTDs may show double zones and/or growth within the zone of inhibition. Such occurrences should be disregarded during zone interpretation, and only the outermost zone diameter should be evaluated. Interpretation of inhibition zone diameters can be subjective and depends on standardized reference tables. Variations in interpretation may result from observer experience or differences in reference standards.

SERIOUS INCIDENTS

Any serious incident related to the device must be reported to Biolab and to the competent authority of the country where the user and/or patient is established.

REFERENCES

1. Clinical & Laboratory Standards Institute (CLSI); M02, Performance Standards for Antimicrobial Disk Susceptibility Tests (Consult latest version)
2. Clinical & Laboratory Standards Institute (CLSI); M100, Performance Standards for Antimicrobial Susceptibility Testing (Consult latest version)
3. Clinical & Laboratory Standards Institute (CLSI); M45, Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria. (Consult latest version)
4. European Committee on Antimicrobial Susceptibility Testing (EUCAST); Disk Diffusion Method (Consult latest version)
5. European Committee on Antimicrobial Susceptibility Testing (EUCAST); Reading guide, EUCAST disk diffusion method for antimicrobial susceptibility testing (Consult latest version)
6. Societe Française de Microbiologie-Comite de L'antibiogramme de la Societe Française de Microbiologie/Recommandations (Consult latest version)



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Pictograms and Descriptions


Consult instructions for use



In vitro diagnostic medical device



Batch code



-20°C / +8°C Temperature limit



Cut the blister to separate



Do not re-use



Use-by date after opening



Contains sufficient for <n> tests



Use-by date



Manufacturer



European Conformity Mark