Liofilchem® Antibiotic Disc

Rx only IVD

SUMMARY AND EXPLANATION OF THE TEST

Antibiotic Disc are paper discs with special features, that are impregnated with antibiotic and used for the susceptibility test according to the Kirby-Bauer antibiotic testing (KB testing or disc diffusion antibiotic sensitivity testing).
The simultaneous growth of the bacteria and diffusion of the antimicrobials compounds forms a zone of inhibition of growth. Zone size observed in a disc diffusion test has no meaning in and of itself. This information is correlated with *in vivo* test able to determinate the resistance and susceptibility to antimicrobials and result in the interpretative standards.

PRINCIPLE OF THE METHOD

The discs are applied to the surface of a culture medium inoculated with a pure colony suspension of the microorganisms under examination. After incubation, the plates are examined, the zone diameter around each disc are examined and compared with the standard inhibition haloes: in this way the microorganisms are defined as being susceptible, intermediate or resistant to the tested antimicrobial agents.

REAGENTS

Antibiotic Disc is supplied in different packaging options (no additional reagents are included):

Disc in cartridge

- The 50-test box contains 1 cartridge with 50 discs packed in desiccant envelops
- The 250-test box contains 5 cartridges of 50 discs, each cartridge individually packed in a desiccant envelope.
- Each package also contains a transparent resealable bag.

Disc in canister

- The canister contains 250 discs and a desiccant tablet.

DIRECTIONS FOR USE

Storage

Unopened cartridges and canisters: On receipt, store Antibiotic Disc at –20°C to +8°C until the given expiry date. Some Antibiotic Disc (e.g. carbapenems) should be stored frozen at –20°C. Check the drug label for the specific storage temperature.

Opened canisters: Disc in canister can be used for up to 2 months from first opening (record the date on which the canister was open) and must be stored at the label storage temperature. Before using the remaining discs, check the expiry date indicated on the packaging. Do not store near sources of heat and do not expose to excessive temperature variations. Protect Antibiotic Disc from moisture, heat and direct exposure to strong light at all times.

Handling

Before using the Antibiotic Disc from an unopened package, visually inspect to ensure the package is intact. Do not use the strips if the package has been damaged. When removed from the refrigerator/freezer, allow the package or storage container to reach room temperature for about 30 minutes. Moisture condensing on the outer surface must evaporate completely before opening the package. Use forceps or a similar device to pick up a disc.
When using Antibiotic Disc from a canister, replace the lid immediately after use and store as outlined under STORAGE.

Precautions

The Antibiotic Disc is not classified as being hazardous according to current regulations. Antibiotic Discs is a disposable product. The Antibiotic Disc is only for diagnostic *in vitro* use and is intended for professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.
Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

Materials Required but Not Provided:

- Agar plate medium (validated by the media manufacturer for use with antimicrobial susceptibility testing, 90- or 150-mm plates)
- Suspension medium
- McFarland turbidity standard

  (The medium to be used as well as the inoculum suspension will depend on the organism under investigation, see the Antibiotic Disc Supplement for more information)
- Sterile loops, swabs (not too tightly spun), test tubes, pipettes and scissors
- Forceps
- Incubator (35 ± 2°C)
- Quality control organisms
- Additional technical information from **www.liofilchem.com**

Inoculum Preparation

Suspend well-isolated colonies from an overnight agar plate into the suspension medium to achieve the turbidity of the recommended McFarland standard. If the inoculum concentration is correct, a confluent or almost confluent lawn of growth will be obtained after incubation. If insufficient growth occurs, the testing should be repeated. McFarland turbidity standards do not guarantee the correct number of viable cells in the suspension. In order to verify that your procedure gives the correct inoculum density in terms of CFU/mL (a 0.5 McFarland approximately corresponds to 1-2 x 10^8 CFU/mL for *E. coli*) performing regular colony counts is recommended. An acceptable inoculum should give approximately 1-2 x 10^8 CFU/ml.

Inoculation

Dip a sterile swab in the broth culture or in a diluted form thereof and squeeze it on the wall of the test tube to eliminate excess liquid. Streak the swab over the entire sterile agar surface. Repeat this procedure by streaking 2 more times, rotating the plate approximately 60 degrees each time to ensure an even distribution of inoculum. Allow excess moisture to be absorbed so that the surface is completely dry before applying discs.
Use well-defined, high-quality media for AST that supports good growth. The brand chosen should have good batch-to-batch reproducibility to ensure that accurate and reliable zone diameters values are obtained.
The agar medium should have a depth of 4.0 ± 0.5 mm, a pH of 7.3 ± 0.1 and all other quality specifications should be fulfilled. Refer to the media manufacturer's instructions for more information.

Application

Using either sterile forceps or disc dispenser apply the disc(s) to the surface of the agar. Once applied, do not move the disc.

Incubation

Incubate the agar plates in an inverted position at the appropriate temperature, atmosphere and time. Refer to the drug-specific Disc Supplement for specific incubation instructions.

NOTES:

- The medium to be used depends on the organism under investigation and the methodology followed and must be validated by the media manufacturer for antimicrobial susceptibility testing.
- It is recommended to use the inoculum suspension within 15 minutes of preparation, apply discs within 15 minutes of inoculation and incubate plates within 15 minutes of disc application.

Eliminating Used Material

After use, the discs and material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.

Reading the inhibition zone diameters

At the end of the incubation period, measure the inhibition zone diameters (mm) with zone edges should be read at the point of complete inhibition as judged by the naked eye with the plate held about 30 cm from the eye.
Measure zone diameters to the nearest millimetre with a ruler or a calliper. If an automated zone reader is used, it must be calibrated to manual reading.
Do not read the plate if the culture appears mixed or if the lawn of growth is too light or too heavy.
For full instructions relating to the interpretation of the results according to CLSI and FDA guidelines, refer to the relevant current standards.

NOTES:

- Excessively wet plates prior to inoculation, insufficient drying before applying discs and/or unevenly streaked surfaces may give non-confluent growth. Repeat the test if the inhibition zone diameter is difficult to read.
- Occasionally, certain antimicrobial agent/microorganism combinations may give unusual results. In these cases, judgment of the inhibition zone diameter may be difficult for the inexperienced personnel.

Result Interpretation
To categorize the result according to the interpretive criteria, refer to the appropriate Antibiotic Disc product supplement for the specific antimicrobial agent interpretive criteria.

QUALITY CONTROL

To check the performance of the Antibiotic Disc result, test the quality control strain(s) as shown in the appropriate Antibiotic Disc product supplement. Patient isolate results are considered satisfactory if the quality control result(s) fall within the expected range(s). Patient isolate results should not be reported if the quality control results are outside of this stated QC range.

LIMITATIONS

Refer to the drug-specific Disc Supplement.

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. Organism resistance patterns will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

Refer to the drug-specific Disc Supplement.

REFERENCES

1. CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*. 12th ed. CLSI standard M07. Wayne, PA: Clinical and Laboratory Standards Institute; 2024.

GLOSSARY OF TERMS

	Do not reuse
LOT	Batch code
	Manufacturer
IVD	*In Vitro* Diagnostic Medical Device
	Fragile, handle with care
	Upper limit of temperature
	Use by
REF	Catalogue number
	Contains sufficient for <n> tests
	Temperature limitation
	Consult instructions for use

Drug Specific Supplement for Antibiotic Disc Ceftobiprole BPR 5 µg

Rx only

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Indications for Use/Intended Use

Liofilchem Antibiotic Discs are a semi-quantitative agar diffusion method for *in vitro* determination of antimicrobial susceptibility of clinical isolates tested on agar media after overnight incubation.

The Ceftobiprole BPR 5 µg Disc is intended to determine suceptibility of Enterobacterales and *Staphylococcus aureus* to ceftobiprole, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). Ceftobiprole at concentrations of 5 µg should be interpreted at 16-18 hours of incubation.

The Ceftobiprole BPR 5 µg Disc demonstrated acceptable performance with the following organisms:

Enterobacterales (*Escherichia coli* and *Klebsiella pneumoniae*)
Staphylococcus aureus (includes methicillin resistant isolates)

Specifications

Antibiotic code: BPR
Concentration: 5 µg
Antibiotic group: Cephem

Directions for Use

Follow the Antibiotic Disc package insert instructions.

Procedures specific to Ceftobiprole BPR 5 µg:

Storage	Temperature between –20°C and +8°C
Organism	Enterobacterales, *S. aureus*
Medium	Mueller Hinton Agar
Inoculum	Suspension in saline (0.85% NaCl) to 0.5 McFarland standard (1 if mucoid)
Incubation	Agar plates in inverted position at 35 ± 2°C for 16-18 hours in ambient atmosphere

FDA ceftobiprole interpretative criteria (zone diameters in mm)

Use the following breakpoints to categorize the result according to the interpretive criteria (i.e., susceptible, intermediate or resistant).

Bacterial Species	Susceptible	Intermediate	Resistant
Enterobacterales	≥23	21-22	≤20
Staphylococcus aureus (includes methicillin resistant isolates)	≥16	14-15	≤13

US FDA Susceptibility Interpretive Criteria (STIC) Ref:

https://www.fda.gov/STIC

Quality Control Range (mm) (CLSI M100S Performance Standards for Antimicrobial Susceptibility Testing, 35ed Edition)

To check the performance of the Antibiotic Disc ceftobiprole, media and procedure, test *E. coli* ATCC 25922 or *S. aureus* ATCC 25923 according to the method as outlined in the Antibiotic Disc package insert.

Quality Control Strain[a]	Zone range (mm)
E. coli, ATCC® 25922	25 – 31
S. aureus ATCC® 25923	20 – 27

[a] Strains recommended for routine QC with ceftobiprole by CLSI M100Ed35

Performance Characteristics

Correlation to Reference Method

	N	% Category Agreement
Enterobacterales	317	98.7
Staphylococcus aureus	325	94.8

N, Number of isolates
CA, Category Agreement

Reproducibility

100.0 % of Ceftobiprole BPR 5 µg disc results for non-fastidious Gram-negative bacteria (4 *E. coli*, 4 *E. cloacae* and 2 *K. pneumoniae* tested in triplicate at 3 sites on 3 days) fell within ± 3 mm of the test mode. 100% of Ceftobiprole BPR 5 µg disc results for *Staphylococcus aureus* (5 methicillin susceptible, 5 methicillin resistant tested in triplicate at 3 sites on 3 days) fell within ± 3 mm of the test mode.

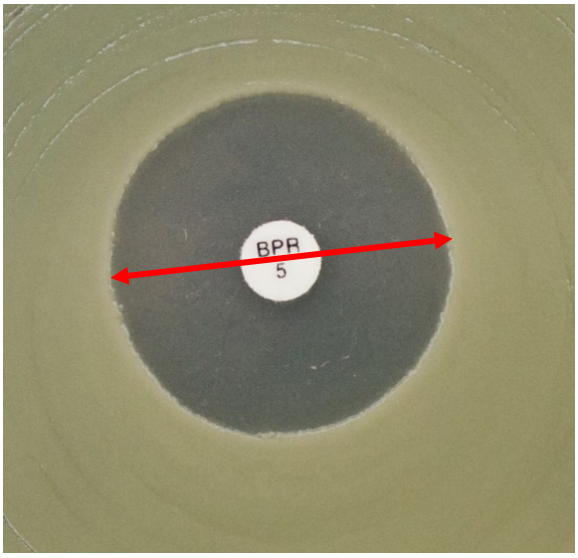
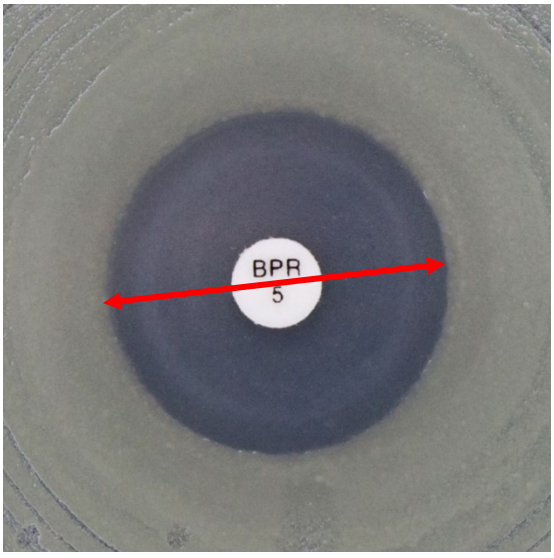
Limitations

Invalid results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

The ability of the Antibiotic Disc to detect resistance or non-susceptibility to antimicrobials as shown below is unknown because resistant strains were not available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.

Ceftobiprole: *Staphylococcus aureus*.

Antibiotic Disc Ceftobiprole BPR 5 µg Reading Examples

Example 1: *Escherichia coli*	Example 2: *Staphylococcus aureus*
	
Inhibition zone diameters marked in red.	

PRESENTATION	µg	Code	Packaging	Ref.
Ceftobiprole	5	BPR	5 x 50 1 x 50 1 x 250	9242 9242/1 9242/2

REVISION HISTORY

Document	Release Date	Change Summary
eIFU 9242 IFU-1 ATB BPR US	2025-06-23	Not applicable (Initial release)

Note: Minor typographical, grammar, and formatting changes are not included in the revision history.

For all inquiries please fill out the form at https://www.liofilchem.com/en-us/contacts.html

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