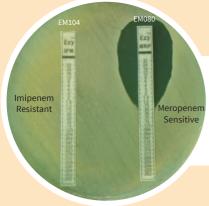
## **Ezy MIC™ Strips**

MIC Determination Strips



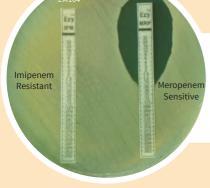
## Carbapenem Sensitivity & MBL Detection



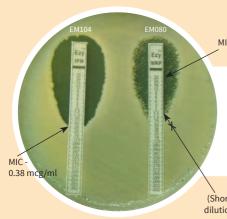
- Meropenem and Imipenem has no cross resistance
- Hence, need to use both Ezy MIC<sup>™</sup> Strip for susceptibility test



Strain B



Strain A

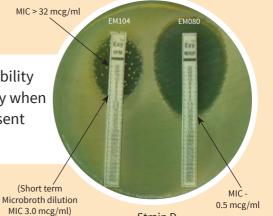


Strain C

MIC > 32 mcg/ml

Short term automated susceptibility result may show false sensitivity when resistant sub-population is present within the organism

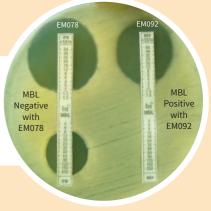
(Short term Microbroth dilution MIC 1.5 mcg/ml)



Strain D

MBL Negative Positive with EM092 EM078

For MBL Detection, both Meropenem with & without EDTA (EM092) and Imipenem with & without EDTA (EM078) Strips must be used.



Strain B

Strain A

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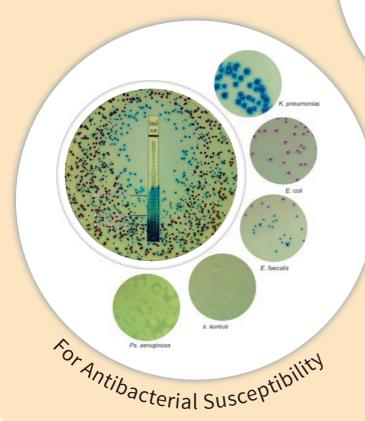
Chromogenic identification

+

Antimicrobial Susceptibility

M2067 HiCrome™ Mueller Hinton Agar (for Antifungal Testing)

M2010 HiCrome™ Mueller Hinton Agar With dual advantage



Tor Antifungal Susceptibility

Features:
Rapid &
Reliable Method
with Dual advantage





he MIC is the lowest concentration of an antimicrobial agent that visually inhibits growth of a microorganism under defined experimental conditions.

MIC testing is a very valuable quantitative assay tool for evaluating the pathogenic microorganism's degree of susceptibility and to detect the specific resistance mechanism. Today clinical microbiology laboratories can provide MIC testing services and in many cases exact values for determining the therapy for individual patient. Selection of the most effective antimicrobial agent and dosing regimen for serious infection will help in eliminating the pathogens and minimize resistance selection and decrease mortality. HiMedia has already adopted this system in the form of HiComb™ (MD), which is based on innovative disc diffusion and gradient-based technique, essentially with a wide choice of antibiotics.

HiMedia® now brings to you the Ezy MIC™ Strips, the patient-sensitive test for selection of most appropriate antimicrobial agent and its dose.



#### Antimicrobial Susceptibility Testing (For In Vitro Diagnostic Use)

#### Introduction

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. However, in the last few decades bacteria have emerged with new forms of virulence and new patterns of resistance to antimicrobial agents leading to various resistant strains. Hence it has become necessary to find the MIC of a drug, so as to control the irrational use of antibiotics and further in controlling spread of these strains and better alternate therapy.

#### Why MIC?

The minimum inhibitory concentration (MIC) is the lowest concentration of the antimicrobial agent required to inhibit growth of a microorganism under defined conditions. It gives us an insight into factors far exceeding the role of antimicrobial susceptibility disc, thus helping us to determine the clinical outcome more precisely.

MIC values lower than the breakpoints are interpreted as susceptible results and those higher as resistant for treatment guidance. MIC breakpoint values are vital in categorizing susceptibility group for *In vitro* antimicrobial susceptibility testing and clinical interpretation. Understanding the concept of MIC and its relations to the interpretive breakpoint is one of the major hassles to microbiologist and clinicians. Since the pharmacokinetics of antimicrobial agents can be different, two agents with the same MIC value for an organism may have totally different interpretations because they have different breakpoints. MIC testing is a very valuable quantitative assay tool for evaluating the pathogenic microorganism degree of susceptibility and to detect the specific resistance mechanism.

#### **Limitations of Disc Diffusion AST**

Antibiotic susceptibility using discs have been often shown to be unreliable in a number of situations including

the testing of beta lactams with non-fermenting Gramnegative bacilli and Haemophilus influenza, glycopeptide with Enterococci and Staphylococci. In the case of vancomycin, the antimicrobial susceptibility testing using disc diffusion test does not differentiate vancomycinsusceptible isolates of S.aureus from Vancomyci n intermediate isolates, nor does the test differentiates among Vancomycin-susceptible, intermediate, and resistant isolates of coagulase-negative staphylococci, all of which may give similar size zones of inhibition hence there is global consensus that a fully quantitative MIC method is needed while reporting vancomycin susceptibility results. In the face of evolving multi drug resistant strains, it has been recently demonstrated that this emerging form of resistance cannot be accurately detected by most currently used methods. With emerging resistance patterns, clinicians require information on the presence of low level and/ or hetero-resistance. The inadequacies of qualitative methods have been well recognized and clinical microbiology laboratories cannot rely on a single susceptibility testing method to detect these emerging resistance phenotypes and also provide discrete MIC data that can be specifically used to finetune individual patient therapy.

#### What are Ezy MIC™ Strips?

Ezy  $\mathsf{MIC^{TM}}$  Strips is a quantitative technique for determining the antimicrobial susceptibility of a wide range of aerobic and fastidious organisms. The system comprises a predefined antibiotic gradient which is coated on a paper strip used to determine the Minimum Inhibitory Concentration (MIC), in  $\mu g/ml$ , of different antimicrobial agents against variety of microorganisms when tested on appropriate agar media under specific incubation conditions.

#### Ezy MIC™ Strips can help you to,

- Determine the MIC of fastidious, slow-growing or nutritionally deficient micro-organisms, or for a specific type of patient or infection.
- Confirm/detect a specific resistant phenotype e.g. ESBL, MBL, AmpC, MRSA, HLAR or VISA/hVISA.
- Detect low levels of resistance.



- Test an antimicrobial not performed in routine use or a new, recently introduced antimicrobial agent.
- It provides high medical value to critical care cases to, refine or guide treatment decisions. Also helps in determining the choice and dosage of antimicrobials in patients with sterile site infections (e.g. endocarditis), severe nosocomial infections, chronic infections (e.g. cystic fibrosis) and immunosuppressed patients.
- Promote antibiotic stewardship.

#### **Underlying Principles**

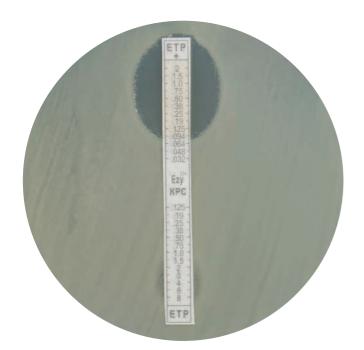
The Ezy MIC™ Strip gradient technology is based on a combination of the concepts of dilution and diffusion principles for susceptibility testing. As with other dilution methods, Ezy MIC™ Strip directly quantifies antimicrobial susceptibility in terms of discrete MIC values. However, in using a predefined, stable and continuous antibiotic concentration gradient Ezy MIC™ Strip MIC values can

Ezy MIC<sup>™</sup>
Ertapenem + Boronic acid Ezy MIC<sup>™</sup> Strip **\Psi**(EM141) tested with
KPC positive strain (1) & KPC negative strain (2)

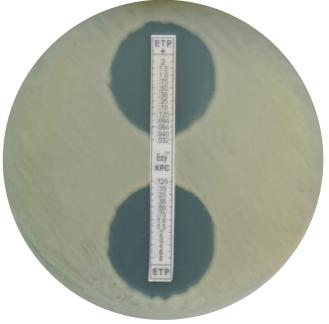
be more precise and reproducible than results obtained from conventional procedures based on discontinuous two-fold serial dilutions.

Although it appears like a modified disc diffusion test, due to its similarity in method of inoculum preparation, choice of test agar media and incubation conditions, Ezy MIC™ Strip is not a diffusion method and differs totally in concept from conventional disc methods. The Ezy MIC™ Strip antimicrobial concentration gradient is preformed, predefined and stable, and is not dependent on diffusion.

Ezy MIC<sup>TM</sup> Strip is a thin, inert and porous paper strip coated with antibiotic. Both sides of the strip are likewise printed with the MIC reading scale in μg/ml and the two or three-letter symbol printed on the top of the strip helps in easy identification of the antibiotic. A predefined exponential gradient of antibiotic, dried and stabilized, is immobilized on either sides of the strip with the concentration maximum at one end and minimum at the other. The gradient covers a continuous concentration range across 15 two-fold dilutions of a conventional MIC method.



K. pneumoniae ATCC BAA - 1705 (KPC Positive Strain)



K. pneumoniae ATCC BAA - 1706 (KPC Negative Strain)



#### **←** Ezy MIC<sup>™</sup> Strips

Ezy<sup>™</sup> VAN

- 256 - 192 - 192 - 126 - 482 - 12 - 12 - 12 - 15 - 15 - 125 - 125 - 125 - 125 - 1064 - 0323 - 016 When an Ezy MIC<sup>TM</sup> Strip is applied to an inoculated agar surface, there is gradual but effective transfer of the preformed antibiotic gradient from the strip into the agar medium. A stable, continuous and exponential gradient of antibiotic concentrations is formed directly underneath the strip. After incubation under appropriate conditions, whereby bacterial growth becomes visible, a symmetrical inhibition ellipse centered along the strip is seen. The MIC value is read from the scale in terms of  $\mu g/ml$  where the ellipse edge intersects the strip.

To obtain reproducible MIC's from a gradient based system, the stability of the gradient must be maintained throughout the critical period when the position of the growth/inhibition edge for a particular bacterium/antibiotic combination is determined. Due to the stability and precision of the Ezy MIC™ Strip predefined gradient, MIC values have been shown to be reproducible and equivalent to those of the CLSI reference dilution procedures.

#### Advantages of Ezy MIC™ Strips

Ezy MIC™ Strip exhibits several advantages over conventional plastic MIC strip.

#### Note

- 1. Ezy MIC<sup>™</sup> Strip is made up of thin inert porous biodegradable paper material.
- 2. Unlike for other strips, Ezy MIC<sup>™</sup> Strip has MIC values printed on both sides identically and therefore MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
- 3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC<sup>™</sup> Strip and hence it can be placed by any side on the agar surface.
- 4. Once placed, Ezy MIC<sup>™</sup> Strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 5. Unlike with plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
- 6. Ezy MIC<sup>™</sup> Strip can be very easily, conveniently and accurately placed on the agar surface with the aid of specially developed and simple to use applicator.

#### **Storage**

All packages must be stored as specified on the product label, until the given expiry date. Products can always be stored lower than the maximum temperature specified.

Ezy MIC™ Strip left over from an opened package must be kept dry. Ideally, strips should be removed from the container in AC room where humidity is controlled and is at minimum level. Moisture should be prevented from penetrating into or forming within the package or storage container.

#### **Handling**

Before using the Ezy MIC™ Strip gradient strips from an unopened package, visually inspect to ensure the package is intact. Do not use the Ezy MIC™ Strips if the package has been damaged.

Allow the original package or storage container to reach room temperature before opening. Ensure that moisture condensing on the outer surface has evaporated completely before opening the package.

#### **Precautions And Warnings**

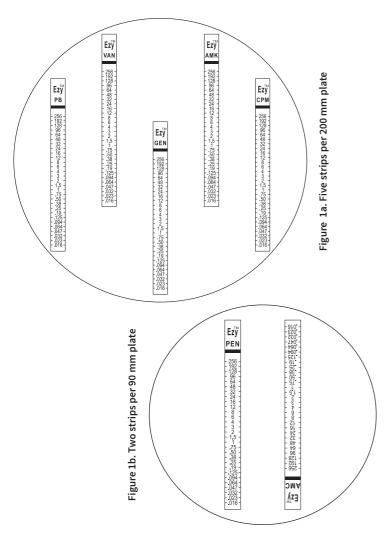
- Ezy MIC<sup>™</sup> Strip is intended for *In vitro* diagnostic use only.
- Although based on simple procedure, Ezy MIC<sup>™</sup> Strip should only be used by at least semi-trained personnel.
- This strip is intended only for agar diffusion method and not for broth dilution method.
- Ezy MIC™ Strip should be used strictly according to procedures described herein.
- Performance of Ezy MIC™ Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- ◆ Before using Ezy MIC<sup>™</sup> Strips, ensure that the strip is at room temperature.

#### **Procedures**

#### **Materials provided**

- ◆ 10/30/60/90/120/150 Ezy MIC<sup>™</sup> Strip of one antibiotic
- ◆ 1 package insert
- Applicator Sticks





#### Materials required but not provided

- Agar plates (90/100 mm or 150 mm) with the appropriate susceptibility test media (Table 1)
- ◆ Inoculum suspension media (Table 1)
- Cotton Swabs (sterile, non-toxic and not too tightly spun), test tubes
- ◆ 0.5 and 1 McFarland turbidity standards
- Incubator (35 ± 2°C), anaerobic jar or chamber or CO<sub>2</sub> enriched chamber (Table 1)
- Quality control organisms

## Guidelines for preparation of medium for antibacterial agents

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45- 50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of  $4 \pm 0.2$ mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

#### Preparation of Inoculum for bacterial strains

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for 2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland (prepared by mixing 0.5 ml of 1.175% barium chloride and 99.5 ml of 0.36N sulfuric acid). Dilute the inoculum or incubate further as necessary to attain comparative turbidity. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 625 nm).

Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland. This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, *Bacteroides* spp, *Clostridium* spp., Streptococci and for testing Staphylococci for potential Methicillin or Oxacillin resistance.

## Guidelines for preparation of the medium for antifungal agents

1. Prepare Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) from dehydrated powder according to the directions specified on the label. Alternately, prepare Mueller Hinton Agar with added 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (this could be added pre or post sterilization). Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

(Note: When testing Caspofungin Ezy MIC<sup>™</sup> Strip (EM119), Anidulafungin Ezy MIC<sup>™</sup> Strip (EM122) & Micafungin Ezy MIC<sup>™</sup> Strip (EM121), surface of the test agar medium should be completely dried before inoculation.)

2. While Testing Flucytosine Ezy MIC™Strip. RPMI 1640 Agar W/ MOPS & 2% Glucose w/o Sodium Bicarbonate (Twin Pack) (M1972) from dehydrated powder according to the directions specified on the label cool the sterlized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow it to solidify.



#### Preparation of Inoculum for fungal strains

- Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at 35°C. Colonies are suspended in 5ml of sterile 0.85% Saline
- 2. Vortex the resulting suspension and adjust the turbidity to yield 1x  $10^6$  5 x  $10^6$  cells /ml (i.e. 0.5 McFarland standard)

#### Test procedure

- 1. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Remove more fluid when streaking a 90 mm plate and less for a 150 mm plate. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Do not allow excess moisture to be absorbed in the medium as adequate moisture on the agar surface is very much desirable.
- 2. Open the package and handle the Ezy MIC™ Strip as described under HANDLING.
- 3. Place the strips using the applicator as shown in Figures 2a to 2i for blister pack and 3a to 3i for glass vial.
- 4. Diagramatic representation has been shown to optimally position Ezy MIC™ Strip in an equidistant pattern on an agar plate. Five Ezy MIC™ Strip can be placed on a 150 mm agar plate (Figure 1a). For single MICs, one or two strips can be used on a 90 mm agar plate (Figure 1b).
  - **Note**: For organisms expected to be highly susceptible, use fewer strips per 150 mm plate and only one on a 90 mm plate.
- 5. One placed Ezy MIC<sup>™</sup> strip should not be repositioned or adjusted. Within 60 seconds, Ezy MIC<sup>™</sup> strip will be adsorbed and will firmly adhere to the agar surface.
- 6. Ensure that the whole strip is in complete contact with the agar surface. Incubate the agar plates in an inverted position after drying for approximately 10 to 15 minutes under appropriate conditions.

#### **Notes:**

1. When the inoculum and inoculation are optimal, an even confluent growth will be obtained.

- McFarland turbidity standards do not guarantee correct number of viable cells in the suspension. Perform colony counts regularly to verify that the inoculum procedure gives the correct number of viable cells in cfu/ml. Please refer to the QUALITY CONTROL section.
- 3. While testing Oxacillin Ezy MIC™Strip Mueller Hinton Agar + 2% NaCl is to be used
- 4. Use the direct colony suspension method using overnight growth when testing *Staphylococcus* spp. with Oxacillin.
- 5. When testing Azithromycin with *S. pneumoniae* incubate the plate under ambient conditions. Incubation in CO<sub>2</sub> will affect the activity of Azithromycin and MIC values, making interpretive and quality control criteria for ambient incubation non-valid.
- 6. Use well defined and high quality medium that supports good growth. The brand chosen should have good batch-to-batch reproducibility to ensure that accurate and reliable MIC values are obtained.
- 7. For Trimethoprim and Trimethoprim/ Sulfamethoxazole, ensure that the brand and batch of agar has a low thymine/thymidine content to minimize antagonism of the activity of Trimethoprim and sulphonamides.
- 8. The inherent calcium content in Mueller Hinton agar may vary between brands and batch to batch. Perform quality control of agar plates on a batch to batch basis to qualify it for use.
- The inherent manganese content in Mueller Hinton agar may vary between brands and batch to batch. Perform quality control of agar plates on a batch to batch basis to qualify it for use, particularly for testing of Tigecycline.
- 10.Ensure the agar plate is incubated for the recommended period before reading, especially for delayed expression of resistance and slow growing and fastidious organisms.
- 11. While testing Flucytosine Ezy MIC™ Strip (EM118), RPMI 1640 Agar w/ MOPS & 2% Glucose w/o Sodium Bicarbonate (Twin Pack) (M1972) is to be used.
- 12. When testing Caspofungin Ezy MIC™ Strip (EM119), Micafungin Ezy MIC™ Strip (EM121) & Anidulafungin Ezy MIC™ Strip (EM122), swabbed plate (with test culture) should be dried for atleast 1 to 1½ hour before placing the Ezy MIC™ Strip.



#### **Interpretation of Results**

#### **Reading the MIC**

- After the required incubation period (Table 1), and only when an even lawn of growth is distinctly visible, read the MIC value where the edge of the inhibition ellipse intersects the side of the strip
- If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the zone
- Do not read the plate if the culture appears mixed or if the lawn of growth is too light or too heavy; repeat the test
- With Ezy MIC<sup>™</sup> Strips the MIC endpoints are usually clear-cut although different growth/inhibition patterns may be seen. Refer the result reading guide for few such illustrations.

#### **Important Reading Observations**

- Forbactericidal drugse.g. Quinolones, Aminoglycosides, ß-lactams, always read the MIC at the point of complete inhibition of all growth, including hazes, microcolonies and isolated colonies. Tilt the plate and/ or use a magnifying glass to carefully examine endpoints, especially for Pneumococci, Streptococci, Enterococci, Fusobacteria, Acinetobacter and Stenotrophomonas species.(fig. 4.1)
- For bacteriostatic drugs e.g. Trimethoprim / Sulfamethoxazole, Linezolid, Erythromycin, Roxithromycin, Clindamycin, Fosfomycin, Tetracycline, Chlorampheni col etc. read trailing endpoints at 80% inhibition, i.e. the first point of significant inhibition as judged by the naked eye. (fig. 4.2)
- Excessively wet plates prior to inoculation or unevenly streaked surfaces may give non-confluent intersections. Repeat the test if MIC endpoints are difficult to read. (fig. 4.3, 4.4)
- When growth occurs along the entire strip i.e. no inhibition ellipse is seen, report the MIC as ≥ the highest value on the MIC scale (fig. 4.5).
- When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC ≤ the lowest value on the MIC scale. (fig. 4.6)
- If inhibition ellipses for Clindamycin or Chloramphenicol "dip" at the endpoint, extrapolate the MIC at the initial indentation, i.e. 0.5-1 dilution above the intersection.

- For Quinupristin / Dalfopristin hazy and trailing growth for Staphylococci and Enterococci should be read 90% inhibition as judged by the naked eye. Read isolated macrocolonies in the inhibition ellipse at complete inhibition.
- Sometimes inhibition ellipses can be narrow. Read the actual intersection at the strip and not growth "hugging" the side of the strip. (fig.4.7)
- When macrocolonies are present within the ellipse for bactericidal agents, read all macrocolonies within 1-3 mm from the strip (fig.4.11).

#### Interpretation

- Interpret the MIC breakpoints as per the interpretative criteria provided by CLSI guidelines.
- Being a fully quantitative MIC method, Ezy MIC™ Strip enables the laboratory to report the exact MIC value together with the interpretive category. Ezy MIC™ Strip generates MIC values from a continuous scale and can give results in-between conventional two-fold dilutions i.e. half dilutions. For a MIC value which falls between standard two-fold dilutions, the value must be rounded up to the next upper two-fold value before categorization. (fig. 4.8)

For Example: Penicillin MIC (µg/mL) breakpoints for *Streptococcus pneumoniae* are:

If the MIC reading is 1  $\mu$ g/ml, it is reported as Intermediate (I) while a MIC of 1.5 is rounded up to 2  $\mu$ g/ml and the category reported is resistant (R). However, MIC value between 1.0 and 1.5 should be reported as 1.0 and hence is to be categorized as Intermediate (I)

 MIC results for a quality control (QC) strain that fall a half dilution below the lower QC limit should be rounded upto the next upper two fold value before establishing QC compliance. However, MIC results that are a half dilution above the upper limit show non-QC compliance

#### **Quality Control**

 In antimicrobial susceptibility testing, QC includes the procedures to monitor the performance of the strips to ensure reliable results. This is achieved by the testing of standard QC strains against the antibiotics using the above mentioned procedures



The major goals of the QC procedures are to monitor the following:

- 1) The precision and accuracy of the strips.
- 2) The performance of the strip used in the tests.
- 3) The performance of the persons carrying out the procedures.
- The strips and test procedure are considered satisfactory if MIC values obtained fall within the quality control specifications provided on each Ezy MIC™ Strip product supplement and as summarized in Table 2
- Do not report patient results when quality control results are outside the stated QC ranges. Frequency of quality control testing should be established by the individual laboratory. Guidelines are provided in CLSI Antimicrobial Susceptibility Testing documents
- Perform regular colony counts to verify the density of the inoculum suspension in terms of cfu/ml of viable cells as McFarland turbidity standards do not guarantee the correct number of viable cells in cfu/ml. For example, dilute the inoculum suspension 1:1000 and subculture 10µl onto the recommended agar (Table 1). An acceptable inoculum should give approximately 100 to 500 colonies, i.e. 10<sup>5</sup> x10<sup>8</sup> cfu/ml.

#### **Performance Characteristics**

Ezy MIC<sup>TM</sup> Strip is considered to be in essential agreement (EA) with the CLSI method when MIC values from both procedures show an EA of  $\geq$  90% within  $\pm 1$  dilution.

#### **Important Observations**

- 1. In Ezy MIC™ Pruduct sheet (Instruction for Use), Interpretive criteria has been given for various organisms according to standard guidelines
- Occasionally, certain antibiotic/bacterium combinations may give unusual results. In these cases, judgment of the MIC endpoint may be difficult for inexperienced personnel. However, individuals can be trained through regular use of quality control strains, Ezy MIC™ Strip reading guides and comparisons with experienced personnel to correctly assess MIC endpoints.
- 3. Being agar based, Ezy MIC<sup>™</sup> Strip has been shown to correlate best with the reference agar dilution. Correlations have been shown with the reference broth microdilution whenever an agar dilution reference is absent.

- 4. As with all AST data, Ezy MIC™ Strip results are used in *In vitro* diagnostics only and may provide an indication of the organism's potential *in vivo* susceptibility. The use of results to guide therapy selection must be the sole decision and responsibility of the attending physician who should base judgment on the particular medical history and knowledge of the patient, pharmacokinetics/ pharmacodynamics of the antibiotic and clinical experience in treating infections caused by the particular bacterial pathogen with the antibiotic, dose and dosing regimen being considered.
- 5. For details of specific interpretive limitations and/ or limitations on the clinical use of an antibiotic in various therapeutic situations, please refer to the tables and footnotes of MIC interpretive standards in the latest CLSI AST documents for dilution procedures (M7-A, M11-A and M100-S series)

#### **Warranty And Disclaimer**

#### **Express Limited Warranty And Disclaimer**

HiMedia expressly warrants that Ezy MIC™ Strip will determine the MIC of the antimicrobial agent on each test strip, if the procedures, precautions and limitations indicated in this package insert are strictly complied with. If the test strip does not do so, HiMedia shall refund the cost of the product or replace the defective test strips.

HiMedia makes no other warranties, expressed or implied, including the implied warranty of merchantability or fitness for particular purpose.

Any change or modification of the product instructions may affect results. HiMedia shall not be liable for any damages resulting from product tampering, variance in transportation, stated storage, handling, testing procedures, precautions and other instructions of the most recently revised version of the package insert.

HiMedia Easy MIC<sup>™</sup> and Ezy MIC<sup>™</sup> Strip are used pending and/or registered trademarks belonging to HiMedia.

#### References

- Clinical and Laboratory Standards Institute (formerly NCCLS), 2018, Performance Standards for Antimicrobial Susceptibility Testing; Twenty Eighth Informational Supplement M100 - S28, Vol 38. No 3, Jan 2018, Wayne, PA
- 2. Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance tor Industry and FDA. Food and Drug Administration, Division of Microbiology Devices, March 2007.
- Performance standards of Antimicrobial Susceptibility Testing; Twenty Eighth Informational Supplement. M100-S28, Vol. 38, No.3, Jan 2018.



#### Determination of MIC using Ezy MIC™ strips depends on various factors

#### Medium used

Mueller Hinton Agar is recommended for determination of MIC of various antibacterials in case of aerobes. The Quality of the medium plays a major role in determining the exact MIC, for example, in case of aminoglycosides and Quinolones, MIC's increase above the acceptable range with higher concentration of Ca++ and Mg++ content and vice-versa. MIC of macrolides, penicillin's and Quinolones are obtained on higher side if the pH of the medium is more towards acidic side, whereas Tetracycline's show lower MIC's with acidic pH. MIC of Carbapenem's goes higher if concentration of Zn++ is on higher side.

It is therefore necessary that MHA medium used for susceptibility testing has acceptable range of Ca++ i.e. 20-25 mg/L and Mg++ i.e. 10-12.5 mg/L. The acceptable range for pH is 7.2-7.4.

#### **MHA Plates**

As Ezy MIC™strips are made of high quality absorbent paper, proper water content in MHA plate is essential for adherence of strips to the medium surface. We therefore recommend freshly in-house prepared MHA plates or properly stored ready prepared plates wherein moisture content is retained for optimum performance.

**Note**: For Echinocandins class, surface of the prepared plates should be completely dry.

#### Reference strains

CLSI (Clinical and Laboratory Standards Institute) recommends use of ATCC strains for validation of MIC determination system such as Ezy MIC™ strips. The values are expected to fall within the acceptable range.

However, if ATCC reference strains are not maintained and subcultured as per the recommended method, it can adversely affect the performance of Ezy MIC™ strips. It is therefore necessary to ensure that these strains are homogenous and does not have resistant or sensitive subpopulation within, which often arises on repeated subculturing. A culture which is pure may also harbour heterogeneous subpopulation. It is interesting to note that such subpopulation may not show morphological variation and also may alter response to a particular or a group of antibiotics as mode of action are different for different classes of antibiotics. For example

*K.pneumoniae* ATCC 700603 shows resistance to betalactam class of antibiotics due to presence of plasmid. However, spontaneous loss of this plasmid renders strain sensitive.

#### Ezy MIC™ Strips storage

The basic property of paper is to absorb moisture from surrounding atmosphere which adversely affects performance of antibiotics particularly beta-lactams. Therefore, it should be ensured that these beta-lactam antibiotic strips are received in cold chain and container is immediately transferred to recommended temperature (-20°C) or below. Before using, the container must be brought to room temperature having maximum dry condition which is created if air condition system is on for long time. After use, the lid should be tightly closed before keeping back in to the cold condition as recommended.

#### Interpretation of results

EzyMIC™strips are easy to read by any technician. However, basic knowledge has to be imparted. Reading instruction chart with photographic illustration is provided. One is advised to get familiar with various situations that may arise. For example, if resistant colonies appear within the zone of inhibition then observe position of such colonies. The highest value where the colony is closer towards the strip is the correct MIC value to be interpreted. Similarly for bacteriostatic antibiotics, MIC is to be read at 80 % inhibition (ie. ½ to 1 fold lower MIC's than that observed at 100% inhibition) and for bactericidal antibiotics at 100 % inhibition point.

#### **Antifungal testing**

Though CLSI recommends microbroth and macro broth MIC determination method for testing antifungal agents, Ezy MIC™ strips for antifungal are designed and standardised to give same reference strain values as per the ATCC criteria while using solid "Methylene Blue Glucose Agar" i.e. Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) which is CLSI recommended for antifungal disc diffusion testing on solid media. This does away the need to use cumbersome and expensive RPMI medium.

At HiMedia Quality Control Labs, Quality of Ezy MIC™ strip is ensured by rigid testing and ensuring equal performance in terms of comparable MIC values.



## Figure 2: Procedure for application of Ezy MIC™ Strips (For Packing with Blister Pack)



Remove the Ezy MIC™ strips from its container after reaching to the room temperature



Remove the outer foil & open the lid



Hold the applicator stick with its narrow tip.





Place the strip at the desired position on an adequately moist, pre swabbed plate



Lift the applicator stick. The strip will adhere to the base of the stick



Hold the applicator stick at it's center & place the broad sticky end gently at the center of the Ezy MIC™ Strips





Gently rotate the applicator stick clockwise, with this action the applicator will detach from the strip



Do not press the Ezy MIC™ Strip. It will be adsorbed within 60 seconds



Replace the pack back into the container & store as recommended



## Figure 3: Procedure for application of Ezy MIC™ Strips (For Packing with Glass Vial)



Remove the Ezy MIC<sup>™</sup> strips from the box after reaching to the room temperature.



Break open the outer seal of the vial.



Remove the rubber stoper of the vial.





Lift the applicator stick. The strip will adhere to the base of the stick.



Hold the applicator stick & place the broader sticky end gently on the Ezy MIC™ Strip.



Hold the applicator stick with its narrow tips.





Place the strip at the desire position on an adequately moist, swabbed plate. gently rotate the applicator stick clockwise, with this action the applicator will detach from the strip.



Do not press the Ezy MIC<sup>™</sup> Strip. It will be adsorbed within 60 seconds.



Replace the vial with the white cap provided with the kit & store as recommended.



### Range of Ezy MIC<sup>™</sup> Product

#### Range of Ezy MIC<sup>™</sup> Strips

HiMedia provides a range of Ezy MIC™ Strips for testing of antibacterial as well as antifungal agents. The range also includes strips that would be handy in detection of MRSA Strains, HLAR Strains, ESBL producers, AmpC producers and MBL producers.

Ezy MIC™ Strips are available in pack size of 10/30/60/90/120/150 strips per pack

Code	Product	Symbol	Range (mcg/ml)
	Antibacterial Ezy MI	C Strips	
EM001	Amikacin	AMK	0.016-256
EM002	Amoxicillin*	AMX	0.016-256
EM003	Amoxyclav*	AMC	0.016-256
EM139	Amoxyclav* (As per EUCAST) (Amoxicillin/ Clavulanic acid)	AUG	0.016-256
EM068	Ampicillin*	AMP	0.016-256
EM109	Ampicillin/Sulbactam*	AMS	0.016-256
EM140	Ampicillin / Sulbactam* (4 mcg/ml) As per EUCAST	SAM	0.016 – 256
EM004	Azithromycin	AZI	0.016-256
EM006	Aztreonam*	AZT	0.016-256
EM126	Bacitracin	BAC	0.016-256
EM107	Cefaclor*	CEC	0.016-256
EM008	Cefazolin*	CFZ	0.016-256
EM009	Cefdinir*	CDR	0.016-256
EM070	Cefepime*	СРМ	0.016-256
EM093	Cefepime/ Tazobactam*	CPT	0.016-256
EM110	Cefixime*	FIX	0.016-256
EM148	Cefixime/Clavulanic acid*	FIC	0.016-256
EM114	Cefmetazole*	CMZ	0.016-256
EM113	Cefonicid*	CID	0.016-256
EM112	Cefoperazone*	CFP	0.016-256
EM094	Cefoperazone/ Sulbactam*	CPS	0.016-256
EM100	Cefotaxime*	CTX	0.002-32
EM064	Cefotaxime*	CTX	0.016-256
EM101	Cefoxitin*	FOX	0.016-256
EM105	Cefotetan*	CTN	0.016-256
EM011	Cefpirome*	CR	0.016-256
EM129	Cefpodoxime*	CPD	0.016-256
EM138	Cefpodoxime/ Clavulanic acid*	CPC	0.016-256
EM130	Cefprozil*	CPR	0.016-256
EM012	Ceftazidime*	CAZ	0.016-256
EM149	Ceftazidime/ Tazobactam*	CAT	0.016-256
EM123	Ceftizoxime*	ZOX	0.016-256
EM013	Ceftriaxone*	CTR	0.002-32
EM066	Ceftriaxone*	CTR	0.016-256
EM097	Ceftriaxone/ Sulbactam*	CTS	0.016-256

Code	Product	Symbol	Range (mcg/ml)		
EM102	Cefuroxime*	CXM	0.016-256		
EM106	Cephalothin*	CEP	0.016-256		
EM016	Chloramphenicol	CHL	0.016-256		
EM017	Ciprofloxacin	CIP	0.002-32		
EM082	Ciprofloxacin	СРН	0.016-256		
EM018	Clarithromycin	CLR	0.016-256		
EM019	Clindamycin	CLI	0.016-256		
EM020	Colistin	CL	0.016-256		
EM021	Co-Trimoxazole	СОТ	0.002-32		
EM083	Co-Trimoxazole	TSH	0.016-256		
EM088	Daptomycin	DAP	0.016-256		
EM090	Doripenem*	DOR	0.002-32		
EM103	Doxycycline	DOX	0.016-256		
EM115	Enrofloxacin	EFX	0.002-32		
EM085	Ertapenem*	ETP	0.002-32		
EM022	Erythromycin	ERY	0.016-256		
EM091	Faropenem*	FAR	0.002-32		
EM147	Flucloxacillin*	FLC	0.016-256		
EM108	Fosfomycin	FOS	0.064-1024		
EM023	Fusidic Acid	FC	0.016-256		
EM024	Gatifloxacin	GAT	0.002-32		
EM076	Gemifloxacin	GEM	0.002-32		
EM025	Gentamicin	GEN	0.016-256		
EM061	Gentamicin	HLG	0.064-1024		
EM104	Imipenem*	IPM	0.002-32		
EM026	Kanamycin	KAN	0.016-256		
EM027	Levofloxacin	LEV	0.002-32		
EM029	Linezolid	LNZ	0.016-256		
EM124	Mecillinam*	MEC	0.016-256		
EM080	Meropenem*	MRP	0.002-32		
EM128	Metronidazole	MTZ	0.016-256		
EM032	Minocycline	MIN	0.016-256		
EM033	Moxifloxacin	MXF	0.002-32		
EM087	Mupirocin	MUP	0.064-1024		
EM035	Nalidixic Acid	NAL	0.016-256		
EM095	Netilmicin	NET	0.016-256		
EM037	Nitrofurantoin	NIT	0.032-512		

Code	Product	Symbol	Range (mcg/ml)
EM038	Norfloxacin	NOR	0.016-256
EM039	Ofloxacin	OFX	0.002-32
EM065	Oxacillin*	OXA	0.016-256
EM084	Penicillin*	PEN	0.002-32
EM062	Penicillin*	PEN	0.016-256
EM041	Piperacillin*	PIP	0.016-256
EM042	Piperacillin/Tazobactam*	PTZ	0.016-256
EM043	Polymixin B	PB	0.016-256
EM044	Pristinomycin (Quinupristin/Dalfopristin)	QDA	0.002-32
EM045	Rifampicin	RIF	0.002-32
EM046	Roxithromycin	ROX	0.016-256
EM047	Sparfloxacin	SPA	0.002-32
EM048	Streptomycin	STR	0.016-256
EM131	Sulbactam*	SUL	0.016-256
EM055	Teicoplanin	TEI	0.016-256
EM056	Tetracycline	TET	0.016-256
EM057	Ticarcillin*	TIC	0.016-256
EM125	Ticarcillin/ Clavulanic Acid*	TCC	0.016-256
EM089	Tigecycline	TGC	0.016-256
EM058	Tobramycin	ТОВ	0.016-256
EM059	Trimethoprim	TMP	0.002-32
EM060	Vancomycin	VAN	0.016-256
	ESBL / AmpC Detection Mult	i Ezy MIC™	Strip
EM116	Cefepime / cefepime + Clavulanic acid*	CPM+/ CPM	0.064 - 4 0.25 - 16
EM099	Cefotaxime / Cefotaxime+ Clavulanic acid*	CTX+/ CTX	0.016-1 0.25-16
EM098	Ceftazidime / Ceftazidime + Clavulanic acid*	CAZ+/ CAZ	0.064-4 0.5-32
EM117	Ceftriaxone/ Ceftriaxone+ Clavulanic acid*	CTR+/ CTR	0.016-1 0.25-16
EM127	Cefotetan/ Cefotetan+ Cloxacillin*	CTN CTN+	0.5-32 0.5-32
EM132	Improved ESBL Detection Strip*	MIX+/ MIX	0.032-4 0.125-16
EM133	Improved AmpC Detection Strip*	MIX+/ MIX	0.032-4 0.125-16
EM136	ESBL- AmpC Co-existance Dete (Kit Contains 10 strips of each I		
	MBL Detection Dual Ezy	MIC™ Stri	р
EM078	Imipenem with & without EDTA*	IPM + EDTA / IPM	1-64 4-256
EM092	Meropenem with & without EDTA*	MRP + EDTA/ MRP	1-64 4-256

Code	Product	Symbol	Range (mcg/ml)
	MBL-ESBL-AmpC Detec	tion Strips	
EM134	MBL plus ESBL Detection Strip*	ESBL+/ ESBL	0.032-4 0.125-16
EM135	MBL plus AmpC Detection Strip*	AmpC+/ AmpC	0.032-4 0.125-16
EM137	MBL-ESBL-AmpC Co-existance I (Kit Contains 10 Strips of each I		
	KPC Detection Ezy MI	C™ Strip	
EM141	Ertapenem/Ertapenem + Boronic acid*	ETP+ /ETP	0.032 - 2 0.125 - 8
	Dual Ezy MIC™ S	trip	
EM063	Oxacillin-Vancomycin*	OXA/ VAN	0.064-8 0.19-16
EM077	Vancomycin -Cefoxitin*	VAN/ CX	0.5-64 0.19-16
EM111	Vancomycin/Teicoplanin	VAN/ TEI	0.5-32 0.5-32
	Antifungal Ezy MIC™	<sup>™</sup> Strips	
EM071	Amphotericin B	AP	0.002-32
EM122	Anidulafungin	AND	0.002-32
EM119	Caspofungin	CAS	0.002-32
EM144	Clotrimazole	CLO	0.002-32
EM072	Fluconazole	FLC	0.016-256
EM118	Flucytosine	FLU	0.002-32
EM143	Griseofulvin	GRI	0.002-32
EM073	Itraconazole	ITR	0.002-32
EM074	Ketoconazole	KET	0.002-32
EM121	Micafungin	MYC	0.002-32
EM146	Miconazole	MIC	0.002-32
EM145	Nystatin	NYT	0.002 – 32
EM120	Posaconazole	POS	0.002-32
EM142	Terbinafine	TRB	0.002-32
EM086	Voriconazole	VRC	0.002-32

#### **Packing**

Each Pack contains following material packed in air-tight plastic container glass vial with a desiccator capsule.

- 1) Ezy MIC<sup>™</sup> strips (10/30/60/90/120/150 Strips per pack).
- 2) Applicator sticks
- 3) Package insert

#### X-Pert™ Ezy MIC™ Teaching Kit HTM006-10PR

Contents: *S. aureus* culture, MIC Strips (Ciprofloxacin, Vancomycin, Azithromycin, Linezolid, Amikacin), Mueller Hinton Agar, Sterile cotton swabs, Applicator, Saline.



### Ezy MIC™ Packing with Glass Vial

#### EM-10ST



10 strips per pack

#### EM-30ST



30 strips per pack

#### EM-60ST



2 x 30 strips per pack

EM-90ST



3 x 30 strips per pack

#### **EM-120ST**



4 x 30 strips per pack

EM-150ST



5 x 30 strips per pack

### Ezy MIC™ Packing with Blister Pack

EM-10ST



10 strips per pack

EM-30ST



30 strips per pack

EM-60ST



2 x 30 strips per pack

EM-90ST



3 x 30 strips per pack

**EM-120ST** 



4 x 30 strips per pack

**EM-150ST** 



5 x 30 strips per pack



## Table 1. Recommended media, inoculum and incubation for various organisms<sup>3</sup>

			lnoculum		Incubation		
Organism group	Medium	Suspension	Turbidity eqvivalent to	Temperature	Atmosphere	Period	
Aerobes (Bacteria)	Mueller Hinton Agar	0.85 % NaCl or MHB	0.5 McFarland standard	35°C ± 2°C	Ambient	16-20 hours	
MRSA/MRSE	Mueller Hinton Agar + 2% NaCl	0.85 % NaCl	0.5 McFarland standard	35°C ± 2°C	Ambient	24 hours MRSA 48 hours MRSE	
Anaerobes* Brucella spp Bacteroides spp. Clostridium spp.		Brucella broth or Mueller Hinton broth	0.5 McFarland standard	35°C ± 2°C	85% N <sub>2</sub> / 5-10%CO <sub>2</sub> / 10% H <sub>2</sub>	24 to72 hours depending on the species	
Haemophilus species	Haemophilus Test Agar (HTM)	Mueller Hinton broth or HTM broth or Saline	0.5 McFarland standard	35°C ± 2°C	5% CO <sub>2</sub>	24-48 hours	
S.pneumoniae, Streptococcus species. Beta haemolytic group, Streptococcus speices Viridans group	Mueller Hinton Agar + 5% defibrinated sheep blood	Mueller Hinton broth or Saline	0.5 McFarland standard	35°C ± 2°C	5% CO <sub>2</sub>	24-48 hours	
Neisseria gonorrhoeae*  GC-agar base + defined supplement		Mueller Hinton broth or 0.9% Phosphate buffered saline, pH 7.0	0.5 McFarland standard	35°C ± 2°C	5% CO <sub>2</sub>	24-48 hours	
Fungal cultures	Mueller Hinton Agar with added 2% Glucose + 0.5 mcg/ml Methylene Blue Dye or Mueller Hinton Agar, Modified, (as per CLSI for Antifungal) (M1825)	0.85 % NaCl	0.5 McFarland standard	35°C ± 2°C	Ambient	24-48 hours	

 $<sup>^{\</sup>star}$  Use the culture suspension for plate inoculation within 15 minutes, after adjusting the turbidity.



### Antibacterial Ezy MIC™ Strips

## Table 2. Interpretive criteria & quality control ranges of Antibacterial Ezy MIC™ Strips

C 1 -	Mana	Cl I	Range	Interpretative criteria for	Interpretative criteria			Quality Control limits(mcg/ml)		
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	I	≥R	Organism (ATCC)	Standard Range	
EM001	Amikacin	АМК	0.016 - 256	Enterobacteriaceae, Acinetobacter spp., P.aeruginosa, other non-Enterobacteriaceae, Staphylococcus spp.\$	16	32	64	S.aureus ATCC 29213 E.coli ATCC 25922 P.aeruginosa ATCC 27853 E. faecalis ATCC 29212	1-4 0.5-4 1-4 64-256	
EM002	Amoxicillin	AMC	0.016-256	S.pneumoniae (non meningitis)	2	4	8	S. pneumoniae ATCC 49619 K. pneumoniae ATCC 700603	0.03-0.12 >128	
EM003	Amoxyclav (2 : 1)	AMC	MC 0.016 - 256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922 E.coli ATCC 35218 K. pneumoniae ATCC 700603	2-8 4-16 4-16	
				Haemophilus spp, Staphylococcus spp.#	4	-	8	S.aureus ATCC 29213 E.faecalis ATCC 29212 H.influeanzae ATCC 49247	0.12-0.5 0.25-1 2-16	
				S.pneumoniae (non-meningitis)	2	4	8	S.pneumoniae ATCC 49619	0.032-0.12	
				Anaerobes	4	8	16	B.fragilis ATCC 25285	0.25-1	
EM139	Amoxyclav (Amoxicillin/ Clavulanic acid (2 mcg/ml) (As per EUCAST)	AUG	0.016-256	Enterobacteriaceae	8		8	E.coli ATCC 25922 E.coli ATCC 35218	2 - 8 4-32	
				Enterobacteriaceae (uncomplicated UTI only)	32		32			
				Enterococcus spp.	4		8			
				Moraxella catarrhalis	1		1			
				Pasteurella multocida	1		1			
				Haemophilus spp.	2		2	H. influenzae ATCC 49766	0.125 - 0.5	
				Gram positive anaerobes (except <i>Clostridium</i> difficile)	4		8			
				Gram negative anaerobes	4		8			
				Non species related breakpoints	2		8			



Code	Name	Symbol	Range	Interpretative criteria for	Interp	retative o	riteria	Quality Control limits	(mcg/ml)
Code	Name	Syllibot	(mcg/ml)	interpretative criteria for	≤S	ı	≥R	Organism (ATCC)	Standard Range
EM068	EM068 Ampicillin	AMP	0.016-256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922 E.coli ATCC 35218 K. pneumoniae ATCC 700603	2-8 >32.0 >128
				Staphylococcus spp <sup>#</sup>	0.25	-	0.5	S.aureus ATCC 29213	0.5-2
				Enterococcus spp	8	-	16	E.faecalis ATCC 29212	0.5-2
				Haemophilus spp	1	2	4	H.influeanzae ATCC 49247	2-8
				Streptococcus spp. Beta haemolytic group	0.25	-	-	S.pneumoniae ATCC 49619	0.06-0.25
				Anaerobes	0.5	1	2	B.fragilis ATCC 25285	16-64
				Streptococcus spp. Viridians group	0.25	0.5-4	8		
				N.meningitidis	0.12	0.25-1	2	-	-
EM109	Ampicillin/ Sulbactam (2:1)	AMS	0.016-256	Enterobacteriaceae, Acinetobacter spp.	8	16	32	E.coli ATCC 25922 E.coli ATCC 35218 K. pneumoniae ATCC 700603	2 - 8 8 - 32 8-32
				Haemophilus spp	2	-	4	H.influenzae ATCC 49247	2 - 8
				Anaerobes	8	16	32	B.fragilis ATCC 25285	0.5-2
EM140	Ampicillin/ Sulbactam (4 mcg/ml)	SAM	0.016-256	Enterobacteriaceae	8		8	E.coli ATCC 25922 E.coli ATCC 35218	1-4 16 - 128
	(EUCAST)			Enterococcus spp.	4		8		
				Moraxella catarrhalis	1		1		
				Haemophilus spp.	1		1	H.influenzae ATCC 49247	0.06 - 0.25
				Gram positive anaerobes (except <i>Clostridium</i> <i>difficile</i> )	4		8		
				Gram negative anaerobes	4		8		
				Non species related breakpoints	2		8		
EM004	Azithromycin	AZI	0.016-256	Enterobacteriaceae	16	-	32	-	-
				Staphylococcus	2	4	8	S.aureus ATCC 29213	0.5-2
				Haemophilus spp.(+ CO <sub>2</sub> )	4	-	-	H.influeanzae ATCC 49247 (+ CO <sub>2</sub> )	1-4
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group (+ CO <sub>2</sub> )	0.5	1	2	S.pneumoniae ATCC 49619 (+CO <sub>2</sub> )	0.5-2
				S.pneumoniae (- CO <sub>2</sub> )*	4	8	16	S.pneumoniae ATCC 49619 (-CO <sub>2</sub> )*	0.064-0.25
				N.meningitidis	2	-	-	-	-



Cada	Name	Cumahal	ol Range (mcg/ml)		Interp	retative o	criteria	Quality Control limits(mcg/ml)		
Code	Name	Symbol		interpretative criteria for	≤S	I	≥R	Organism (ATCC)	Standard Range	
EM006	Aztreonam	AZT	0.016 - 256	Enterobacteriaceae	4	8	16	E.coli ATCC 25922 E.coli ATCC 35218 K. pneumoniae ATCC 700603	0.06 - 0.25 0.03-0.125 8-64	
				Other non- Enterobacteriaceae, Pseudomonas aeruginosa	8	16	32	P. aeruginosa ATCC 27853	2 - 8	
				Haemophilus spp	2	-	-	H.influenzae ATCC 49247	0.12 - 0.5	
EM126	Bacitracin	BAC	0.016 - 256	Not available	-	-	-	S.aureus ATCC 29213*	8 – 32	
EM107	EM107 Cefaclor	CEC	0.016 - 256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922 S.aureus ATCC 29213	1-4 1-4	
				S.pneumoniae	1	2	4	S. pneumoniae ATCC 49619	1-4	
				Haemophilus spp.	8	16	32	H. influenzae ATCC 49766	1-4	
EM008	Cefazolin	CFZ	0.016 -256	Enterobacteriaceae	2	4	8	E.coli ATCC 25922 S.aureus ATCC 29213	1-4 0.25-1	
				Enterobacteriaceae (parenteral & oral) (Surrogate test for uncomplicated UTI)	16	-	32	-	-	
EM009	Cefdinir	CDR	0.016 - 256	Enterobacteriaceae	1	2	4	E.coli ATCC 25922 S.aureus ATCC 29213	0.12 - 0.5 0.12 - 0.5	
				S.pneumoniae	0.5	1	2	S. pneumoniae ATCC 49619	0.03 - 0.25	
				Haemophilus spp.	1	-	-	H. influenzae ATCC 49766	0.12 - 0.5	
EM070	Cefepime	СРМ	PM 0.016-256	Enterobacteriaceae, other non-Enterobacteriaceae, Acinetobacter spp, P.aeruginosa spp, Staphylococcus spp#	8	16	32	S.aureus ATCC 29213 E.coli ATCC 25922 P.aeruginosa ATCC 27853 K. pneumoniae ATCC 700603	1-4 0.016-0.12 0.5-4 0.5-2	
				N. gonorrhoeae	0.5			-	-	
				Haemophilus spp	2	-	-	H.influenzae ATCC 49247	0.5-2	
				Streptococcus spp. Beta haemolytic group	0.5	-	-	S.pneumoniae ATCC 49619	0.03-0.25	
				S.pneumoniae (meningitis)	0.5	1	2			
				S.pneumoniae (non meningitis), Streptococcus spp. Viridans group	1	2	4	-	-	
EM093	Cefepime/ Tazobactam	СРТ	0.016-256	Not available	-	-	-	S.aureus ATCC 29213 E.coli ATCC 25922 P.aeruginosa ATCC 27853 K. pneumoniae ATCC 700603 H.influenzae ATCC 49247 S.pneumoniae ATCC 49619	1-4 0.03-0.12 0.5-4 0.12-0.5 0.5-2 0.03-0.12	
EM110	Cefixime	FIX		Enterobacteriaceae	1	2	4	E.coli ATCC 25922 S.aureus ATCC 29213	0.25 - 1 8 -32	
				Haemophilus spp.	1	-	-	H. influenzae ATCC 49766	0.12 - 1	
				N.gonorrhoeae	0.25	-	-	N.gonorrhoeae ATCC49226	0.5 - 2	



Cada	Name	Cumphal	Range	Internaciona oritoria for	Interp	retative c	riteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	I	≥R	Organism (ATCC)	Standard Range
EM114	Cefmetazole	CMZ	0.016 - 256	Enterobacteriaceae	16	32	64	E.coli ATCC 25922 S.aureus ATCC 29213 P.aeruginosa ATCC 27853	0.25 - 1 0.5 - 2 >32
				N. gonorrhoeae	2	4	8	H.influeanzae ATCC 49247	2 - 16
				Anaerobes	16	32	64	-	-
EM113	Cefonicid	CID	0.016 - 256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922 S.aureus ATCC 29213	0.25 - 1 1 - 4
				Haemophilus spp	4	8	16	H. influenzae ATCC 49766	0.06 - 0.25
EM112 EM094	Cefoperazone Cefoperazone/ Sulbactam <sup>a</sup>	CFP CPS	0.016-256 0.016-256	Enterobacteriaceae, other non-Enterobacteriaceae, Staphylococcus spp, <sup>#</sup> Anaerobes	16	32	64	S.aureus ATCC 29213 E.coli ATCC 25922 P.aeruginosa ATCC 27853 E.coli ATCC 35218	1-4 0.12-0.5 2-8 0.25-1
EM100	Cefotaxime	СТХ	0.002-32	Enterobacteriaceae	1	2	4	E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.03-012 8-32
EM064	CM064 Cefotaxime	СТХ	0.016-256	Other non- Enterobacteriaceae, Acinetobacter spp, Staphylococcus spp#	8	16-32	64	S.aureus ATCC 29213	1-4
				Haemophilus spp	2			H.influeanzae ATCC 49247	0.12-0.5
				Streptococcus spp. Beta haemolytic group, N.gonorrhoeae	0.5			S.pneumoniae ATCC 49619 N.gonorrhoeae ATCC49226	0.03-0.12 0.016-0.06
				S.pneumoniae (meningitis)	0.5	1	2	-	-
				S.pneumoniae (non- meningitis)	1	2	4	-	-
				Streptococcus spp. Viridans group	1	2	4	-	-
				N.meningitidis	0.12			-	-
				Anaerobes	16	32	64	B.fragilis ATCC 25285	8-32
EM101	Cefoxitin	FOX	0.016-256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922	2-8
				S.aureus and S.lugdunensis	4		8	S.aureus ATCC 29213	1-4
				N. gonorrhoeae	2	4	8	N.gonorhoeae ATCC 49226	0.5-2
				Anaerobes	16	32	64	B.fragilis ATCC 25285	4-16
EM105	Cefotetan	CTN	0.016-256	Enterobacteriaceae, Staphylococcus spp.#	16	32	64	E.coli ATCC 25922 S.aureus ATCC 29213	0.06 -0.25 4 - 16
				N. gonorrhoeae	2	4	8		
				Anaerobes	16	32	64		
EM011	Cefpirome	CR	0.016 - 256	Not available	-	-	-	S.aureus ATCC 29213* P.aeruginosa ATCC 27853* H.influenzae ATCC 49766	0.25 - 2.0 1.0 - 4.0 0.25 - 1.0
EM129	Cefpodoxime	CPD	0.016 - 256	Enterobacteriaceae	2	4	8	E.coli ATCC 25922 S.aureus ATCC 29213	0.25 - 1.0 1.0 -8.0
				Haemophilus spp	2	-	-	H.influeanzae ATCC 49247	0.25 - 1.0
				N.gonorrhoeae	0.5	-	-	-	-
				S.pneumoniae	0.5	1	2	S.pneumoniae ATCC 49619	0.03 - 0.12



6.1	N	6 1 1	Range		Interp	retative o	criteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	1	≥R	Organism (ATCC)	Standard Range
EM138	Cefpodoxime/ Clavulanic acid	CPC	0.016-256	Not available				S.aureus ATCC 29213 E.coli ATCC 25922 S.pneumoniae ATCC 49619 H.influenzae ATCC 49247	1.0 - 8.0 0.25 - 1.0 0.03 - 0.12 0.25 - 1
EM130	Cefprozil	CPR	0.016 - 256	Enterobacteriaceae, Haemophilus spp	8	16	32	E.coli ATCC 25922 S.aureus ATCC 29213	1.0 - 4.0 0.25 - 1.0
				S.pneumoniae	2	4	8	S.pneumoniae ATCC 49619	0.25 - 1.0
				Haemophilus spp	8	16	32	H.influeanzae ATCC 49766	1.0 - 4.0
EM012	Ceftazidime	CAZ	0.016-256	Enterobacteriaceae	4	8	16	E.coli ATCC 25922	0.064 - 0.5
				Staphylococcus spp <sup>#</sup> , other non-Enterobacteriaceae, Acinetobacter spp, P.aeruginosa, S.maltophila, B.cepacia	8	16	32	S.aureus ATCC 29213 P.aeruginosa ATCC 27853 K. pneumoniae ATCC 700603	4-16 1-4 16-64
				Haemophilus spp	2	-	-	H.influeanzae ATCC 49247	0.125-1
				N. gonorrhoeae	0.5	-	-	-	-
EM123	Ceftizoxime	ZOX	0.016 -256	Enterobacteriaceae	1	2	4	E.coli ATCC 25922	0.03 - 0.12
				Other non- Enterobacteriaceae	8	16-32	64	S.aureus ATCC 29213 P. aeruginosa ATCC 27853	2.0 - 8.0 16 - 64
				Haemophilus spp	2	-	-	H.influenzae ATCC 49247 S. pneumoniae ATCC 49619	0.06 -0.5 0.12 - 0.5
				N. gonorrhoeae	0.5	-	-	-	-
				Anaerobes	32	64	128	-	-
EM013	Ceftriaxone	CTR	0.002-32	Enterobacteriaceae	1	2	4	E.coli ATCC 25922 E.coli ATCC 35218	0.03-0.12 0.06-0.25
EM066	Ceftriaxone	CTR	0.016-256	Staphylococcus spp <sup>#</sup> , other non-Enterobacteriaceae, Acinetobacter spp	8	16-32	64	S.aureus ATCC 29213 P.aeruginosa ATCC 27853	1-8 8-64
EM097	Ceftriaxone/ Sulbactam*b	CTS	0.016-256	Haemophilus spp	2	-	-	H.influeanzae ATCC 49247	0.06-0.25
				N. gonorrhoeae	0.25	-	-	-	-
				N.meningitidis	0.12	-	-	-	-
				Anaerobes	16	32	64	-	-
				Streptococcus spp. Beta haemolytic group	0.5	-	-	S.pneumoniae ATCC 49619	0.03-0.12
				S.pneumoniae (meningitis)	0.5	1	2		
				S.pneumoniae (non meningitis), Streptococcus spp. Viridans group	1	2	4		
EM102	M102 Cefuroxime	cime CXM	CXM 0.016-256	Enterobacteriaceae, Staphylococcus spp (Parenteral)	8	16	32	E.coli ATCC 25922  S.aureus ATCC 29213	2-8 0.5-2
				Enterobacteriaceae, Staphylococcus spp <sup>#</sup> (Oral)	4	8-16	32	-	-



Code	Name	Symbol	Range	Interpretative criteria for	Interp	retative o	criteria	Quality Control limits	s(mcg/ml)
Code	Name	Symbol	(mcg/ml)	interpretative criteria ioi	≤S	- 1	≥R	Organism (ATCC)	Standard Range
				Haemophilus spp (Parenteral & Oral)	4	8	16	H.influeanzae ATCC 49247	0.25-1
				N. gonorrhoeae	1	2	4	N. gonorrhoeae ATCC 49226	0.25-1
				S.pneumoniae (Parenteral)	0.5	1	2	S.pneumoniae ATCC 49619	0.25-1
				S.pneumoniae (Oral)	1	2	4		
EM106	Cephalothin	CEP	0.016 - 256	Enterobacteriaceae <sup>⊙</sup>	8	16	32	E.coli ATCC 25922 S.aureus ATCC 29213 S.pneumoniae ATCC 49619	4 - 16 0.12 - 0.5 0.5 - 2
EM016 Chloramphenicol	CHL	0.016-256	Enterobacteriaceae, Enterococcus spp., Staphylococcus spp., S.maltophila, B.cepacia, V.cholerae, other non-Enterobacteriaceae, Anaerobes	8	16	32	S.aureus ATCC 29213 E.coli ATCC 25922 E.faecalis ATCC 29212	2-16 2-8 4-16	
				Haemophilus spp, N.meningitidis	2	4	8	H.influeanzae ATCC 49247	0.25-1
				Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	4	8	16	S.pneumoniae ATCC 49619	2-8
				S.pneumoniae	4	-	8		
EM017 EM082	Ciprofloxacin Ciprofloxacin <sup>c</sup>	CIP CPH	0.002-32 0.016-256	Enterobacteriaceae, other than S.Typhi and extraintestinal Salmonella spp, Enterococcus spp, Staphylococcus spp, other non-Enterobacteriaceae, Acinetobacter spp, P.aeruginosa	1	2	4	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.125-0.5 0.25-2 0.004-0.015 0.25-1
				For S.Typhi and extraintestinal Salmonella spp.	0.06	0.12- 0.5	1		
				Haemophilus spp	1	-	-	H.influeanzae ATCC 49247	0.004-0.03
				N.gonorhoeae	0.06	0.12- 0.5	1	N.gonorrhoeae ATCC 49226	0.001-0.008
				N.meningitidis	0.03	0.06	0.12		
EM018	Clarithromycin	CLR	0.016 - 256	Staphylococcus spp.	2	4	8	S.aureus ATCC 29213	0.12 - 0.5
				Haemophilus spp.	8	16	32	H.influenzae ATCC 49247	4 - 16
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	0.25	0.5	1	S. pneumoniae ATCC 49619	0.03 - 0.12



Code	Name	Symbol	Range	Interpretative criteria for	Interp	retative o	riteria	Quality Control limits	s(mcg/ml)
Code	Name	Symbol	(mcg/ml)	interpretative criteria for	≤S	- 1	≥R	Organism (ATCC)	Standard Range
EM019	Clindamycin	CLI	0.016-256	Staphylococcus spp	0.5	1-2	4	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.06-0.25 4-16
				Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	0.25	0.5	1	S.pneumoniae ATCC 49619	0.03-0.12
				Anaerobes	2	4	8	B.fragilis ATCC 25285	0.5-2
EM020	Colistin	CL	0.016-256	Acientobacter spp., P.aeruginosa	2	-	4	E.coli ATCC 25922	0.25-2
				other non-Enterobacteriaceae◆	2	4	8	P.aeruginosa ATCC 27853	0.5-4
EM021 EM083	Co-Trimoxazole (1: 19) Co-Trimoxazole (1: 19)	COT	0.002-32 0.016-256	Enterobacteriaceae Acientobacter spp, B.cepacia, S.maltophila, other non-Enterobacteriaceae	2	-	4	E.coli ATCC 25922 S.aureus ATCC 29213 E.faecalis ATCC 29212	<0.5 <0.5 <0.5
				Haemophilus spp,* S.pneumoniae*	0.5	1-2	4	H.influeanzae ATCC 49247 S.pneumoniae ATCC 49619	0.032-0.25 0.125-1.0
				N.meningitidis	0.12	0.25	0.5	-	
EM088	Daptomycin (Supplemented with Calcium ion)	DAP	0.016-256	Staphylococcus spp	1	-	-	S.aureus ATCC 29213	0.12-1
				Enterococcus spp	4	-	-	E.faecalis ATCC 29212	1-4
				Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	1	-	-	S.pneumoniae ATCC 49619	0.06-0.5
EM090	Doripenem	DOR	0.002-32	Enterobacteriaceae	1	2	4	E.coli ATCC 25922	0.015-0.06
				P.aeruginosa, Acientobacter spp,	2	4	8	P.aeruginosa ATCC 27853	0.12-0.5
				Staphylococcus <sup>#</sup>	0.5	-	-	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.016-0.6 1-4
				Haemophilus spp, S.pneumoniae, Streptococcus spp., Viridans group	1	-	-	H.influeanzae ATCC 49766	0.06-0.25
				Streptococcus spp. Beta haemolytic group	0.12	-	-	S.pneumoniae ATCC 49619	0.03-0.12
				Anaerobes	2	4	8	B.fragilis ATCC 25285	0.12-0.5
EM103	Doxycycline	DOX	OOX 0.016-256	Enterobacteriaceae, Other non-Enterobacteriaceae, Acientobacter spp, Staphylococcus spp, Enterococcus spp	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922	0.12-0.5 2-8 0.5-2
				S.pneumoniae	0.25	0.5	1	-	-
				Streptococcus spp. Beta haemolytic group <sup>d</sup> , Streptococcus spp. Viridans group <sup>d</sup>	2	4	8	S.pneumoniae ATCC 49619	0.016-0.12



<sup>\*=</sup>Not as per CLSI guidelines
•=Interpretive criteria are as per CLSI guidelines 2016 & have been deleted thereafter
#=Interpretive criteria are as per CLSI guidelines 2012 & have been deleted thereafter
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C	Nama	Cb I	Range		Interp	retative o	criteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	1	≥R	Organism (ATCC)	Standard Range
EM115	Enrofloxacin	EFX	0.002 - 32	refer product insert				S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.03 - 0.12 0.12 - 1 0.008 - 0.03 1 - 4
EM085	Ertapenem	ETP	0.002-32	Enterobacteriaceae	0.5	1	2	E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.004-0.016 2-8
				Staphylococcus spp <sup>#</sup>	2	4	8	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.06-0.25 4-16
				Haemophilus spp	0.5	-	-	H.influeanzae ATCC 49766	0.016-0.06
				S.pneumoniae	1	2	4	S.pneumoniae ATCC 49619	0.03-0.25
				Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	1	-	-		
				Anaerobes	4	8	16	B.fragilis ATCC 25285	0.06-0.25
EM022	Erythromycin	ERY	0.016-256	Staphylococcus spp, Enterococcus spp	0.5	1-4	8	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.25-1 1-4
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	0.25	0.5	1	S.pneumoniae ATCC 49619	0.03-0.12
EM091	Faropenem	FAR	0.002-32	Not available	-	-	-	S.aureus ATCC 29213 E.coli ATCC 25922 S.pneumoniae ATCC 49619 H.influenzae ATCC 49766	0.03-0.12 0.25-1 0.03-0.25 0.12-0.5
EM108	Fosfomycin (Supplemented with Glucose-6- phosphate)	FOS	0.064 - 1024	Enterobacteriaceae, Enterococcus spp.	64	128	256	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.5 - 4 32-128 0.5 -2 2 -8
EM023	Fusidic acid	FC	0.016 -256	Not available	-	-	-	S.aureus ATCC 29213 S.pneumoniae ATCC 49619	0.06 - 0.25 4 -32
EM024	Gatifloxacin	GAT	0.002 - 32	Enterobacteriaceae, other non-Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter spp., Enterococcus spp.	2	4	8	E.coli ATCC 25922 P. aeruginosa ATCC 27853 E. faecalis ATCC 29212	0.008 - 0.03 0.5 - 2 0.12 - 1
				Staphylococcus spp	0.5	1	2	S.aureus ATCC 29213	0.03 - 0.12
				Haemophilus spp.	1	-	-	H.influenzae ATCC 49247	0.004 - 0.03
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridians group.	1	2	4	S. pneumoniae ATCC 49619	0.12 - 0.5
EM076	Gemifloxacin	GEM	0.002 - 32	Enterobacteriaceae,	0.25	0.5	1	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.008 - 0.03 0.016 - 0.12 0.004-0.016 0.25 - 1
				Haemophilus spp.	0.12	-	-	H.influenzae ATCC 49247	0.002-0.008
				S.pneumoniae	0.12	0.25	0.50	S. pneumoniae ATCC 49619	0.008 - 0.03



C	Name -	Cb I	Range		Interp	retative o	riteria	aureus ATCC 29213 faecalis ATCC 29212 coli ATCC 25922 aeruginosa ATCC 27853  coli ATCC 25922 pneumoniae ATCC 700603 pneumoniae ATCC 27853  coli ATCC 25922 pneumoniae ATCC 27853  1 - 4 aureus ATCC 29213 aureus ATCC 29212 coli ATCC 25921 coli ATCC 29212 coli ATCC 29213 faecalis ATCC 29212 coli ATCC 29212 coli ATCC 29213 faecalis ATCC 29212 coli ATCC 25922 aureus ATCC 49619  coli ATCC 25922 aureus ATCC 29213 faecalis ATCC 29213 faecalis ATCC 29213 faecalis ATCC 29212  coli ATCC 25922 aureus ATCC 29213 faecalis ATCC 29212  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29212  aureus ATCC 29213 coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29212  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 27853 faecalis ATCC 29213  coli ATCC 25922 aeruginosa ATCC 29213  coli ATCC 25922  coli ATCC	mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	- 1	≥R	Organism (ATCC)	Standard Range
EM025	Gentamicin	GEN	0.016-256	Enterobacteriaceae, other non-Enterobacteriaceae, Acinetobacter spp, P.aeruginosa, Staphylococcus spp	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.25-1
EM061	Gentamicin	HLG	0.064-1024	Enterococcus spp	500 <sup>△</sup>	-	500 <sup>△</sup>	E.faecalis ATCC 51299	> 500
EM104	Imipenem	IPM	0.002 - 32	Enterobacteriaceae	1	2	4	E.coli ATCC 25922 K. pneumoniae ATCC 700603 K. pneumoniae ATCC BAA1705	0.06 - 0.25 0.03 - 0.25 4 - 16
				Pseudomonas aeruginosa	2	4	8	P. aeruginosa ATCC 27853	1 - 4
				Acinetobacter spp, other non-Enterobacteriaceae	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.016 - 0.06 0.5 - 2
				Haemophilus spp.	4	-	-	H.influenzae ATCC 49766	0.25 - 1
				S.pneumoniae	0.12	0.25 -0.5	1	S. pneumoniae ATCC 49619	0.03 - 0.12
				Anaerobes	4	8	16		
EM026	Kanamycin	KAN	0.016-256	Enterobacteriaceae, Staphylococcus spp. <sup>\$</sup>	16	32	64	E.coli ATCC 25922 S.aureus ATCC 29213 E.faecalis ATCC 29212	
EM027	Levofloxacin	LEV	0.002 - 32	Enterobacteriaceae except Salmonella spp., other non Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter spp., B.cepecia, S. maltophilia, Enterococcus spp.	2	4	8	E.coli ATCC 25922 P. aeruginosa ATCC 27853 E. faecalis ATCC 29212	0.008 - 0.06 0.5 -4 0.25 - 2
				Staphylococcus spp	1	2	4	S.aureus ATCC 29213	0.06 - 0.5
				S.Typhi, S. Paratyphi A-C	0.12	0.25 -1	2	-	-
				Haemophilus spp.	2	-	-	H.influenzae ATCC 49247	0.008 - 0.03
				S. pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridians group.	2	4	8	S. pneumoniae ATCC 49619	0.5 - 2
				N.meningitidis	0.03	0.06	0.12		
EM029	Linezolid	LNZ	0.016-256	Staphylococcus spp	4	-	8	S.aureus ATCC 29213	1-4
				Enterococcus spp	2	4	8	E.faecalis ATCC 29212	1-4
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	2	-	-	S.pneumoniae ATCC 49619	0.25-2
EM124	Mecillinam	MEC	0.016 - 256	Enterobacteriaceae	8	16	32	E.coli ATCC 25922	0.03 - 0.25



Code	Name	Symbol	Range	Interpretative criteria for	Interp	retative o	riteria	Quality Control limits	(mcg/ml)
Code	Ivaille	Syllibot	(mcg/ml)	interpretative criteria ioi	≤S	1	≥R	Organism (ATCC)	Standard Range
EM080	Meropenem	MRP	0.002-32	Enterobacteriaceae	1	2	4	E.coli ATCC 25922 E.coli ATCC 35218	0.008-0.06 0.008-0.06
				P.aeruginosa, Acinetobacter spp	2	4	8	P.aeruginosa ATCC 27853	0.12-1
				B.cepecia, other non- Enterobacteriaceae, Anaerobes, Staphylococcus spp#	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 K. pneumoniae ATCC BAA1705	0.03-0.12 2-8 8 - 64
				Haemophilus, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	0.5	-	-	H.influeanzae ATCC 49766	0.03-0.12
				S.pneumoniae	0.25	0.5	1	S.pneumoniae ATCC 49619	0.03-0.25
				N.meningitidis	0.25	-	-		
EM128	Metronidazole	MTZ	0.016 - 256	Anaerobes	8	16	32	B. fragilis ATCC 25285	0.25 - 1
EM032	Minocycline	MIN	0.016 -256	Enterobacteriaceae, other non-Enterobacteriaceae, Acinetobacter spp, B. cepacia, S.maltophilia, Staphylococcus spp, Enterococcus spp	4	8	16	E.coli ATCC 25922 S.aureus ATCC 29213 E.faecalis ATCC 29212	0.25 - 1 0.06 - 0.25 1 - 4
				S.pneumoniae <sup>d</sup>	1	2	4	-	-
				Streptococcus spp. Beta haemolytic group <sup>d</sup> , Streptococcus spp, Viridans group, <sup>d</sup> Haemophilus spp <sup>d</sup>	2	4	8	-	-
				N. gonorrhoeae	0.25	0.5 - 1	2	-	-
				N. meningitidis	2	-	-	-	-
EM033	Moxifloxacin	MXF	0.002 - 32	Staphylococcus spp.	0.5	1	2	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.015 - 0.12 0.06 - 0.5 0.008 - 0.06 1 - 8
				Haemophilus spp	1	-	-	H.influenzae ATCC 49247	0.008 - 0.03
				S.pneumoniae	1	2	4	S. pneumoniae ATCC 49619	0.06 -0.25
				Anaerobe	2	4	8	N. gonorrhoeae	0.008-0.03
EM087	Mupirocin	MUP	0.064 - 1024			0.06 - 0.5 16 - 128			
EM035	Nalidixic Acid	NAL	0.016-256	Enterobacteriaceae	16	-	32	E.coli ATCC 25922	1-4
EM095	Netilmicin	NET	0.016-256	Enterobacteriaceae, P.aeruginosa, Acientobacter spp, other non-Enterobacteriaceae, Staphylococcus spp <sup>\$</sup>	8	16	32	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	≤0.25 4-16 ≤0.5-1 0.5-8



6.1	N	6 1 1	Range		Interp	retative c	riteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	- 1	≥R	Organism (ATCC)	Standard Range
EM037	Nitrofurantoin	NIT	0.032-512	Enterobacteriaceae, Staphylococcus spp, Enterococcus spp	32	64	128	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922	8-32 4-16 4-16
								S.pneumoniae ATCC 49619	4-16
EM038	Norfloxacin	NOR	0.016 -256	Enterobacteriaceae, other non-Enterobacteriaceae, Pseudomonas aeruginosa, Enterococcus spp., Staphylococcus spp.	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853 S.pneumoniae ATCC 49619	0.5-2 2-8 0.03-0.12 1-4 2-8
EM039	Ofloxacin	OFX	0.002 - 32	Enterobacteriaceae except Salmonella spp., other non-Enterobacteriaceae, Pseudomonas aeruginosa	2	4	8	E.coli ATCC 25922 P. aeruginosa ATCC 27853 E. faecalis ATCC 29212	0.016-0.12 1 - 8 1 - 4
				Salmonella spp including S. Typhi and S. Paratyphi A-C	0.12	0.25-1	2		
				Staphylococcus spp	1	2	4	S.aureus ATCC 29213	0.12 - 1
				Haemophilus spp.	2	-	-	H.influenzae ATCC 49247	0.016 - 0.06
				N. gonorrhoeae	0.25	0.5-1	2	N. gonorrhoeae	0.004-0.016
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridians group	2	4	8	S. pneumoniae ATCC 49619	1 - 4
EM065	Oxacillin	ОХ	0.016-256	S.aureus and S.lugdunensis	2	-	4	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.12-0.5 8-32
				Coagulase-negative Staphylococci except S.lugdunensis	0.25	-	0.5	S.aureus ATCC 43300	16-64
EM084 EM062	Penicillin Penicillin	PEN PEN	0.002-32 0.016 -256	Staphylococcus spp	0.12	-	0.25	S.aureus ATCC 29213	0.25-2
				Enterococcus spp	8	-	16	E.faecalis ATCC 29212	1-4
				S.pneumoniae (meningitis)	0.06	-	0.12	S.pneumoniae ATCC 49619	0.25-1
				S.pneumoniae (non-meningitis)	2	4	8		
				S.pneumoniae (oral)	0.06	0.12-1	2	-	-
				Streptococcus spp. Beta haemolytic group	0.12	-	-		
				Streptococcus spp. Viridians group	0.12	0.25-2	4		
			N.gonorrhoeae	0.06	0.12-1	2	N.gonorhoeae ATCC 49226	0.25-1	
				N.meningitidis	0.06	0.12- 0.25	0.5		
				Anaerobes	0.5	1	2		



Code	Name	Symbol	Range	Interpretative criteria for	Interp	retative o	riteria	Quality Control limits	(mcg/ml)
Code	Name	Syllibot	(mcg/ml)	interpretative criteria ioi	≤S	- 1	≥R	Organism (ATCC)	Standard Range
EM041	Piperacillin	PIP	0.016-256	Enterobacteriaceae, other non-Enterobacteriaceae, P.aeruginosa Acinetobacter spp	16	32-64	128	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853 E.coli ATCC 35218	1-4 1-4 1-4 1-8 >64
				Anaerobes	32	64	128	B.fragilis ATCC 25285	2-8
EM042	Piperacillin/ Tazobactam	PTZ	0.016-256	Enterobacteriaceae, other non-Enterobacteriaceae, Paeruginosa, Acinetobacter spp.	16	32-64	128	E.coli ATCC 25922 E.coli ATCC 35218 P.aeruginosa ATCC 27853 K.pneumoniae ATCC 700603	1-4 0.5-2 1-8 8-32
				Staphylococcus spp	8	-	16	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.25-2 1-4
				Haemophilus spp	1	-	2	H.influeanzae ATCC 49247	0.064-0.5
				Anaerobes	16	32-64	128	B.fragilis ATCC 25285	0.125-0.5
EM043	Polymyxin B	РВ	0.016 - 256	Pseudomonas aeruginosa., other non-Enterobacteriaceae	2	4	8	E.coli ATCC 25922	0.25 - 2
				Acinetobacter spp.	2	-	4	P. aeruginosa ATCC 27853	1 - 4
EM044	Pristinomycin	QDA	0.002 -32	Staphylococcus spp., Enterococcus spp.	1	2	4	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.25 - 1 2 - 8
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridians group.	1	2	4	S. pneumoniae ATCC 49619 H.influenzae ATCC 49247	0.25 - 1 2 - 8
EM045	Rifampicin	RIF	0.002 - 32	Staphylococcus spp., Enterococcus spp	1	2	4	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.004 -0.016 0.5 - 4 4 - 16 16-64
				Haemophilus spp., S.pneumoniae	1	2	4	S. pneumoniae ATCC 49619 H.influenzae ATCC 49247	0.015 - 0.06 0.25 - 1
				N.meningitidis	0.5	1	2		
EM046	Roxithromycin*	ROX	0.016 -256	Not available	-	-	-	S.aureus ATCC 29213 S.pneumoniae ATCC 49619	0.25 - 1 0.12 - 0.5
EM047	Sparfloxacin	SPA	0.002 - 32	Staphylococcus spp	0.5	1	2	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.03 - 0.12 0.12 - 0.5 0.004 -0.016 0.5 - 2
				Haemophilus spp.	0.25	-	-	H.influeanzae ATCC 49247	0.004 -0.016
				S.pneumoniae	0.5	1	2	S.pneumoniae ATCC 49619	0.12 - 0.5
								N. gonorrhoeae	0.004-0.016
EM048	Streptomycin*	STR	0.016 -256	Enterococci (HLAR)	-	-	1000	E.coli ATCC 25922 P. aeruginosa ATCC 27853 E. faecalis ATCC 29212	2 - 8 8 - 32 64 - 256



			Range		Interp	retative o	riteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	I	≥R	Organism (ATCC)	Standard Range
EM131	Sulbactam*	SUL	0.016 - 256	Not available				E.coli ATCC 25922 S.aureus ATCC 29213 A.baumanii ATCC 19606 A.baumanii ATCC BAA-747 A.baumanii ATCC BAA-1605	16 - 64 64-256 0.25 - 2 1.0 - 4.0 8 - 64
EM055	Teicoplanin	TEI	0.016-256	Staphylococcus spp., Enterococcus spp.	8	16	32	S.aureus ATCC 29213 E.faecalis ATCC 29212	0.25-1 0.25-1
EM056	Tetracycline	TET	0.016-256	Enterobacteriaceae, Other non-Enterobacteriaceae, Acientobacter spp, Staphylococcus spp, Enterococcus spp	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.12-1 8-32 0.5-2 8-32
				Haemophilus spp	2	4	8	H.influeanzae ATCC 49247	4-32
				S.pneumoniae	1	2	4	-	-
				Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	2	4	8	S.pneumoniae ATCC 49619	0.06-0.5
				N.gonorrhoeae	0.25	0.5-1	2	N.gonorhoeae ATCC 49226	0.25-1
				Anaerobes	4	8	16	B.fragilis ATCC 25285	0.125-0.5
EM057	Ticarcillin	TIC	0.016 -256	Enterobacteriaceae, Other non- Enterobacteriaceae, P.aeruginosa, Acinetobacter spp	16	32-64	128	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853 E.coli ATCC 35218 K.pneumoniae ATCC 700603	2 - 8 16 - 64 4 - 16 8 - 32 > 128 > 256
				Anaerobes	32	64	128	-	-
EM125	Ticarcillin / Clavulanic acid	тсс	0.016 - 256	Enterobacteriaceae, Other non-Enterobacteriaceae, P.aeruginosa, Acinetobacter spp, B. cepacia, S. maltophilia	16	32-64	128	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 E.coli ATCC 25922 P.aeruginosa ATCC 27853 K.pneumoniae ATCC 700603	0.5-2 16 -64 4 - 16 8 - 32 8 - 32 32 - 128
				Anaerobes	32	64	128	-	-
EM089	Tigecycline	TGC	0.016-256	Not available	-	-	-	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 S.pneumoniae ATCC 49619 H.influenzae ATCC 49247 B.fragilis ATCC 25285	0.03-0.25 0.03-0.12 0.03-0.25 0.015-0.12 0.06-0.5 0.12-1
EM058	Tobramycin	ТОВ	0.016 - 256	Enterobacteriaceae, other non-Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter spp, Staphylococcus spp. \$	4	8	16	S.aureus ATCC 29213 E.faecalis ATCC 29212 E.coli ATCC 25922 P.aeruginosa ATCC 27853	0.12 - 1 8 - 32 0.25 - 1 0.25 - 1
EM059	Trimethoprim	ТМР	0.016 - 256	Enterobacteriaceae, Staphylococcus spp	8	-	16	E.coli ATCC 25922 S.aureus ATCC 29213 E.faecalis ATCC 29212 P.aeruginosa ATCC 27853	0.5 - 2 1 - 4 0.12 - 0.5 >64



Cada	Name	Cumahal	Range	Internaciative oritoria for	Interp	retative o	riteria	Quality Control limits	(mcg/ml)
Code	Name	Symbol	(mcg/ml)	Interpretative criteria for	≤S	- 1	≥R	Organism (ATCC)	Standard Range
EM060	Vancomycin	VAN	0.016-256	Staphylococcus spp	2	4-8	16	S.aureus ATCC 29213	0.5-2
				Enterococcus spp, Coagulase-negative Staphylococci	4	8-16	32	E.faecalis ATCC 29212	1-4
				S.pneumoniae, Streptococcus spp. Beta haemolytic group, Streptococcus spp. Viridans group	1	-	-	S.pneumoniae ATCC 49619	0.12-0.5
EM063	Oxacillin- Vancomycin	OXA / VAN	OXA: 0.064-8 VAN: 0.19-16	For interpretive criteria refer EM065 for Oxacillin & EM060 for Vancomycin. However using, Oxacillin - Vancomycin Ezy MIC™ Strip, MIC determination of Oxacillin for <i>Enterococcus</i> can not be established since highest concentration is 8.0 mcg/ml.					•
EM077	Vancomycin -Cefoxitin	VAN/ CX	VAN: 0.19-16 CX: 0.5-64	For interpretive criteria refer EM101 for Cefoxitin & EM060 for Vancomycin.					
EM111	Vancomycin- Teicoplanin	VAN/ TEI	VAN: 0.5 -32 TEI: 0.5 - 32	For interpretive criteria refe	er EM060	for Vanc	omycin 8	& EM055 for Teicoplanin	

a = Interpretative criteria and Quality Control limits are that of Cefoperazone except for that obtained for E.coli ATCC 35218

#### References

- $1. \quad \text{Performance standards of Antimicrobial Susceptibility Testing; Twenty Eighth Informational Supplement.} \ M100-S28, Vol. 38, No. 3, Jan 2018.$
- 2. Performance standards of Antimicrobial Susceptibility Testing; Twenty Seventh Informational Supplement. M100-S27, Vol. 37, No.1, Jan 2017.
- 3. Performance standards of Antimicrobial Susceptibility Testing; Twenty Sixth Informational Supplement. M100-S26, Vol. 36, No.1, Jan 2016.
- 4. Performance standards of Antimicrobial Susceptibility Testing; Twenty Fifth Informational Supplement. M100-S25, Vol. 35, No.3, Jan 2015
- 5. Performance standards of Antimicrobial Susceptibility Testing; Twenty Second Informational Supplement. M100-S22, Vol. 32, No. 3, Jan 2012.
- 6. European Committee on Antimicrobial Susceptibility Testing Breakpoint tables for interpretation of MICs and zone diameters Version 8.0, valid from 2018-01-01.
- 7. European Committee on Antimicrobial Susceptibility Testing Routine and extended internal quality control as recommended by EUCAST Version 8.0, valid from 2018-01-01.
- 8. Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard Third Edition. VET01-A3, No. 8, Feb 2008



b = Interpretative criteria and Quality Control limits are that of Ceftriaxone except for that obtained for *E.coli* ATCC 35218

c = EM082 strips cannot be used for testing of standard ATCC strains of *E.coli*, *H.influenaze* and *N.gonorrhoeae* 

<sup>△</sup> Resistant (R) = Gentamicin is not synergistic with cell wall active agents like Ampicillin, Penicillin & Vancomycin & hence resistant to synergism. Report as HLAR.

<sup>△</sup> Susceptible (S) = Gentamicin is synergistic with cell wall active agents like Ampicillin, Penicillin & Vancomycin.

d = Interpretive criteria are that of Tetracycline, Because as per CLSI, organism that are susceptible for Tetracycline are also considered susceptible to Doxycycline and Minocycline

## Phenotypic Determination Ezy MIC™ Strips

### **Interpretive Criteria for MBL detection**

Code	Name	Symbol	Range	Report	Formula	Interpretative criteria	Quality Contro (mcg/ml	
			(mcg/ml)	·			Organism (ATCC)	Standard
EM078	Imipenem with & without EDTA	IPM +EDTA/ IPM	IPM + EDTA: 1-64 IPM: 4-256	MBL positive strain	$\frac{IPM}{IPM + EDTA} = >8$ or $\frac{IPM}{IPM + EDTA} = \frac{>256}{<64}$ or $\frac{IPM}{IPM + EDTA} = \frac{>256}{<1}$	When the ratio of the value obtained for Imipenem (IPM): the value of Imipenem + EDTA (IPM+EDTA) is more than to 8 or If zone is observed on the side coated with Imipenem+EDTA & no zone is observed on the opposite the side coated with Imipenem, interpret the culture as MBL positive.	S. maltophila ATCC 13636 K.pneumoniae ATCC BAA 2146	Ratio > 8 Ratio > 8
				MBL negative strain	$\frac{1 + M}{1 + EDTA} = \frac{4}{4}$	When the ratio of the value obtained for Imipenem (IPM): the value of Imipenem + EDTA (IPM+EDTA) is less than or equal to 8 or If the zones obtained are below the lowest concentration on either side or on both the sides, interpret the culture as MBL negative.	P.aeruginosa ATCC 27853	Ratio ≤ 8
				MBL (non- determinative)	$\frac{\text{IPM}}{\text{IPM+ EDTA}} = \frac{>256}{>64}$	When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than MBL production. These have to be further investigated before reporting.	-	-
EM092	Meropenem with & without EDTA	MRP +EDTA/ MRP	MRP + EDTA: 1-64 MRP: 4- 256	MBL positive strain	$\frac{MRP}{MRP+EDTA} = >8$ or $\frac{MRP}{MRP+EDTA} = \frac{>256}{<64}$ or $\frac{MRP}{MRP+EDTA} = \frac{>8}{\leq 1}$	When the ratio of the value obtained for Meropenem (MRP): the value of Meropenem + EDTA (MRP+EDTA) is more than to 8 or  If zone is observed on the side coated with Meropenem+EDTA & no zone is observed on the opposite the side coated with Meropenem, interpret the culture as MBL positive.	S. maltophila ATCC 13636 K.pneumoniae ATCC BAA 2146	Ratio > 8 Ratio > 8
				MBL negative strain	$\frac{MRP}{MRP + EDTA} = \le 8$ or $\frac{IPM}{IPM + EDTA} = \frac{\le 4}{\le 1}$	When the ratio of the value obtained for Meropenem (MRP): the value of Meropenem + EDTA (MRP+EDTA) is less than or equal to 8 or  If the zones obtained are below the lowest concentration on either side or on both the sides, interpret the culture as MBL negative.	P.aeruginosa ATCC 27853	Ratio ≤ 8
				MBL (non- determinative)	MRP+ EDTA = >256 MRP+ EDTA = >64	When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than MBL production. These have to be further investigated before reporting.	-	-



## **Interpretive Criteria for ESBL detection**

Code	Name	Symbol	Range	Report	Formula	Interpretative criteria	Quality Contro (mcg/m	
			(mcg/ml)			·	Organism (ATCC)	Standard
EM116	Cefepime/ Cefepime + Clavulanic acid	CPM+/ CPM	CPM+: Cefepime with Clavulanic acid: 0.064-4	ESBL positive strain	<u>CPM</u> =>8	When the ratio of the value obtained for CPM: the value of CPM in combination with Clavulanic acid (CPM+) is more than 8 or No zone is obtained for CPM and Zone obtained in CPM+	K.pneumoniae ATCC 700603	Ratio > 8
			CPM: Cefepime: 0.25-16	ESBL negative strain	$\frac{\text{CPM}}{\text{CPM+}} = \le 8$ or $\frac{\text{CPM}}{\text{CPM+}} = \frac{< 0.25}{< 0.064}$	When Ratio of the value obtained for CPM: the value of CPM in combination with Clavulanic acid (CPM+) is less than or equal to 8.  or  If the zones obtained are below the lowest concentration on both the sides	E.coli ATCC 25922	Ratio ≤ 8
				ESBL (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting		
ЕМ099	Cefotaxime/ Cefotaxime + Clavulanic acid	CTX+ / CTX	CTX+: Cefotaxime with Clavulanic acid: 0.016-1	ESBL positive strain	<u>CTX</u> =>8	When the ratio of the value obtained for CTX: the value of CTX in combination with Clavulanic acid (CTX+) is more than or equal to 8 or No zone is obtained for CTX and Zone obtained in CTX+	K.pneumoniae ATCC 700603	Ratio > 8
			CTX: Cefotaxime : 0.25-16	ESBL negative strain	$\frac{\text{CTX}}{\text{CTX+}} = \le 8$ or $\frac{\text{CTX}}{\text{CTX+}} = \frac{\le 0.25}{\le 0.016}$	When Ratio of the value obtained for CTX: the value of CTX in combination with Clavulanic acid (CTX+) is less than or equal to 8 or If the zones obtained are below the lowest concentration on both the sides	E.coli ATCC 25922	Ratio ≤ 8
				ESBL (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting.		



Code	Name	Symbol	Range (mcg/ml)	Report	Formula	Interpretative criteria	Quality Contro (mcg/m	
			(mcg/mi)				Organism (ATCC)	Standard
ЕМ098	Ceftazidime /Ceftazidime + Clavulanic acid	CAZ+/ CAZ	CAZ+: Ceftazidime with Clavulanic acid: 0.064-4	ESBL positive strain	<u>CAZ</u> = >8	When the ratio of the value obtained for CAZ: the value of CAZ in combination with Clavulanic acid (CAZ+) is more than 8 or No zone is obtained for CAZ and Zone obtained in CAZ+	K.pneumoniae ATCC 700603	Ratio > 8
			CAZ : Ceftazidime: 0.5-32	ESBL negative strain	$\frac{\text{CAZ}}{\text{CAZ+}} = \le 8$ or $\frac{\text{CAZ}}{\text{CAZ+}} = \frac{<05}{<0.064}$	When Ratio of the value obtained for CAZ: the value of CAZ in combination with Clavulanic acid (CAZ+) is less than or equal to 8. or If the zones obtained are below the lowest concentration on both the sides	E.coli ATCC 25922	Ratio ≤ 8
				ESBL (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting.		
EM117	Ceftriaxone / Ceftriaxone + Clavulanic acid	CTR+/ CTR	CTR+: Ceftriaxone with Clavulanic acid: 0.016 - 1	ESBL positive strain	<u>CTR</u> = >8	When the ratio of the value obtained for CTR: the value of CTR in combination with Clavulanic acid (CTR+) is more than 8 or No zone is obtained for CTR and Zone obtained in CTR+	K.pneumoniae ATCC 700603	Ratio > 8
			CTR: Ceftriaxone : 0.25 -16	ESBL negative strain	$\frac{\text{CTR}}{\text{CTR+}} = \le 8$ or $\frac{\text{CTR}}{\text{CTR+}} = \frac{< 0.25}{< 0.016}$	When Ratio of the value obtained for CTR: the value of CTR in combination with Clavulanic acid (CTR+) is less than or equal to 8. or If the zones obtained are below the lowest concentration on both the sides	E.coli ATCC 25922	Ratio ≤ 8
				ESBL (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting.		
EM132	Improved ESBL detection Ezy MIC™ Strip	MIX+/ MIX	Ceftazidime, Cefotaxime & Clavulanic acid (MIX+) 0.032-4	ESBL positive strain	MIX = >8	When the ratio of the value obtained for MIX: the value of MIX in combination with Clavulanic acid (MIX+) is more than 8 or No zone is obtained for MIX and Zone obtained in MIX+	K.pneumoniae ATCC 700603	Ratio > 8
			Ceftazidime & Cefotaxime (MIX): 0.125-16	ESBL negative strain	$\frac{MIX}{MIX+} = \le 8$ or $\frac{MIX}{MIX+} = \frac{<0.12}{<0.032}$	When Ratio of the value obtained for MIX: the value of MIX in combination with Clavulanic acid (MIX+) is less than or equal to 8. or If the zones obtained are below the lowest concentration on both the sides	E.coli ATCC 25922	Ratio ≤ 8
				ESBL (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting.		



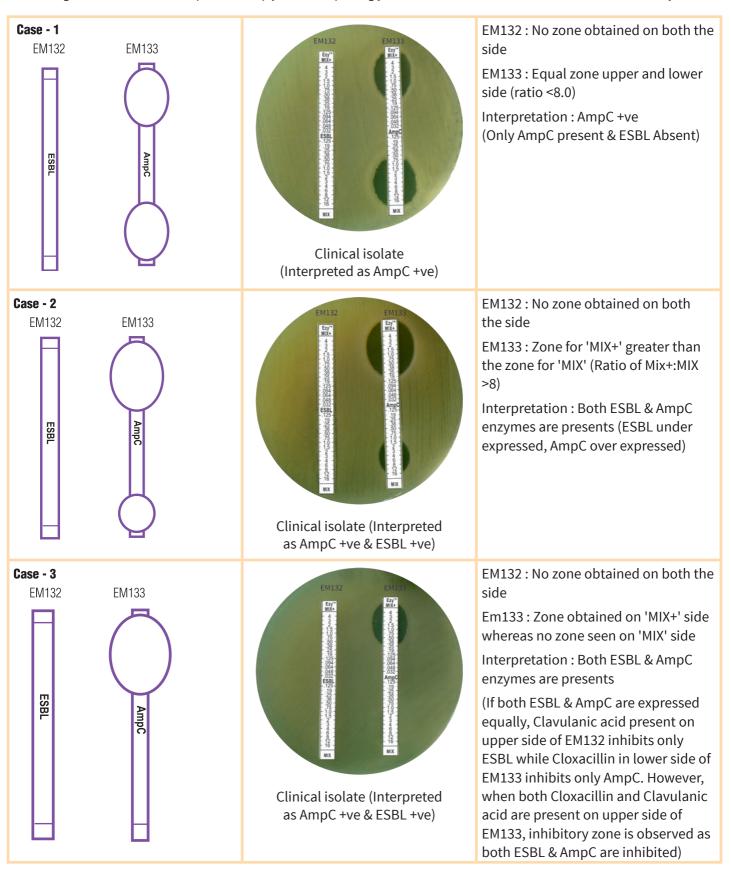
# Interpretive Criteria for AmpC detection

	Name			Report	Formula		Quality Control limits (mcg/ml)			
Code		Symbol	Range (mcg/ml)			Interpretative criteria	Organism (ATCC)	Standard		
Code	Name	Symbol				interpretative criteria		Ratio	Tentative MIC	
									CTN*	CTN+*
EM127	Cefotetan + CTN Cloxacillin		Cefotetan + Cloxacillin (CTN+): 0.5 - 32 mcg/ml	. CTN /		When the ratio of the value obtained for Cefotetan (CTN): the value of Cefotetan in combination with Cloxacillin (CTN+) is more than 8 or No zone is obtained for CTN and Zone obtained in CTN+	K. pneumoniae ATCC BAA 1144	>8	≥32.0	≤ 0.5 - 2
			Cefotetan (CTN): 0.5 – 32 mcg/ml	AmpC negative strain	<u>CTN</u> = ≤8	When Ratio of the value obtained for Cefotetan (CTN): the value of Cefotetan in combination with Cloxacillin (CTN+) is less than or equal 8.	K. pneumoniae ATCC 700603	≤8	≤ 0.5 - 2	≤ 0.5 - 2
				AmpC (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than AmpC production. These have to be further investigated before reporting.				

Code	Name	Symbol	Range (mcg/ml)	Report	Formula	Interpretative criteria
EM133	Improved AmpC detection Ezy MIC™ Strip	MIX+/ MIX	Ceftazidime, Cefotaxime, Cloxacillin & Clavulanic acid (MIX+) 0.032- 4	ESBL+AmpC positive strain (ESBL present along with AmpC)	<u>MIX</u> = >8	When the ratio of the value obtained for MIX: the value of MIX in combination with Clavulanic acid (MIX+) is more than 8 or  No zone is obtained for MIX and Zone obtained in MIX+
			Ceftazidime, Cefotaxime & Cloxacillin (MIX): 0.125-16	AmpC Positive (AmpC Present, ESBL Absent)	<u>MIX</u> MIX+ = ≤8	When Ratio of the value obtained for MIX : the value of MIX in combination with Clavulanic acid (MIX+) is less than or equal to 8.
				ESBL+AmpC (non- conclusive)		When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than ESBL production. These have to be further investigated before reporting.

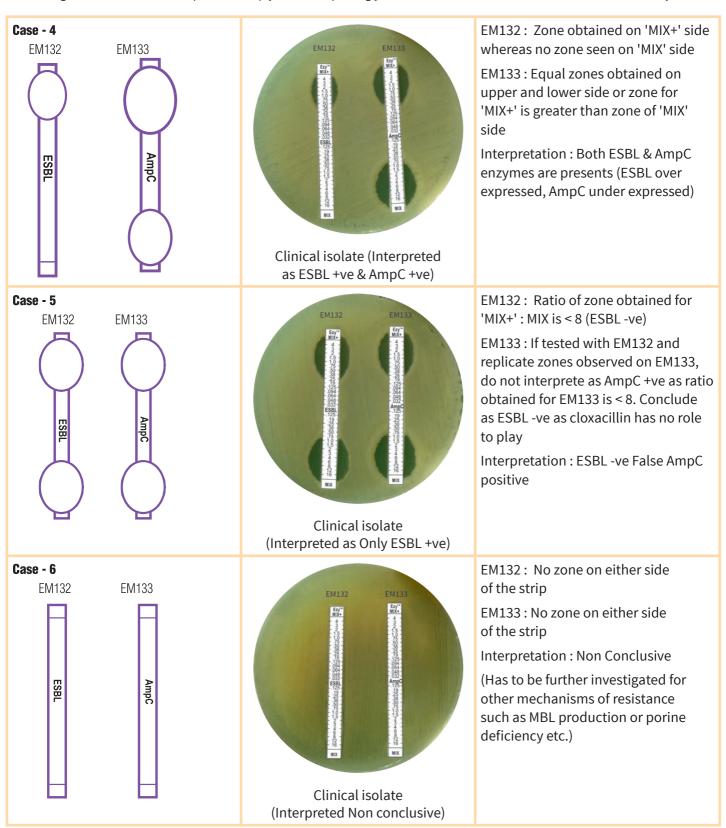


Following illustrations and examples will help you in interpreting your results when EM132 & EM133 are simultaneously tested.





Following illustrations and examples will help you in interpreting your results when EM132 & EM133 are simultaneously tested.



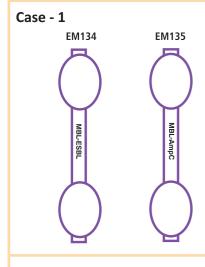


## Interpretive Criteria For MBL with ESBL & AmpC Detection

Code	Name	Symbol	Range (mcg/ml)	Report	Formula	Interpretative criteria						
Note : T	Note: This strip should be tested on ESBL and AmpC non-conclusive strain. Otherwise false positive results may be concluded											
EM134	MBL plus ESBL Detection Ezy MIC™ strip	ESBL+/ ESBL	Ceftazidime, Cefotaxime, EDTA & Clavulanic acid (ESBL+): 0.032 - 4	MBL + ESBL Positive Strain	ESBL = >8	When the ratio of the value obtained for ESBL: the value of ESBL+ is more than 8 or No zone is obtained for ESBL and zone obtained for ESBL+						
			Ceftazidime, Cefotaxime & EDTA (ESBL): 0.125 - 16	MBL Positive Strain (ESBL is not present along with MBL)	<u>ESBL</u> = ≤8	When the ratio of the value obtained for ESBL : the value of ESBL+ is less than or equal to 8						
				MBL + ESBL (Non - conclusive)	-	When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than AmpC production. These have to be further investigated before reporting.						
	etection Ezy					. Detection Ezy MIC™ strip (EM134). In Case MBL plus king presence of MBL & ESBL, false positive results may be						
EM135	MBL plus AmpC Detection Ezy MIC™ strip	AmpC+/ AmpC	Ceftazidime, Cefotaxime, Cloxacilin, EDTA & Clavulanic acid (AmpC+): 0.032 - 4	MBL + AmpC + ESBL Positive Strain	AmpC AmpC+ =>8	When the ratio of the value obtained for ESBL: the value of ESBL+ is more than 8 or No zone is obtained for ESBL and zone obtained for ESBL+						
			Ceftazidime, Cefotaxime, Cloxacillin & EDTA (AmpC+): 0.125 - 16	MBL + AmpC Positive Strain (ESBL is not present along with MBL)	AmpC AmpC+ = ≤8	When the ratio of the value obtained for ESBL : the value of ESBL+ is less than or equal to 8						
				MBL + AmpC (Non - conclusive)	-	When no zone of inhibition is obtained on either side. In such cases resistance may be due to mechanisms other than AmpC production. These have to be further investigated before reporting.						



Following illustrations and examples will help you in interpreting your results when EM134 & EM135 are simultaneously tested.



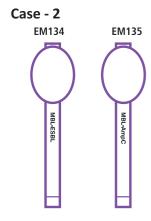


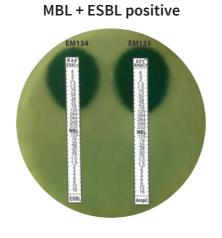
EM134 : Equal zones upper and lower side (Ratio <8).

EM135 : Equal zones upper and lower

Interpretation: MBL positive
Ratio: Lower side IC value
Upper side IC value = <8

(Only MBL enzyme expressed, as EDTA present on upper and lower side of strip inhibits MBL enzyme)





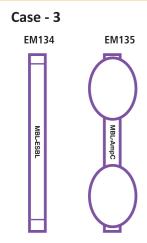
Clinical Isolate

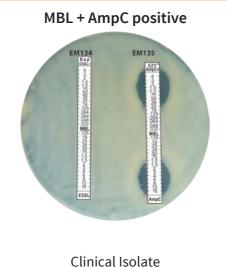
EM134: Zone on upper side.lower side may show small or no zone.

EM135: Zone on upper side No zone on lower side

Interpretation: MBL& ESBL present.

(No zone on lower side of EM134 as EDTA alone does not have role to play. Whereas upper side of EM134 shows inhibitory zone as EDTA in combination with Clavulanic acid inhibits both ESBL and MBL. Replicate zones observed for EM135 as Clavulanic acid present on upper side of strip gives inhibitory zone and cloxacillin present in a strip does not play any role.)



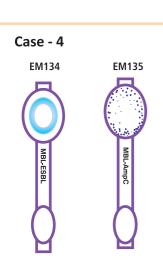


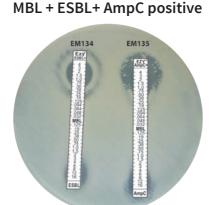
EM134: No zones obtained on both side EM135: Equal zone on upper and lower side

Interpretation: MBL and AmpC enzymes are present.

(No zone observed on both side of EM134 as EDTA alone or EDTA in combination with Clavulanic acid does not have role to play. Whereas EDTA in combination with Cloxacillin gives inhibitory zone on both sides of EM135 due to the presence of MBL & AmpC enzymes.)

Following illustrations and examples will help you in interpreting your results when EM134 & EM135 are simultaneously tested.





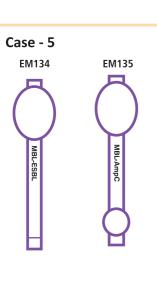
Clinical Isolate

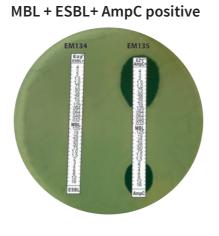
EM134 : Zone obtained on upper side. Small hazy zone on lower side

EM135: Larger zone obtained on upper side small hazy on lower side same as obtained on lower side of EM134.

Interpretation: MBL, ESBL and AmpC enzymes are expressed.

(Smaller zone of inhibition is observed on upper side of EM134 due to over production of ESBL. Similarly smaller zone is observed on lower side of EM135 due to over production of AmpC. Enhanced zone is observed on upper side of EM135 due to combined effect of EDTA, Cloxacillin and Clavulanic acid indicating presence of MBL, ESBL and AmpC enzymes.)





Clinical Isolate

EM134: No Zone obtained on upper or lower side.

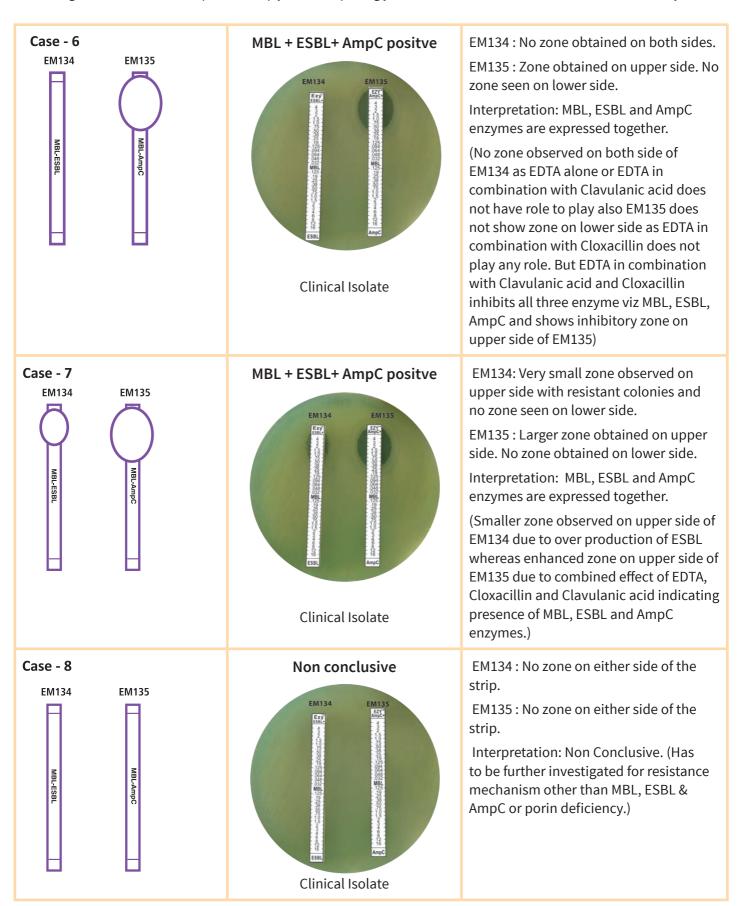
EM135: Larger zone obtained on upper side whereas smaller zone obtained on lower side.

Interpretation: MBL, ESBL and AmpC enzymes are expressed.

(EDTA alone or in combination with Clavulanic acid does not show inhibitory zone to EM134 whereas smaller zone observed on lower side of EM135 as over production of AmpC. Enhanced zone observed on upper side of EM135 due to combined effect of EDTA, Cloxacillin and Clavulanic acid indicating presence of MBL, ESBL and AmpC enzymes.)



Following illustrations and examples will help you in interpreting your results when EM134 & EM135 are simultaneously tested.



# Interpretive criteria & quality control ranges of Antifungal Ezy MIC™ Strips

Code	News	Complete	Range (mcg/ml)	Intermediation with the C	Interp	retative o	criteria	Quality Control limits(mcg/ml)		
Code	Name	Symbol		Interpretative criteria for	≤S	S-DD*	≥R	Organism (ATCC)	Standard Range	
EM071	Amphotericin B	AP	0.002-32	Not Available	Not Available		ole	C.albicans ATCC 90028 C.albicans ATCC 24433 C.parapsilosis ATCC 22019 C. parapsilosis ATCC 90018 C.tropicalis ATCC 750 C. krusei ATCC 6258	0.5 - 2 0.25-1 0.25-1 0.5-2 0.5-2 0.25-2	
EM122	Anidulafungin	AND	0.002-32	Candida krusei Candida parapsilosis Candida albicans Candida glabrata Candida tropicalis Candida guilliermondii	0.25 2 0.25 0.12 0.25 2	0.5 4 0.5 0.25 0.5 4	1 8 1 0.5 1 8	C. krusei ATCC 6258 C.parapsilosis ATCC 22019	0.03 - 0.12 0.25 - 2	
EM119	Caspofungin	CAS	0.002 - 32	Candida krusei Candida parapsilosis Candida albicans Candida glabrata Candida tropicalis Candida guilliermondii	0.25 2 0.25 0.12 0.25 2	0.5 4 0.5 0.25 0.5 4	1 8 1 0.5 1 8	C. krusei ATCC 6258 C.parapsilosis ATCC 22019	0.12 - 1 0.25 - 1	
EM144	Cotrimazole	CLO	EM144	Not Available	Not Available		ole	C. parapsilosis ATCC 22019 C. krusei ATCC 6258 C.albicans ATCC 10231	0.016 - 0.06 0.016 - 0.06 0.06 - 0.25	
EM072	Fluconazole	FLC	0.016-256	Candida albicans Candida glabrata Candida parapsilosis Candida tropicalis	2 - 2 2	4 ≤32 4 4	8 ≥ 64 8 8	C.albicans ATCC 90028 C.albicans ATCC 24433 C.parapsilosis ATCC 22019 C. parapsilosis ATCC 90018 C.tropicalis ATCC 750 C. krusei ATCC 6258 C.albicans ATCC 10231 <sup>a</sup>	0.25 - 1 0.25-1 1-8 0.25-1 1-4 16-64 0.5-8	
EM118	Flucytosine	FLU	0.002-32	Not Available			ole	C.albicans ATCC 90028 C.albicans ATCC 24433 C.parapsilosis ATCC 22019 C. parapsilosis ATCC 90018 C.tropicalis ATCC 750 C. krusei ATCC 6258	0.5 - 2 1 - 4 0.06 - 0.5 ≤0.12 - 0.25 ≤0.12 - 0.25 4 - 16	
EM143	Griseofulvin	GRI	0.002-32	Not Available	Not Available		ole	T. mentagrophytes MRL 1957 ATCC MYA 4439	0.125 - 0.5	
EM073	Itraconazole	ITR	0.002-32	Candida spp ##	0.12	0.25- 0.5	1	C.parapsilosis ATCC 22019 C. krusei ATCC 6258	0.06-0.5 0.12-1	
EM074	Ketoconazole	KET	0.002-32	Not Available	Not Available		ole	C. parapsilosis ATCC 22019 C. krusei ATCC 6258	0.06-0.25 0.12-1	
EM121	Micafungin	MYC	0.002-32	Candida krusei Candida parapsilosis Candida albicans Candida glabrata Candida tropicalis Candida guilliermondii	0.25 2 0.25 0.06 0.25 2	0.5 4 0.5 0.12 0.5 4	1 8 1 0.25 1 8	C. krusei ATCC 6258 C.parapsilosis ATCC 22019	0.12 - 0.5 0.5 - 4	

C 1 -	Nama	C	Range (mcg/ml)	Interpretative criteria for	Interpretative criteria			Quality Control limits(mcg/ml)	
Code	Name	Symbol			≤S	S-DD*	≥R	Organism (ATCC)	Standard Range
EM146	Miconazole	MIC	0.002-32	Not Available			le	C. albicans ATCC 24433 C.tropicalis ATCC 750 Candida glabrata ATCC 2001	0.06-0.25 1-4 0.12-0.5
EM145	Nystatin	NYT	0.002-32	Not Available			le	C.parapsilosis ATCC 22019 C.tropicalis ATCC 750 C.krusei ATCC 6258	0.25 - 1 0.125 - 1 0.5 - 2
EM120	Posaconazole	POS	0.002-32	Not Available			le	C.parapsilosis ATCC 22019 C. krusei ATCC 6258	0.03 - 0.25 0.06 - 0.5
EM142	Terbinafine	TRB	0.002 - 32	Not Available	Not Available		le	T. mentagrophytes MRL 1957 ATCC MYA 4439	0.002 - 0.008
EM086	Voriconazole	VRC	0.002-32	Candida albicans Candida krusei Candida parapsilosis Candida tropicalis	0.12 0.5 0.12 0.12	0.25-0.5 1 0.25-0.5 0.25-0.5	2 1	C.parapsilosis ATCC 22019 C. krusei ATCC 6258	0.016-0.12 0.06-0.5

<sup>\*</sup> S-DD - Susceptible - Dose Dependent.

The results of Fluconazole susceptibility testing should not be interpreted using this criterion for this species.

##: For Itraconazole, the data are based entirely on experience with mucosal infections, and data supporting breakpoints for invasive infections due to Candida spp. is not available.

a: Limits may not match with CLSI guidelines.

#### Reference:

- Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Edition. Vol.28 No.14, April- 2008 CLSI document M27-S3.
- 2. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. Vol.32 No.17, December 2012 CLSI document M27-S4.





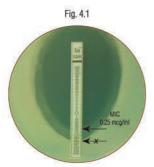
<sup>#:</sup> Isolates of C.krusei are assumed to be intrinsically resistant to Fluconazole.

### **Publications**

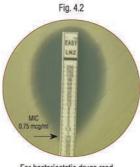
- 1. Bandyopadhyay, S. et al., Co-infection of methicillin-resistant Staphylococcus epidermidis, methicillin-resistant Staphylococcus aureus and extended spectrum ß-lactamase producing Escherichia coli in bovine mastitis- three cases reported from India. (2014). Veterinary Quarterly, 2014.
- 2. *Chauhan, R., Sharma, P. C.* Phenotypic detection of Metallo-ß-lactamase (MBL) producers among multidrug resistant (MDR) strains of *P. aeruginosa* in Himachal Pradesh. (2013) *Indian Journal of Basic and Applied Medical Research.*,Vol.-3, Issue-1, P.303-313.
- 3. Davra, P., Pandya, Y., Shethwala, N. An Evaluation of Various Methods For The Detection Of Metallo ß Lactamase In Clinical Isolates Of Pseudomonas aeruginosa In A Teaching Hospital Of Rural Gujarat, India. (2014). J of Evolution of Med and Dent Sci.Vol 3, Issue 45, 11064-11071.
- 4. *Khan, F., Ali, S., Sultan, A., Rizvi, M., Shukla, I.* Clindamycin Resistance Constitutive and Inducible Patterns in Erythromycin Resistant Clinical Isolates of *Staphylococcus* Species; (2014). *Intl. J. Microbial. Res.*, 5 (3): 185-189.
- 5. Lall, N., Basak, S. High level Aminoglycoside Resistant Enterococcus species: A study; (2014). IJCRR., 6(3): 16-21
- 6. *Mobashshera, T., Aruna, K* Phenotypic and Molecular Characterization of MBL Genes among Uropathogens Isolated in Mumbai City. (2014). *Bri Micro Res J.* Vol.: 5, Issue: 4, Page 368-383.
- 7. Rathod, S., Williamson, M. Antibacteri al activity of green tea extract in combination with cefotaxime on diarrhea causing ESBL producing E. coli. (2015). Int J Pharm PharmSci, Vol 7, Issue 6, 258-262.
- 8. Rathod, S., Williamson, M. In vitro antimicrobial effect of Punicagranatum extracts on Extended Spectrum ß Lactamases (ESBL) producing E.coli causing diarrhea. (2015). Asian J Biochem and Pharm Res. Vol. 5, Issue 1, 38-45.
- 9. *Sasirekha*, *B*.Prevalence of ESBL, AmpC ß-lactamases and MRSA among uropathogens and its antibiogram. (2013). *EXCLI Journal* 2013;12:81-88.
- 10. Shah P. J., Williamson, M. T., Antibacteri al and Synergistic activity of Calendula officinalis Methanolic Petal Extract on Klebsiellapneumoniae Co-producing ESBL and AmpC ß-Lactamase. (2015) Int.J.Curr.Microbial.App.Sci. 4(4): 107-117
- 11. *Thool, V. U., Bhoosreddy, G. L., Wadher, B.J.* Detection of resistance to linezolid in *Staphylococcus aureus* infecting orthopedic patients.(2012). *Indian J PatholMicrobiol*. 55(3):361-4.
- 12. *Vanisree, R., Kavita Lala, M., Neelima, A.* Umblical Stump Infections In Neonates With Special References To MRSA. (2014). *World J of Pharmacy and Pharm Sci*, Vol 3, Issue 7, 724-731.
- 13. Farshadzadeh, Z. et al., Wide distribution of carbapenem resistant Acinetobacter baumannii in burns patients in Iran. (2015) *Front. Microbiol.*
- 14. Aruna, K., Mobashshera1, T., Prevalence of extended spectrum beta-lactamase production among uropathogens in south Mumbai and its antibiogram pattern. (2012) *EXCLI J*; 11: 363–372.
- 15. Prabha, R., Easow, J.M., Swapna, M. Phenotypic detection of Extended Spectrum Beta Lactamase producing uropathogens using DDST, PCT, Chrom agar and E-test –A comparitive study (2016). *Int.J.Curr.Microbiol.App.Sci*, 5(4): 565 577.
- 16. Panjabi, K. et al., Efficiency of Biosynthesized Silver and Zinc Nanoparticles Against Multi-Drug Resistant Pathogens. (2018). *Front Microbiol*; 9: 2207.



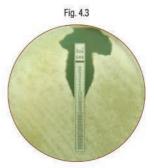
# **Reading Observations**



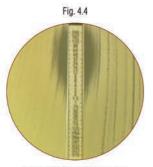
For bactericidal drugs read at the point of complete inhibition



For bacteriostatic drugs read at 80% inhibition



For Echinocandins class of drug, excessively wet plates prior to inoculation may give distorted zones



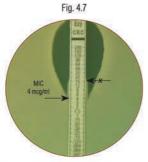
Unevenly swabbed surfaces may give non-confluent intersections



Growth occurs along the entire strip,  $\label{eq:MIC} \text{MIC} \geq 256\text{mcg/mI}.$ 

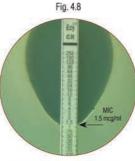


When the ellipse does not intersect the strip, MIC < 0.016mcg/ml

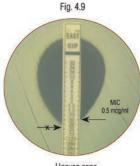


Ignore the growth "hugging" the side of the strip.

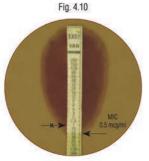
Read at actual intersection



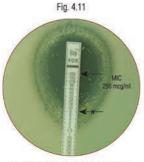
Intersection in between the dilutions, read the higher value



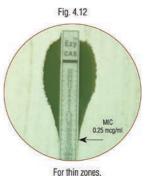
Uneven zone. Read the higher value



Ignore haemolysis.
Read at the point of complete inhibition



Isolated microcolonies within ellipse, read MIC at a point where no colonies observed close to strip



read at the bottom of zone



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