



Amphotericin B Ezy MIC™ Strip (AP) (0.002-32 mcg/ml) EM071

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Amphotericin B on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002 mcg/ml to 32 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC™ strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip FEATURES AND ADVANTAGES

Ezy MIC™ strip exhibits several advantages over existing plastic strip.

1. Ezy MIC™ strip is made up of porous paper material unlike plastic non-porous material
2. Ezy MIC™ strip has MIC values printed on both sides identically.
3. The antifungal agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4. For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar or Mueller Hinton Agar, 2% glucose with methylene blue is employed.
5. Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
7. **The strips give reproducible MIC values that are equivalent to the standard reference MIC obtained by Broth dilution performed as per guidelines with less efforts.**

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

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 ± 0.2 mm and allow solidifying. 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**

1. 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 $35 \pm 2^\circ\text{C}$. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1×10^6 - 5×10^6 cells /ml (i.e. 0.5 McFarland standard).

- **Test Procedure**

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye i.e. Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) as mentioned above.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15 minutes before opening.
4. Remove one applicator from the self sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

1. Read the plates only when sufficient growth is seen.
2. Read the MIC where the ellipse intersects the MIC scale on the strip.
3. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniform and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation
4. Isolated colonies, pinpoint microcolonies and hazes may appear within the zone of inhibition frequently and they should be ignored. In such cases, consider reading for MIC determination at a point on the scale at which prominent reduction of growth is seen.
5. Since Ezy MIC™ strip has continuous gradient, MIC values “in-between” two fold dilutions can be obtained.
6. Always round up these values to the next two-fold dilution before categorization. For example: Amphotericin B showing reading of 0.75 mcg/ml should be rounded up to next concentration ie. 1.0 mcg/ml.
7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC $<$ the lowest value on the MIC scale.

Warning and Precautions:

1. Ezy MIC™ Strip is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, Ezy MIC™ Strip should only be used by at least semi-trained personnel.
3. This strip is intended only for agar diffusion method and not for broth dilution method.
4. Ezy MIC™ Strip should be used strictly according to procedures described herein.
5. Performance of Ezy MIC™ Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
7. Before using Ezy MIC™ Strips, ensure that the strip is at room temperature.
8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL:**Interpretation**

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	Incubation	Interpretative Criteria		
		< S	I	> R
<i>Candida</i> spp	35-37°C for 24 - 48 hrs	1	-	2

Quality control

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC cultures on Mueller Hinton Agar + 2% Glucose + 0.5mcg/ml Methylene Blue incubated at 35-37°C for 24 - 48 hrs.

Table 2: Following are the reference MIC values (mcg/ml) range for Amphotericin B.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
<i>C.albicans</i> ATCC 90028	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.5 - 1.0 - 2.0
<i>C.albicans</i> ATCC 24433	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 – 0.5 – 1.0
<i>C.parapsilosis</i> ATCC 22019	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 - 0.5 - 1.0
<i>C. parapsilosis</i> ATCC 90018	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.5 - 1.0 - 2.0
<i>C.tropicalis</i> ATCC 750	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.5 – 1.0 – 2.0
<i>C. krusei</i> ATCC 6258	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 – 0.5 – 1.0 – 2.0

Storage & Shelf Life:

- Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at 2-8°C, for prolonged use store below -20°C.
- Use before expiry date on the label.
- Ezy MIC™ Strip left over from opened package must be kept dry.
- Moisture should be prevented from penetrating into or forming within the package or storage container.
- Check whether the batch number and expiry date are marked on the storage container.
- Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *in vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume
5. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Forth Edition. Vol.37 No.13, November-2017 CLSI document M27-Ed4.
6. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. Vol.32 No.17, December 2012 CLSI document M27-S4.
7. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement. Vol.28 No.15, December 2007 CLSI document M27-S3.
8. Performance Standards of Antifungal Susceptibility Testing of Yeast; Second Edition. M61-E02, Vol.40, No.9, Jan-2020.

Packing:

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

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

Revision: 05/2024



On receipt store at -20°C



In vitro diagnostic medical device



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Road No. 21Y, MIDC,
Wagle Industrial Estate,
Thane (W) - 400604,
Maharashtra, India



Indicates a single sterile barrier system with protective packaging outside



Do not re-use



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Do not use if package is damaged

Disclaimer :

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Itraconazole Ezy MIC™ Strip (ITR) (0.002- 32 mcg/ml)

EM073

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Itraconazole on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002mcg/ml to 32 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC™ strip is useful for quantitative determination of susceptibility of fungal cultures to antifungal agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip FEATURES AND ADVANTAGES

Ezy MIC™ strip exhibits several advantages over existing plastic strip.

1. Ezy MIC™ strip is made up of porous paper material unlike plastic non-porous material
2. Ezy MIC™ strip has MIC values printed on both sides identically.
3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4. For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
5. Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
7. **The strips give reproducible MIC values that are equivalent to the standard reference MIC obtained by Broth dilution performed as per guidelines with less efforts.**

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

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 ± 0.2 mm and allow solidifying. 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**

1. 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 $35 \pm 2^\circ\text{C}$. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield $1 \times 10^6 - 5 \times 10^6$ cells /ml (i.e. 0.5 McFarland standard).

- **Test Procedure**

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye i.e. Mueller Hinton Agar, modified (as per CLSI for antifungal) (M1825) as mentioned above.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15 minutes before opening.
4. Remove one applicator from the self-sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

1. Read the plates only when sufficient growth is seen.
2. Read the MIC where the ellipse intersects the MIC scale on the strip.
3. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniform and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation
4. Isolated colonies, pinpoint microcolonies and hazes may appear within the zone of inhibition frequently and they should be ignored. In such cases, consider reading for MIC determination at a point on the scale at which prominent reduction of growth is seen.
5. Since Ezy MIC™ strip has continuous gradient, MIC values “in-between” two-fold dilutions can be obtained.
6. Always round up these values to the next two-fold dilution before categorization. For example: Itraconazole showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC $<$ the lowest value on the MIC scale.

Warning and Precautions:

1. Ezy MIC™ Strip is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, Ezy MIC™ Strip should only be used by at least semi-trained personnel.
3. This strip is intended only for agar diffusion method and not for broth dilution method.
4. Ezy MIC™ Strip should be used strictly according to procedures described herein.
5. Performance of Ezy MIC™ Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
7. Before using Ezy MIC™ Strips, ensure that the strip is at room temperature.
8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL:**Interpretation:**

Table 1: Use following interpretive criteria for susceptibility categorization.

When testing	Incubation	Interpretative Criteria		
		≤ S	S-DD*	≥ R
<i>Candida</i> spp. #	35-37°C for 24 hrs.	0.125	0.25-0.5	1

* S-DD - Susceptible - Dose Dependent.

#: 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.

Quality control

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.

Table 2: Following are the reference MIC values (mcg/ml) range for Itraconazole.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
<i>C.parapsilosis</i> ATCC 22019	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.06 - 0.12- 0.25- 0.5
<i>C.krusei</i> ATCC 6258	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.12 – 0.25 - 0.5 – 1.0

Storage & Shelf Life:

1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at 2-8°C, for prolonged use store below -20°C.
2. Use before expiry date on the label.
3. Ezy MIC™ Strip left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume

5. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Forth Edition. Vol.37 No.13, November-2017 CLSI document M27-Ed4.
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7. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement. Vol.28 No.15, December 2007 CLSI document M27-S3.
8. Performance Standards of Antifungal Susceptibility Testing of Yeast; Second Edition. M61-E02, Vol.40, No.9, Jan-2020.

Packing:

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

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

Revision: 05/2024



On receipt store at -20°C



In vitro diagnostic medical device



Plot No. C-40,
Road No. 21Y, MIDC,
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Maharashtra, India



Indicates a single sterile barrier system with protective packaging outside



Do not re-use



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Do not use if package is damaged

Disclaimer :

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Nystatin Ezy MIC™ Strip (NYT) (0.002-32 mcg/ml)

EM145

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Nystatin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002 mcg/ml to 32 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC™ strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MIC™ Strip FEATURES AND ADVANTAGES

Ezy MIC™ strip exhibits several advantages over existing plastic strip.

1. Ezy MIC™ strip is made up of porous paper material unlike plastic non-porous material
2. Ezy MIC™ strip has MIC values printed on both sides identically.
3. The antifungal agent is evenly distributed on either side of the Ezy MIC™ strip and hence it can be placed by any side on the agar surface.
4. For Ezy MIC™ strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar or Mueller Hinton Agar, 2% glucose with methylene blue is employed.
5. Once placed, Ezy MIC™ strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
7. **The strips give reproducible MIC values that are equivalent to the standard reference MIC obtained by Broth dilution performed as per guidelines with less efforts.**

METHOD AND USE OF EZY MIC™ STRIPS

- **Type of specimen**

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

- **Guidelines for preparation of the medium**

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 ± 0.2 mm and allow solidifying. 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**

1. 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 $35 \pm 2^\circ\text{C}$. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield $1 \times 10^6 - 5 \times 10^6$ cells /ml (i.e. 0.5 McFarland standard).

- **Test Procedure**

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye i.e. Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) as mentioned above.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Remove Ezy MIC™ strip container from cold and keep it at room temperature for 15 minutes before opening.
4. Remove one applicator from the self sealing bag stored at room temperature.
5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC™ strip.
6. Lift the applicator along with attached Ezy MIC™ strip.
7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
8. DO NOT PRESS EZY MIC™ STRIP. Within 60 seconds, Ezy MIC™ strip will be adsorbed and will firmly adhere to the agar surface.
9. Ezy MIC™ strip should not be repositioned or adjusted once placed.
10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

1. Read the plates only when sufficient growth is seen.
2. Read the MIC where the ellipse intersects the MIC scale on the strip.
3. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniform and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation
4. Isolated colonies, pinpoint microcolonies and hazes may appear within the zone of inhibition frequently and they should be ignored. In such cases, consider reading for MIC determination at a point on the scale at which prominent reduction of growth is seen.
5. Since Ezy MIC™ strip has continuous gradient, MIC values “in-between” two fold dilutions can be obtained.
6. Always round up these values to the next two-fold dilution before categorization. For example: Nystatin showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC $<$ the lowest value on the MIC scale.

Warning and Precautions:

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

8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
9. Place the unused strips back to recommended temperature.

QUALITY CONTROL

Quality control of Ezy MIC™ Strip is carried out by testing the strips with standard ATCC cultures.

Table 1: Following are the reference MIC values (mcg/ml) range for Nystatin.

Organism	Medium Used	Incubation	Std. Quality Control limits (mcg/ml)
<i>C.parapsilosis</i> ATCC 22019	Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) Or Mueller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue	35-37°C for 24 - 48 hrs.	0.25 – 0.5 – 1.0
<i>C.tropicalis</i> ATCC 750			0.125 – 0.25 – 0.5 – 1.0
<i>C. krusei</i> ATCC 6258			0.5 – 1.0 – 2.0

Storage & Shelf Life:

1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC™ strips container at 2-8°C, for prolonged use store below -20°C.
2. Use before expiry date on the label.
3. Ezy MIC™ Strip left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MIC™ Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MIC™ Strips provides *in vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen, J. H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Forth Edition. Vol.37 No.13, November-2017 CLSI document M27-Ed4.
5. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Third Edition. Vol.37 No.15, November- 2017 CLSI document M38-Ed3.

6. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. Vol.32 No.17, December 2012 CLSI document M27-S4.
7. Performance Standards of Antifungal Susceptibility Testing of Filamentous Fungi; Second Edition. M60-E02, Vol.40, No.8, Jan-2020.
8. Performance Standards of Antifungal Susceptibility Testing of Yeast; Second Edition. M61-E02, Vol.40, No.9, Jan-2020.

Packing:

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

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

Revision: 05/2024



On receipt store at -20°C 



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SP Selective Supplement II

FD094

An antimicrobial supplement recommended for selective isolation of *Trichomonas* species and *Candida* species.

Composition

Per vial sufficient for 500 ml medium

*Ingredients

Streptomycin
Penicillin G

Concentration

250mg
500000Unit

Directions:

Rehydrate the contents of 1 vial aseptically with 5 ml of sterile distilled water. Mix well, avoiding frothing of the solution. Aseptically add the contents of 1 vial to 460 ml of sterile, molten, cooled (45-50°C) *Trichomonas* Agar Base [M665](#)/ *Trichomonas* HiVeg™ Agar Base [MV665](#) along with 40 ml of inactivated Horse Serum [RM1239](#). Mix well and pour into sterile petri plates.

Type of specimen

Clinical samples - vaginal and urethral secretions (women), anterior urethral or prostatic secretions (men)

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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Technical Data

MeRS Selective Supplement

FD229

An antimicrobial supplement recommended for the selective isolation of Methicillin Resistant *Staphylococcus aureus* from clinical specimens.

Composition

Per vial sufficient for 500 ml medium

*Ingredients	Concentration
Methicillin	2mg

Directions:

Rehydrate the contents of one vial with 5 ml of sterile distilled water and aseptically add to 500 ml of sterile, molten, cooled (45-50°C) MeReSa Agar Base [M1594](#)/ HiCrome™ MeReSa Agar, Base [M1674](#)/ HiCrome™ MeReSa HiVeg™ Agar Base [MV1674](#)/ HiCrome™ MeReSa HiCynth™ Agar Base [MCD1674](#)/ HiCrome™ MRSA Agar Base, Modified [M1953](#).

This supplement can either be used individually or in combination with FD259 Cf Selective Supplement II for more selectivity. Mix well and pour into sterile Petri plates. Mix well and pour into sterile petri plates.

Type of specimen

Clinical samples - Mouth, skin, intestine, upper respiratory tract of humans, urine, pus, wound samples etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

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Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



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Technical Data

AC Selective Supplement

FD271

This antibiotic supplement is recommended for selective isolation of MDR strains of *Acinetobacter*.

Composition

Per vial sufficient for 500 ml medium

*Ingredients	Concentration
Ampicillin, sodium salt	5mg
Ceftazidime	5mg

Directions:

Rehydrate the contents of 1 vial aseptically with 5ml of sterile distilled water. Mix gently to dissolve the contents completely. Aseptically add the rehydrated contents to 500ml of sterile, molten, cooled (45-50°C) Leeds Acinetobacter Agar Base [M1839](#) / 500ml of HiCrome™ Acinetobacter Agar Base [M1938](#). Mix well and pour into sterile Petri plates.

Type of specimen

Clinical- stool, urine, abscess, skin, wounds swabs, nasal swabs, etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

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Reference

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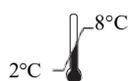
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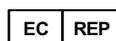
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VF Selective Supplement

FD277

Intended use:

Recommended for selective isolation of Vancomycin Resistant Enterococci (VRE).

Composition

Per vial sufficient for 500 ml medium

*Ingredients	Concentration
Vancomycin	4mg
Fluconazole	5mg

Directions:

1. This product is available in one size containing 5 vials.
2. The bottles when supplied are intact. Ensure that bottles do not have any cracks or defects.
3. User may remove the desired number of bottles from the box as per their requirement.
4. It should be handled by trained person wearing appropriate personal protective equipment (PPE) and sterile gloves.
5. Place the bottles on sterile surfaces such as laminar air flow or sterile working bench.
6. Label them accordingly.
7. Disinfect the outer surface of cap or closures with suitable disinfectant example 70% IPA.
8. Rehydrate the contents of 1 vial aseptically with 5 ml of 50% v/v aqueous ethanol.
9. Mix well and aseptically add to 500ml of sterile, molten, cooled (45-50°C) HiCrome™ VRE Agar Base M1830/ HiCrome™ VRE Agar Base, Modified M1925. Mix well and pour into sterile Petri plates.
10. Follow good lab practices for procedures and disposal.

Type of specimen

Clinical samples - faecal sample

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

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1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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Packaging

FD277-5VL - VF Selective Supplement



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AC3F Selective Supplement

FD278

Recommended for the detection of Extended Spectrum Beta lactamase producing organisms.

Composition

Per vial sufficient for 500 ml medium

*Ingredients	Concentration
Ceftazidime	1.50mg
Cefotaxime	1.50mg
Ceftriazone	1.00mg
Aztreonam	1.00mg
Fluconazole	5.00mg

Directions:

Rehydrate the contents of 1 vial aseptically with 5 ml sterile distilled water. Mix well and aseptically add to 500ml of sterile, molten, cooled (45-50°C) HiCrome™ ESBL Agar [M1829](#). Mix well and pour into sterile Petri plates.

Type of specimen

Clinical samples - rectal screening swabs, faecal samples, etc. or from isolated colony

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg (Ed.),2004, Clinical Microbiology Procedures Handbook, Vol.3, American Society for Microbiology, Washington. D.C.
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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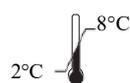
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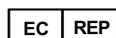
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VCC Selective Supplement

FD3353

Recommended for the selective isolation of *Acinetobacter* species.

Composition**

Per vial, sufficient for 1000 ml medium

Ingredients	Concentration
Vancomycin	10.00 mg
Cefsulodin	15.00 mg
Cefradine	50.00 mg

Directions

Rehydrate the contents of 1 vial aseptically with 5ml of sterile distilled water. Mix gently to dissolve the contents completely. Aseptically add the rehydrated contents to 1000ml of sterile, molten, cooled (45-50°C) Leeds Acinetobacter Agar Base [M1839](#) / HiCrome® Acinetobacter Agar Base [M1938](#). Mix well and pour into sterile Petri plates.

Type of specimen

Clinical- stool, urine, abscess, skin, wounds swabs, nasal swabs, etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

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2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology,11th Edition. Vol. 1.

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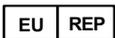
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Technical Data

Carba Selective Supplement

FD357

Recommended for isolation of Carbapenem resistant *Enterobacteriaceae* from clinical samples.

Composition

Per vial sufficient for 1000 ml medium

*Ingredients

Selective mix

Concentration

50mg

Directions:

Rehydrate the contents of one vial aseptically with 2 ml of 0.2N NaOH and 8ml of sterile distilled water. Mix well and aseptically add to 1000 ml of sterile, molten, cooled (45-50°C) HiCrome™ CarbaResist Agar Base [M2099](#). Mix well and pour into sterile Petri plates.

Type of specimen

Clinical samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning & Precautions

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Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Disposal

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Reference

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2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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Sabouraud Dextrose Agar, Granulated[®]

GM063

Intended Use:

Recommended for the cultivation of yeasts, moulds and aciduric microorganisms from clinical and non-clinical samples.

Composition**

Ingredients	g / L
Dextrose (Glucose)	40.000
Mycological, peptone	10.000
Agar	15.000
Final pH (at 25°C)	5.6±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 65.0 gram in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Sabouraud Dextrose Agar is Carlier's modification (1) of the formulation described by is a modification of Sabouraud Dextrose Agar which is described by Sabouraud (2) for the cultivation of fungi (yeasts, moulds), particularly useful for the fungi associated with skin infections. This medium is also employed to determine microbial contamination in food, cosmetics, and clinical specimens (3,4). This medium is recommended by ISO 11133 for recovery of fungi and as a reference medium for other selective media for fungi (5)

Mycological Peptone provides nitrogenous compounds. Dextrose provides an energy source. High dextrose concentration and low pH favors fungal growth and inhibits contaminating bacteria from test samples .

Type of specimen

Clinical samples: skin scrapings, Food samples ; Cosmetics.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3-4).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines(5-9).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions:

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. For heavily contaminated samples, the plate must be supplemented with inhibitory agents for inhibiting bacterial growth with lower pH.
2. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet
3. Further biochemical tests should be carried out for confirmation.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow coloured granular media.

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow to amber coloured clear to slightly opalescent gel forms in Petri plates.

Reaction

Reaction of 6.5% w/v aqueous solution at 25°C (after sterilization). pH : 5.6±0.2

pH

5.40-5.80

Cultural Response

Productivity : Cultural response was observed after an incubation at 20-25°C for upto 5 days. Recovery is considered as 100% on previously approved and validated batch of Sabouraud Dextrose Agar

Productivity

Organism	Inoculum (CFU)	Growth	Recovery
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	Luxuriant (white colonies)	≥70 %
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	≥70 %
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	≥70 %
<i>Saccharomyces cerevisiae</i> ATCC 9763 (00058*)	50 -100	luxuriant	≥70 %
<i>Mucor racemosus</i> ATCC 42647 (00181)*	50 -100	luxuriant	≥70 %
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	≥70 %
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	≥70 %
\$ <i>Lactobacillus paracasei</i> ATCC 334	50 -100	luxuriant	≥70 %
<i>Trichophyton rubrum</i> ATCC 28191		luxuriant	

Key : (*) - Corresponding WDCM numbers.

(#) - Formerly known as *Aspergillus niger*

(\$) - Formerly known as *Lactobacillus casei*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Carlier G. I. M., 1948, Brit. J. Derm. Syph., 60:61.
2. Sabouraud K., 1892, Ann. Dermatol. Syphilol, 3:1061.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
5. Microbiology of food, animal feeding stuffs and water- Preparation, production, storage and performance testing of culture media, EN ISO 11133:2014 /Amd. 2 :2020 (E).

6. Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. AOAC, Washington D.C.
7. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
8. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
9. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

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Nutrient Agar

M001

Intended use

Nutrient Agar is used as a general purpose medium for the cultivation of less fastidious microorganisms, can be enriched with blood or other biological fluids.

Composition**

Ingredients	g / L
Peptone	5.000
Sodium chloride	5.000
HM peptone B [#]	1.500
Yeast extract	1.500
Agar	15.000
Final pH (at 25°C)	7.4±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Beef extract

Directions

Suspend 28.0 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. If desired ,the medium can be enriched with 5-10% blood or other biological fluids. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Nutrient media are basic culture media used for maintaining microorganisms, cultivating fastidious organisms by enriching with serum or blood and are also used for purity checking prior to biochemical or serological testing (1,2). Nutrient Agar is ideal for demonstration and teaching purposes where a more prolonged survival of cultures at ambient temperature is often required without risk of overgrowth that can occur with more nutritious substrate. This relatively simple formula has been retained and is still widely used in the microbiological examination of variety of materials and is also recommended by standard methods. It is one of the several non-selective media useful in routine cultivation of microorganisms (3,4). It can be used for the cultivation and enumeration of bacteria which are not particularly fastidious. Addition of different biological fluids such as horse or sheep blood, serum, egg yolk etc. makes it suitable for the cultivation of related fastidious organisms. Peptone, HM peptone B and yeast extract provide the necessary nitrogen compounds, carbon, vitamins and also some trace ingredients necessary for the growth of bacteria. Sodium chloride maintains the osmotic equilibrium of the medium.

Type of specimen

Clinical samples - faeces, urine ; Food and dairy samples; Water samples

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines

(3,4,7). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (8). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 2.8% w/v aqueous solution at 25°C. pH : 7.4±0.2

pH

7.20-7.60

Cultural Response

Productivity : Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Productivity			
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	good-luxuriant	≥70%
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50-100	good-luxuriant	≥70%
<i>Salmonella</i> Typhi ATCC 6539	50-100	good-luxuriant	≥70%
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50-100	good-luxuriant	≥70%
<i>Streptococcus pyogenes</i> ATCC 19615	50-100	good-luxuriant	≥70%
<i>Salmonella</i> Enteritidis ATCC 13076 (00030*)	50-100	good-luxuriant	≥70%
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50-100	good-luxuriant	≥70%
<i>Yersinia enterocolitica</i> ATCC 9610 (00038*)	50-100	good-luxuriant	≥70%
<i>Yersinia enterocolitica</i> ATCC 23715 (00160*)	50-100	good-luxuriant	≥70%

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

- 1.Lapage S., Shelton J. and Mitchell T., 1970, Methods in Microbiology', Norris J. and Ribbons D., (Eds.), Vol. 3A, Academic Press, London.
- 2.MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd Ed., Lippincott, Williams and Wilkins,Baltimore.
- 3.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
- 4.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
- 5.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 6.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 7.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed.,APHA Inc., Washington, D.C.
- 8.Lipps WC, Braun-Howland EB, Baxter TE,eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

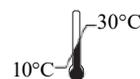
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Technical Data

Soyabean Casein Digest Medium (Tryptone Soya Broth)

M011

Intended Use:

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms and recommended for sterility testing of moulds and lower bacteria.

Composition**

Ingredients	g / L
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Dextrose (Glucose)	2.500
Dipotassium hydrogen phosphate	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 30.0 grams in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Mix well and dispense in tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Note: If any fibres are observed in the solution, it is recommended to filter the solution through a 0.22 micron filter to eliminate the possibility of presence of fibres.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium (1,2,3). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (4).

The combination of Tryptone and soya peptone makes the medium nutritious by providing nitrogenous, carbonaceous substances, amino acids and long chain peptides for the growth of microorganisms. Dextrose/glucose serve as the carbohydrate source and dibasic potassium phosphate buffer the medium. Sodium chloride maintains the osmotic balance of the medium.

Type of specimen

Pharmaceutical samples, Clinical samples - urine, pus, wound samples.

Specimen Collection and Handling

For clinical samples, follow appropriate techniques for handling specimens as per established guidelines (5,6). For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
2. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

Reaction

pH of 3.0% w/v aqueous solution at 25°C (after sterilization). pH : 7.3±0.2

pH

7.10-7.50

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5days for fungal) Growth promotion is carried out as per USP/EP/BP/JP/IP.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas paraaeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus subsp. aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
\$ <i>Kokuria rhizophila</i> ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	20 -25 °C	<=5 d
<i>Staphylococcus aureus subsp. aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Sterility Testing- Growth promotion+Validation				
<i>Staphylococcus aureus subsp. aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	20 -25 °C	<=3 d
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	20 -25 °C	<=5 d
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	30 -35 °C	<=5 d
<i>Staphylococcus aureus subsp. aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	20 -25 °C	<=3 d

^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	20 -25 °C	<=3 d
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	20 -25 °C	<=3 d
\$ <i>Kokuria rhizophila</i> ATCC 9341	50 -100	luxuriant	20 -25 °C	<=3 d

Key : (*) Corresponding WDCM numbers

^ Formerly known as *Pseudomonas aeruginosa*

**Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Formerly known as *Aspergillus niger*

\$ Formerly known as *Micrococcus luteus*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1. Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
2. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams & Wilkins, Baltimore, M.d.
3. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
4. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.
5. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
6. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

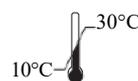
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Bile Esculin Azide Agar

M493

Intended Use:

For selective isolation and presumptive identification of faecal Streptococci.

Composition**

Ingredients	g/ L
Tryptone	17.000
HM peptone B #	5.000
Proteose peptone	3.000
Bile ##	10.000
Esculin	1.000
Ferric ammonium citrate	0.500
Sodium chloride	5.000
Sodium azide	0.150
Agar	15.000
Final pH (at 25°C)	7.1±0.2

Equivalent to Beef extract ## - Equivalent to Oxgall

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 56.65 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Caution: Sodium azide has a tendency to form explosive metal azides with plumbing materials. It is advisable to use enough water to flush off the disposables.

Principle And Interpretation

Group D Streptococci possess the group D lipoteichoic acid antigen in their cell walls. Former Group D species, which are predominant normal inhabitants of the human gastrointestinal tract, are termed as faecal Streptococci or Enterococci (1). The unique ability of Enterococci to split esculin was reported by Meyer and Schonfeld (2). Enterococci and Group D Streptococci hydrolyse esculin to esculetin and dextrose, which reacts with ferric citrate producing brownish black precipitate (3). The use of esculin hydrolysis in identification of Enterococci was first cited by Rochaix (4). Bile Esculin Agar was originally formulated by Swan (5) for the isolation and identification of Group D Streptococci from food. Facklam and Moody (6) further reported that using Bile Esculin Agar, Group D Streptococci could be differentiated from non Group D Streptococci.

Bile Esculin Agar was also shown to aid differentiation of *Enterobacteriaceae*, *Klebsiella*, *Enterobacter*, *Serratia* from other *Enterobacteriaceae* genera (7) on the basis of esculin hydrolysis. However, other tests such as salt tolerance should be performed for identifying Enterococci (8).

Bile Esculin Azide Agar is a modification of Bile Esculin Agar as per Isenberg (9). In this medium the bile concentration is reduced and additional sodium azide is incorporated.

Tryptone, proteose peptone and HM peptone B serves as sources of carbon, nitrogen, amino acids, vitamins and essential growth nutrients. Bile and sodium azide inhibits most of the other accompanying bacteria. Esculin in the medium is hydrolyzed to esculetin and dextrose. Esculetin reacts with ferric citrate to form a dark brown or black complex, visualized as a zone of black precipitate around the colonies. If the media is dispensed in tubes in the form of slants, a positive reaction is indicated by blackening of more than half of the slant within 24-48 hours. If blackening is totally absent or if less than half of the slant is blackened within 24-48 hours, the test is negative. Viridans Streptococci sometimes exhibit a weak positive reaction. Also, *Leuconostoc*, *Pediococcus*, *Lactococcus* species causing human infections give a positive bile esculin test (10). To enhance the growth of Enterococci, Bile Esculin Agar can be supplemented with 50ml/l horse serum (3). Suspected water samples are filtered using membrane filters. These membrane filters are aseptically placed on Slanetz and Bartely Medium (M612I). Red or maroon coloured colonies observed after incubation are further confirmed by aseptically transferring the membrane filter on to Bile Esculin Azide Agar plate preheated to 44°C. Incubation at 44 ± 0.5°C for 2 hours is done following the inoculation.

All typical colonies exhibiting a brown black colouration in the surrounding medium are counted as intestinal Enterococci (10). Alternatively Bile Esculin Azide Agar can also be used for direct isolation of Enterococci (without membrane filter), by incubation at 35-37°C for 18-24 hours.

Type of specimen

Clinical- Faeces, Food samples

Specimen Collection and Handling:

For food samples, follow appropriate techniques for sample collection and processing as per guidelines (4).

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Amber coloured, clear to slightly opalescent gel with a bluish tinge forms in Petri plates.

Reaction

Reaction of 5.67% w/v aqueous solution at 25°C. pH : 7.1±0.2

pH

6.90-7.30

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Esculin Hydrolysis
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	50-100	luxuriant	≥50%	positive reaction, blackening of medium around the colony
<i>Escherichia coli</i> ATCC 25922 (00013*)	≥10 ⁴	inhibited	0%	
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50-100	good	40-50%	negative reaction
<i>Proteus mirabilis</i> ATCC 25933	50-100	good	40-50%	negative reaction
<i>Streptococcus pyogenes</i> ATCC 19615	50-100	none-poor	≤10%	negative reaction

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

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Reference

1. Edberg S. C., Pittman S., and Singer J. M., 1977, J. Clin. Microbiol., 6:111.
2. Murray P. R., Baron E. J., Jorgensen J. H., Pfaller M. A., Tenover F. C., Tenover F. C., (Eds.), 8th Ed., 2003, Manual of Clinical Microbiology, ASM, Washington, D.C.
3. Facklam R., 1972, Appl. Microbiol., 23:1131.
4. Salfinger Y., and Tortorello M.L. , 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
5. Swan, 1954, J. Clin. Pathol., 7:160.
6. Facklam R. R and Moody M. D., 1970, Appl. Microbiol., 20(2):245.
7. Meyer and Schonfeld, 1926, Zentralbl. Bakteriologie, Parasitenkunde, Infektionskrankheiten, Hygiene, Abt. Origin. 99:402.
8. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
9. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
10. Rochaix, 1924, Compt. Rend. Soc. Biol., 90:771.

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Slanetz and Bartley medium w/o TTC

M612A

Intended Use:

Recommended for detection and enumeration of faecal Streptococci by membrane filtration technique from water and food samples. It can also be used for clinical samples.

Composition**

Ingredients	Gms / Litre
Tryptose	20.000
Yeast extract	5.000
Dextrose (Glucose)	2.000
Disodium hydrogen phosphate	4.000
Sodium azide	0.400
Agar	15.000
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 46.4 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. If desired add sterile 1% TTC solution (FD057) to the medium.

Principle And Interpretation

Slanetz and Bartley Medium was originally devised by Slanetz and Bartley (7) for the detection and enumeration of Enterococci by membrane filtration technique. It can be also used as a direct plating medium (1,6). M612A media formulation is devoid of triphenyl tetrazolium chloride that is present in M612.

Tryptose and yeast extract serves as the source of essential nutrients to the organisms. The medium is highly selective for Enterococci. Sodium azide has inhibitory effect on gram-negative organisms. If Triphenyl Tetrazolium Chloride(TTC) is added to the medium, it is reduced to the insoluble formazan inside the bacterial cell forming dark red-coloured colonies. When the medium is incubated at higher temperature (44-45°C), all red or maroon colonies can be considered as presumptive Enterococci (5,8).

The Department of Health (2) has recommended similar medium with TTC to be used for enumeration of Enterococci in water supplies.

Type of specimen

Food samples; Water samples, Clinical samples

Specimen Collection and Handling:

For water samples: Water is filtered through a membrane filter, which is then placed on the surface of the Slanetz and Bartley Medium plates and incubated at 35°C for 4 hours and then at 44-45°C for 44-48 hours. Red or maroon colonies are counted as Enterococci. The preliminary incubation at 35°C helps for the recovery of stressed organisms. Not all the species reduce TTC; hence pale colonies also should be considered.

For analyzing food samples, it is homogenized and diluted with normal saline to give countable 15-150 colonies on each Petri plate when spread on agar surface and incubated at 35°C for 48 hours. Pink or dark red colonies with a narrow whitish border are counted (6).

Warning and Precautions

In Vitro Diagnostic use. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Further biochemical testing is required for identification of species.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 4.64% w/v aqueous solution at 25°C. pH : 7.2±0.2

pH

7.00-7.40

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours with added TTC solution (FD057).

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
<i>Escherichia coli</i> ATCC 25922 (00013*)	≥10 ⁴	inhibited	0%	
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	50-100	good-luxuriant	≥50%	red or maroon

Key: (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. Burkwall M.K. and Hartman P.A., 1964, Appl. Microbiol., 12:18.
2. Department of Health and Social Security, 1982, Report 71, HMSO, London.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
5. Mead G.C., 1966, Proc. Soc. Wat. Treat. Exam.,15:207.
6. Nordic Committee on Food Analysis, 1968, Leaflet 68.
7. Slanetz L. W. and Bartley C.H., 1957, J. Bact., 74:591.

8. Taylor E.W. and Burman N.P., 1964, J. Appl. Bact., 27:294.

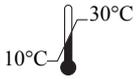
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Trichomonas Agar Base

M665

Intended Use:

Recommended for detection and isolation of *Trichomonas vaginalis* and *Candida albicans* from clinical specimens.

Composition**

Ingredients	g/ L
HL digest #	25.000
Sodium chloride	6.500
Dextrose (Glucose)	5.000
Agar	1.000
Final pH (at 25°C)	6.4±0.2

**Formula adjusted, standardized to suit performance parameters

Equivalent to Liver digest

Directions

Suspend 37.5 grams in 920 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool below 60°C. Inactivate 80 ml of horse serum (RM1239) adjust to pH 6.0 and add it to the medium for diagnostic work. Add SP Selective Supplement - II (FD094) to increase selectivity of the medium.

Principle And Interpretation

Trichomonas Agar is formulated as per the formulation of Feinberg and Whittington for the detection and isolation of *Trichomonas vaginalis* and *Candida albicans* from clinical specimens (1).

Stenton reported that the incorporation of liver digest in the medium plays an important role in detection of *Trichomonas vaginalis* (2). Addition of small quantity of agar in the medium creates a slightly reducing atmosphere which in turn favours better growth of *Trichomonas* species. From a mixed culture of *Trichomonas* and *Candida*, good growth of *Trichomonas* can be obtained as *Candida* does not interfere with *Trichomonas*. The medium is equally suitable for the examination of urethral and vaginal swabs and urine specimens.

HL digest provide the nitrogenous substances. Dextrose acts as the energy source. The selective agents chloramphenicol and penicillin (FD094) are inhibitory to gram-positive and gram-negative bacteria but not for *Trichomonas* species. Sodium chloride maintains the osmotic equilibrium of the medium. Under anaerobic conditions massive inocula are required.

Type of specimen

Clinical samples - vaginal and urethral secretions (women), anterior urethral or prostatic secretions (men)

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Further wet mount examination of infected material should be done.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light yellow to light brown homogeneous free flowing powder

Colour and Clarity of prepared medium

Dark amber coloured clear to slightly opalescent viscous solution in tubes.

Reaction

Reaction of 3.75% w/v aqueous solution at 25°C. pH : 6.4±0.2

pH

6.20-6.60

Cultural Response

Cultural characteristics observed with added inactivated Horse Serum (RM1239) and SP Selective Supplement - II (FD094), after an incubation at 35-37°C for 3-5 days.

Organism	Growth
<i>Candida albicans</i> ATCC 10231 (00054*)	good-luxuriant
<i>Trichomonas vaginalis</i> ATCC 30001	good-luxuriant
<i>Escherichia coli</i> ATCC 25922 (00013*)	inhibited

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

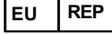
1. Feinberg J.G. and Whittington J.M., 1957, J. Clin. Path., 10:327.
2. Stenton P., 1957, J. Med. Lab. Technol., 14:228.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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HM Peptone B Broth

M807

Intended Use:

Recommended for routine cultivation of non fastidious bacteria.

Composition**

Ingredients	g / L
Peptone	10.000
HM peptone B#	3.000
Sodium chloride	5.000
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

- Equivalent to Beef extract

Directions

Suspend 18.0 grams in 1000 ml purified/distilled water. Heat if necessary to dissolve the medium completely. Dispense in tubes or flasks or as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Principle And Interpretation

The majority of organisms to be studied in medical bacteriology are either pathogens or commensals of the human body, and in order to obtain suitable growth the artificial culture medium should provide nutrients and a pH (about 7.2) approximating to those of the tissues and body fluids. For routine purposes many of these nutrients are supplied by aqueous extracts of HM peptone B and peptone, which is a product of the digestion of protein (1). HM peptone B Broth can be used as a general-purpose nutrient medium and is also recommended for preparation of pure culture of *Candida* species for carrying out fermentation studies (2). HM peptone B Broth is a non-selective nutrient medium containing HM peptone B and peptone as a source of nitrogen and carbon source, long chain amino acids, vitamins and other essential nutrients. Sodium chloride as a source of electrolytes.

Type of specimen

Clinical samples - faeces, stool ; Food and dairy sample; Water samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (5-7).

For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards.(8)

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Further biochemical and serological tests must be carried out for further identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Yellow coloured, clear solution without any haziness in tubes

Reaction

Reaction of 1.8% w/v aqueous solution at 25°C. pH : 7.2±0.2

pH

7.00-7.40

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	luxuriant
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50-100	luxuriant
<i>Salmonella</i> Typhi ATCC 6539	50-100	luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50-100	luxuriant

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store below 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

- 1.Collee J. G., Fraser A. G., Marimon B. P., Simmons A., (Eds.) ,1996, Mackie and McCartney Practical Medical Microbiology, 14th Ed., Churchill Livingstone.
- 2.Finegold S. M. and Baron E. J., (Ed.), Bailey and Scott's Diagnostic Microbiology, 1986, 7th Edition, The C.V. Mosby Company, St. Louis.
- 3.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 4.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W.(2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 5.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
- 6.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
- 7.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.
- 8.Lipps WC, Braun-Howland EB, Baxter TE,eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

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Hugh Leifson Medium

M826

Intended use:

Recommended for detecting aerobic and anaerobic breakdown of glucose.

Composition**

Ingredients	g / L
Peptone	2.000
Sodium chloride	5.000
Dipotassium hydrogen phosphate	0.300
Dextrose (Glucose)	10.000
Bromothymol blue	0.050
Agar	2.000
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 19.35 grams in 1000 ml purified/distilled water. Heat with frequent stirring. Heat to boiling to dissolve the medium completely. Dispense into test tubes in duplicate for aerobic and anaerobic fermentations. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool the tubed medium in an upright position.

Principle And Interpretation

Hugh Leifson Medium was formulated by Hugh and Leifson (1). They described the taxonomic significance of fermentative and oxidative metabolism of carbohydrates in gram-negative intestinal bacteria. There are two ways of utilizing carbohydrates by microorganisms, namely fermentation and oxidation. This property may be frequently used for the differentiation of some bacteria. The medium contains a high concentration of carbohydrate and low concentration of peptone to avoid the possibility of an aerobic organism utilizing peptone and producing an alkaline condition which would neutralize slight acidity produced by an oxidative organism (2,3). Dipotassium phosphate promotes fermentation and acts as pH controlling buffer. Agar concentration enables the determination of motility and aids in distribution of acid throughout the tube produced at the surface of medium. Bromthymol blue is the pH indicator.

Type of specimen

Isolated microorganism from Clinical and Non-clinical samples

Specimen Collection and Handling:

The tubes for aerobic and anaerobic fermentation are inoculated and the agar surface of one tube of duplicate is covered with layer of sterile paraffin oil, about 25 mm thickness and incubated at 37°C. Oxidative organisms produce acid in unsealed tube with little or no growth and no acid formation in sealed tube while fermentative organisms produce acid in both sealed and unsealed tubes. If acid is produced, it is indicated by change in colour from greenish blue to yellow throughout the medium. Liquid paraffin tube used should be dry sterilized at 160-170°C for 2 hours. Wet sterilization with high pressure is not sufficient for the purpose.

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Other biochemical tests must be performed in conjunction for confirmation.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light yellow to bluish green homogeneous free flowing powder

Gelling

Semisolid, comparable with 0.2% Agar gel.

Colour and Clarity of prepared medium

Greenish blue coloured, clear to slightly opalescent gel forms in tubes as butts

Reaction

Reaction of 1.94% w/v aqueous solution at 25°C. pH : 6.8±0.2

pH

6.60-7.00

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours.

Organism	Motility	Aerobic fermentation	Anaerobic fermentatoin
# <i>Klebsiella aerogenes</i> ATCC 13048 (00175*)	positive, growth away from stabline causing turbidity	acid (yellow) and gas production	acid (yellow) and gas production
<i>Escherichia coli</i> ATCC 25922 (00013*)	positive, growth away from stabline causing turbidity	acid (yellow) and gas production,	acid (yellow) and gas production
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	positive, growth away from stabline causing turbidity	acid (yellow) production	unchanged (green) or alkaline (blue)
<i>Salmonella</i> Typhi ATCC 6539	positive, growth away from stabline causing turbidity	acid (yellow) and gas production	acid (yellow) and gas production
<i>Shigella sonnei</i> ATCC 25931	negative, growth along the stabline, surrounding medium	acid (yellow) production	acid (yellow) and gas production

Key : (*)Corresponding WDCM numbers. (#) Formerly known as *Enterobacteraerogenes*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1. Hugh and Leifson, 1953, J. Bacteriol., 66:24.
2. Finegold S. M., Martin W. J., and Scott E. G., 1978, Bailey and Scotts Diagnostic Microbiology, 5th Ed., The C.V. Mosby Co., St. Louis.
3. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification- Maintenance of Medical Bacteria, Vol. I, Williams and Wilkins, Baltimore.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

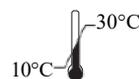
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Mueller Hinton Agar 2% Glucose w/ Methylene blue

M1825

Intended Use:

Recommended for performing antifungal disc diffusion susceptibility of yeasts.

Composition**

Ingredients	g / L
HM infusion B #	2.000
Acicase®	17.500
Starch	1.500
Dextrose (Glucose)	20.000
Methylene blue	0.0005
Agar	17.000
Final pH (at 25°C)	7.3±0.1

**Formula adjusted, standardized to suit performance parameters

Equivalent to Beef Infusion from

Directions

Suspend 58.0 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

The performance of this batch has been tested and standardized as per the current CLSI (formerly NCCLS) document M44-A2 in Method for Antifungal Disk Diffusion susceptibility testing of yeasts.

Principle And Interpretation

The Mueller Hinton formulation was originally developed as a simple, transparent agar medium for the cultivation of pathogenic species (1). Mueller Hinton Agar, Modified (as per CLSI for antifungal) is recommended for the diffusion of antifungal agents impregnated on paper disc through an agar gel as described in CLSI Approved Standard (2). When supplemented with glucose to a final concentration of 2%, it provides for suitable fungal growth. The addition of methylene blue to a final concentration of 5µg/ml enhances zone edge definition.

Kirby-Bauer et al recommended Mueller Hinton Agar for performing antibiotic susceptibility tests using a single disc of high concentration (3). WHO Committee on Standardization of Susceptibility Testing has accepted Mueller Hinton Agar for determining the susceptibility of microorganisms because of its reproducibility (4). Mueller Hinton Agar with 5% sheep blood and Mueller Hinton Agar with Haemoglobin have been recommended for antimicrobial susceptibility testing of *Streptococcus pneumoniae* and *Haemophilus influenzae*. Similarly Mueller Hinton Agar, Modified (as per CLSI for antifungal) is recommended for antifungal susceptibility testing of discs.

HM infusion B and Acicase® provide nitrogenous compounds, carbon, sulphur and other essential nutrients. Starch acts as a protective colloid against toxic substances present in the medium. Starch hydrolysis yields dextrose, which serves as a source of energy. Dextrose (Glucose) serves as an energy source for fungal cultures while Methylene blue enhances zone edge definition.

Technique:

Preparation of Inoculum:

1. 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 ± 2°C. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10⁶ - 5 x 10⁶ cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Mueller Hinton Agar, Modified (as per CLSI for antifungal) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the Petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube

to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5-15 minutes with lid in place.

3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart. (Not more than 12 discs should be placed on a 150-mm plate or not more than 5 discs on a 100-mm plate).

4. Invert the plates and place in an incubator set to $35 \pm 2^\circ\text{C}$ within 15 minutes after the discs are applied.

5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Type of specimen

Isolated Microorganism from clinical samples.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. This medium is recommended for susceptibility testing of pure cultures only.
2. Inoculum density may affect the zone size. Heavy inoculum may result in smaller zones or bigger zones.
3. Fastidious organisms may not grow on this medium due to nutritional variations.
4. Antifungal disc are used to carry out the susceptibility, proper storage of the disc is desired of the disc.
5. Under certain circumstances, the in vitro results of antifungal susceptibility may not show the same in vivo.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period at recommended temperature.

Quality Control

Appearance

Light yellow to yellow may have slight blue tinge homogeneous free flowing powder

Gelling

Firm, comparable with 1.7% agar gel.

Colour and Clarity of prepared medium

amber coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 5.8% w/v aqueous solution at 25°C . pH : 7.3 ± 0.1

pH

7.20-7.40

Cultural response

A luxuriant growth of test organisms was observed on Mueller Hinton Agar, Modified (as per CLSI for antifungal) in 24-48 hours at $33-37^\circ\text{C}$ along with inhibition zones with respective antibiotic concentrations

Organism	Inoculum (CFU)	Growth	Recovery	Amphotericin-B AP(100units)	Amphotericin-B AP(20 mcg)	Amphotericin-B AP(50 mcg)
<i>Candida albicans</i> ATCC 90028	50-100	luxuriant	$\geq 70\%$	10 -17 mm	10 -15 mm	31- 42 mm
<i>Candida parapsilosis</i> ATCC 22019	50-100	luxuriant	$\geq 70\%$	11 -20 mm	10 -17 mm	28 -37 mm
<i>Candida tropicalis</i> ATCC 750	50-100	luxuriant	$\geq 70\%$	8 -12 mm	8 -10 mm	13 -17 mm

<i>Candida krusei</i> ATCC 6258	50-100	luxuriant	$\geq 70\%$	9 -14 mm	8 -12 mm	16 -25 mm
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	luxuriant	$\geq 70\%$	10 -18 mm	10 -16 mm	30 -40 mm
<i>Saccharomyces cerevisiae</i> ATCC 9763 (00058*)	50-100	luxuriant	$\geq 70\%$	11 -18 mm	8 -12 mm	29 -38 mm

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

- Mueller J. H. and Hinton J., 1941, Proc. Soc. Exp. Biol. Med., 48:330.
- Method for Antifungal Disk Diffusion Susceptibility Testing of yeasts; Approved Guideline Second Edition M44-A2 Vol.24 No.17.
- Bauer A. W., Kirby W. M., Sherris J. L. and Turck M., 1966, Am. J. Clin. Pathol., 45:493.
- Present Status and Future Work, WHO Sponsored collaborative study, Chicago, Oct. 1967.
- Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

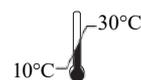
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HiCrome® ESBL Agar Base

M1829

Intended Use:

Recommended for selective isolation Extended-Spectrum β -lactamase-Producing *Enterobacteriaceae*.

Composition**

Ingredients	g/ L
Peptone mix	12.000
Chromogenic mixture	4.000
Sodium chloride	5.000
Buffer mix	4.000
Agar	15.000
Final pH (at 25°C)	6.8±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 40.0 gram in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C and add rehydrated contents of two vials of AC3F Selective Supplement (FD278). Mix well and pour into sterile Petri plates.

Principle And Interpretation

Extended-spectrum β -lactamase (ESBL)-producing organisms are an increasing challenge for healthcare practitioners fighting healthcare-associated infections (HAIs). *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca* are the most common ESBL-producing pathogens (1). ESBL-producing organisms are generally resistant to many classes of antibiotics, including aminoglycosides and fluoroquinolones; ESBL-producing organisms are able to attack newer cepheims and monobactams as well as narrow-spectrum cephalosporins and antigram-negative penicillins (1). They are associated with increased mortality and are difficult to detect and treat. The widespread use of extended-spectrum, third-generation cephalosporins, introduced in the 1980's to treat antibiotic-resistant bacteria, is believed to be a major contributor to the emergence of ESBL-producing organisms.

HiCrome® ESBL Agar Base is chromogenic screening medium for the selective isolation of ESBL producing organisms. It contains peptone mix which serves as the carbon and nitrogen sources, long chain amino acids, vitamins and other growth nutrients. Chromogenic mixture is used to differentiate the ESBL producing organisms on the basis of colour. AC3F Selective Supplement (FD278) helps in inhibition of other contaminating organisms. ESBL producing *E.coli* grow as either pink or purple colonies.

ESBL producing members of the KESC group produce bluish green colonies; *Proteus*, *Morganella* and *Providencia* do not utilize any chromogen resulting in colourless to light brown colonies. This medium can be inoculated with liquid suspension equivalent to 0.5 McFarland turbidity, prepared from rectal screening swabs, faecal samples or from isolated colony. Isolated colonies should not be directly plated on to this medium, because the high level inoculum may cause false positive results. Further confirmation using biochemical identification tests is recommended.

Type of specimen

Clinical samples - rectal screening swabs, urine, faecal samples, etc. or from isolated colony.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (2,3).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Some species may show poor growth due to nutritional variations.
2. Slight colour variation may be observed depending upon strains.
3. Isolated colonies should not be directly plated on to this medium, because the high level inoculum may cause false positive results.
4. Further confirmation using biochemical identification tests is recommended.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Yellow coloured opalescent gel forms in Petri plates

Reaction

Reaction of 4.0% w/v aqueous solution at 25°C. pH : 6.8±0.2

pH

6.60-7.00

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 24 hours with added AC3F Selective Supplement (FD278).

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
<i>Escherichia coli</i> NCTC 13351	50-100	luxuriant	≥50%	pink to purple
<i>Klebsiella pneumoniae</i> ATCC 700603	50-100	luxuriant	≥50%	bluish green
<i>Enterobacter cloacae</i> ATCC 23355	≥10 ⁴	inhibited	0%	-
<i>Citrobacter freundii</i> ATCC 8090	≥10 ⁴	inhibited	0%	
<i>Candida albicans</i> ATCC 10231 (00054*)	≥10 ⁴	inhibited	0%	

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Reference

1. Journal of Clinical Microbiology, February 2007, Page 501-505, Vol. 45, No. 2
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015), Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Revision : 07/2026



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HiCrome® VRE Agar Base

M1830

Intended Use

Recommended as a selective media for isolation of Vancomycin Resistant Enterococci (VRE) from clinical specimens.

Composition**

Ingredients	g / L
Peptone special	25.000
Chromogenic mixture	0.450
Sodium chloride	5.000
Buffering agent	1.250
Salt mixture	4.250
Agar	15.000
Final pH (at 25°C)	6.5±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 50.95 gram in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C and aseptically add the rehydrated contents of two vials of VF Selective Supplement (FD277). Mix well and pour into sterile Petri plates.

Principle And Interpretation

Enterococci are the common habitants of the normal flora residing in the intestines of mammals (1). Vancomycin Resistant Enterococci are the group of Enterococci that have developed resistance towards many antibiotics particularly vancomycin. Enterococcal infections that result in human disease can be fatal, particularly those caused by strains of vancomycin-resistant enterococci (VRE) (2). Early detection of VRE is important to prevent the emergence of vancomycin resistant in *Enterococcus faecalis*. VRE can be transmitted from person to person, especially in a hospital or chronic-care facility. Microscopic amounts of fecal material from an infected or colonized patient can contaminate the hospital environment and be a reason for the spread of infection. There are many traditional media for the detection of VRE which includes Vancomycin Resistant Enterococci Broth Base/Agar or Bile Esculin Agar supplemented with vancomycin. Peptone special in the medium supplies nitrogenous and carbonaceous compounds, long chain amino acids, vitamins and other necessary nutrients required for the growth of microorganisms. Sodium chloride maintains the osmotic balance. Buffering agents provides buffering to the medium. *Enterococcus faecalis* cleaves the chromogenic substrate in the medium to produce blue coloured colonies, which are clearly visible against the opaque background. The supplement added to the medium allows the selective isolation of Vancomycin Resistant Enterococci. This medium can be inoculated directly from screening swab, isolated colony prepared as a liquid suspension approximately equivalent to 0.5 McFarland turbidity.

Type of specimen

Clinical samples - faeces, urine, etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Some intermediate species may show poor growth due to nutritional variations and tolerance to vancomycin.
2. Slight colour variation may be observed depending upon the utilization of the substrate by the organism.
3. Interspecies differentiation between *Enterococcus faecalis* and *Enterococcus faecium* cannot be confirmed.
4. Further confirmation has to be carried using sensitivity testing.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel.

Colour and Clarity of prepared medium

Off white coloured opaque gel forms in Petri plates.

Reaction

Reaction of 5.1% w/v aqueous solution at 25°C. pH : 6.5±0.2

pH

6.30-6.70

Cultural Response

Cultural characteristics observed with added VF Selective Supplement (FD277), after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
<i>Enterococcus faecalis</i> (VRE) ATCC 51299 (00085*)	50-100	luxuriant	≥50%	bluish green
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	≥10 ⁴	inhibited	0%	
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	≥10 ⁴	inhibited	0%	

Key : * Corresponding WDCM numbers.

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

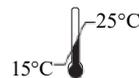
1. Mara D., Horan NJ: The Handbook of water, wastewater and microbiology, Amsterdam, The Netherlands, Academic Press; 2003.
2. Mascini EM, Bonten MJ: Vancomycin-resistant enterococci: consequences for therapy and infection control. Clin Microbiol Infect. 2005, 11 (Suppl.4) :43-56
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



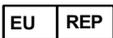
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HiCrome® Acinetobacter Agar Base

M1938

Intended Use

Recommended for selective isolation of *Acinetobacter* species from environmental and clinical samples.

Composition**

Ingredients	g/ L
Peptone special	9.000
Sodium chloride	5.000
Selective mix	0.500
Chromogenic mixture	1.350
Agar	15.000
Final pH (at 25°C)	7.0±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 30.85 gram in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. **DO NOT AUTOCLAVE**. Cool to 45-50°C and add the rehydrated contents of two vials of AC Selective Supplement (FD271) or one vial of VCC Selective Supplement (FD335). Mix well and pour into sterile Petri plates.

Principle And Interpretation

Acinetobacter species are gram negative bacteria that have been isolated from patients with nosocomial infection, environment, soil, and water. *Acinetobacter* is mostly found in every type of infections (1). There is an alarming situation as *Acinetobacter baumannii* is found to be resistant to most commonly used antibiotics which includes beta-lactams and aminoglycosides (1,2). Immunocompromised patients requiring mechanical respirations are at more risk of infection by *Acinetobacter* species (3).

Peptone special provides nitrogenous, carbonaceous compounds, amino acids, vitamins and other growth factors essential to the organism. Sodium chloride maintains the osmotic balance. Selective mix inhibits gram positive organisms. The chromogenic mixture in the medium allows the differentiation of *Acinetobacter* species from other organisms.

Type of specimen

Clinical sample: Urine, wounds, nasal swabs, etc.

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3. Slight colour variation may be observed depending upon the utilization of the substrate by the organism.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light yellow to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

White to cream opaque gel forms in Petri plate.

Reaction

Reaction of 3.09% w/v aqueous solution at 25°C. pH : 7.0±0.2

pH

6.8-7.2

Cultural Response

Cultural characteristics observed with added supplement (FD271 or FD335) after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
<i>Acinetobacter baumannii</i> ATCC BAA-1605	50 -100	luxuriant	≥50 %	Light purple -purple
<i>Acinetobacter baumannii</i> ATCC BAA-747	≥10 ⁴	Inhibited	0 %	-
<i>Acinetobacter baumannii</i> ATCC 19606	≥10 ⁴	Inhibited	0 %	-
<i>Acinetobacter lwoffii</i> ATCC 15309	≥10 ⁴	Inhibited	0 %	-
<i>Acinetobacter haemolyticus</i> ATCC 19002	≥10 ⁴	Inhibited	0 %	-
<i>Escherichia coli</i> ATCC 25922 (00013*)	≥10 ⁴	Inhibited	0 %	-
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	≥10 ⁴	Inhibited	0 %	-

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store dehydrated powder and prepared medium between 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

- 1.Valentine, S.C., et.al. 2008 Phenotypic and molecular characterization of *Acinetobacter baumannii*. Clinical isolates from nosocomial outbreaks in Los Angeles County, California. J.Clin. Microbiology.; 46:2499-2507
- 2.Montefour, K., et.al.2008. *Acinetobacter baumannii* : An Emerging Multidrug Resistant pathogen in critical care Nurse;28:15-25.
- 3.Bergogne- Berezin, E., m. L. Joly-Guillou, and J.F. View. 1987. Epidemiology of nosocomial infections due to *Acinetobacter calcoaceticus* . J. Hosp. Infect. 10:105-113.
- 4.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 5.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



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HiCrome[®] MRSA Agar Base, Modified

M1953

Intended Use:

Recommended for the differentiation and identification of MRSA and MRSE *Staphylococcus* species from clinical samples.

Composition**

Ingredients	g / L
Peptone	23.000
Sodium chloride	10.000
Sodium puruvate	5.000
Chromogenic substrate	0.770
Inhibitor mixture	7.000
Agar	15.000
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 30.38 gram in 500 ml distilled water. Heat to boiling to dissolve the medium completely. **DO NOT AUTOCLAVE.** Cool to 45-50°C. Aseptically add sterile rehydrated contents of 1 vial of MeRS Selective Supplement (FD229) or CF Selective Supplement II (FD259) or both in combination for more selectivity as desired. Mix well and pour into sterile Petri plates.

Principle And Interpretation

MRSA is a resistant variation of the common bacterium *Staphylococcus aureus* and MRSE is a resistant variation of the common bacterium *Staphylococcus epidermidis*. *Staphylococcus aureus* is an invasive pathogen that can cause disease in almost any tissue or organ in the human body, primarily in compromised individuals (1,2). Staphylococcal infections were earlier treated using Penicillin. But over the years resistance to this drug developed. Methicillin was the next drug of choice. While methicillin is very effective in treating most *Staphylococcus* infections, some strains have developed resistance to methicillin and can no longer be killed by this antibiotic. These resistant bacteria are called Methicillin Resistant *Staphylococcus aureus* (MRSA) (3).

Patients with breaks in their skin due to wounds, indwelling catheters or burns are those with certain risk of developing MRSA infection. Spread of MRSA infections can be controlled to a great extent by maintaining personal hygiene after interaction with an MRSA infected person (3).

Peptone provide the essential nutrients along with carbonaceous, nitrogenous and Vitamin B complex nutrients. The chromogenic mixture incorporated in the medium is specifically cleaved by *Staphylococcus aureus* to give green coloured colonies. Sodium pyruvate enhances the growth of *Staphylococcus* species. Sodium chloride in the medium helps to maintain the osmotic equilibrium of the medium. High concentration of sodium chloride also helps in inhibiting the accompanying microflora. Cefoxitin is recommended to use for selective isolation of MRSA. The medium is made selective for MRSA by the addition of MeRS Selective Supplement (FD229) or CF Selective Supplement II (FD259) or both in combination.

Type of specimen

Clinical samples - Mouth, skin lesions, intestine, upper respiratory tract of humans, urine, wound samples, etc.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Some intermediate strains may show poor growth due to nutritional variations and resistance to methicillin/cefoxitin.
2. Slight colour variation may be observed depending upon the utilization of the substrate by the organism.
3. Further confirmation must be carried out by sensitivity testing.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to beige homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light purple, clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 6.08% w/v aqueous solution 25°C. pH : 7.2±0.2

pH

7.00-7.40

Cultural Response

Cultural characteristics observed with added MeRS Selective Supplement (FD229) or CF Selective Supplement II (FD259) or both after an incubation at 35-37°C for 18-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
<i>Escherichia coli</i> ATCC 25922 (00013*)	≥10 ⁴	inhibited	0%	-
<i>Staphylococcus aureus</i> , MRSA ATCC 43300	50-100	luxuriant	≥50%	green
<i>Staphylococcus epidermidis</i> , MRSE	50-100	luxuriant	≥50%	blue
<i>Staphylococcus xylosus</i> ATCC 29971	≥10 ⁴	inhibited	0%	-
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	≥10 ⁴	inhibited	0%	-

Key : (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

- 1.DWorkin M et. al 2006. The Prokaryotes (a Handbook on the Biology of Bacteria) 3rd ed, Vol. 2, page 345.
- 2.Dr. Alan Johnson, methicillin resistant staphylococcus aureus (MRSA) infection. The Support group for MSRA sufferers and Dependents, Aug 1st , 2005.
- 3.Methicillin Resistant Staphylococcus aureus Copyright a 1997-2005 Canadian Centre for Occupational Health and Safety, Sept 19th, 2005.
- 4.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
- 5.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

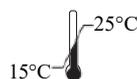
Revision : 06/ 2026



HiMedia Laboratories Pvt. Limited,
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Thane (W) -400604, MS, India



**In vitro diagnostic
medical device**



Storage temperature



AR Experts BV
Boeingavenue 209
1119 PD Schiphol-Rijk
The Netherlands



CE Marking



**Do not use if
package is damaged**

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HiCrome® CarbaResist Agar Base

M2099

Intended Use:

Recommended for isolation and differentiation of Carbapenem resistant *Enterobacteriaceae* from clinical samples.

Composition**

Ingredients	g / L
Acicase#	24.000
Chromogenic mixture	1.500
Agar	17.000
Final pH (at 25°C)	7.2±0.2

**Formula adjusted, standardized to suit performance parameters

Casein Acid Hydrolysate

Directions

Suspend 42.50 gram in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Aseptically add rehydrated content of 1 vial of Carba Selective Supplement (FD357). Mix well and pour into sterile Petri plates.

Principle And Interpretation

HiCrome® CarbaResist Agar Base is a chromogenic medium designed for the detection and differentiation of Carbapenemase producing *Enterobacteriaceae* species. Carbapenems are the last line of defense against invasive or serious infections and are used to treat these life threatening infections that are caused by gram negative, drug resistant pathogens (1). Production of carbapenemase enzyme results in resistance to penicillins, cephalosporins (i.e. cefepime, ceftriaxone), carbapenems (i.e. meropenem, ertapenem) and aztreonam there by making these pathogens multi drug resistant. Most carbapenemase producing bacteria are included in the family *Enterobacteriaceae*, and are thus termed as carbapenem resistant *Enterobacteriaceae* (CRE). Enterobacterales exhibiting low level of carbapenemase expression typically demonstrate poor to good growth on the media. Besides the *Enterobacteriaceae* family, rare strains of *Pseudomonas aeruginosa* and *Acinetobacter baumannii* have also been found to produce carbapenemase (1,2,3).

Acicase provide nitrogenous and carbonaceous compounds, long chain amino acids, sulphur and other essential nutrients. Chromogenic mixture incorporated helps in colour differentiation. The chromogenic substrates are specifically cleaved by enzyme β -D-galactosidase produced by colistin resistant *E.coli* resulting in pink to purple coloured colonies. Whereas colistin resistant *K. pneumoniae* cleaves the other chromogenic substrate producing metallic blue coloured colonies. *Pseudomonas* species produce colourless colonies or may produce with light greenish pigment. The medium is intended to be used as a screening medium. Isolates should be tested further for Carbapenem susceptibility following CLSI guidelines.

Type of specimen

Clinical Samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Final identification must be carried out by biochemical tests or antibiotic susceptibility as per CLSI.
2. Some intermediate strains of carbapenem may show poor growth.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.7% agar gel.

Colour and Clarity of prepared medium

Light amber coloured clear to slight opalescent gel forms in Petri plates.

Reaction

Reaction of 4.25% w/v aqueous solution at 25°C. pH : 7.2±0.2

pH

7.00-7.40

Cultural Response

Cultural characteristics observed after incubation at 35-37°C for 18 -24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Carba Resistant <i>Klebsiella pneumoniae</i> ATCC BAA 1705	50 -100	luxuriant	≥50 %	metallic blue
Carba Resistant <i>Klebsiella pneumoniae</i> NCTC 13438	50 -100	luxuriant	≥50 %	metallic blue
Carba Resistant <i>Escherichia coli</i>	50 -100	luxuriant	≥50 %	pink-purple
Carba Sensitive <i>Enterobacteriaceae</i>	≥10 ⁴	inhibited	0 %	-
<i>Enterococcus faecalis</i> 29212 (00087*)	≥10 ⁴	inhibited	0 %	-

Key: (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 15-25°C and prepared medium on receipt at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

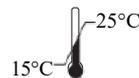
- Samra, Z., 2008, J. Clin. Microbiol; Vol. 146, P.3110-3111.
- Hindiyyeth, M., et. al. 2008, J. Clin. Microbiol.; Vol. 46, p.2879 -2883.
- Pillai D.R. et.al. 2009. Emerg. Infect. Dis; Vol. 15, P.827-829.
- Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
- Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W.(2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



HiMedia Laboratories Pvt. Limited,
Plot No.C-40, Road No.21Y,
MIDC,WagleIndustrial Area,
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In vitro diagnostic
medical device



Storage temperature



AR Experts BV
Boeingavenue 209
1119 PD Schiphol-Rijk
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CE Marking



Do not use if
package is damaged

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Colistin HiMIC™ Plate Kit (CL) (0.25 - 16 mcg/ml)

MPK020

Antimicrobial Susceptibility Testing
For *In Vitro* Diagnostic use

Intended Use:

Colistin HiMIC™ Plate Kit is ready to use Minimum Inhibitory Concentration (MIC) determination kit by broth microdilution method, capable of showing MIC's of Colistin against test organism in the range of 0.25 mcg/ml to 16 mcg/ml following specified incubation condition.

Kit Contains:

No.	Content	1 KT	3KT
1.	96 Well HiMIC™ Plate	1 No.	3 No.
2.	HiMIC™ Diluent Tubes	12 No.	36 No.
3.	HiMIC™ Reading card	1 No.	3 No.
4.	HiMIC™ Incubation Tray	1 No.	3 No.

Introduction:

HiMIC™ Plate Kit is a broth microdilution method consisting of 96 well microtiter plate with detachable wells. It covers 7 two-fold dilutions in a single detachable well strip covering breakpoint scale which helps in reliable interpretation for Sensitive, Intermediate and Resistance detection with easy visual inspection, in compliance with CLSI and EUCAST guidelines. Detachable well strip is coated with gradient of antibiotics and growth medium which releases upon the rehydration. The detachable strip is coated with highest concentration in the top most well i.e. in "A" well and lowest concentration in the second last well i.e. "G" well whereas last well is a growth control i.e. "H" well. Each detachable well is given along with the antibiotic symbol at the top. HiMIC™ reading card is provided for easy interpretation of the MIC value by visible colour change.

METHOD AND USE OF HiMIC™ Plate Kit

- **Type of specimen**

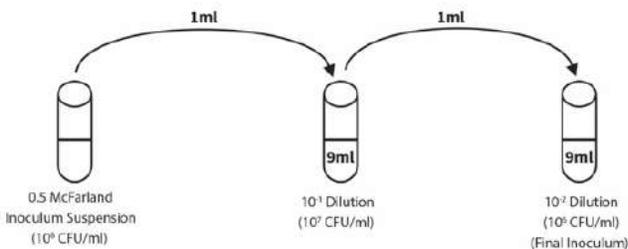
Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

- **Clinical specimen collection, handling and processing**

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1,3).

- **Preparation of Inoculum**

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. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm). Dilute the inoculum for further two dilutions to get final inoculum of 10⁶ cfu/ml.

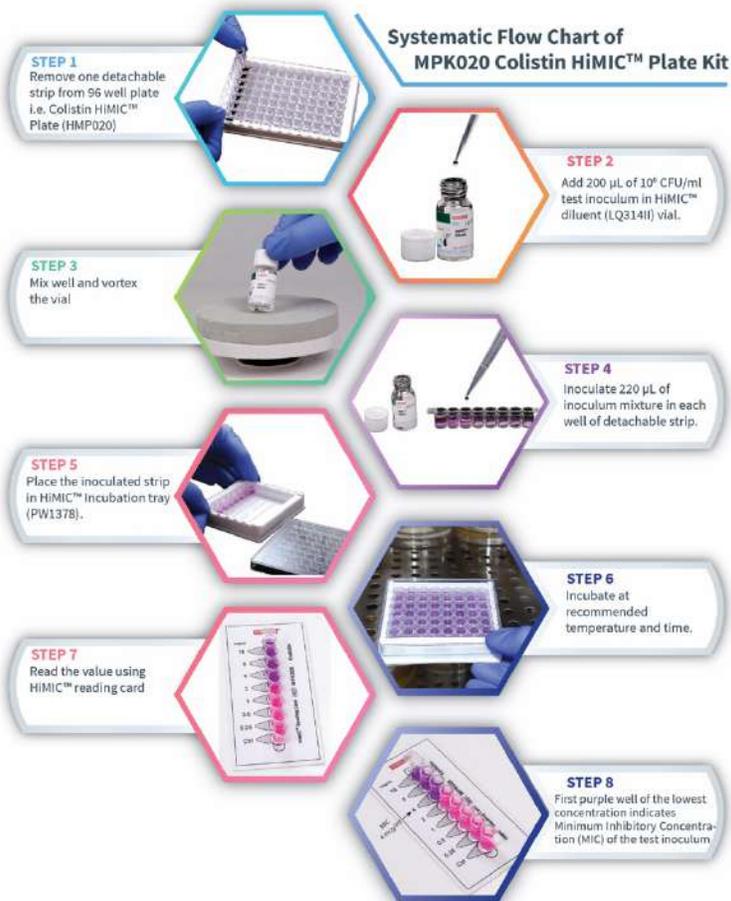


- **Test Procedure**

1. Remove the Colistin HiMIC™ plate (HMP020) from Aluminum Zip Pouch.
2. Pick up the required number of detachable well strips and cover the remaining wells with the lid provided.
3. Inoculate 200 μL of 10^6 CFU/ml inoculum into HiMIC™ diluent tube (LQ314II).
(Note: Use one vial for single inoculum.)
Mix well and vortex the tube
4. Inoculate 220 μL of inoculum mixture from above tube into the all 8 wells i.e. “A” to “H” wells
5. Gently shake the well strip and keep it in an incubator tray provided with the kit.
6. Transfer the tray in the incubator under appropriate conditions.

MIC Reading:

1. Read the wells when visible color change from purple to pink will be observed (or Read the wells after appropriate incubation.)
2. Remove the detachable well Strip from incubator tray.
3. Place it on the HiMIC™ reading card in the proper direction
4. Read the MIC where lowest concentration of the purple colored well is observed



Warning and Precautions:

1. HiMIC™ Plate Kit is intended for *In vitro* diagnostic use only.
2. Although based on simple procedure, HiMIC™ Plate Kit should only be used by at least semi-trained personnel.
3. HiMIC™ Plate Kit, should be used strictly according to procedures described herein.
4. Performance of HiMIC™ Plate Kit depends on use of proper inoculum and control cultures and proper storage temperature.
5. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
6. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL (As per CLSI Guidelines) :**Interpretation**

Table 1: Use following interpretive criteria of Colistin for susceptibility categorization as per CLSI.

When testing	Incubation	Interpretative Criteria (mcg/ml)		
		≤ S	I	≥ R
<i>Enterobacteriales</i> (Excluding <i>Salmonella/Shigella</i> spp), <i>P. aeruginosa</i> , <i>Acinetobacter</i> spp.	35-37°C for 18 hrs.	-	≤ 2	4
Other non- <i>Enterobacteriales</i>	35-37°C for 18 hrs.	2	4	8

Quality Control:

Quality control of Colistin HiMIC™ Plate Kit is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on a suitable medium incubated appropriately.

Table 2: Following are the reference MIC values (mcg/ml) range for Colistin.

Organism	Incubation	Std. Quality Control limits (mcg/ml)
<i>E. coli</i> ATCC 25922 ^a	35-37°C for 18 hrs.	0.25 - 0.5 – 1.0 - 2.0
<i>P. aeruginosa</i> ATCC 27853	35-37°C for 18 hrs.	0.25 - 0.5 – 1.0 - 2.0

^a: Quality Control Limit deleted in CLSI 2024.

INTERPRETATION & QUALITY CONTROL (As per EUCAST Guidelines):**Interpretation:**

Table 3: Use following interpretive criteria of Colistin for susceptibility categorization as per EUCAST.

When testing	Incubation	Interpretative Criteria (mcg/ml)	
		≤ S	> R
<i>Enterobacteriales</i> , <i>Acinetobacter</i> spp.	35-37°C for 18 hrs.	2	2
<i>Pseudomonas</i> spp.	35-37°C for 18 hrs.	4	4

Quality Control: Colistin HiMIC™ Plate Kit MIC™ Strips is carried out by testing the strips with standard ATCC Cultures recommended by EUCAST on a suitable medium incubated appropriately.

Table 4: Following are the reference MIC values (mcg/ml) range for Colistin.

Organism	Incubation	Target MIC Value (mcg/ml)	Std. Quality Control limits (mcg/ml)
<i>E. coli</i> ATCC 25922	35-37°C for 18 hrs.	0.5	0.25 - 0.5 – 1.0
<i>P. aeruginosa</i> ATCC 27853	35-37°C for 18 hrs.	1	0.5 -1.0 - 2.0
<i>E. coli</i> NCTC 13846	35-37°C for 18 hrs.	4	2 – 4 - 8

Storage & Shelf Life:

1. Once the consignment is received, store the HiMIC™ Plate Kit at -20°C to 8°C.
2. Use before expiry date on the label.
3. HiMIC™ Plate Kit left over from opened package must be kept dry.
4. Moisture should be prevented from penetrating into or forming within the package or storage container.
5. Check whether the batch number and expiry date are marked on the storage container.
6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, HiMIC™ Plate Kit and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

HiMIC™ Plate Kit provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI & EUCAST standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
3. Jorgensen, J. H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
4. Performance Standards of Antimicrobial Susceptibility Testing; 33rd Edition. M100-Ed33, Vol.43, No.3, Jan-2023.
5. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.
6. European Committee on Antimicrobial Susceptibility Testing Breakpoint tables for interpretation of MICs and zone diameters Version 14.0, valid from 2024-01-01.
7. European Committee on Antimicrobial Susceptibility Testing Routine and extended internal quality control as recommended by EUCAST Version 14.0, valid from 2024-01-01.

Packing:

Each Pack contains following material packed in a desired packing.

- 1) Colistin HiMIC™ Plate Kit (1KT/3KT)
- 2) HiMIC™ Diluent tubes (12NO./36NO)
- 3) HiMIC™ Reading Card. (1NO / 3NO)
- 4) HiMIC™ Incubation Tray (1NO / 3NO)
- 5) Package Insert

Layout of plate

Product Code: MPK020

Product Name: Colistin HiMIC™ Plate Kit

Concentration: 16 - 0.25 mcg/ml

	1	2	3	4	5	6	7	8	9	10	11	12
A	16	16	16	16	16	16	16	16	16	16	16	16
B	8	8	8	8	8	8	8	8	8	8	8	8
C	4	4	4	4	4	4	4	4	4	4	4	4
D	2	2	2	2	2	2	2	2	2	2	2	2
E	1	1	1	1	1	1	1	1	1	1	1	1
F	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
G	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
H	Growth Control											



On receipt store at -20°C



In vitro diagnostic medical device



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Wagle Industrial Estate,
Thane (W) - 400604,
Maharashtra, India



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Indicates a single sterile barrier system with protective packaging outside



Do not re-use

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Gentamicin GEN 10 mcg**SD016**

Gentamicin GEN 10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Gentamicin	10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Gentamicin 10 mcg	<i>Enterobacteriaceae, P.aeruginosa, Acientobacter & Staphylococcus</i>	15	13-14	12

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "GEN 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	19-26
<i>S.aureus</i> (25923)	19-27
<i>P.aeruginosa</i> (27853)	17-23

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

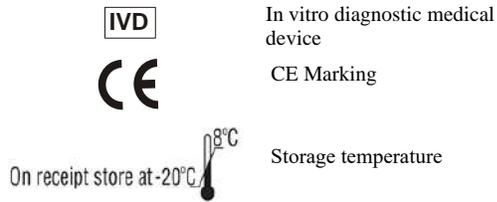
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**



In vitro diagnostic medical device

CE Marking

Storage temperature

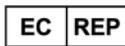
On receipt store at -20°C



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Polymyxin-B

PB 300 Units

SD029

Polymyxin-B PB 300 Units discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Polymyxin-B	300 Units/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Polymyxin-B 300 Units	<i>P.aeruginosa</i>	12	-	11

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "PB 300" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	13-19
<i>P.aeruginosa</i> (27853)	14-18

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

- Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
- Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
- EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

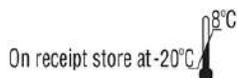
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

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CE Marking



Storage temperature



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Streptomycin S 10 mcg

SD031

Streptomycin S 10mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

Ingredients	Concentration
Streptomycin	10mcg /disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Streptomycin 10mcg	<i>Enterobacteriaceae</i>	15	12-14	11

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "S 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	12-20
<i>S.aureus</i> (25923)	14-22

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

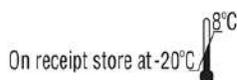
For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

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CE Marking



Storage temperature



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Cefotaxime CTX 30 mcg (Cephotaxime)

SD040

Cefotaxime (Cephotaxime) CTX 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

Ingredients	Concentration
Cefotaxime (Cephotaxime)	30 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby-Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Cefotaxime (Cephataxime) CTX 30 mcg	<i>Enterobacteriaceae</i>	26	23-25	22
	<i>P.aeruginosa, Acientobacter & Staphylococcus</i>	23	15-22	14
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	26	-	-
	<i>Neisseria meningitidis</i>	34	-	-
	<i>Neisseria gonorrhoeae</i>	31	-	-
	<i>Streptococcus spp. Viridians group</i>	28	26-27	25
	<i>Streptococcus spp. beta haemolytic gruop</i>	24	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CTX 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	29 - 35
<i>S.aureus</i> (25923)	25 - 31
<i>P.aeruginosa</i> (27853)	18 - 22

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

- Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
- Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
- EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.



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Storage temperature

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Cefoxitin (Cephoxitin)

CX

30 mcg

SD041

Cefoxitin (Cephoxitin) CX 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby- Bauer Method

Composition

*Ingredients

	Concentration
Cefoxitin (Cephoxitin)	30 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby- Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby- Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Cefoxitin (Cephoxitin) 30 mcg	<i>Enterobacterales</i>	16	13-15	14
	<i>For S.aureus & S.lugdunensis</i>	22	-	21
	<i>For Coagulase- negative Staphylococci except S.lugdunensis & S.pseudintermedius</i>	25	-	24
	<i>Neisseria gonorrhoeae</i>	28	24-27	23

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CX 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	23-29
<i>S.aureus</i> (25923)	23-29

* = Interpretive criteria & QC ranges as per CLSI & EUCAST standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

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CE Marking



Storage temperature



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Ciprofloxacin

CIP 5 mcg

SD060

Ciprofloxacin CIP 5 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Ciprofloxacin	5 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Ciprofloxacin 5 mcg	<i>Enterobacteriaceae other than S.Typhi</i> and extraintestinal <i>Salmonella</i> spp., <i>P.aeruginosa</i> , <i>Acinetobacter</i> , <i>Staphylococcus</i> & <i>Enterococcus</i>	21	16-20	15
	For <i>S.Typhi</i> and extraintestinal <i>Salmonella</i> spp.	31	21-30	20
	<i>Haemophilus influenzae</i> & <i>Haemophilus parainfluenzae</i>	21	-	-
	<i>Neisseria meningitidis</i>	35	33-34	32
	<i>Neisseria gonorrhoeae</i>	41	28-40	27

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CIP 5" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	29-37
<i>S.aureus</i> (25923)	22-30
<i>P.aeruginosa</i> (27853)	25-33
<i>S.aureus</i> (29213)	21-27
<i>E.faecalis</i> (29212)	19-25

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

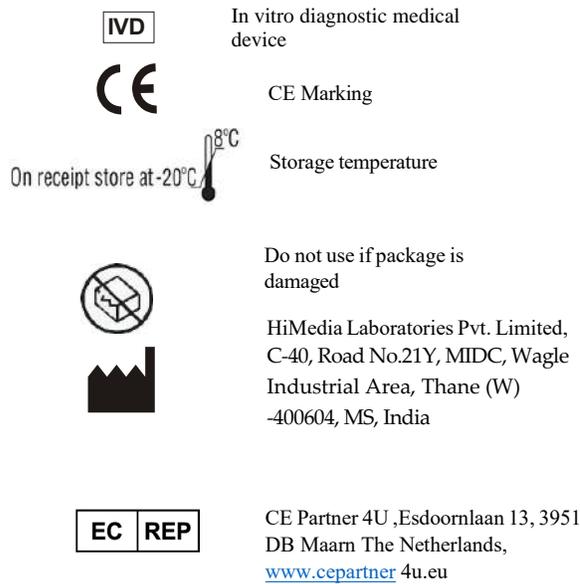
For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* Not for Medicinal Use



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Ceftriaxone CTR 30 mcg**SD065**

Ceftriaxone CTR 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Ceftriaxone	30 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Ceftriaxone 30 mcg	<i>Enterobacteriaceae</i>	23	20-22	19
	<i>P.aeruginosa, Acinetobacter & Staphylococcus</i>	21	14-20	13
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	26	-	-
	<i>Neisseria meningitidis</i>	34	-	-
	<i>Neisseria gonorrhoeae</i>	35	-	-
	<i>Streptococcus spp. Viridians group</i>	27	25-26	24
	<i>Streptococcus spp. beta haemolytic group</i>	24	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CTR 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	29-35
<i>S.aureus</i> (25923)	22-28
<i>P.aeruginosa</i> (27853)	17-23
<i>K.pneumoniae</i> (700603)	16-24

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**

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Cefoperazone CPZ 75 mcg

SD072

Cefoperazone CPZ 75 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Cefoperazone	75 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Cefoperazone 75 mcg	<i>Enterobacteriaceae, P.aeruginosa</i>	21	16-20	15

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CPZ 75" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	28-34
<i>S.aureus</i> (25923)	24-33
<i>P.aeruginosa</i> (27853)	23-29

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**



In vitro diagnostic medical device



CE Marking

On receipt store at -20°C 

Storage temperature



Do not use if package is damaged



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Amoxicillin AMX 30 mcg

SD076

Amoxicillin AMX 30mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Amoxicillin	30mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "AMX 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>E. coli</i> (25922)	19-25
<i>S.aureus</i> (25923)	28-36

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* Not for Medicinal Use



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CE Marking



Storage temperature



Do not use if package is damaged



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Ofloxacin OF 5 mcg

SD087

Ofloxacin OF 5 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Ofloxacin	5 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Ofloxacin 5 mcg	<i>Enterobacteriaceae, P.aeruginosa, S.pneumoniae, Streptococcus spp. Viridians group, Streptococcus spp. beta haemolytic group</i>	16	13-15	12
	<i>Staphylococcus</i>	18	15-17	14
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	16	-	-
	<i>Neisseria gonorrhoeae</i>	31	25-30	24

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "OF 5" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	29-33
<i>S.aureus</i> (25923)	24-28
<i>P.aeruginosa</i> (27853)	17-21

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**



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CE Marking

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Storage temperature



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Ceftriaxone CTR 10 mcg

SD109

Ceftriaxone CTR 10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

*Ingredients	Concentration
Ceftriaxone	10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CTR 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>E. coli</i> (25922)	29-35
<i>S.aureus</i> (25923)	22-28
<i>P.aeruginosa</i> (27853)	17-23

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* Not for Medicinal Use



In vitro diagnostic medical device



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Ampicillin/Sulbactam A/S 10/10 mcg

SD112

Ampicillin/Sulbactam A/S 10/10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby- Bauer Method

Composition

Ingredients	Concentration
Ampicillin/Sulbactam	10/10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby- Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby- Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Ampicillin/ Sulbactam 10/10 mcg	<i>Enterobacteriaceae, Acinetobacter</i>	15	12-14	11
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	20	-	19

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "A/S 10/10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E. coli (25922)</i>	19-24
<i>S. aureus (25923)</i>	29-37
<i>E. coli (35218)</i>	13-19

* = Interpretive criteria & QC ranges as per CLSI standards & EUCAST standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S. pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C. Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**



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Clotrimazole CC 10 mcg

SD115

Clotrimazole CC 10 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients	Concentration
Clotrimazole	10 mcg/disc

Susceptibility Test Procedure:

Preparation of Inoculum:

1. 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 $35 \pm 2^\circ\text{C}$. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield $1 \times 10^6 - 5 \times 10^6$ cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (M1825) for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to $35 \pm 2^\circ\text{C}$ within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation.

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CC 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>C.albicans</i> (90028)*	18-32
<i>C.parapsilosis</i> (22019)*	16-30
<i>C.tropicalis</i> (750)*	10-20
<i>C.krusei</i> (6528)*	14-24
<i>C.albicans</i> (10231)	12-18
<i>S.cerevesiae</i> (9763)	17-25

* = Q.C. Strains recommended by CLSI

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume

* Not for Medicinal Use

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Azithromycin AZM 30 mcg**SD124**

Azithromycin AZM 30mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby- Bauer Method

Composition

*Ingredients	Concentration
Azithromycin	30 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby- Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby- Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "AZM 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>S.aureus</i> (25923)	24-30

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

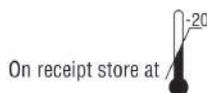
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Storage temperature

On receipt store at



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Cefaclor CF 30 mcg

SD157

Cefaclor CF 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method.

Composition

*Ingredients	Concentration
Cefaclor	30 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Cefaclor 30 mcg	<i>Enterobacteriaceae, Staphylococcus</i>	18	15-17	14
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	20	17-19	16

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CF 30" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	23-27
<i>S.aureus</i> (25923)	27-31

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

- Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
- Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
- EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

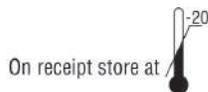
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Clarithromycin

CLR 15 mcg

SD192

Clarithromycin CLR 15 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby- Bauer Method

Composition

*Ingredients	Concentration
Clarithromycin	15 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby- Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby- Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Clarithromycin 15 mcg	<i>Staphylococcus spp.</i>	18	14-17	13
	<i>Haemophilus influenzae</i> & <i>Haemophilus parainfluenzae</i>	13	11-12	10
	<i>S.pneumoniae</i> , <i>Streptococcus spp. Viridians group</i> , <i>Streptococcus spp. beta haemolytic group</i>	21	17-20	18

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CLR 15" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>S.aureus</i> (25923)	26-32

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**



In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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Ticarcillin / Clavulanic Acid

TCC 75/10 mcg

SD201

Ticarcillin/Clavulanic Acid TCC 75/10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

Ingredients	Concentration
Ticarcillin / Clavulanic Acid	75/10 mcg /disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby-Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Ticarcillin / Clavulanic Acid 75/10 mcg	<i>Enterobacteriaceae & Acinetobacter</i>	20	15-19	14
	<i>P.aeruginosa</i>	24	16-23	15
	<i>Staphylococcus</i> spp.	23	-	22

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "TCC 75/10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	24-30
<i>S.aureus</i> (25923)	29-37
<i>P.aeruginosa</i> (27853)	20-28

* = Interpretive criteria & QC ranges as per CLSI & EUCAST standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* Not for Medicinal Use

IVD

In vitro diagnostic medical device



CE Marking

On receipt store at -20°C 

Storage temperature



Do not use if package is damaged



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Levofloxacin LE 5 mcg

SD216

Levofloxacin LE 5 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby- Bauer Method

Composition

*Ingredients	Concentration
Levofloxacin	5 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby- Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby- Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Levofloxacin 5 mcg	<i>Enterobacterales, S.typhi</i>	21	17-20	16
	<i>P.aeruginosa</i>	22	15-21	14
	<i>Acinetobacter spp., S.maltophila, Enterococcus spp., S.pneumoniae, Streptococcus spp. Viridians group, Streptococcus spp. beta haemolytic group</i>	17	14- 16	13
	<i>Staphylococcus spp.,</i>	19	16-18	15
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	17	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "LE 5" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli (25922)</i>	29-37
<i>S.aureus (25923)</i>	25-30
<i>P.aeruginosa (27853)</i>	19-26

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spp : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spp : G.C.Agar +1% defined growth supplement (M434 + FD025)

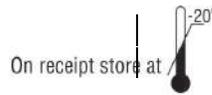
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IVD

In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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Streptomycin

HLS 300mcg

SD236

Streptomycin HLS 300mcg discs are used for screening of high-level Aminoglycosides Resistance (HLAR)

Composition

*Ingredients	Concentration
Streptomycin	300mcg /disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However, during past few decades, enterococci resistant to multiple antimicrobial agents have been recognized, including strains resistant to Vancomycin, β -Lactams and aminoglycosides, making it a formidable nosocomial pathogen. Such strains are not detected by routine disc diffusion. Hence, several alternative methods have been proposed for detection of HLAR. These methods are: agar screening, high content discs and broth dilution. High content discs for screening of high-level Aminoglycosides Resistance are Gentamicin (120 μ g) & Streptomycin (300 μ g).

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Streptomycin 300mcg	<i>Enterococcus</i>	10	7-9	6

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "HLS 300" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>E. faecalis</i> (29212)	14-20*

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spp : Haemophilus Test Agar (M1259 + FD117)

For *S. pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For Neisseria spp : G.C. Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**

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Meropenem MRP 10 mcg**SD727**

Meropenem MRP 10 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients	Concentration
Meropenem	10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Bauer-Kirby Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Meropenem 10 mcg	<i>Enterobacteriaceae</i>	23	20-22	19
	<i>P.aeruginosa</i>	19	16-18	15
	<i>Acinetobacter & Staphylococcus</i>	16	14-15	13
	<i>B.cepacia</i>	20	16-19	15
	<i>Haemophilus influenzae & Haemophilus parainfluenzae</i>	20	-	-
	<i>Neisseria meningitidis</i>	30	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "MRP 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)*
<i>E.coli</i> (25922)	28-34
<i>S.aureus</i> (25923)	29-37
<i>P.aeruginosa</i> (27853)	27-33

* = Interpretive criteria & QC ranges as per CLSI standards.

Storage and Shelf-life:

On receipt discs should always be stored at -20°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note :

Use following media to carry out susceptibility test

For rapidly growing aerobic organisms : Mueller Hinton Agar (M173/M1084)

For *Haemophilus* spps : Haemophilus Test Agar (M1259 + FD117)

For *S.pneumoniae* : Muller Hinton Agar supplemented with 5% Sheep Blood

For *Neisseria* spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

* **Not for Medicinal Use**

IVD

In vitro diagnostic medical device



CE Marking

On receipt store at



Storage temperature



Do not use if package is damaged



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Neomycin N 10 mcg

SD731

Neomycin N 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

*Ingredients	Concentration
Neomycin	10 mcg/disc

Susceptibility Test Procedure:

1. Prepare plates with Mueller Hinton Agar (M173/M1084) for rapidly growing aerobic organisms as per Kirby-Bauer Method. The medium in the plates should be sterile and should have a depth of about 4 mm.
2. Inoculate 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)
3. 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. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
4. Apply the discs using aseptic technique. When using cartridges, the discs can be applied using the specially designed applicator. When the vials are used, apply the discs using sterile forceps.
5. Deposit the discs with centers at least 24 mm apart. For fastidious organisms and for Penicillins and Cephalosporins, the discs should preferably be deposited with centers 30 mm apart.
6. Incubate immediately at 35 ± 2°C and examine after 16-18 hours or longer, if necessary. For fastidious organisms incubate at appropriate temperature and time.
7. Measure the zones showing complete inhibition and record the diameters of the zones to the nearest millimeter using a calibrated instrument like zone scales (PW096/PW297)

Principle:

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. Till the 1950s, laboratories were lacking in the methodologies and equipments for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Kirby-Bauer Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS)(2). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified.

Interpretation:

Use following interpretive criteria for susceptibility categorization*

Antimicrobial agent	Interpretative criteria for	Sensitive	Intermediate	Resistant
		mm or more	mm	mm or less
Neomycin N 10 mcg	<i>S.pseudonintermedius</i> & <i>S. schelfer</i>	20	-	20

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "N 10" on centre of each side of the disc.

Cultural response: Average diameter of zone of inhibition observed on Mueller Hinton Agar (M173) after 18 hours incubation at 35-37°C for standard cultures.

Organisms (ATCC)	Std. zone of diameter (mm)
<i>E. coli</i> (25922)	13 - 19
<i>S.aureus</i> (29213)	17 - 25

*= Interpretive criteria & QC ranges as per EUCAST standards.

Storage and Shelf-life:

Discs should always be stored at -20°C to +8°C under dry conditions, along with the dessicator provided in individual pack. Use before expiry date on the label.

References:

1. Bauer, Kirby, Sherris and Turck, 1966, Am. J. Clin. Path., 45: 493
2. Performance standards of Antimicrobial Disc Susceptibility Tests, M100S, 32nd Ed., CLSI Vol. 42 No.2, Feb-2022.
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For Neisseria spps : G.C.Agar +1% defined growth supplement (M434 + FD025)

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GC Agar

SM434

Intended Use:

GC Agar Base, with added haemoglobin is recommended for selective isolation and cultivation of Gonococci.

Composition**

Ingredients	g / L
Peptone, special	15.000
Corn starch	1.000
Dipotassium hydrogen phosphate	4.000
Potassium dihydrogen phosphate	1.000
Sodium chloride	5.000
Agar	10.000
Final pH (at 25°C)	7.2±0.2

Ingredients	Concentration
Haemoglobin(FD022)	10.00g

Vitamins growth supplement (FD025)

Ingredients	Concentration
Part I	"
Vitamin B12	0.100mg
L-Glutamine	100mg
Adenine sulphate	10mg
Guanine hydrochloride	0.300mg
p-Aminobenzoic acid (PABA)	0.130mg
L-Cystine	11mg
NAD (Coenzyme I)	2.500mg
Coccarboxylase	1mg
Ferric nitrate	0.200mg
Thiamine hydrochloride	0.030mg
Cysteine hydrochloride	259mg
Part II (Rehydrating fluid)	"
Dextrose	1g
Distilled water	10ml

**Formula adjusted, standardized to suit performance parameters

Directions

GC Agar is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence it does not need sterilization. Medium in the bottle can be melted either by using a pre-heated water bath or any other method. Slightly loosen the cap before melting. When complete melting of medium is observed dispense the medium in tubes as butts /slants or in plates as desired and allow to solidify. If on plate, either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically.

Principle And Interpretation

Majority of gonococcal infections are uncomplicated lower genital tract infection caused by direct infection of the columnar epithelium of mucosal membranes. *Neisseria gonorrhoeae* is the causative agent of gonococcal infections. Most *Neisseria* strains have complex growth requirements; some strains may be exquisitely sensitive to fatty acids, necessitating the incorporation of soluble starch in the growth media (1). Johnston developed a medium that could obtain the growth of *Neisseria* within 24 hours rather than the usual 48 hours (2). This medium was later modified by Carpenter and Morton (3), by the addition of haemoglobin. This can be replaced with a chemically defined supplement containing essential growth factors available from yeast extract in Vitamins Growth Supplement (Twin Pack) (FD025). X-factor needed for the growth of fastidious *Haemophilus* species is provided by haemoglobin (FD022).

GC Agar contains special peptone, which supplies essential nutrients to the organisms. The presence of starch ensures that the toxic metabolites produced by *Neisseria* are neutralized. Phosphates prevent changes in the pH due to amine production that can affect the survival of the organisms. Factor-X (hemin) needed for *Haemophilus* species is provided by haemoglobin. The other supplements added provide factor-V i.e. NAD (Nicotinamide Adenine dinucleotide) for *Haemophilus* species and amino acids, coenzymes, ferric ions etc, which improve the growth of pathogenic *Neisseria*. Avoid cotton wool for specimen collection. Inoculate immediately after specimen collection. Specimens should be streaked on the surface of plates so as to get some areas heavily seeded and other areas lightly seeded. Incubation is done at 37°C in an atmosphere of 70% humidity and 5-10% carbon dioxide. All presumptive *Neisseria* must be confirmed by carbohydrate fermentation tests and other serological tests.

Type of specimen

Clinical samples : Respiratory exudates

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use only. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Growth supplements like haemoglobin and Vitamino growth supplements must be added for growth of fastidious organisms like *Haemophilus* and Gonococci.
2. Carry out confirmatory tests of all the colonies.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Part A

Sterile glass bottle containing light amber coloured slightly opalescent G.C Agar Base

Part B

Chocolate brown coloured solution

Part C

Pale yellow coloured, homogeneous, free flowing powder soluble in 2ml sterile distilled water

Colour of medium

Chocolate brown coloured opaque gel forms in Petri plates

Quantity of medium

50 ml of Part A and 50 ml of Part B in sterile glass bottles.

pH

7.00-7.40

Sterility Check

Passes release criteria

Cultural Response

Cultural characteristics observed after melting the medium and pouring into sterile petri plates. The plates are inoculated with following test organisms In presence of 5-10% Carbon dioxide (CO₂) and 70% humidity after an incubation at 35-37°C for 40-48 hours.

Organism

Organism	Inoculum (CFU)	Growth	Recovery
<i>Haemophilus influenzae</i> ATCC 19418	50-100	good-luxuriant	≥50%
<i>Neisseria gonorrhoeae</i> ATCC 19424	50-100	good-luxuriant	≥50%

<i>Neisseria meningitidis</i> ATCC 13090	50-100	good-luxuriant	$\geq 50\%$
<i>Streptococcus pyogenes</i> ATCC 19615	50-100	good-luxuriant	$\geq 50\%$
<i>Streptococcus pneumoniae</i> ATCC 6303	50-100	good-luxuriant	$\geq 50\%$

Storage and Shelf Life

On receipt store between 2-8°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques

Reference

- 1.Murray P. R., Baron E. J., Pfaller M. A., Tenover J. C. and Tenover F. C., (Eds.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.
- 2.Johnston J., 1945, J. Vener.26:239.
- 3.Carpenter C. M. and Morton H. E., 1947, Proc. N.Y. State
- 4.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 5.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S Manual of Clinical Microbiology, 11th Edition. Vol. 1.and Warnock, D.W.(2015).

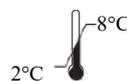
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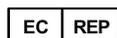
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Storage temperature



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