

Amoxycillin AMX 30 mcg

SD076

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

Composition

*Ingredients Concentration Amoxycillin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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)
E. coli (25922)	19-25
S.aureus (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



In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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Revision: 03 / 2022

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Nitrofurantoin NIT 100 mcg

SD086

Nitrofurantoin NIT 100 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients Concentration
Nitrofurantoin 100 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "NIT 100" 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)
E. coli (25922)	17-23
S.aureus (29213)	17-23
E.faecalis (29212)	18-24

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:

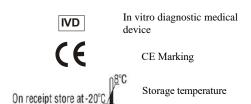
Use following media to carry out susceptibility test

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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Disclaimer: Revision: 03 / 2022



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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
og :	Enterobacteriaceae, P.aeruginosa, S.pneumoniae, Streptococcus spp. Viridians group ,Streptococcus spp. beta haemolytic gruop	16	13-15	12
Ofloxacin 5 mcg	Staphylococcus	18	15-17	14
-	Haemophilus influenzae & Haemophilus parainfluenzae	16	-	-
	Neisseria gonorhoeae	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)*
E.coli (25922)	29-33
S.aureus (25923)	24-28
P.aeruginosa (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



In vitro diagnostic medical device



CE Marking



Storage temperature



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Revision: 02 / 2022

Disclaimer:



Oxacillin OX 1 mcg

SD088

Oxacillin OX 1 mcg discs are used for antimicrobial susceptibility testing of of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients Concentration
Oxacillin 1 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Oxacillin	Staphylococcus	13	11-12	10
1 mcg	S.pneumoniae	20	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "OX 1" 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)*
S.aureus (25923)	18-24

^{* =} 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:

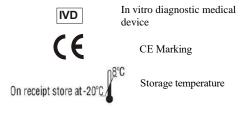
Use following media to carry out susceptibility test

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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Revision: 02 / 2022



Penicillin G P 1 unit

SD089

Penicillin G P 1 unit discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

Ingredients* Concentration Penicillin G 1 unit/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 $35 \pm 2^{\circ}$ 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.

- 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 "P 1" 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)
S.aureus (29213)	12-18

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)



In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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Lincomycin L 15 mcg

SD098

 $\begin{array}{ll} Lincomycin & L \\ \end{array} 15 \ mcg \ discs \ are \ used \ for \ antimicrobial \ susceptibility \ testing \ of \ bacterial \ cultures \\ as \ per \ Bauer-Kirby \ Method \\ \end{array}$

Composition

*Ingredients Concentration
Lincomycin 15 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "L 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)
S.aureus (25923)	22-32

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:

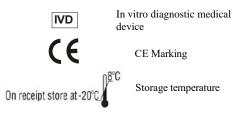
Use following media to carry out susceptibility test

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





Do not use if package is damaged



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Disclaimer:



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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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)
E. coli (25922)	29-35
S.aureus (25923)	22-28
P.aeruginosa (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

dev

CE Marking



Storage temperature



Do not use if package is damaged



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Disclaimer: Revision: 03 / 2022



Amphotericin-B AP 100 units

SD111

Amphotericin-B AP 100 units discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients Concentration
Amphotericin-B 100 units/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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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 "AP 100" 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)		
C.albicans (90028)*	10-17		
C.parapsilosis (22019)*	11-20		
C.tropicalis (750)*	8-12		
C.krusei (6528)*	9-14		
C.albicans(10231)	10-18		
S.cerevesiae (9763)	11-18		

^{* =} 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:

 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

Revision: 1/2012

CE

Disclaimer:

^{*} Not for Medicinal Use



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-BauerMethod

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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Ampicillin/ Sulbactam	Enterobacteriaceae, Acientobacter	15	12-14	11
10/10 mcg	Haemophilus influenzae & Haemophilus parainfluenzae	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)*
E. coli (25922)	19-24
S.aureus (25923)	29-37
E.coli (35218)	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





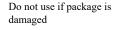
In vitro diagnostic medical device

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Storage temperature







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Revision: 03 / 2022

Disclaimer:





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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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)		
C.albicans (90028)*	18-32		
C.parapsilosis (22019)*	16-30		
C.tropicalis (750)*	10-20		
C.krusei (6528)*	14-24		
C.albicans(10231)	12-18		
S.cerevesiae (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:

 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

Revision: 1/2012



Disclaimer:

^{*} Not for Medicinal Use



Novobiocin NV 5 mcg SD121

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

Composition

*Ingredients Concentration
Novobiocin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "NV 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)
S.aureus (25923)	22-31

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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Revision: 03 / 2022

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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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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)
S.aureus (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:

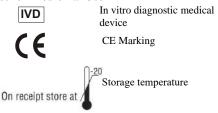
Use following media to carry out susceptibility test

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)

* Not for Medicinal Use



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(6

Disclaimer:



Roxithromycin RO 30 mcg

SD126

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

Composition

*Ingredients Concentration
Roxithromycin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "RO 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)
S.aureus (25923)	22-30

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, CLSI Vol. 32 No.3, Jan 2012.
- * Not for Medicinal Use

Revision: 1/2012

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Disclaimer:



Vancomycin VA 5 mcg

SD155

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

Composition

*Ingredients Concentration
Vancomycin 5mcg/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 $35 \pm 2^{\circ}$ 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.

- 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 "VA 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)
E.faecalis (29212)	15-19
S.pneumoniae (49619)	17-23

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





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Disclaimer



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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Cefaclor	Enterobacteriaceae, Staphylococcus	18	15-17	14
30 mcg	Haemophilus influenzae & Haemophilus parainfluenzae	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)*
E.coli (25922)	23-27
S.aureus (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:

- 1. 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.
- 3. EUCAST, Breakpoint tables for interpretation of MIC's & zone diameters, version 12.0, valid from 01.01.2022.

Note:

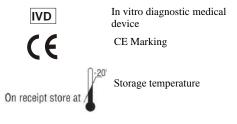
Use following media to carry out susceptibility test

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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Gentamicin GEN 30 mcg

SD170

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

Composition

*Ingredients Concentration
Gentamicin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "GEN 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)
E. faecalis (29212)	12-18

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
- 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)

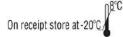
* Not for Medicinal Use



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CE Marking



Storage temperature



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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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Staphylococcus spp.	18	14-17	13
Clarithromycin	Haemophilus influenzae & Haemophilus parainfluenzae	13	11-12	10
15 mcg	S.pneumoniae, Streptococcus spp. Viridians group, Streptococcus spp. beta haemolytic gruop	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)*
S.aureus (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





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Revision: 03 / 2022

Disclaimer:



Nitroxoline NO 30 mcg SD196

Nitroxoline NO 30 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients Concentration
Nitroxoline 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "NO 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)
E. coli (25922)	18-24

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



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Revision: 03 / 2022

Disclaimer



Ticarcillin / Clavulanic Acid

TCC 75/10 mcg

SD201

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

Composition

IngredientsConcentrationTicarcillin / Clavulanic Acid75/10 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Ticarcillin /	Enterobacteriaceae & Acientobacter	20	15-19	14
Clavulanic Acid	P.aeruginosa	24	16-23	15
75/10 mcg	Staphylococcus 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)*
E.coli (25922)	24-30
S.aureus (25923)	29-37
P.aeruginosa (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



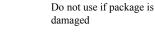
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Storage temperature







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Disclaimer:



Fosfomycin FO 200 mcg

SD205

Fosfomycin FO 200 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method.

Composition

IngredientsConcentrationFosfomycin200 mcg/discGlucose -6-phosphate50mcg/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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Fosfomycin 200 mcg	Enterobacterales, Enterococcus spp.	16	13-15	12

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "FO 200" 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)*
E.coli (25922)	22-30
S.aureus (25923)	25-33

^{* =} 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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Storage temperature



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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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacterales, S.typhi	21	17-20	16
Levofloxacin	P.aeruginosa	22	15-21	14
5 mcg	Acinetobacter spp., S.maltophila , Enterococcus spp., S.pneumoniae, Streptococcus spp. Viridians group, Streptococcus spp. beta haemolytic gruop	17	14- 16	13
	Staphylococcus spp.,	19	16-18	15
	Haemophilus influenzae & Haemophilus parainfluenzae	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)*
E.coli (25922)	29-37
S.aureus (25923)	25-30
P.aeruginosa (27853)	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 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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Storage temperature



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SD217

Moxifloxacin MO 5 mcg

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

Composition

*Ingredients Concentration
Moxifloxacin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacteriaceae	-	-	-
Moxifloxacin	Staphylococcus	24	21-23	20
5 mcg	Haemophilus influenzae & Haemophilus parainfluenzae	18	-	-
	S.pneumoniae	18	15-17	14

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "MO 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)*
E.coli (25922)	28-35
S.aureus (25923)	28-35
P.aeruginosa (27853)	17-25
S.aureus (29213)	25-31

^{* =} 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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Storage temperature







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Cefepime CPM 30 mcg

SD219

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

Composition

*Ingredients Concentration
Cefepime 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacteriaceae, P.aeruginosa, Acientobacter & Staphylococcus	18	15-17	14
Cafanima	Haemophilus influenzae & Haemophilus parainfluenzae	26	-	-
Cefepime 30 mcg	Neisseria gonorhoeae	31	-	1
	Streptococcus spp. Viridians group	24	22-23	21
	Streptococcus spp. beta haemolytic gruop	24	-	-

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CPM 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)*
E.coli (25922)	31-37
S.aureus (25923)	23-29
P.aeruginosa (27853)	25-31

^{* =} 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:

- 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)





In vitro diagnostic medical device

CE Marking



Storage temperature





Do not use if package is damaged

HiMedia Laboratories Pvt. Limited, C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) -400604, MS, India



CE Partner 4U ,Esdoornlaan 13, 3951 DB Maarn The Netherlands, www.cepartner 4u.eu

Revision: 03 / 2022

Disclaimer:



Itraconazole IT 10 mcg

SD221

Itraconazole IT 10 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

, Ingredients Concentration Itraconazole 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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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 "IT 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)
C.albicans (90028)*	16-20
C.parapsilosis (22019)*	11-18
C.tropicalis (750)*	8-13
C.krusei(6528)*	8-15
C.albicans(10231)	18-22

^{* =} 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

Revision: 1/2012

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Disclaimer:

^{*} Not for Medicinal Use



Ketoconazole KT 10 mcg

SD224

Ketoconazole KT 10 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients Concentration
Ketoconazole 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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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 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.

- 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 "KT 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)
C.albicans (90028)*	20-32
C.parapsilosis (22019)*	14-29
C.tropicalis (750)*	17-28
C.krusei(6528)*	10-14
C.albicans(10231)	18-22

^{* =} 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-Third edition Vol.38 No.24, Dec- 2018 CLSI document M44-A2. For more details refer to this volume
- Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts, Third International Supplement CLSI document - M44-S3- Aug 2009

* Not for Medicinal Use



In vitro diagnostic medical device



CE Marking

Storage temperature



Do not use if package is damaged



HiMedia Laboratories Pvt. Limited, C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) -400604, MS, India



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Revision: 02 / 2022



Disclaimer:



Fluconazole FLC 25 mcg

SD232

Fluconazole FLC 25mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients Concentration
Fluconazole 25mcg/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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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	Resistant mm or less	S-DD# mm	S mm or more
Fluconazole 25mcg	Candida spps	14	15-18	19

S-DD - Susceptible - Dose dependent

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "FLC 25" 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)
C.albicans (90028)*	28-39
C.parapsilosis (22019)*	22-33
C.tropicalis (750)*	26-37
C.albicans(10231)	25-30

^{* =} 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:

- 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
- Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC)
 Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility
 Testing Of Yeasts, Third International Supplement CLSI document M44-S3.

Revision: 1 / 2012

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Disclaimer:

^{*} Not for Medicinal Use



Cefoperazone/Sulbactam CFS 75/10 mcg

SD254

Cefoperazone/Sulbactam CFS 75/10mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method

Composition

*Ingredients Concentration
Cefoperazone/Sulbactam 75/10 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "CFS 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)
	E. coli (25922)	27-33
Г	S.aureus (25923)	23-30
	P.aeruginosa (27853)	20-25

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



Miconazole MIC 30 mcg

SD273

Miconazole MIC 30 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients Concentration
Miconazole 30 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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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 "MIC 30" 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)
C.albicans (90028)*	22-26
C.parapsilosis (22019)*	13-17
C.tropicalis (750)*	14-20
C.krusei(6528)*	19-26
C.albicans(10231)	20-27
S.cerevisiae(9763)	20-28

^{* =} 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:

 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

Revision: 1/2012

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Disclaimer:

^{*} Not for Medicinal Use



Voriconazole VRC 1 mcg

SD277

Voriconazole VRC 1 mcg discs are used for antimicrobial susceptibility testing of fungal cultures

Composition

*Ingredients Concentration
Voriconazole 1mcg/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 $35 \pm 2^{\circ}$ 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 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 $35 \pm 2^{\circ}$ 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.

- 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		Resistant	S-DD#	S
agent	Interpretative criteria for	mm or less	mm	mm or more
Voriconazole 1 mcg	Candida spps	13	14-16	17

S-DD - Susceptible - Dose dependent

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "VRC 1" 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)
C.albicans (90028)*	31-42
C.parapsilosis (22019)*	28-37
C.krusei (6528)*	16-25
C.albicans(10231)	30-40
S.cerevesiae (9763)	29-38

^{* =} 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
- Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC)
 Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility
 Testing Of Yeasts, Third International Supplement CLSI document M44-S3.

Revision: 1/2012

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Disclaimer:

^{*} Not for Medicinal Use



Cefotaxime CTX 5 mcg (Cephotaxime)

SD295E

Cefotaxime (Cephotaxime) CTX 5 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

IngredientsConcentrationCefotaxime5 mcg/disc(Cephotaxime)

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 $35 \pm 2^{\circ}$ 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*

•		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacterales (indications other than meningitis)	20	17-19	17
	Enterobacterales (meningitis)	20	-	20
Cefotaxime (Cephotaxime) 5 mcg	Haemophilus influenzae	27	-	27
	Moraxella catarrhalis	20	17-19	17
	Pasteurella multocida	26	-	26
	Streptococcus spp. viridans group	23	-	23
	Kingella kingae	27	-	27

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "CTX 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)*
E.coli (25922)	25 - 31
<i>K.pneumoniae</i> (700603)	12 - 18
S.pneumoniae (49619)	28 - 34

^{*=} Interpretive criteria & QC ranges as per 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

IVD

In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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Disclaimer: Revision: 03 / 2022



Linezolid LZ 10 mcg SD296E

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

Composition

IngredientsConcentrationLinezolid10 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Linezolid 10 mcg	Staphylococcus spp.	21	-	21
	Enterococcus spp.	20	-	20
	Streptococcus group A, B, C & G	19	-	19
	Corynebacterium spp.	25	-	25
	S.pneumoniae	22	-	22

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "LZ 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)*
S.aureus(29213)	21-27
E.faecalis (29212)	19-25
S. pneumoniae (49619)	23-29

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

Storage and Shelf-life:

Discs should always be stored at -20° C to $+8^{\circ}$ 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



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Revision: 03 / 2022

Disclaimer:



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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacteriaceae	23	20-22	19
	P.aeruginosa	19	16-18	15
Meropenem	Acientobacter & Staphylococcus	16	14-15	13
10 mcg	B.cepacia	20	16-19	15
	Haemophilus influenzae & Haemophilus parainfluenzae	20	-	-
	Neisseria meningitidis	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)*
E.coli (25922)	28-34
S.aureus (25923)	29-37
P.aeruginosa (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





In vitro diagnostic medical device

CE Marking



Storage temperature



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Revision: 03 / 2022

Disclaimer:



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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
Neomycin N 10 mcg	S.pseudontermedius & S. schelfer	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)
E. coli (25922)	13 - 19
S.aureus (29213)	17 - 25

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

Storage and Shelf-life:

Discs should always be stored at -20° C to $+8^{\circ}$ 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



Storage temperature



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Disclaimer



Bacitracin B 0.05 units

SD736

Bacitracin B 0.05 units discs are used for antimicrobial susceptibility testing of bacterial cultures as per Kirby-Bauer Method

Composition

*Ingredients Concentration
Bacitracin 0.05 units/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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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 "B 0.05" 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)
S.aureus(25923)	12 - 22

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
- 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 tes

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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Revision: 03 / 2022

Disclaimer:



Gatifloxacin GAT 5 mcg

SD737

Gatifloxacin GAT 5 mcg discs are used for antimicrobial susceptibility testing of bacterial cultures as per Bauer-Kirby Method.

Composition

*Ingredients Concentration
Gatifloxacin 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 for2-8 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 $35 \pm 2^{\circ}$ 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.

- 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*

		Sensitive	Intermediate	Resistant
Antimicrobial agent	Interpretative criteria for	mm or more	mm	mm or less
	Enterobacteriaceae, P.aeruginosa, Acientobacter & Enterococcus	18	15-17	14
	Staphylococcus	23	20-22	19
Gatifloxacin 5 mcg	Haemophilus influenzae & Haemophilus parainfluenzae	18	-	
3 meg	Neisseria gonorhoeae	38	34-37	33
	S.pneumoniae, Streptococcus spp. Viridians group, Streptococcus spp. beta haemolytic gruop	21	18-20	17

Quality Control:

Appearance: Filter paper discs of 6mm diameter with printed "GAT 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)*
E.coli (25922)	30-37
S.aureus (25923)	27-33
P.aeruginosa (27853)	20-28
S.pneumoniae (49619)	24-31

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



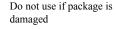
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CE Marking



Storage temperature







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