

DISKS FOR ANTIBIOTIC SUSCEPTIBILITY TESTING

50 DISKS CARTRIDGE

Study of susceptibility to antimicrobial agents.



2014/06

(BG)	• Други езици можете да получите от представителя на Bio-Rad. Задължително използвайте варианта на листовката, описан върху опаковката ([1]).	(FR)	• Pour obtenir d'autres langues, contacter votre agent Bio-Rad. Utiliser obligatoirement la version de la notice mentionnée sur la boîte ([1]).	(PL)	• Informacje w innych językach można otrzymać u miejscowego przedstawiciela firmy Bio-Rad. Należy bezwzględnie zapoznać się z ulotką dołączoną do produktu wskazaną na opakowaniu ([1]).
(CZ)	• Ostatní požadované jazyky jsou k dispozici u vašeho místního prodejce Bio-Rad. Používejte pouze verzi příbalového letáku uvedenou na obalu ([1]).	(GR)	• Τις άλλες απαιτούμενες γλώσσες μπορείτε να τις πάρετε από τον τοπικό πρoκτορά σας Bio-Rad. Χρησιμοποιήστε οπωσδήποτε την παραλλαγή ένθετου συσκευασίας που αναγράφεται στο κουτί ([1]).	(PT)	• É possível obter outros idiomas solicitados junto da sua agência Bio-Rad local. Consulte obrigatoriamente a versão do folheto informativo referida na embalagem ([1]).
(DE)	• Andere Sprachen sind auf Anfrage von Ihrer Bio-Rad -Vertretung vor Ort erhältlich. Es ist zwingend die auf der Schachtel genannte Version der Packungsbeilage zu verwenden ([1]).	(HR)	• Ostali traženi jezici mogu se dobiti od lokalnog Bio-Rad agenta. Potrebno je koristiti onu verziju uputstva za upotrebu koja je navedena na kutiji ([1]).	(RO)	• Alte limbi solicitate pot fi obținute de la agentul dumneavoastră local Bio-Rad. Este imperativ să utilizați versiunea prospectului menționată pe cutie ([1]).
(DK)	• Hvis der ønskes andre sprog, kan de fås hos den lokale Bio-Rad-repræsentant. Indlægssedlen, som er angivet på kassen, skal altid anvendes ([1]).	(HU)	• Egyéb nyelveken a helyi Bio-Rad képviselőtől szerezhető be. A dobozon szereplő verziószámú tájékoztatót kell kötelező érvénnyel használni ([1]).	(SE)	• Andra språk kan fås av din lokala Bio-Rad-återförsäljare. Använd alltid den version av bipacksedeln som anges på förpackningen ([1]).
(EE)	• Teistes keeltes juhendi saate soovi korral kohalikul Bio-Rad esindajalt. Kõigestuslik on kasutada karbil mainitud pakendi infolehe versiooni ([1]).	(IT)	• È possibile avere i Manuali di Istruzioni in altre lingue richiedendoli al collaboratore Bio-Rad di zona. Utilizzare tassativamente il manuale di istruzioni della versione citata sulla confezione ([1]).	(SI)	• Druge zelene jezike lahko dobite pri krajevem zastopniku Bio-Rad. Obvezno uporabite različico navodil za uporabo, navedeno na škatli ([1]).
(EN)	• Other requested languages can be obtained from your local Bio-Rad agent. Imperatively use the package insert version mentioned on the box ([1]).	(LT)	• Informacija gimtąja kalba galima gauti iš vietinio „Bio-Rad“ atstovo. Privaloma naudoti įdėtine paketo versiją, nurodytą ant dėžutės ([1]).	(SK)	• Ďalšie jazyky si môžete vyžiadať u svojho miestneho zástupcu Bio-Rad. Bezpodmienečne používajte verziu príbalového letáku uvedenú na škatuli ([1]).
(ES)	• Puede solicitar otros idiomas a su agente local Bio-Rad. Utilice obligatoriamente el paquete adjunto, versión indicada en la caja ([1]).	(NL)	• Andere gevraagde talen kunnen worden verkregen bij uw plaatselijke Bio-Rad agent. Gebruik uitsluitend de op de doos vermelde versie van de bijsluiter ([1]).		
(FI)	• Muita kielä on saatavilla omalta Bio-Rad -edustajaltanne. Käytävä ehdottomasti laatikossa mainittua tuoteselosteversiota ([1]).	(NO)	• Andre etterspurte språk kan fås fra din lokale Bio-Rad representant. Om nødvendig bruk pakningsvedlegget som følger med ([1]).		

1- CLINICAL VALUE

These disks are used to semi quantitatively evaluate the in vitro susceptibility to antimicrobial agents of rapidly growing bacteria and several difficult species by an agar diffusion method.

This method is based on a standardized procedure published by the WHO⁽¹⁾ and adopted as consensual standard by the CLSI^(2,3), CA-SFM⁽⁴⁾ and EUCAST⁽⁵⁾ (it is periodically revised).

Consult the most recent CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾ documents for guidelines concerning antibiotic susceptibility testing and interpretation of the results.

2- PRINCIPLE

Paper disks impregnated with a defined concentration of antimicrobial agent are deposited on the surface of an appropriate medium^(A) previously inoculated with a calibrated inoculum^(A) of pure and fresh culture of the bacterial strain to be tested. After incubation^(A), the Petri dishes are examined and the zones of inhibition around the disks are measured and compared to critical values^(A) for the various antimicrobial agents tested, in order to determine the clinical category of susceptibility (resistant, intermediate, susceptible...). The diameter of the zone of inhibition is proportional to the susceptibility of the bacterial strain tested

^(A)According to current guidelines CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾.

3- PRESENTATION

Bio-Rad disks are 6.5 mm disks made from superior quality absorbent paper and impregnated with precise concentrations of antimicrobial agents. The disks are clearly identified by a code, comprising 1 to 3 letters, printed on each side of the disk (see table 1). Bio-Rad disks are supplied in cartridges of 50 disks packaged in watertight containers containing a desiccant.

Table 1 : Bio-Rad disks for antibiotic susceptibility testing

	DISK CONTENT	SYMBOL	PACK SIZE	ORDER N°
Amikacin	30 µg	AKN30	4 x 50 Disks	66148
Amoxicillin	25 µg	AMX25	4 x 50 Disks	66138
Amoxicillin + Clavulanic Acid	2/1 µg	AUG3	4 x 50 Disks	66680
	20/10 µg	AMC30	4 x 50 Disks	66178
Ampicillin	2 µg	API2	4 x 50 Disks	67288
	10 µg	AMP10	4 x 50 Disks	66128
Ampicillin + Sulbactam	10/10 µg	SAM20	4 x 50 Disks	67018
Azithromycin	15 µg	AZM15	4 x 50 Disks	67008
Aztreonam	30 µg	ATM30	4 x 50 Disks	66928
Bacitracin	10 IU (130 µg)	BCT130	4 x 50 Disks	66158
Carbenicillin	100 µg	CRB100	4 x 50 Disks	66198
Cefaclor	30 µg	CEC30	4 x 50 Disks	67498
Cefalexin	30 µg	CXN30	4 x 50 Disks	66208
Cefamandole	30 µg	FAM30	4 x 50 Disks	66238




	DISK CONTENT	SYMBOL	PACK SIZE	ORDER N°
Cefazolin	30 µg	CZN30	4 x 50 Disks	66258
Cefepime	30 µg	FEP30	4 x 50 Disks	66098
Cefixime	5 µg	FIX5	4 x 50 Disks	67588
	10 µg	CFM10	4 x 50 Disks	66418
Cefoperazone	75 µg	CFP75	4 x 50 Disks	67618
	30 µg	CPZ30	4 x 50 Disks	66298
Cefoperazone + Sulbactam	75/30 µg	SCF105	4 x 50 Disks	66734
Cefotaxime	5 µg	COX5	4 x 50 Disks	67718
	30 µg	CTX30	4 x 50 Disks	66368
Cefotetan	30 µg	CTT30	4 x 50 Disks	66428
Cefoxitin	30 µg	FOX30	4 x 50 Disks	66228
Cefpirome	30 µg	CPO30	4 x 50 Disks	66468
Cefpodoxime	10 µg	CPD10	4 x 50 Disks	66918
Cefprozil	30 µg	CPR30	4 x 50 Disks	66488
Cefsulodin	30 µg	CFS30	4 x 50 Disks	66938
Ceftaroline	5 µg	CPN5	4 x 50 Disks	68658
Ceftazidime	10 µg	CZD10	4 x 50 Disks	67298
	30 µg	CAZ30	4 x 50 Disks	66308
Ceftibuten	30 µg	CTB30	4 x 50 Disks	67638
Ceftriaxone	30 µg	CRO30	4 x 50 Disks	66188
Cefuroxime	30 µg	CXM30	4 x 50 Disks	66358
Cephalothin	30 µg	CEF30	4 x 50 Disks	66218
Chloramphenicol	30 µg	CHL30	4 x 50 Disks	66278
Ciprofloxacin	5 µg	CIP5	4 x 50 Disks	68648
Clarithromycin	15 µg	CLR15	4 x 50 Disks	67058
Clindamycin	2 µg	CMN2	4 x 50 Disks	66328
Colistin	10 µg	COL10	4 x 50 Disks	67268
	50 µg	CST50	4 x 50 Disks	66348
Doripenem	10 µg	DOR10	4 x 50 Disks	67348
Doxycycline	30 µg	DOX30	4 x 50 Disks	66388
Ertapenem	10 µg	ETP10	4 x 50 Disks	67518
Erythromycin	15 µg	ERY15	4 x 50 Disks	66448
Flumequine	30 µg	UBN30	4 x 50 Disks	68918
Fosfomycin	50 µg	FSF50	4 x 50 Disks	66458
	200 µg	FOS200	4 x 50 Disks	67658
Fusidic Acid	10 µg	FAD10	4 x 50 Disks	66518
Gentamicin	10 µg	GMN10	4 x 50 Disks	66608
	10 IU (15 µg)	GMI15	4 x 50 Disks	66548
	30 µg	GME30	4 x 50 Disks	67318
Gentamicin (high load)	120 µg	HLG120	4 x 50 Disks	67598
	500 µg	GEN500	4 x 50 Disks	66578
Imipenem	10 µg	IPM10	4 x 50 Disks	66568
Isepamicin	30 µg	ISP30	4 x 50 Disks	66838
Kanamycin	30 µg	KMN30	4 x 50 Disks	66618
Kanamycin (high load)	1 mg	KAN1	4 x 50 Disks	66628
Levofloxacin	5 µg	LVX5	4 x 50 Disks	66858
Lincomycin	15 µg	LCN15	4 x 50 Disks	66678
Linezolid	10 µg	LIN10	4 x 50 Disks	67878
	30 µg	LZD30	4 x 50 Disks	67388
Mecillinam	10 µg	MEC10	4 x 50 Disks	66768
Meropenem	10 µg	MEM10	4 x 50 Disks	67048
Metronidazole	4 µg	MTR4	4 x 50 Disks	68908
Mezlocillin	75 µg	MZN75	4 x 50 Disks	66708
Minocycline	30 µg	MNO30	4 x 50 Disks	66728
Moxalactam	30 µg	MOX30	4 x 50 Disks	66698
Moxifloxacin	5 µg	MXF5	4 x 50 Disks	67098
Mupirocin	5 µg	MUP5	4 x 50 Disks	67088
	200 µg	PUM200	4 x 50 Disks	67078
Nalidixic Acid	30 µg	NAL30	4 x 50 Disks	68618
Neomycin	30 IU	NEO30	4 x 50 Disks	66748
Netilmicin	10 µg	NTM10	4 x 50 Disks	67798
	30 µg	NET30	4 x 50 Disks	66758
Nitrofurantoin	100 µg	NFE100	4 x 50 Disks	67328
	300 µg	FTN300	4 x 50 Disks	68678
Nitroxolin	20 µg	NIT20	4 x 50 Disks	68778
Norfloxacin	10 µg	NXN10	4 x 50 Disks	66338

	DISK CONTENT	SYMBOL	PACK SIZE	ORDER N°
	5 µg	NOR5	4 x 50 Disks	68238
Ofloxacin	5 µg	OFX5	4 x 50 Disks	68938
Oleandomycin	15 µg	OLE	4 x 50 Disks	66818
Oxacillin	1 µg	OXC1	4 x 50 Disks	66888
	5 µg	OXA5	4 x 50 Disks	66848
Oxolinic Acid	10 µg	OAD10	4 x 50 Disks	68628
Pefloxacin	5 µg	PEF5	4 x 50 Disks	68228
Penicillin	1 IU	PNG1	4 x 50 Disks	67788
	6 µg (10 IU)	PEN10	4 x 50 Disks	67218
Pipemidic Acid	20 µg	PIM20	4 x 50 Disks	68638
Piperacillin	30 µg	PIL30	4 x 50 Disks	68478
	75 µg	PIP75	4 x 50 Disks	67258
	100 µg	PIR100	4 x 50 Disks	67228
Piperacillin + Tazobactam	30/6 µg	PTZ36	4 x 50 Disks	67338
	75/10 µg	PPT85	4 x 50 Disks	66498
	100/10 µg	TZP110	4 x 50 Disks	67238
Polymixin	300 IU (50 µg)	PXB300	4 x 50 Disks	67248
Pristinamycin	15 µg	PTN15	4 x 50 Disks	67278
Quinupristin-Dalfopristin	15 µg	QDF15	4 x 50 Disks	67528
Rifampicin	5 µg	RIF5	4 x 50 Disks	66648
	30 µg	RAM30	4 x 50 Disks	67308
Sparfloxacin	5 µg	SPX5	4 x 50 Disks	66538
Spectinomycin	100 µg	SPT100	4 x 50 Disks	68798
Spiramycin	100 µg	SPN100	4 x 50 Disks	67378
Streptomycin	10 µg	SMN10	4 x 50 Disks	67418
Streptomycin (high load)	300 µg	HLS300	4 x 50 Disks	67608
	500 µg	STR500	4 x 50 Disks	67428
Sulphonamides	300 µg	SSS300	4 x 50 Disks	67578
	200 µg	SUL200	4 x 50 Disks	68408
Teicoplanin	30 µg	TEC30	4 x 50 Disks	68948
Telithromycin	15 µg	TEL15	4 x 50 Disks	67538
Temocillin	30 µg	TEM30	4 x 50 Disks	66068
Tetracycline	30 µg	TET30	4 x 50 Disks	67448
Ticarcillin	75 µg	TIC75	4 x 50 Disks	67458
Ticarcillin + Clavulanic Acid	75/10 µg	TCC85	4 x 50 Disks	67468
Tigecycline	15 µg	TGC15	4 x 50 Disks	67398
Tobramycin	10 µg	TMN10	4 x 50 Disks	67488
	30 µg	TOB30	4 x 50 Disks	67358
Trimethoprim + Sulfamethoxazole	1.25/23.75 µg	SXT25	4 x 50 Disks	68898
Trimethoprim	5 µg	TMP5	4 x 50 Disks	68888
Vancomycin	5 µg	VNC5	4 x 50 Disks	67828
	30 µg	VAN30	4 x 50 Disks	68928

4- STORAGE

The expiry date applies exclusively to disks contained in intact cartridges stored according to the manufacturer's instructions. The expiry date and batch number are indicated on each packaging (cartridge and container).

- Cartridges of disks must be stored in their containers at a temperature between +2°C and +8°C in a dry place.
- Container must be allowed to adjust to room temperature (18-30°C) before opening. After applying the disks, return unused cartridges to a temperature between +2°C and +8°C.
- Do not use disks after the expiry date. Do not use any cartridge of disks left at room temperature (18-30°C) for more than 8 hours without verifying an acceptable level of performance before continuing to use this cartridge⁽⁶⁾.
- If the cartridge remains in the distributor after dispatch, it is necessary to preserve at +2-8°C in a dry place **with desiccants inside**.

The stability of the disks, of open cartridges placed in distributors (preserved according to the recommendations with desiccants) was validated in routine conditions during 6 weeks, except for the antibiotic discs marked with the symbol , for which the stability in weeks is shown inside this symbol.

5- MATERIAL REQUIRED BUT NOT SUPPLIED

- disk dispenser: 6-7 disks Ref. # 50294
12-16 disks Ref. # 50295
- culture media according to current guidelines (CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾)
- reagents
- bacterial strains for quality control • opacity control equivalent to the Mac Farland 0.5 standard
- laboratory equipment necessary for antibiotic susceptibility testing by the agar diffusion method.



6- PRECAUTIONS

Follow the instructions of the current guidelines (CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾). Always observe the current techniques and precautions concerning protection against microbiological hazards. After use, sterilize the cultures and all contaminated material.

7- PROCEDURE

- Samples: disks must not be used for tests performed directly on biological samples. Refer to the current guidelines (CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾) defining preparation of the inoculum from a pure, fresh culture.
- Refer to the instructions recommended by the CLSI^(2,3), the CA-SFM⁽⁴⁾ or the EUCAST⁽⁵⁾ for all steps of antibiotic susceptibility testing and interpretation of the results: the CLSI^(2,3), CA-SFM⁽⁴⁾, or EUCAST⁽⁵⁾ propose standardised techniques for preparation of the inoculum, inoculation of Petri dishes, the choice and arrangement of test disks, the incubation temperature and incubation time. Good laboratory practice should also be applied at all times.

8- INTERPRETATION OF THE RESULTS

- Precisely measure the diameters of the zones of inhibition observed and refer to the critical diameters indicated by current guidelines (CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾).
- A clinical category (intermediate resistant, susceptible or not susceptible...) is given to each micro-organism as a function of the observed diameter and the critical diameters for the antibiotic tested.
- These criteria of clinical categorization according to critical diameters are periodically revised by the CLSI^(2,3), CA-SFM⁽⁴⁾, EUCAST⁽⁵⁾.

9- PERFORMANCE/QUALITY CONTROL

The performances of antibiotic disks are systematically controlled by using the following strains:

- *Escherichia coli* ATCC 25922
- *Pseudomonas aeruginosa* ATCC 27853
- *Neisseria gonorrhoeae* ATCC 49226
- *Enterococcus faecalis* ATCC 33186
- *Enterococcus faecalis* ATCC 29212
- *Staphylococcus aureus* ATCC 25923
- *Streptococcus pneumoniae* ATCC 49619
- *Haemophilus influenzae* ATCC 49247
- *Clostridium perfringens* ATCC 13124
- *Clostridium sporogenes* ATCC 19404

The table 2 indicates the accepted limits for the diameters of inhibition obtained by the agar diffusion method for the reference strains indicated below.

	Disk Content	Standard	Acceptable Zone Diameter (mm) Quality Control Limits				
			<i>E. coli</i> ATCC 25922	<i>S. aureus</i> ATCC 25923	<i>P. aeruginosa</i> ATCC 27853	<i>S. pneumoniae</i> ATCC 49619	<i>H. influenzae</i> ATCC 49247
Amikacin	30 µg	CLSI	19-26	20-26	18-26		
Amoxicillin	25 µg	Internal	19-25				
Amoxicillin + Clavulanic Acid	20/10 µg	CLSI	18-24	28-36			
Ampicillin	10 µg	CLSI	16-22	27-35			
Ampicillin + Sulbactam	10/10 µg	CLSI	19-24	29-37			
Azithromycin	15 µg	CLSI		21-26			
Aztreonam	30 µg	CLSI	28-36		23-29		
Bacitracin	10 UI	Internal		17-22			
Carbenicillin	100 µg	CLSI	23-29		18-24		
Cefaclor	30 µg	CLSI	23-27	27-31			
Cefalexin	30 µg	Internal	15-21	22-28			
Cefamandole	30 µg	CLSI	26-32	26-34			
Cefazolin	30 µg	CLSI	21-27	29-35			
Cefepime	30 µg	CLSI	31-37	23-29	24-30		
Cefixime	10 µg	Internal	26-30				
Cefixime	5 µg	CLSI	23-27				
Cefoperazone	30 µg	Internal	26-30	23-28	21-25		
Cefoperazone	75 µg	CLSI	28-34	24-33	23-29		
Cefoperazone + Sulbactam	75/30 µg	Internal	27-33	23-30			
Cefotaxime	30 µg	CLSI	29-35	25-31	18-22		
Cefotetan	30 µg	CLSI	28-34	17-23			
Cefoxitin	30 µg	CLSI	23-29	23-29			

	Disk Content	Standard	Acceptable Zone Diameter (mm) Quality Control Limits				
			<i>E. coli</i> ATCC 25922	<i>S. aureus</i> ATCC 25923	<i>P. aeruginosa</i> ATCC 27853	<i>S. pneumoniae</i> ATCC 49619	<i>H. influenzae</i> ATCC 49247
Cefpirome	30 µg	Internal	29-35	26-32	23-29		
Cefpodoxime	10 µg	CLSI	23-28	19-25			
Cefprozil	30 µg	CLSI	21-27	27-33			
Cefsulodin	30 µg	Internal		20-28	25-32		
Ceftazidime	30 µg	CLSI	25-32	16-20	22-29		
Ceftibuten	30 µg	CLSI	27-35				
Ceftriaxone	30 µg	CLSI	29-35	22-28	17-23		
Cefuroxime	30 µg	CLSI	20-26	27-35			
Cephalothin	30 µg	CLSI	15-21	29-37			
Chloramphenicol	30 µg	CLSI	21-27	19-26			
Ciprofloxacin	5 µg	CLSI	30-40	22-30	25-33		
Clarithromycin	15 µg	CLSI		26-32			
Clindamycin	2 µg	CLSI		24-30			
Colistin	10 µg	CLSI	11-17		11-17		
Colistin	50 µg	CA-SFM			17-22		
Doxycycline	30 µg	CLSI	18-24	23-29			
Ertapenem	10 µg	CLSI	29-36		13-21		
Erythromycine	15 µg	CLSI		22-30			
Flumequine	30 µg	Internal	25-31				
Fosfomycin	50 µg	CA-SFM		24-35			
Fosfomycin	200 µg	CLSI	22-30	25-33			
Fusidic acid	10 µg	CA-SFM		29-34			
Gentamicin	10 µg	CLSI	19-26	19-27	17-23		
Gentamicin	10 UI	CA-SFM	22-26	24-28	16-22		
Imipenem	10 µg	CLSI	26-32		20-28		
Isepamicin	30 µg	Internal	21-26	17-23	16-23		
Kanamycin	30 µg	CLSI	17-25	19-26			
Levofloxacin	5 µg	CLSI	29-37	25-30	19-26		
Lincomycin	15 µg	CA-SFM		25-29			
Linezolid	30 µg	CLSI		25-32			
Mecillinam	10 µg	CLSI	24-30				
Meropenem	10 µg	CLSI	28-34	29-37	27-33		
Mezlocillin	75 µg	CLSI	23-29		19-25		
Minocycline	30 µg	CLSI	19-25	25-30			
Moxalactam	30 µg	CLSI	28-35	18-24	17-25		
Moxifloxacin	5 µg	CLSI	28-35	28-35	17-25		
Mupirocin	5 µg	Internal		18-26			
Mupirocin	200 µg	CLSI		29-38			
Nalidixic Acid	30 µg	CLSI	22-28				
Neomycin	30 UI	Internal	17-23	18-27			
Netilmicin	30 µg	CLSI	22-30	22-31	17-23		
Nitrofurantoin	300 µg	CLSI	20-25	18-22			
Nitroxolin	20 µg	Internal	15-22				
Norfloxacin	5 µg	Internal	26-33	13-23	20-27		
Norfloxacin	10 µg	CLSI	28-35	17-28	22-29		
Ofloxacin	5 µg	Internal	25-32	21-28	14-20		
Oleandomycin	15 µg	Internal		19-28			
Oxacillin	5 µg	CA-SFM		27-34			
Oxacillin	1 µg	CLSI		18-24			
Oxolinic Acid	10 µg	Internal	22-30				
Pefloxacin	5 µg	CA-SFM	29-35	26-29			
Penicillin	6 µg	CLSI		26-37			
Pipemidic Acid	20 µg	Internal	22-30				
Piperacillin	100 µg	CLSI	24-30		25-33		

	Disk Content	Standard	Acceptable Zone Diameter (mm) Quality Control Limits				
			<i>E. coli</i> ATCC 25922	<i>S. aureus</i> ATCC 25923	<i>P. aeruginosa</i> ATCC 27853	<i>S. pneumoniae</i> ATCC 49619	<i>H. influenzae</i> ATCC 49247
Piperacillin	75 µg	Internal			24-33		
Piperacillin + Tazobactam	75/10 µg	Internal	22-29	24-31	24-33		
Piperacillin + Tazobactam	100/10 µg	CLSI	24-30	27-36	25-33		
Polymixin	300 UI	CLSI	13-19				
Pristinamycin	15 µg	CA-SFM		27-32			
Quinupristin-Dalfopristin	15 µg	CLSI		21-28		19-24	15-21
Rifampicin	5 µg	CLSI		26-34			
Rifampicin	30 µg	CA-SFM		34-39			
Sparfloxacin	5 µg	CLSI	30-38	27-33	21-29		
Spectinomycin	100 µg	Internal	19-25				
Spiramycin	100 µg	Internal		18-26			
Streptomycin	10 µg	CLSI	12-20	14-22			
Sulfonamides	300 µg	CLSI		24-34			
Sulfonamides	200 µg	Internal		17-27			
Teicoplanin	30 µg	CLSI		15-21			
Telithromycin	15 µg	CLSI				27-33	17-23
Temocillin	30 µg	Internal	17-23				
Tetracycline	30 µg	CLSI	18-25	24-30			
Ticarcillin	75 µg	CLSI	24-30		21-27		
Ticarcillin + Clavulanic Acid	75/10 µg	CLSI	24-30	29-37	20-28		
Tigecycline	15 µg	CLSI	20-27	20-25		23-29	
Tobramycin	10 µg	CLSI	18-26	19-29	20-26		
Trimethoprim	5 µg	CLSI	21-28	19-26			
Trimethoprim + Sulfamethoxazole	1,25/23,75 µg	CLSI	23-29	24-32			
Vancomycin	30 µg	CLSI		17-21			

For control limits (Internal standards or CLSI):

- Gentamicin 120 µg : *E. faecalis* ATCC 29212 (16-23 mm)
- Streptomycin 300 µg : *E. faecalis* ATCC 29212 (14-20 mm)
- Gentamicin 500 µg : *S. aureus* ATCC 25923 (30-34 mm) ; *E. faecalis* ATCC 29212 (18 -28 mm)
- Kanamycin 1mg : *S. aureus* ATCC 25923 (\geq 14 mm) ; *E. faecalis* ATCC 29212 (> 14 mm).
- Streptomycin 500 µg : *S. aureus* ATCC 25923 (24-28 mm) ; *E. faecalis* ATCC 29212 (14-25 mm).
- Metronidazole 4 µg : *Clostridium perfringens* ATCC 13124, *Clostridium sporogenes* ATCC 19404 \geq 15 mm
- Cefoperazone + Sulbactam 75 / 30 µg: *E. coli* ATCC 35218 (24-30 mm)
- Mupirocin 200 µg : *S. aureus* ATCC BAA-1708 (6 mm)
- Temocillin 30 µg : *E. coli* ATCC 35218 (22-28 mm)

Haemophilus influenzae ATCC 10211 is recommended as a useful additional quality control strain to verify the growth promotion properties of HTM.

Despite the lack of reliable disk diffusion interpretative criteria for *S.pneumoniae* with certain Beta-lactams, *Streptococcus pneumoniae* ATCC 49619 is the strain designated for quality control of all disks diffusion tests with all *Streptococcus* spp.

Neisseria gonorrhoeae ATCC 49226 is recommended to test spectinomycin disk with acceptable diameters of 23 to 29 mm (CLSI). Deterioration in oxacillin 1µg disk content is best assessed with QC organism *Staphylococcus aureus* ATCC 25923, with acceptable diameter of 18 to 24 mm.

Following the EUCAST guidelines (version V3.1. 2013), the performances of antibiotic disks are systematically controlled by using the following strains:

- | | |
|--|--|
| - <i>Escherichia coli</i> ATCC 25922 | - <i>Staphylococcus aureus</i> ATCC 29213 |
| - <i>Pseudomonas aeruginosa</i> ATCC 27853 | - <i>Streptococcus pneumoniae</i> ATCC 49619 |
| - <i>Enterococcus faecalis</i> ATCC 29212 | - <i>Haemophilus influenzae</i> NCTC 8468 |

The table 3 indicates the accepted limits for the diameters of inhibition obtained by the agar diffusion method for the reference strains indicated below.

	Disk Content	Acceptable Zone Diameter (mm) Quality Control Limits					
		<i>E. coli</i> ATCC 25922	<i>S. aureus</i> ATCC 29213	<i>P. aeruginosa</i> ATCC 27853	<i>S. pneumoniae</i> ATCC 49619	<i>H. influenzae</i> NCTC 8468	<i>E. faecalis</i> ATCC 29212
Amoxicillin + Clavulanic Acid	2/1 µg					17-23	
Ampicillin	2 µg					19-25	15-21
Cefotaxime	5 µg	25-31				29-35	
Ceftazidime	10 µg	23-29		21-27			
Ceftaroline	5 µg	24-30	24-30				
Doripenem	10 µg	27-35		28-35	31-37		
Gentamicin	30 µg						12-18
Linezolid	10 µg		21-27		23-29		19-25
Netilmicin	10 µg	18-24	20-26	15-21			
Nitrofurantoin	100 µg		17-23				18-24
Penicillin	1 IU		12-18				
Piperacillin	30 µg	21-27					
Piperacillin + Tazobactam	30/6 µg			23-29			20-26
Tobramycin	30 µg						12-18
Vancomycin	5 µg				17-23		10-16

10- QUALITY CONTROL OF THE MANUFACTURER

All manufactured and commercialized reagents are under complete quality system starting from reception of raw material to the final commercialization of the product.

Each lot is submitted to a quality control and only is released on the market when conforming to the acceptance criteria.

The records relating to production and control of each single lot are kept within our company

11- LIMITATIONS OF USE

- Clinical categorisations (resistant, intermediate, susceptible...) vary by only one millimeter, which corresponds to a common margin of error in the laboratory.
- Antimicrobial agents other than indicated in table 2 may be used. Susceptibility tests employing these agents should be interpreted on the basis of presence or absence of a definite zone of inhibition and should be considered as only qualitative until such time as interpretative zones have been established. All zone diameters should be recorded.
- The performances of the test depend not only on the activity of the disks, but also on factors such as the use of an appropriate inoculum and control strains, appropriate and previously tested culture media, an adequate storage.
- The final interpretation, as for all laboratory interpretations, can not be based on the results of one single test but on an overview of the clinical data and the biochemical, cytological and immunological results.

12- REFERENCES

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