

BD Diagnostics

QUALITY CONTROL LOG FOR BBL™ SENSI-DISC™ ANTIMICROBIAL DISCS†

Record Observed Zone Diameters in Millimeters (mm) Under Appropriate QC Strains Below

DATE: _____

TECHNOLOGIST'S _____

INITIALS: _____

Sensi-Disc™ Antimicrobial Agent	Disc Content	Sensi-Disc™ Lot Number	<i>E. coli</i> (ATCC™ 25922) ^a		<i>S. aureus</i> (ATCC™ 25923) ^a		<i>P. aeruginosa</i> (ATCC™ 27853) ^a		<i>E. coli</i> (ATCC™ 35218) ^a		<i>E. faecalis</i> (ATCC™ 29212) ^a		<i>H. influenzae</i> (ATCC™ 49247) ^b		<i>H. influenzae</i> (ATCC™ 49766) ^b		<i>N. gonorrhoeae</i> (ATCC™ 49226) ^c		<i>S. pneumoniae</i> (ATCC™ 49619) ^c	
			Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)	Control Limits (mm)	Results (mm)
Amikacin	30µg		19-26		20-26		18-26		–		–		–		–		–		–	
Amoxicillin/Clavulanic Acid ^d	20/10µg		18-24		28-36		–		17-22 ^f		–		15-23		–		–		–	
Ampicillin ^f	10µg		16-22		27-35		–		6 ^f		–		13-21		–		–		–	30-36
Ampicillin/Sulbactam ^f	10/10µg		19-24		29-37		–		13-19 ^f		–		14-22		–		–		–	–
Azithromycin	15µg		–		21-26		–		–		–		13-21		–		–		–	19-25
Azlocillin	75µg		–		–		24-30		–		–		–		–		–		–	–
Aztreonam	30µg		28-36		–		23-29		–		–		30-38		–		–		–	–
Carbenicillin	100µg		23-29		–		18-24		–		–		–		–		–		–	–
Cefaclor	30µg		23-27		27-31		–		–		–		–		25-31		–		–	24-32
Cefamandole	30µg		26-32		26-34		–		–		–		–		–		–		–	–
Cefazolin	30µg		21-27		29-35		–		–		–		–		–		–		–	–
Cefdinir	5µg		24-28		25-32		–		–		–		–		24-31 ^h		–		40-49	26-31
Cefepime	30µg		31-37		23-29		24-30		–		–		25-31		–		–		37-46 ^h	28-35
Cefixime	5µg		23-27		–		–		–		–		25-33		–		–		37-45	16-23
Cefmetazole	30µg		26-32		25-34		–		–		–		16-21		–		–		31-36	–
Cefonicid	30µg		25-29		22-28		–		–		–		–		30-38		–		–	–
Cefoperazone	75µg		28-34		24-33		23-29		–		–		–		–		–		–	–
Cefotaxime	30µg		29-35		25-31		18-22		–		–		31-39		–		–		38-48	31-39
Cefotaxime/Clavulanic Acid ⁱ	30/10µg		–		–		–		–		–		–		–		–		–	–
Cefotetan	30µg		28-34		17-23		–		–		–		–		–		–		–	30-36
Cefoxitin	30µg		23-29		23-29		–		–		–		–		–		–		33-41	–
Cefpodoxime	10µg		23-28		19-25		–		–		–		25-31		–		–		35-43	28-34
Cefprozil	30µg		21-27		27-33		–		–		–		–		20-27		–		–	25-32
Ceftazidime	30µg		25-32		16-20		22-29		–		–		27-35		–		–		35-43	–
Ceftazidime/Clavulanic Acid ⁱ	30/10µg		–		–		–		–		–		–		–		–		–	–
Ceftibuten	30µg		27-35 ^h		–		–		–		–		29-36 ^h		–		–		–	–
Ceftizoxime	30µg		30-36		27-35		12-17		–		–		29-39		–		–		42-51	28-34
Ceftriaxone	30µg		29-35		22-28		17-23		–		–		31-39		–		–		39-51	30-35
Cefuroxime	30µg		20-26		27-35		–		–		–		–		28-36		–		33-41	–
Cephalothin	30µg		15-21		29-37		–		–		–		–		–		–		–	26-32
Chloramphenicol	30µg		21-27		19-26		–		–		–		31-40		–		–		–	23-27
Cinoxacin	100µg		26-32		–		–		–		–		–		–		–		–	–
Ciprofloxacin	5µg		30-40		22-30		25-33		–		–		34-42		–		–		48-58	–
Clarithromycin	15µg		–		26-32		–		–		–		11-17		–		–		–	25-31
Clindamycin ^k	2µg		–		24-30		–		–		–		–		–		–		–	19-25
Doxycycline	30µg		18-24		23-29		–		–		–		–		–		–		–	–

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Enoxacin	10µg		28-36		22-28		22-28		–		–		–		–		43-51		–	
Ertapenem	10µg		29-36		24-31		13-21		–		–		20-28		27-33		–		28-35	
Erythromycin ^e	15µg		–		22-30		–		–		–		–		–		–		25-30	
Fosfomycin ^h	200µg		22-30		25-33		–		–		–		–		–		–		–	
Gatifloxacin	5µg		30-37		27-33		20-28		–		–		33-41		–		45-56		24-31	
Gemifloxacin	5µg		29-36		27-33		19-25		–		–		30-37		–		–		28-34	
Gentamicin	10µg		19-26		19-27		16-21		–		–		–		–		–		–	
Gentamicin ^g	120µg		–		–		–		–		16-23 ^g		–		–		–		–	
Imipenem	10µg		26-32		–		20-28		–		–		21-29		–		–		–	
Kanamycin	30µg		17-25		19-26		–		–		–		–		–		–		–	
Levofloxacin	5µg		29-37		25-30		19-26		–		–		32-40		–		–		20-25	
Linezolid	30µg		–		25-32		–		–		–		–		–		–		25-34	
Lomefloxacin	10µg		27-33		23-29		22-28		–		–		33-41		–		45-54		–	
Loracarbef	30µg		23-29		23-31		–		–		–		–		26-32		–		22-28	
Meropenem	10µg		28-34		29-37 ^h		27-33		–		–		20-28		–		–		28-35	
Mezlocillin	75µg		23-29		–		19-25		–		–		–		–		–		–	
Minocycline	30µg		19-25		25-30		–		–		–		–		–		–		–	
Moxalactam	30µg		28-35		18-24		17-25		–		–		–		–		–		–	
Moxifloxacin	5µg		28-35		28-35		17-25		–		–		31-39		–		–		25-31	
Nafcillin	1µg		–		16-22		–		–		–		–		–		–		–	
Nalidixic Acid	30µg		22-28		–		–		–		–		–		–		–		–	
Netilmicin	30µg		22-30		22-31		17-23		–		–		–		–		–		–	
Nitrofurantoin	300µg		20-25		18-22		–		–		–		–		–		–		23-29	
Norfloxacin	10µg		28-35		17-28		22-29		–		–		–		–		–		15-21	
Ofloxacin	5µg		29-33		24-28		17-21		–		–		31-40		–		43-51		16-21	
Oxacillin	1µg		–		18-24		–		–		–		–		–		–		≤ 12 ⁱ	
Penicillin	10 U		–		26-37		–		–		–		–		–		26-34		24-30	
Piperacillin ^f	100µg		24-30		–		25-33		12-18 ^f		–		–		–		–		–	
Piperacillin/Tazobactam ^f	100/10µg		24-30		27-36		25-33 ^h		24-30 ^f		–		33-38		–		–		–	
Polymyxin B ^e	300 U		13-19		–		14-18		–		–		–		–		–		–	
Quinupristin/Dalfopristin ^h	15µg		–		21-28 ^h		–		–		–		15-21		–		–		19-24 ^h	
Rifampin	5µg		8-10		26-34		–		–		–		22-30		–		–		25-30	
Sparfloxacin	5µg		30-38		27-33		21-29 ^h		–		–		32-40		–		43-51		21-27	
Spectinomycin	100µg		–		–		–		–		–		–		–		23-29		–	
Streptomycin	10µg		12-20		14-22		–		–		–		–		–		–		–	
Streptomycin ^g	300µg		–		–		–		–		14-20 ^g		–		–		–		–	

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Sulfisoxazole	250µg		15-23		24-34		–		–		–		–		–		–		–	
Telithromycin	15µg		–		24-30		–		–		–		17-23		–		–		27-33	
Tetracycline	30µg		18-25		24-30		–		–		–		14-22		–		30-42		27-31	
Ticarcillin ^f	75µg		24-30		–		21-27		6 ⁱ		–		–		–		–		–	
Ticarcillin/Clavulanic Acid ^f	75/10µg		24-30		29-37		20-28		21-25 ⁱ		–		–		–		–		–	
Tigecycline	15µg		20-27		20-25		9-13		–		–		23-31		–		30-40		23-29	
Tobramycin	10µg		18-26		19-29		19-25		–		–		–		–		–		–	
Trimethoprim	5µg		21-28		19-26		–		–		–		–		–		–		–	
Trimethoprim/Sulfamethoxazole ^a	1.25/23.75µg		23-29		24-32		–		–		–		24-32		–		–		20-28	
Vancomycin	30µg		–		17-21		–		–		–		–		–		–		20-27	

† Adapted in part from CLSI (formerly NCCLS) Document M100-S16 (M2), *Performance Standards for Antimicrobial Susceptibility Testing; Sixteenth Informational Supplement* to CLSI Approved Standard M2-A8, *Performance Standards for Antimicrobial Disk Susceptibility Tests, 8th ed.*, with permission. The complete standard may be obtained from the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898. (610) 688-1100.

- a New lots of BBL™ Mueller Hinton II Agar may be tested for sufficiently low levels of thymidine and thymine by testing with *Enterococcus faecalis* ATCC™ 29212 or 33186 and the trimethoprim/sulfamethoxazole disc. An inhibition zone ≥ 20 mm which is essentially free of fine colonies indicates a sufficiently low level of thymidine and thymine.
- b These quality control limits apply only to tests conducted with *Haemophilus influenzae* ATCC 49247 and 49766 using Haemophilus Test Medium Agar (HTM) incubated in 5% CO₂ (16-18 h). *H. influenzae* ATCC 10211 is recommended as a useful additional quality control strain to verify the growth promotion properties of HTM.
- c These quality control limits are applicable only to tests performed by disc diffusion using GC agar base and 1% defined growth supplement (e.g., BBL™ GC II Agar with IsoVitalEX™ Enrichment) incubated in 5% CO₂ (20-24 h).
- d These quality control limits are applicable only to tests performed by disc diffusion using Mueller Hinton Agar with 5% Sheep Blood incubated in 5% CO₂ (20-24 h).

e FDA-approved zone size recommendations from drug manufacturers not included in the CLSI M100-S16(M2).

f *Escherichia coli* ATCC 35218 has been designated for use in conjunction with *E. coli* ATCC 25922 for quality control of discs containing combinations of β-lactam and β-lactamase inhibitors. *E. coli* ATCC 35218 produces β-lactamase which should be inactivated by the inhibitor.

g For control limits of gentamicin 120µg and streptomycin 300µg discs, use *Enterococcus faecalis* ATCC 29212.

h CLSI-recommended zone sizes that differ from FDA-approved zone size recommendations.

i Following are quality control recommendations for combination discs used in screening and confirmatory tests for ESBLs in *Klebsiella pneumoniae*, *K. oxytoca* and *E. coli*. For *E. coli* ATCC 25922, see the control limits in the table for standard discs; with combination discs, a ≤ 2mm increase in zone diameter for antimicrobial agent tested alone vs. its zone when tested in combination with clavulanic acid. For the ESBL-producing *K. pneumoniae* ATCC 700603 tested with: cefpodoxime, 9-16mm; ceftazidime, 10-18mm; aztreonam, 9-17mm; cefotaxime, 17-25mm; ceftriaxone, 16-24mm. With the combination disc, a ≥ 3mm increase in cefotaxime/clavulanic acid zone diameter; ≥ 5mm increase in ceftazidime/clavulanic acid zone diameter.

j Deterioration in oxacillin disc content is best assessed with quality control organism *S. aureus* ATCC 25923, with an acceptable zone diameter of 18 to 24 mm.

k When disc approximation tests are performed with erythromycin and clindamycin, *S. aureus* ATCC™ BAA-977 (containing inducible *ermA*-mediated resistance) and *S. aureus* ATCC™ BAA-976 (containing *msrA*-mediated macrolide-only efflux) are recommended for quality assessment purposes (e.g., training, competency assessment, or test evaluation). *S. aureus* ATCC™ BAA-977 should demonstrate inducible clindamycin resistance (i.e., a positive D-zone test), while *S. aureus* ATCC™ BAA-976 should not demonstrate inducible clindamycin resistance. *S. aureus* ATCC™ 25923 should be used for routine quality control (e.g., weekly or daily) of erythromycin and clindamycin disks using standard Mueller-Hinton agar.

