ضمائم

ضمیمه شماره ۱

جداول زیر بر گرفته از کتاب Tietz و شامل مقادیر عدم دقت مجاز برای برخی کمیتها بر اساس معیارهای CLIA و Fraser می‌باشد.

درستون اول با عنوان Analyte اسامی کمیتها نوشته شده است.

در ستون دوم با عنوان Decision level xc غلظتی از آنالیت که به لحاظ بالینی ارزش دارد و انحراف معیار مجازبرای آن غلظت محاسبه شده، آمده است.

ستون سوم محدوده مجاز خطا را به درصد و براساس معیارهای CLIA نشان می‌دهد.

ستون چهارم مقدار انحراف معیارمجاز را براساس معیارهای CLIA نشان می‌دهد. که خود از تقسیم عدد مندرج در ستون ششم بر ۴ بدست می‌آید. برای مثال فوق $10 : 4 = 2.5$

ستون پنجم مقدار انحراف معیار مجاز را بر اساس نظریه Fraser نشان می‌دهد. این مقدار برای ALT معادل 6.1 می‌باشد.

ستون ششم محدوده مجاز خطا را به غلظت و براساس معیارهای CLIA نشان می‌دهد. بعنوان مثال خطای مجاز برای ALT در غلظت50U/L معادل 20% است. که این مقدار خود برابر 10U/L (ستون ششم) می‌باشد.

$$50 \times 20\% = 10$$

برای محاسبه CV% از فرمول زیر استفاده می‌شود.

$$CV\% = \frac{SD \times 100}{mean}$$

بر این اساس CV% مجاز برای ALT بر اساس معیارهای CLIA معادل ۵٪ =۵۰÷ ۱۰۰× ۲/۵ و بر اساس نظریه Fraser معادل ۱۲٪= ۵۰÷۱۰۰×۶/۱ خواهد بود.

بدیهی است که آزمایشگاه با توجه به توانایی و نیاز خود، می‌بایست حتی‌المکان کوچکترین خطای مجاز را انتخاب نماید.

ضمیمه شماره ۱

Analytical Goals

Analyte	Decision Level, x_c	Acceptable Performance, CLIA '88[104]	PRECISION GOALS (MAXIMUM SD)		Fixed-Limit Goals (Maximum Total Error) CLIA '88
			$x_c \times$ CLIA/4	Fraser[a]	
Routine Chemistry					
Alanine aminotransferase[b]	50 U/L	20%	2.5	6.1	10
Albumin	3.5 g/dL	10%	0.09	0.06	0.35
Alkaline phosphatase	150 U/L	30%	11	4.8	45
Amylase	100 U/L	30%	7.5	4.8	30
Aspartate aminotransferase[b]	30 U/L	20%	1.5	1.8	6.0
Bicarbonate	20 mmol/L			0.46[c]	
	30 mmol/L			0.69[c]	
Bilirubin, total[b]	1.0 mg/dL	0.4	0.10	0.13	0.40
	20 mg/dL	20%	1.0	2.6	4.0
Blood gas, PCO_2	35 mm Hg	5 mm Hg	1.3	0.84	5.0
	50 mm Hg	5 mm Hg	1.3	1.2	5.0
Blood gas, PO_2	30 mm Hg	3 SD[d]	0.75 SD[d]		3 SD[d]
	80 mm Hg	3 SD	0.75 SD		3 SD
	195 mm Hg	3 SD	0.75 SD		3 SD
Blood gas, pH	7.35	0.04	0.01	0.01[e]	0.04
	7.45	0.04	0.01	0.01[e]	0.04
Calcium, total[b]	7.0 mg/dL	1.0	0.25	0.07	1.0
	10.8 mg/dL	1.0	0.25	0.11	1.0
	13.0 mg/dL	1.0	0.25	0.13	1.0
Chloride[b]	90 mmol/L	5.0%	1.1	0.54	4.5
	110 mmol/L	5.0%	1.4	0.66	5.5
Cholesterol, total[b]	200 mg/dL	10%	5.0	6.0	20
Cholesterol, high-density lipoprotein	35 mg/dL	30%	2.6	1.3	10.5
	65 mg/dL	30%	4.9	2.3	19.5
Creatine kinase[b]	200 U/L	30%	15	23	60
Creatine kinase, MB isoenzyme	13 µg/L	3 SD	0.75 SD	1.2	3 SD
Creatinine	1.0 mg/dL	0.30	0.08	0.02	0.30
	3.0 mg/dL	15%	0.11	0.07	0.45

Analytical Goals—*Continued*

Analyte	Decision Level, x_c	Acceptable Performance, CLIA '88[104]	Precision Goals (Maximum SD)		Fixed-Limit Goals (Maximum Total Error) CLIA '88
			$x_c \times$ CLIA/4	Fraser[a]	
Routine Chemistry—Cont'd					
Glucose[b]	50 mg/dL	6.0	1.5	1.7	6.0
	126 mg/dL	10%	3.15	4.2	12.6
	200 mg/dL	10%	5.0	6.6	20
Iron	150 µg/dL	20%	7.5	20	30
Lactate dehydrogenase	300 U/L	20%	15	13	60
Lactate dehydrogenase isoenzymes	100 U/L	30%	7.5	3.8	30
Magnesium	2.0 mg/dL	25%	0.13	0.04	0.50
Phosphate, inorganic	4.5 mg/dL			0.19	
Potassium[b]	3.0 mmol/L	0.50	0.13	0.07	0.50
	6.0 mmol/L	0.50	0.13	0.14	0.50
Protein, total[b]	7.0 g/dL	10%	0.18	0.10	0.70
Sodium[b]	130 mmol/L	4.0	1.0	0.52	4.0
	150 mmol/L	4.0	1.0	0.60	4.0
Triglycerides	160 mg/dL	25%	1	17	40
Urea nitrogen[b]	27.0 mg/dL	9%	0.6	1.7	2.4
Uric acid	6.0 mg/dL	17%	0.25	0.26	1.02
Endocrinology and Related Markers					
11-Deoxycortisol	8.0 µg/L			0.86[f]	
17-OH Progesterone	0.5 µg/L			0.073[c]	
Aldosterone	15 ng/dL			2.2	
	30 ng/dL			4.4	
Androstenedione	260 ng/dL			15	
CA 15-3	25 U/mL			0.73	
CA 125	35 U/mL			2.4	
CA 549	11 U/mL			0.5	
Carcinoembryonic antigen	5 ng/mL			0.23	
Chorionic gonadotropin	25 IU/L	3 SD	0.75 SD		
	10,000 IU/L	3 SD	0.75 SD		
Cortisol	5 µg/dL	25%	0.31	0.53	1.25
	30 µg/dL	25%	1.88	3.15	7.5
C-peptide	37 µg/L			1.7	
Dehydroepiandrosterone sulfate	2000 µg/L			34	
	4500 µg/L			77	
Estradiol	60 ng/L			6.8	
	450 ng/L			51	
Follicle-stimulating hormone	10 U/L			0.51	
	95 U/L			4.8	
Luteinizing hormone	6 U/L			0.44	
	55 U/L			4.0	
Prolactin	15 µg/L			0.53[c]	
	200 µg/L			7.0[c]	
Prostate-specific antigen	2 µg/L			0.14	
T_3 uptake	25%	3 SD	0.75 SD		3 SD

Analytical Goals—*Continued*

Analyte	Decision Level, x_c	Acceptable Performance, CLIA '88[104]	PRECISION GOALS (MAXIMUM SD)		Fixed-Limit Goals (Maximum Total Error) CLIA '88
			$x_c \times$ CLIA/4	Fraser[a]	
Endocrinology and Related Markers—Cont'd					
Testosterone	90 ng/dL			4.0	
	1000 ng/dL			44	
Thyroid-stimulating hormone	0.3 mIU/L	3 SD	0.75 SD	0.030	3 SD
	5.0 mIU/L	3 SD	0.75 SD	0.50	3 SD
Thyroxine, free	0.8 ng/dL	3 SD	0.75 SD	0.023[c]	3 SD
	4.0 ng/dL	3 SD	0.75 SD	0.11[c]	3 SD
Thyroxine, total	3.0 µg/dL	1.0	0.25	0.09	1.0
	13 µg/dL	20%	0.65	0.39	2.6
Transferrin	375 mg/dL			5.6	
Triiodothyronine	80 ng/dL	3 SD	0.75 SD	3.5	3 SD
	200 ng/dL	3 SD	0.75 SD	8.8	3 SD
Toxicology and Therapeutic Drug Monitoring					
Alcohol, blood	0.10 g/dL	25%	0.006		0.025
Carbamazepine	8 mg/L	25%	0.50	0.51[f]	2.0
	12 mg/L	25%	0.75	0.77[f]	3.0
Digoxin	0.8 µg/L	0.20	0.05	0.03[f]	0.20
	2.0 µg/L	20%	0.10	0.08[f]	0.40
Ethosuximide	40 mg/L	20%	2.0	2.0[g]	8.0
	100 mg/L	20%	5.0	4.9[g]	20.0
Gentamicin	10 mg/L	25%	0.6		2.5
Lead, blood	10 µg/dL	4.0	1.0		4.0
	40 µg/dL	4.0	1.0		4.0
Lithium	0.5 mmol/L	0.3	0.08	0.02[f]	0.3
	1.5 mmol/L	20%	0.08	0.06[f]	0.3
Phenobarbital	15 mg/L	20%	0.75	0.33[f]	3.0
	40 mg/L	20%	2.0	0.88[f]	8.0
Phenytoin	10 mg/L	25%	0.6	0.36[f]	2.5
	20 mg/L	25%	1.2	0.72[f]	5.0
Primidone	5 mg/L	25%	0.3	0.56[g]	1.3
	12 mg/L	25%	0.75	1.36[g]	3.0
Procainamide	4 mg/L	25%	0.25		1.0
	20 mg/L	25%	1.25		5.0
Quinidine	7 mg/L	25%	0.45		1.8
Theophylline	10 mg/L	25%	0.63	1.1[f]	2.5
	20 mg/L	25%	1.2	2.2[f]	5.0
Valproate	50 mg/L	25%	3.1	3.2[f]	12.5
	100 mg/L	25%	6.2	6.4[f]	25
Hematology					
Cell identification		90% consensus			
Erythrocyte count	4.5 M/µL	6%	0.07	0.07	0.27
	5.9 M/µL	6%	0.09	0.09	0.35
Fibrinogen	150 mg/dL	20%	7.5	8	30
Hematocrit	35%	6%	0.53%	0.49%	2.1%
	50%	6%	0.75%	0.70%	3.0%

Analytical Goals—*Continued*

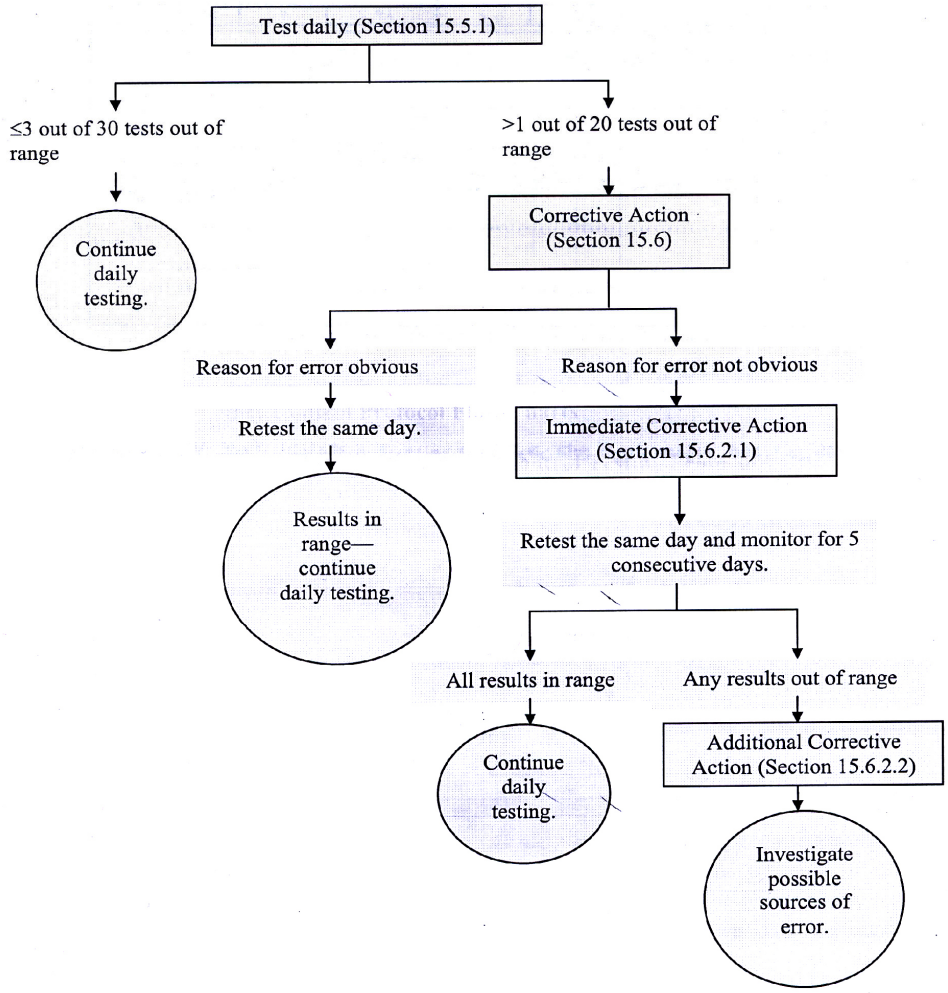
Analyte	Decision Level, x_c	Acceptable Performance, CLIA '88[104]	Precision Goals (Maximum SD)		Fixed-Limit Goals (Maximum Total Error) CLIA '88
			$x_c \times$ CLIA/4	Fraser[a]	
Hematology—Cont'd					
Hemoglobin	12 g/dL	7%	0.21	0.17	0.84
	17 g/dL	7%	0.30	0.24	1.19
Leukocyte count	3.5 K/μL	15%	0.13	0.19	0.52
	11 K/μL	15%	0.41	0.58	1.65
Partial thromboplastin time	40 s	15%	1.5		6.0
Platelet count	50 K/μL	25%	3.12	2.3	12.5
	500 K/μL	25%	31.2	23	125
Prothrombin time	INR 3.6	15%	INR 0.14		INR 0.54
White cell differentiation		3 SD			3 SD
Immunology					
$Alpha_1$- antitrypsin	80 mg/dL	3 SD	0.75 SD		3 SD
Alpha-fetoprotein	10 μg/L	3 SD	0.75 SD		3 SD
Antinuclear antibody		2 Titers or ±	1 Titer		
Antistreptolysin O		2 Titers or ±	1 Titer		
Antihuman immunodeficiency virus		R/N	R/N		
Complement C3	100 mg/dL	3 SD	0.75 SD	2.6	3 SD
Complement C4	20 mg/dL	3 SD	0.75 SD	0.9	3 SD
Hepatitis (HB_sAg, anti-HB_c, HB_eAg)		R/N	R/N		
IgA	400 mg/dL	3 SD	0.75 SD	10	3 SD
IgE	200 IU/mL	3 SD	0.75 SD		3 SD
IgG	500 mg/dL	25%	31	12	125
	2000 mg/dL	25%	125	46	500
IgM	300 mg/dL	3 SD	0.75 SD	9.0	3 SD
Infectious mononucleosis		2 Titers or ±	1 Titer		
Rheumatoid factor		2 Titers or ±	1 Titer		
Rubella		2 Titers or ±	1 Titer		

R/N, Reactive/nonreactive.

ضمیمه شماره ۲

Appendix A. Quality Control Protocol Flow Charts

Disk Diffusion Daily Quality Control Testing Protocol

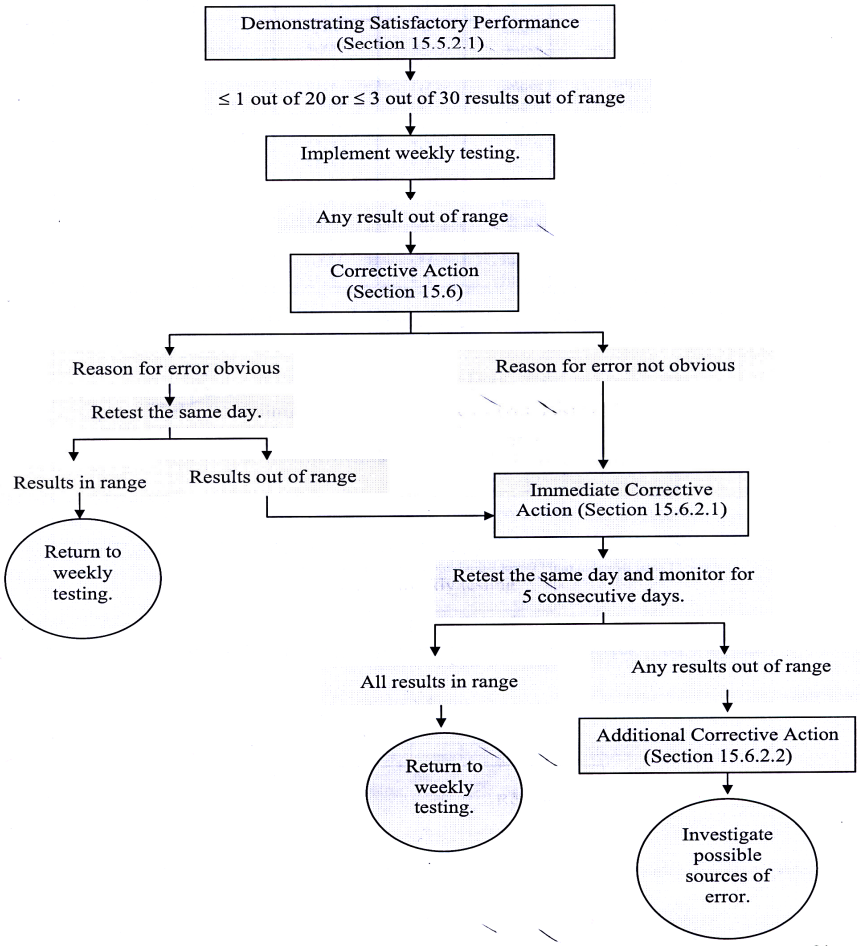


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ضمیمه شماره ۲ / ادامه

Appendix A. (Continued)

Disk Diffusion Weekly Quality Control Testing Protocol



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ضمیمه شماره ۳

Table 3. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Disk Diffusion Testing of Nonfastidious Organisms (Using Mueller-Hinton Medium Without Blood or Other Supplements)

Antimicrobial Agent	Disk Content	*Escherichia coli* ATCC® 25922[a]	*Staphylococcus aureus* ATCC® 25923	*Pseudomonas aeruginosa* ATCC® 27853	*Escherichia coli* ATCC® 35218[b]
Amikacin	30 µg	19-26	20-26	18-26	-
Amoxicillin-clavulanic acid	20/10 µg	18-24	28-36	-	17-22
Ampicillin	10 µg	16-22	27-35	-	6
Ampicillin-sulbactam	10/10 µg	19-24	29-37	-	13-19
Azithromycin	15 µg	-	21-26	-	-
Azlocillin	75 µg	-	-	24-30	-
Aztreonam	30 µg	28-36	-	23-29	-
Carbenicillin	100 µg	23-29	-	18-24	-
Cefaclor	30 µg	23-27	27-31	-	-
Cefamandole	30 µg	26-32	26-34	-	-
Cefazolin	30 µg	21-27	29-35	-	-
Cefdinir	5 µg	24-28	25-32	-	-
Cefditoren	5 µg	22-28	20-28	-	-
Cefepime	30 µg	31-37	23-29	24-30	-
Cefetamet	10 µg	24-29	-	-	-
Cefixime	5 µg	23-27	-	-	-
Cefmetazole	30 µg	26-32	25-34	-	-
Cefonicid	30 µg	25-29	22-28	-	-
Cefoperazone	75 µg	28-34	24-33	23-29	-
Cefotaxime	30 µg	29-35	25-31	18-22	-
Cefotetan	30 µg	28-34	17-23	-	-
Cefoxitin	30 µg	23-29	23-29	-	-
Cefpodoxime	10 µg	23-28	19-25	-	-
Cefprozil	30 µg	21-27	27-33	-	-
Ceftazidime	30 µg	25-32	16-20	22-29	-
Ceftibuten	30 µg	27-35	-	-	-
Ceftizoxime	30 µg	30-36	27-35	12-17	-
Ceftobiprole	**30 µg**	**30-36**	**26-34**	**24-30**	-
Ceftriaxone	30 µg	29-35	22-28	17-23	-
Cefuroxime	30 µg	20-26	27-35	-	-
Cephalothin	30 µg	15-21	29-37	-	-
Chloramphenicol	30 µg	21-27	19-26	-	-
Cinoxacin	100 µg	26-32	-	-	-
Ciprofloxacin	5 µg	30-40	22-30	25-33	-
Clarithromycin	15 µg	-	26-32	-	-
Clinafloxacin	5 µg	31-40	28-37	27-35	-
Clindamycin[c]	2 µg	-	24-30	-	-
Daptomycin[d]	30 µg	-	18-23	-	-
Dirithromycin	15 µg	-	18-26	-	-
Doripenem	10 µg	28-35	33-42	29-35	-
Doxycycline	30 µg	18-24	23-29	-	-
Enoxacin	10 µg	28-36	22-28	22-28	-
Ertapenem	10 µg	29-36	24-31	13-21	-
Erythromycin[c]	15 µg	-	22-30	-	-
Fleroxacin	5 µg	28-34	21-27	12-20	-
Fosfomycin[e]	200 µg	22-30	25-33	-	-
Garenoxacin	5 µg	28-35	30-36	19-25	-
Gatifloxacin	5 µg	30-37	27-33	20-28	-
Gemifloxacin	5 µg	29-36	27-33	19-25	-
Gentamicin[f]	10 µg	19-26	19-27	16-21	-
Grepafloxacin	5 µg	28-36	26-31	20-27	-
Imipenem	10 µg	26-32	-	20-28	-
Kanamycin	30 µg	17-25	19-26	-	-
Levofloxacin	5 µg	29-37	25-30	19-26	-
Linezolid	30 µg	-	25-32	-	-
Lomefloxacin	10 µg	27-33	23-29	22-28	-
Loracarbef	30 µg	23-29	23-31	-	-
Mecillinam	10 µg	24-30	-	-	-

ضمیمه شماره ۳/ادامه

Table 3. (Continued)

Antimicrobial Agent	Disk Content	*Escherichia coli* ATCC® 25922[a]	*Staphylococcus aureus* ATCC® 25923	*Pseudomonas aeruginosa* ATCC® 27853	*Escherichia coli* ATCC® 35218[b]
Meropenem	10 µg	28-34	29-37	27-33	-
Methicillin	5 µg	-	17-22	-	-
Mezlocillin	75 µg	23-29	-	19-25	-
Minocycline	30 µg	19-25	25-30	-	-
Moxalactam	30 µg	28-35	18-24	17-25	-
Moxifloxacin	5 µg	28-35	28-35	17-25	-
Nafcillin	1 µg	-	16-22	-	-
Nalidixic acid	30 µg	22-28	-	-	-
Netilmicin	30 µg	22-30	22-31	17-23	-
Nitrofurantoin	300 µg	20-25	18-22	-	-
Norfloxacin	10 µg	28-35	17-28	22-29	-
Ofloxacin	5 µg	29-33	24-28	17-21	-
Oxacillin	1 µg	-	18-24	-	-
Penicillin	10 units	-	26-37	-	-
Piperacillin	100 µg	24-30	-	25-33	12-18
Piperacillin-tazobactam	100/10 µg	24-30	27-36	25-33	24-30
Quinupristin-dalfopristin	15 µg	-	21-28	-	-
Rifampin	5 µg	8-10	26-34	-	-
Sparfloxacin	5 µg	30-38	27-33	21-29	-
Streptomycin[f]	10 µg	12-20	14-22	-	-
Sulfisoxazole[g]	250 µg or 300 µg	15-23	24-34	-	-
Teicoplanin	30 µg	-	15-21	-	-
Telavancin	30 µg	-	16-20	-	-
Telithromycin	15 µg	-	24-30	-	-
Tetracycline	30 µg	18-25	24-30	-	-
Ticarcillin	75 µg	24-30	-	21-27	6
Ticarcillin-clavulanic acid	75/10 µg	24-30	29-37	20-28	21-25
Tigecycline	15 µg	20-27	20-25	9-13	-
Tobramycin	10 µg	18-26	19-29	19-25	-
Trimethoprim[g]	5 µg	21-28	19-26	-	-
Trimethoprim-sulfamethoxazole[g]	1.25/23.75 µg	23-29	24-32	-	-
Trospectomycin	30 µg	10-16	15-20	-	-
Trovafloxacin	10 µg	29-36	29-35	21-27	-
Vancomycin	30 µg	-	17-21	-	-

NOTE: Information in boldface type is considered tentative for one year.

Footnotes

a. ATCC is a registered trademark of the American Type Culture Collection.
b. Careful organism maintenance is required; refer to M2-A9, Section 15.3.
c. When disk 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 *msr*A- 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.
d. Some lots of Mueller-Hinton agar are deficient in calcium and give small zones.
e. The 200-µg fosfomycin disk contains 50 µg of glucose-6-phosphate.
f. For control limits of gentamicin 120-µg and streptomycin 300-µg disks, use *Enterococcus faecalis* ATCC® 29212 (gentamicin: 16 to 23 mm; streptomycin: 14 to 20 mm).
g. These agents can be affected by excess levels of thymidine and thymine. See M2-A9, Section 7.1.4 for guidance should a problem with quality control occur.

ضمیمه شماره ۳/ادامه

Table 3A. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Disk Diffusion Testing of Fastidious Organisms

Antimicrobial Agent	Disk Content	*Haemophilus influenzae* ATCC® 49247[a]	*Haemophilus influenzae* ATCC® 49766	*Neisseria gonorrhoeae* ATCC® 49226	*Streptococcus pneumoniae* ATCC® 49619[b]
Amoxicillin-clavulanic acid[c]	20/10 µg	15-23	-	-	-
Ampicillin	10 µg	13-21	-	-	30-36
Ampicillin-sulbactam	10/10 µg	14-22	-	-	-
Azithromycin	15 µg	13-21	-	-	19-25
Aztreonam	30 µg	30-38	-	-	-
Cefaclor	30 µg	-	25-31	-	24-32
Cefdinir	5 µg	-	24-31	40-49	26-31
Cefditoren	5 µg	25-34	-	-	27-35
Cefepime	30 µg	25-31	-	37-46	28-35
Cefetamet	10 µg	23-28	-	35-43	-
Cefixime	5 µg	25-33	-	37-45	16-23
Cefmetazole	30 µg	16-21	-	31-36	-
Cefonicid	30 µg	-	30-38	-	-
Cefotaxime	30 µg	31-39	-	38-48	31-39
Cefotetan	30 µg	-	-	30-36	-
Cefoxitin	30 µg	-	-	33-41	-
Cefpodoxime	10 µg	25-31	-	35-43	28-34
Cefprozil	30 µg	-	20-27	-	25-32
Ceftazidime	30 µg	27-35	-	35-43	-
Ceftibuten	30 µg	29-36	-	-	-
Ceftizoxime	30 µg	29-39	-	42-51	28-34
Ceftobiprole[d]	**30 µg**	**28-36**	**30-38**	-	**33-39**
Ceftriaxone	30 µg	31-39	-	39-51	30-35
Cefuroxime	30 µg	-	28-36	33-41	-
Cephalothin	30 µg	-	-	-	26-32
Chloramphenicol	30 µg	31-40	-	-	23-27
Ciprofloxacin	5 µg	34-42	-	48-58	-
Clarithromycin	15 µg	11-17	-	-	25-31
Clinafloxacin	5 µg	34-43	-	-	27-34
Clindamycin	2 µg	-	-	-	19-25
Daptomycin[e]	30 µg	-	-	-	19-26
Dirithromycin	15 µg	-	-	-	18-25
Doripenem	10 µg	21-31	-	-	30-38
Enoxacin	10 µg	-	-	43-51	-
Ertapenem	10 µg	20-28	27-33	-	28-35
Erythromycin	15 µg	-	-	-	25-30
Fleroxacin	5 µg	30-38	-	43-51	-
Garenoxacin	5 µg	33-41	-	-	26-33
Gatifloxacin	5 µg	33-41	-	45-56	24-31
Gemifloxacin	5 µg	30-37	-	-	28-34
Grepafloxacin	5 µg	32-39	-	44-52	21-28
Imipenem	10 µg	21-29	-	-	-
Levofloxacin	5 µg	32-40	-	-	20-25
Linezolid	30 µg	-	-	-	25-34
Lomefloxacin	10 µg	33-41	-	45-54	-
Loracarbef	30 µg	-	26-32	-	22-28
Meropenem	10 µg	20-28	-	-	28-35
Moxifloxacin	5 µg	31-39	-	-	25-31
Nitrofurantoin	300 µg	-	-	-	23-29
Norfloxacin	10 µg	-	-	-	15-21
Ofloxacin	5 µg	31-40	-	43-51	16-21
Oxacillin	1 µg	-	-	-	≤ 12[f]
Penicillin	10 units	-	-	26-34	24-30
Piperacillin-tazobactam	100/10 µg	33-38	-	-	-
Quinupristin-dalfopristin	15 µg	15-21	-	-	19-24
Rifampin	5 µg	22-30	-	-	25-30

ضمیمه شماره ۳/ادامه

Table 3A. (Continued)

Antimicrobial Agent	Disk Content	*Haemophilus influenzae* ATCC® 49247[a]	*Haemophilus influenzae* ATCC® 49766	*Neisseria gonorrhoeae* ATCC® 49226	*Streptococcus pneumoniae* ATCC® 49619[b]
Sparfloxacin	5 µg	32-40	-	43-51	21-27
Spectinomycin	100 µg	-	-	23-29	-
Telavancin	30 µg	-	-	-	17-24
Telithromycin	15 µg	17-23	-	-	27-33
Tetracycline	30 µg	14-22	-	30-42	27-31
Tigecycline	15 µg	23-31	-	30-40	23-29
Trimethoprim-sulfamethoxazole	1.25/23.75 µg	24-32	-	-	20-28
Trospectomycin	30 µg	22-29	-	28-35	-
Trovafloxacin	10 µg	32-39	-	42-55	25-32
Vancomycin	30 µg	-	-	-	20-27

Disk Diffusion Testing Conditions for Clinical Isolates and Performance of Quality Control

Organism	*Haemophilus influenzae*	*Neisseria gonorrhoeae*	Streptococci and *Neisseria meningitidis*
Medium	*Haemophilus* Test Medium	GC agar base and 1% defined growth supplement. The use of a cysteine-free growth supplement is not required for disk diffusion testing.	MHA supplemented with 5% defibrinated sheep blood
Inoculum	Direct colony suspension	Direct colony suspension	Direct colony suspension
Incubation Characteristics	5% CO_2; 16 to 18 hours; 35 °C	5% CO_2; 20 to 24 hours; 35 °C	5% CO_2; 20 to 24 hours; 35 °C

NOTE: Information in boldface is considered tentative for one year.

Footnotes

a. ATCC is a registered trademark of American Type Culture Collection.

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

c. When testing *Haemophilus* on HTM, the acceptable limits for QC strain *E. coli* ATCC® 35218 are 17 to 22 mm for amoxicillin-clavulanic acid **when incubated in ambient air**.

d. Either *H. influenzae* ATCC® 49247 or 49766 may be used for routine quality control testing.

e. Some lots of Mueller-Hinton agar are deficient in calcium and give small zones.

f. Deterioration in oxacillin disk content is best assessed with QC organism *Staphylococcus aureus* ATCC® 25923, with an acceptable zone diameter of 18 to 24 mm.

ضمیمه شماره ۴

