

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-16

DATE: January 8, 2004

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Policy and Data Reporting Guidance for First Survey Cycle Following the Effective Date of CMS-2226-F

Letter Summary

Begin Laboratory Survey Process Effective January 12, 2004:

The national implementation date for the State agencies to use the revised laboratory regulations, interpretive guidelines and survey protocol is January 12, 2004.

This memorandum contains information addressing:

- **ASPEN Survey Explorer** updates to include the current CLIA regulations and the associated Interpretive Guidelines
- **OSCAR System Conversion** to accommodate “new” D tags
- **Special Reporting** for tracking deficiency citations
- **Guidance** on laboratory survey protocol

In this memorandum we provide official notification to the State Survey Agencies (SAs) and Centers for Medicare & Medicaid Services (CMS) regional offices (ROs) of the date to begin using the revised regulations, interpretive guidelines and survey protocols to implement CMS-2226-F (“Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications,” 68 FR 3640). The new interpretive guidelines will be available on CLIA’s web site (<http://www.cms.hhs.gov/clia>) on that date.

The CLIA final rule reorganized portions of the prior CLIA regulations. However, the provisions outlined in Subpart K-Quality Systems for Nonwaived Testing at 42 CFR section 493.1250, Analytic systems requirements, now apply to all laboratories performing nonwaived testing.

Prior to the above rule, laboratories that performed moderate complexity tests using an instrument, kit, or test system cleared by the Food and Drug Administration through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use were not held to all of these requirements. In keeping with CMS' educational approach and the continued use of the outcome-oriented survey process, surveyors are to use the two attached letters when laboratories are not in compliance with the analytic systems provisions that are new to the laboratory. (See Attachment 1 for examples of two model letters provided in the 8/14/2003 S&C 03-33 policy letter.) In addition, refer to Attachment 2 for specific guidance on the survey protocol to follow when applying the provisions of the final rule.

The final rule also made a number of data reporting and system changes in ASPEN Survey Explorer and in the Online Survey, Certification, and Reporting (OSCAR) system, to accommodate the revised laboratory regulations. The changes include:

- **ASPEN Survey Explorer**

The ASPEN Survey Explorer has been updated to include the current CLIA regulations, published in the *Federal Register* on January 24, 2003 and their associated interpretive guidelines. Refer to Attachment 3 for specific information and guidance on the contents of the laboratory information available in ASPEN Explorer. In a separate memorandum, the QIES Technical Support Office will notify the QIES State Coordinators that the revised Laboratory Regulation Sets are available for ASPEN Survey Explorer users. The Laboratory Regulation Sets will be posted on the QTSO website to be downloaded for use during laboratory surveys.

- **OSCAR System**

The OSCAR system will be converted to accommodate the 'new D tags' associated with the revised laboratory requirements. This means that any initial or recertification surveys conducted using the 'old D tags' must be entered into the OSCAR system prior to OSCAR's software release. If the surveys using the 'old D' tags are not entered into OSCAR/ODIE until after the release, the SA data entry staff will need to convert the deficiency tags to the 'new D tags' using the 'D' tag crosswalk provided in Attachment 4. (CMS will provide additional instructions to users closer to OSCAR's software release date.)

- **Special Data Reporting**

To keep track of the citations for statistical and planning purposes and to determine subsequent eligibility for Alternative Quality Assessment Surveys (AQAS), each state will need to count the number of times each of the 30 specified 'D tags' are cited, and the number of times Letters 1 and 2 are issued. The totals will be sent to the RO on a monthly basis. The citations will be tallied on the Excel sheet provided at Attachment 5. In addition, at the time a survey record is entered into the OSCAR/ODIE system, a new field will be established to determine if the laboratory received Letter 1 or 2. This information will be used to determine eligibility for AQAS during subsequent survey cycles.

Timeline for Data System Changes

January 12: The SAs will begin the survey process by using the revised laboratory regulations and interpretive guidelines and by following the survey policy outlined in Attachments 1 and 2.

January 12: The ASPEN Survey Explorer will be updated with the newest version of the 'D' tags, regulatory text and interpretive guidelines. (Refer to Attachment 3.) The QTSO will notify the QIES State Coordinators in a separate memorandum that the revised Laboratory Regulation Sets are available for ASPEN Survey Explorer users. The Laboratory Regulation Sets will be posted on the QTSO website to be downloaded.

January 12 through the end of FY2005: The SAs will keep track of the number of times each of the 30 specified 'D tags' are cited, and the number of times Letters 1 and 2 are issued. Send the counts to the RO on a monthly basis in the format provided in Attachment 5.

February 26: The SAs will complete entry of all surveys conducted using the 'old D tags' into the OSCAR/Online Data Input and Edit (ODIE) system, prior to OSCAR's system conversion.

March 1: The OSCAR system will be converted by changing the 'old D tags' to the comparable 'new D tags' in the OSCAR system, and the OSCAR dictionary will be revised to contain the new prefix tags and descriptions.

March 1 and thereafter: Surveys conducted using the 'new D tags' will be entered into ODIE by the SAs. Any surveys conducted using the 'old D tags' that are not entered by February 26 (cut-off date) will be converted to the 'new D tags' using the 'D tag' crosswalk (see Attachment 4).

If you need additional clarification on the survey policies and procedures, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. If you have questions concerning data issues, please contact Kate Kremann on 410-786-3400 or Carol Zeller on 410-786-3113.

We appreciate your ongoing dedication to the effective administration of the CLIA program and your assistance during this upcoming survey cycle.

Effective Date: January 12, 2004.

Training: This information should be shared with all appropriate survey and certification staff, their managers, QIES coordinators, and the state/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
RO Laboratory Consultants

Attachment 1 – Survey and Certification 03-33 policy letter, dated 08/14/2003

Attachment 2 – Survey Protocol for First Cycle Surveys

Attachment 3 – ASPEN Survey Explorer Update

Attachment 4 – CLIA Deficiency Crosswalk

Attachment 5 - Special Data Reporting (Dtag Exclusions)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations

Ref: S&C-03-30

DATE: August 14, 2003

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Policy Letters for First Survey Cycle Following the Effective Date of CMS-2226-F

TO: Survey and Certification Regional Office Management (G-5)
State Survey Agency Directors

This memorandum presents two letters for use in certain first survey cycle (FY2004-FY2005) compliance situations involving CMS-2226-F ("Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications," 68 FR 3640).

For the most part, this final rule simply reorganizes portions of the prior CLIA regulations. However, the provisions outlined in Subpart K-Quality Systems for Nonwaived Testing at section 493.1250, Analytic systems requirements, now apply to all laboratories performing nonwaived testing. Prior to this rule, laboratories that performed moderate complexity tests using an instrument, kit, or test system cleared by the Food and Drug Administration through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use were not held to all of these requirements. In keeping with CMS' educational approach and the continued use of the outcome-oriented survey process, surveyors are to use the two attached letters when laboratories are not in compliance with the analytic systems provisions that are new to the laboratory.

Letter number 1 (first survey cycle letter without accompanying CMS-2567) is to be used when the laboratory's only deficiencies include analytic systems provisions that are new to that laboratory. Letter number 2 (first survey cycle letter with accompanying CMS-2567) will be used to accompany a survey report form (CMS-2567) when the laboratory has deficiencies in items that were required under the former rule as well as deficiencies in the analytic systems provisions of CMS-2226-F that are new to the laboratory.

If you have questions or would like further clarification, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. We appreciate your ongoing dedication to the effective administration of the CLIA program and your assistance during this upcoming survey cycle.

/s/
Steven A. Pelovitz

Attachments

First survey cycle letter without accompanying CMS-2567

Date _____

[Laboratory Director]

[Laboratory's Name]

[Address]

[City], [State], [Zip Code]

Re: CLIA # _____
State ID # _____

Dear [Laboratory Director]:

A representative [or name of the surveyor] of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for CLIA purposes. I hope the on-site survey was helpful to you and your staff.

During the exit conference, the representative [or the surveyor's name] discussed some items **needing** correction due to provisions contained in the newly effective revised CLIA regulations. (See 68 Federal Register 3640 that became effective April 24, 2003.) The majority of the material contained in this regulation was merely a reorganization of existing provisions, but there are a limited number of new provisions in the rule as well.

During this survey cycle, CMS is seeking to educate providers about the new regulatory requirements, and hopes to obtain voluntary compliance with these requirements. As such, these items are listed in this letter rather than the survey report. We encourage you and your staff to familiarize yourselves with these new provisions. Correction of the items listed below will improve the quality of care for your patients and will assist you in the future, when deficiencies in meeting these requirements will be included as part of the survey report and resolution process.

At the time of your survey on [date], your laboratory was not in compliance with the following new provisions contained in the revised CLIA regulations:

[List any of the following that are applicable]

- Section 493.1253: Establishment and verification of performance specifications
- Section 493.1254: Maintenance and function checks
- Section 493.1255: Calibration and calibration verification procedures
- Section 493.1256: Control procedures

[Include any pertinent specific information that will clarify the concern or help the laboratory understand how to comply here.]

The representative [or surveyor's name] will follow up in [x days] to determine if your laboratory has addressed the areas needing correction. In the meantime if you would like additional information or need further assistance, please contact [State Representative's name] at [phone number].

Sincerely,

State Agency Signature
Name and Title

Model Letter # 2
First survey cycle letter with CMS-2567

Date _____

[Laboratory Director]
[Laboratory's Name]
[Address]
[City], [State], [Zip Code]

Re: CLIA # _____
State ID # _____

Dear [Laboratory Director]:

A representative [or name of the surveyor] of the [State Survey Agency] surveyed your laboratory on [date] for the Centers for Medicare & Medicaid Services (CMS) for CLIA purposes. I hope the on-site survey was helpful to you and your staff.

During the exit conference, the representative [or the surveyor's name] discussed some items that appear on the survey report **requiring** correction by you/your staff. Details concerning those items are provided in the accompanying letter and survey report. Please note that the items listed on the survey report form are those items that were required of your laboratory both under the former CLIA rules and the newly effective revised rules. (See 68 Federal Register 3640 that became effective April 24, 2003.) These items **must** be addressed by the time frame specified in the accompanying letter in order to avoid any adverse actions by CMS.

The representative [or surveyor's name] also discussed some items **needing** correction due to provisions solely contained in the newly effective revised rules. During this survey cycle, CMS is seeking to educate providers about the new regulatory requirements, and hopes to obtain voluntary compliance with these requirements. As such, these items are listed in this letter rather than the survey report. We encourage you and your staff to familiarize yourselves with these new provisions. Correction of the items listed below will improve the quality of care for your patients and will assist you in the future, when deficiencies in meeting these requirements will be included as part of the survey report and resolution process.

At the time of your survey on (date), your laboratory was not in compliance with the following new provisions contained in the revised CLIA regulations:

[List any of the following that are applicable]

- Section 493.1253: Establishment and verification of performance specifications
- Section 493.1254: Maintenance and function checks
- Section 493.1255: Calibration and calibration verification procedures
- Section 493.1256: Control procedures

[Include any pertinent specific information that will clarify the concern or help the laboratory understand how to comply here.]

Please note that the deficiencies listed above are in addition to any items listed on the survey report form. Both lists of deficiencies need correction before your laboratory will be in complete compliance with the CLIA regulations.

The representative [or surveyor's name] will follow up in [x days] to determine if your laboratory has addressed the areas needing correction that are listed on this letter. In the meantime if you would like additional information or need further assistance, please contact [State Representative's name] at [phone number].

Sincerely,

State Agency Signature
Name and Title

Attachment 2

Survey Protocol for First Cycle (FY2004-FY2005) (Includes Initial and Recertification Surveys)

Outlined below are four survey finding scenarios listing the required forms that need to be completed and entered into the ODIE/CLIA systems and in ASPEN Survey Explorer.

Scenario 1 Laboratory has no deficiencies.

Forms: CMS-1539, Certification & Transmittal form: mark 'in compliance with program requirements.'
CMS-1557, Laboratory Survey Report Form: update with personnel and specialty/test volume information.
CMS-670, Survey Team Composition and Workload form: complete according to standard instructions.
CMS-2567, Statement of Deficiencies and Plan of Correction form: update ASPEN Survey Explorer by annotating D0000 with 'no deficiencies.'
CMS-116, Laboratory Application form: ask laboratory to provide any updates to information on record.

Scenario 2 Laboratory's only deficiency(ies) include analytic systems provisions that are new to that laboratory.

Forms: CMS-1539: mark 'in compliance with program requirements, based on receipt of an acceptable plan of correction'; annotate State Agency Remarks to state that Model Letter 1 was sent to laboratory.
CMS-1557: update with personnel and specialty/test volume information; also update the 'Letter Sent' field in ODIE.
CMS-2567: update ASPEN Survey Explorer by annotating D0000 with 'see attached letter.'
Model Letter 1: prepare and present to laboratory.
CMS-670: complete according to standard instructions, count time taken to prepare Model Letter 1 in Off-Site Report Preparation category.
CMS-116: ask laboratory to provide any updates to information on record.

Scenario 3 Laboratory's only deficiency(ies) include provisions that were required under the former CLIA rules.

Forms: CMS-1539: mark 'in compliance with program requirements, based on receipt of an acceptable plan of correction.'
CMS-1557: update with personnel and specialty/test volume information.
CMS-2567, CMS-2567B: update ODIE and ASPEN Survey Explorer with required deficiency data.
CMS-670: complete according to standard instructions.
CMS-116: ask laboratory to provide any updates to information on record.

Scenario 4 Laboratory has deficiencies in items that were required under the former rule as well as deficiencies in the analytic systems provisions of CMS-2226-F that are new to the laboratory.

Forms: CMS-1539: mark ‘in compliance with program requirements, based on receipt of an acceptable plan of correction;’ annotate State Agency Remarks to state that Model Letter 2 was sent to laboratory, along with CMS-2567.
CMS-1557: update with personnel and specialty/test volume information; also update the ‘Letter Sent’ field.
CMS-2567, CMS-2567B: update ODIE and ASPEN Explorer with required deficiency data, as appropriate. Also, annotate D0000 with ‘see attached letter.’
Model Letter 2: prepare and present with CMS-2567.
CMS-670: complete according to standard instructions, include time taken to prepare Model Letter 2 in report preparation category.
CMS-116: ask laboratory to provide any updates to information on record.

Other Survey Protocols for First Cycle (FY2004-FY2005)

Follow-up/Revisit Surveys

Any deficiencies cited at the time of the survey on the CMS-2567 will require corrective action by the laboratory. Use the standard operating procedures already in place. For deficiencies listed in either letter, encourage the laboratory to correct by the next recertification survey. In lieu of a follow-up survey, contact laboratories to provide education and assistance. Any time immediate jeopardy is found, consult with the CMS RO.

- Deficiencies cited that apply to former CLIA rules must be collected on the Post-Certification Revisit Report form, CMS-2567B, and reported in both OSCAR/ODIE and in ASPEN Survey Explorer.
- Deficiencies cited that apply to provisions solely contained in the newly effective revised rules, as listed in Model Letters 1 and 2, are not reported in OSCAR/ODIE or in ASPEN Survey Explorer.

Complaint Surveys

Investigate complaint allegations according to existing survey policies and procedures. If problems are noted in provisions contained in the newly effective revised rules, base deficiency citations/letter issuances and enforcement action(s) on whether or not the issue concerns analytic systems provisions that are new to the laboratory and have an impact on patient care (see Attachment 1). Consult the CMS RO when in doubt. Follow standard operating procedures for problems identified that are contained in the final regulations, but not new to the laboratory.

Validation surveys

As always, validation surveys are to be conducted like compliance surveys and copies of all validation packages (including Letter 1 or 2, if used) forwarded to the CMS RO as soon as the survey is closed out. For the validation review, no action will be necessary regarding deficiencies related to analytic systems provisions new to the laboratory surveyed that are communicated in Letters 1 or 2. The rationale is two-fold:

- In the validation review, determinations about similarity of accreditation

organization inspection findings/CLIA survey findings and the calculation of disparity rate are focused only on condition-level deficiencies cited on the CMS-2567.

- For the first cycle, CMS will have an educational approach for those laboratories having deficiencies related to the analytic provisions newly applicable to them (except for harm or potential risk of harm).

Please note: Even though deficiencies listed a Letter 1 and 2 will not be included in the validation review comparisons and disparity rate calculations, include the letter, if issued, with the validation package when forwarded to Central Office. It will help provide a fuller picture of the case, which is helpful for the overall review.

Enforcement Actions

The enforcement procedures remain the same for the CLIA regulations that **have not** changed in the final regulation.

In order to help laboratories understand the new requirements, the first cycle survey conducted under the final regulation will take an educational approach. For first cycle surveys, no enforcement actions will be taken when a laboratory is not in compliance with analytic systems provisions that are new to the laboratory.

However, enforcement action may be taken during the first cycle of the final regulation requirements when there is immediate jeopardy. If there is any question regarding enforcement during this first survey cycle, consult with the CMS RO or Central Office.

After the first cycle survey, enforcement for all final regulation requirements will be handled as for the former regulation requirements, i.e., all deficiencies will be cited on the CMS-2567 and enforcement actions will be taken if deficiencies are not corrected.

ASPEN Survey Explorer Update

The ASPEN Survey Explorer program has been updated to include the current CLIA regulations, published in the *Federal Register* on January 24, 2003. Because it has been a while since there has been an update for CLIA, we want to remind you of what is included in the ASPEN program:

- Only tagged regulation text, along with its associated interpretive guidelines and probes, are included in the ASPEN program. For example, the first "D tags" in the Interpretive Guidelines for Laboratories and Laboratory Services is D1000, §493.15(c) Certificate of waiver tests.
- Regulation text that is not tagged is not included in the ASPEN program. For example, none of the regulation text prior to D1000, or the associated interpretive guidelines and probes, is included in ASPEN.

Given that only tagged regulation text can be included in ASPEN, you may need to ensure that certain information is available to your State and Regional surveyors. For example:

- The Survey Process
- The Definitions section at §493.2
- The certificate sections at §§493.19, 493.20 and 493.25
- Subparts B, C, and D

In addition, due to the formatting of certain tables in the Interpretive Guidelines, the below listed tables are not included in ASPEN Explorer. Please ensure that your State and Regional surveyors either take these tables or bring a copy of the Interpretive Guidelines to the laboratory at the time of the survey. (The Interpretive Guidelines are available in (<http://www.cms.hhs.gov/clia>)). They are provided for you here.

The tables not in ASPEN Survey Explorer (but included in the Interpretive Guidelines) are:

- The NCCLS M2-A8 Antimicrobial Disk Diffusion Susceptibility (Bauer, Kirby, Sherris and Turk Method) appropriate control strains and the associated Table 3 quality control limits tables at D5507;
- The NCCLS M7-A6 Minimum Inhibitory Concentration (MIC) appropriate control strains and the associated Table 3 breakpoint tables at D5507;
- The table that defines the frequency and type of quality control to be performed for each container of antisera and reagent red cells in immunohematology testing at D5551;
- The table at Interpretive Guidelines §493.1276(b)(1)-(b)(3) in Clinical cytogenetics;

- The NCCLS M22-A2 Quality Assurance for Commercially Prepared Microbiological Culture Media; Approved Standard-Second Edition Table 2 at D5477.

ANTIMICROBIAL DISK DIFFUSION SUSCEPTIBILITY (BAUER, KIRBY, SHERRIS AND TURK METHOD)

Each new batch of medium and each new lot/shipment of antimicrobial disks must be checked as follows:

ANTIMICROBIAL DISK SUSCEPTIBILITY TEST

<i>Appropriate Control Strain</i>	<i>Each New Batch of Media and Disks</i>	<i>Each Day If Isolates Are:</i>
<i>S. aureus</i> ATCC 25923 or equivalent**	X	<i>Staphylococcus</i> spp.
<i>E. coli</i> ATCC 25922 or equivalent**	X	<i>Enterobacteriaceae</i>
<i>P. aeruginosa</i> ATCC 27853 and <i>E. coli</i> ATCC 25922 or equivalent**	X	<i>Pseudomonas aeruginosa</i> <i>Acintebacter</i> spp.

NOTE 1: Routine quality control testing of commercially prepared Mueller-Hinton agar for thymine and thymidine is not needed. However, if problems with quality control of sulfonamides and trimethoprim occur, the Mueller-Hinton agar should be checked with

E. faecalis ATCC 29212 or alternatively, *E. faecalis* ATCC 33186 with trimethoprim-sulfamethoxazole disks. Satisfactory media will provide essentially clear distinct zones of inhibition 20 mm or greater in diameter. Unsatisfactory media will produce no zone of inhibition, growth within the zone, or a zone of less than 20 mm.

NOTE 2: If testing beta-lactam/beta-lactamase inhibitor antimicrobial agents (e.g., ampicillin-sulbactam, amoxicillin-clavulanic acid, piperacillin-tazobactam, or ticarcillin-clavulanic acid), the laboratory should test *E. coli* ATCC 35218 (beta-lactamase producing strain).

NOTE 3: If performing extended spectrum beta-lactamase (ESBL) tests, the laboratory should test *Klebsiella pneumoniae* ATCC 700603 (ESBL-producing strain).

Zone sizes must be recorded for each antimicrobial control and limits must be established.

**An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Refer to Table 3A*** of the NCCLS Standard, "Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard-Eighth Edition (M2-A8)" to determine the control strain to be used when performing antimicrobial disk susceptibility tests on isolates of *Haemophilus* spp., *Neisseria gonorrhoeae*, *Streptococcus pneumoniae* or other organisms as applicable.

MINIMUM INHIBITORY CONCENTRATION (MIC)

Each new batch of microdilution tubes, microdilution trays, or agar dilution plates must be checked as follows:

MINIMUM INHIBITORY CONCENTRATION (MIC)

<i>Appropriate Control Strain</i>	<i>Each New Batch of Media</i>	<i>Each Day If Isolates are:</i>
<u><i>S. aureus</i></u> ATCC 29213 or equivalent**	X	<u><i>Staphylococcus</i></u> spp.
<u><i>E. coli</i></u> ATCC 25922 or equivalent**	X	<u>Enterobacteriaceae</u>
<u><i>P. aeruginosa</i></u> ATCC 27853 and <u><i>E. coli</i></u> ATCC 25922 or equivalent **	X	Non- <u>Enterobacteriaceae</u> to include <u><i>Acintebacter</i></u> spp., <u><i>Stenotrophomonas maltophilia</i></u> , <u><i>Pseudomonas</i></u> spp. and other nonfastidious, glucose nonfermenting, gram-negative bacilli
<u><i>E. faecalis</i></u> ATCC 29212 or equivalent**	X	<u>Enterococcus</u> spp.

NOTE 1: To determine the suitability of the Mueller-Hinton broth for sulfonamide and trimethoprim tests, MICs may be performed with *E. faecalis* ATCC 29212. Routine quality control testing of commercially manufactured panels for thymine and thymidine is not needed. However, should problems with QC of sulfonamides and trimethoprim occur, an MIC test should be performed with *E. faecalis* ATCC 29212 with trimethoprim-sulfamethoxazole. If the MIC for trimethoprim-sulfamethoxazole is < 0.5/9.5 ug/ml, the medium may be considered adequate.

NOTE 2: If testing beta-lactam/beta-lactamase inhibitor antimicrobial agents (e.g., ampicillin-sulbactam, amoxicillin-clavulanic acid, piperacillin-tazobactam, or ticarcillin-clavulanic acid), the laboratory should test *E. coli* ATCC 35218.

NOTE 3: If performing extended spectrum beta-lactamase (ESBL) tests, the laboratory should test *Klebsiella pneumoniae* ATCC 700603 (ESBL-producing strain).

NOTE 4: If performing oxacillin salt agar screen tests, the laboratory should test *S. aureus* ATCC 29213 and 43300.

NOTE 5: If performing vancomycin BHI screen tests, the laboratory must test *E. faecalis* 29212 and 51299.

**An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

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	<i>Escherichia coli</i> ATCC® 25922 ^b	<i>Staphylococcus aureus</i> ATCC® 25923	<i>Pseudomonas aeruginosa</i> ATCC® 27853	<i>Escherichia coli</i> ATCC® 35218 ^f
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	–
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	2 µg	–	24–30	–	–
Daptomycin ^d	30 µg	–	18–23	–	–
Dirithromycin	15 µg	–	18–26	–	–
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	15 µg	–	22–30	–	–
Fleroxacin	5 µg	28–34	21–27	12–20	–
Fosfomycin ^c	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 ^a	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	–

Antimicrobial Agent	Disk Content	<i>Escherichia coli</i> ATCC® 25922^b	<i>Staphylococcus aureus</i> ATCC® 25923	<i>Pseudomonas aeruginosa</i> ATCC® 27853	<i>Escherichia coli</i> ATCC® 35218^f
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	–	–	–

Table 3. (Continued)

Antimicrobial Agent	Disk Content	<i>Escherichia coli</i> ATCC® 25922 ^b	<i>Staphylococcus aureus</i> ATCC® 25923	<i>Pseudomonas aeruginosa</i> ATCC® 27853	<i>Escherichia coli</i> ATCC® 35218 ^f
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 ^a	10 µg	12-20	14-22	–	–
Sulfisoxazole ^e	250 µg or 300 µg	15-23	24-34	–	–
Teicoplanin	30 µg	–	15-21	–	–
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
Tobramycin	10 µg	18-26	19-29	19-25	–
Trimethoprim ^e	5 µg	21-28	19-26	–	–
Trimethoprim-sulfamethoxazole ^e	1.25/23.75 µg	23-29	24-32	–	–
Trospectomycin	30 µg	10-16	15-20	–	–
Trovafoxacin	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

- 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).
- ATCC is a registered trademark of the American Type Culture Collection.
- The 200-µg fosfomycin disk contains 50 µg of glucose-6-phosphate.
- Some lots of Mueller-Hinton agar are deficient in calcium and give small zones.
- These agents can be affected by excess levels of thymidine and thymine. See M2, Section 4.1.4 for guidance should a problem with quality control occur.
- Careful organism maintenance is required; refer to M2, Section 10.3.

Table 3. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Minimal Inhibitory Concentrations (MICs) ($\mu\text{g/mL}$) of Nonfastidious Organisms (Using Mueller-Hinton Medium Without Blood or Other Supplements)

Antimicrobial Agent	<i>Staphylococcus aureus</i> ATCC® 29213 ^a	<i>Enterococcus faecalis</i> ATCC® 29212	<i>Escherichia coli</i> ATCC® 25922	<i>Pseudomonas aeruginosa</i> ATCC® 27853	<i>Escherichia coli</i> ATCC® 35218 ^b
Amikacin	1–4	64–256	0.5–4	1–4	–
Amoxicillin-clavulanic acid	0.12/0.06–0.5/0.25	0.25/0.12–1.0/0.5	2/1–8/4	–	4/2–16/8
Ampicillin	0.5–2	0.5–2	2–8	–	–
Ampicillin-sulbactam	–	–	2/1–8/4	–	8/4–32/16
Azithromycin	0.5–2	–	–	–	–
Azlocillin	2–8	1–4	8–32	2–8	–
Aztreonam	–	–	0.06–0.25	2–8	–
Carbencillin	2–8	16–64	4–16	16–64	–
Cefaclor	1–4	–	1–4	–	–
Cefamandole	0.25–1	–	0.25–1	–	–
Cefazolin	0.25–1	–	1–4	–	–
Cefdinir	0.12–0.5	–	0.12–0.5	–	–
Cefditoren	0.25–2	–	0.12–1	–	–
Cefepime	1–4	–	0.016–0.12	1–8	–
Cefetamet	–	–	0.25–1	–	–
Cefixime	8–32	–	0.25–1	–	–
Cefmetazole	0.5–2	–	0.25–2	> 32	–
Cefonicid	1–4	–	0.25–1	–	–
Cefoperazone	1–4	–	0.12–0.5	2–8	–
Cefotaxime	1–4	–	0.03–0.12	8–32	–
Cefotetan	4–16	–	0.06–0.25	–	–
Cefoxitin	1–4	–	2–8	–	–
Cefpodoxime	1–8	–	0.25–1	–	–
Cefprozil	0.25–1	–	1–4	–	–
Ceftazidime	4–16	–	0.06–0.5	1–4	–
Ceftibuten	–	–	0.12–0.5	–	–
Ceftizoxime	2–8	–	0.03–0.12	16–64	–
Ceftriaxone	1–8	–	0.03–0.12	8–64	–
Cefuroxime	0.5–2	–	2–8	–	–
Cephalothin	0.12–0.5	–	4–16	–	–
Chloramphenicol	2–8	4–16	2–8	–	–
Cinoxacin	–	–	2–8	–	–
Ciprofloxacin	0.12–0.5	0.25–2	0.004–0.016	0.25–1	–
Clarithromycin	0.12–0.5	–	–	–	–
Clinafloxacin	0.008–0.06	0.03–0.25	0.002–0.016	0.06–0.5	–
Clindamycin	0.06–0.25	4–16	–	–	–
Daptomycin ^c	0.25–1	1–8	–	–	–
Dirithromycin	1–4	–	–	–	–
Doxycycline	–	–	0.5–2	–	–
Enoxacin	0.5–2	2–16	0.06–0.25	2–8	–
Ertapenem	0.06–0.25	4–16	0.004–0.016	2–8	–
Erythromycin	0.25–1	1–4	–	–	–
Fleroxacin	0.25–1	2–8	0.03–0.12	1–4	–
Fosfomycin ^d	0.5–4	32–128	0.5–2	2–8	–
Garenoxacin	0.004-0.03	0.03-0.25	0.004-0.03	0.5-2	–
Gatifloxacin	0.03–0.12	0.12–1.0	0.008–0.03	0.5–2	–
Gemifloxacin	0.008–0.03	0.016–0.12	0.004–0.016	0.25–1	–
Gentamicin ^e	0.12–1	4–16	0.25–1	0.5–2	–
Grepafloxacin	0.03–0.12	0.12–0.5	0.004–0.03	0.25–2.0	–
Imipenem	0.016–0.06	0.5–2	0.06–0.25	1–4	–
Kanamycin	1–4	16–64	1–4	–	–
Levofloxacin	0.06–0.5	0.25–2	0.008–0.06	0.5–4	–
Linezolid	1–4	1–4	–	–	–

Table 3. (Continued)

Antimicrobial Agent	<i>Staphylococcus aureus</i> ATCC® 29213 ^a	<i>Enterococcus faecalis</i> ATCC® 29212	<i>Escherichia coli</i> ATCC® 25922	<i>Pseudomonas aeruginosa</i> ATCC® 27853	<i>Escherichia coli</i> ATCC® 35218 ^b
Lomefloxacin	0.25–2	2–8	0.03–0.12	1–4	–
Loracarbef	0.5–2	–	0.5–2	>8	–
Mecillinam	–	–	0.03–0.25 ^f	–	–
Meropenem	0.03–0.12	2–8	0.008–0.06	0.25–1	–
Methicillin	0.5–2	>16	–	–	–
Mezlocillin	1–4	1–4	2–8	8–32	–
Minocycline	0.06–0.5	1–4	0.25–1	–	–
Moxalactam	4–16	–	0.12–0.5	8–32	–
Moxifloxacin	0.016–0.12	0.06–0.5	0.008–0.06	1–8	–
Nafcillin	0.12–0.5	2–8	–	–	–
Nalidixic acid	–	–	1–4	–	–
Netilmicin	≤ 0.25	4–16	≤ 0.5–1	0.5–8	–
Nitrofurantoin	8–32	4–16	4–16	–	–
Norfloxacin	0.5–2	2–8	0.03–0.12	1–4	–
Ofloxacin	0.12–1	1–4	0.015–0.12	1–8	–
Oxacillin	0.12–0.5	8–32	–	–	–
Penicillin	0.25–2	1–4	–	–	–
Piperacillin	1–4	1–4	1–4	1–8	–
Piperacillin-tazobactam	0.25/4–2/4	1/4–4/4	1/4–4/4	1/4–8/4	0.5/4–2/4
Quinupristin-dalfopristin	0.25–1	2–8	–	–	–
Rifampin	0.004–0.016	0.5–4	4–16	16–64	–
Sparfloxacin	0.03–0.12	0.12–0.5	0.004–0.016	0.5–2	–
Sulfisoxazole ^g	32–128	32–128	8–32	–	–
Teicoplanin	0.25–1	0.06–0.25	–	–	–
Telithromycin	0.06–0.25	0.016–0.12	–	–	–
Tetracycline	0.12–1	8–32	0.5–2	8–32	–
Ticarcillin	2–8	16–64	4–16	8–32	–
Ticarcillin-clavulanic acid	0.5/2–2/2	16/2–64/2	4/2–16/2	8/2–32/2	8/2–32/2
Tobramycin	0.12–1	8–32	0.25–1	0.25–1	–
Trimethoprim ^g	1–4	≤ 1	0.5–2	>64	–
Trimethoprim-sulfamethoxazole	≤ 0.5/9.5	≤ 0.5/9.5	≤ 0.5/9.5	8/152–32/608	–
Trospectomycin	2–16	2–8	8–32	–	–
Trovafoxacin	0.008–0.03	0.06–0.25	0.004–0.016	0.25–2	–
Vancomycin ^h	0.5–2	1–4	–	–	–

NOTE 1: These MICs were obtained in several reference laboratories by broth microdilution. If four or fewer concentrations are tested, quality control may be more difficult.

NOTE 2: Information in boldface type is considered tentative for one year.

NOTE 3: For four-dilution ranges, results at the extremes of the acceptable range(s) should be suspect. Verify control validity with data from other control strains.

Footnotes

- ATCC is a registered trademark of the American Type Culture Collection.
- Careful organism maintenance is required; refer to M7, Section 12.4.
- QC ranges reflect MICs obtained when Mueller-Hinton broth is supplemented with calcium to a final concentration of 50 µg/mL.
- The approved MIC susceptibility testing method is agar dilution. Agar media should be supplemented with 25 µg/mL of glucose-6-phosphate. Broth dilution should not be performed.
- For control organisms for gentamicin and streptomycin high-level aminoglycoside screen tests for enterococci, see Table 2D.
- This test should be performed by agar dilution only.
- Very medium-dependent, especially with enterococci.
- For control organisms for vancomycin screen test for enterococci, see Table 2D.

Table 3A. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Minimal Inhibitory Concentrations (MICs) (µg/mL) of Fastidious Organisms

Antimicrobial Agent	<i>Haemophilus influenzae</i> ATCC® 49247 ^a	<i>Haemophilus influenzae</i> ATCC® 49766	<i>Neisseria gonorrhoeae</i> ATCC® 49226	<i>Streptococcus pneumoniae</i> ATCC® 49619	<i>Helicobacter pylori</i> ATCC® 43504	<i>Campylobacter jejuni</i> ATCC® 33560 ^b 36 °C/48 hours	<i>Campylobacter jejuni</i> ATCC® 33560 ^b 42 °C/24 hours
Amoxicillin	–	–	–	0.03–0.12	0.016–0.12	–	–
Amoxicillin-clavulanic	2/1–16/8	–	–	0.03/0.016–0.12/0.06	–	–	–
Ampicillin	2–8	–	–	0.06–0.25	–	–	–
Ampicillin-sulbactam	2/1–8/4	–	–	–	–	–	–
Azithromycin	1–4	–	–	0.06–0.25	–	–	–
Aztreonam	0.12–0.5	–	–	–	–	–	–
Cefaclor	–	1–4	–	1–4	–	–	–
Cefamandole	–	0.25–1	–	–	–	–	–
Cefdinir	–	0.12–0.5	0.008–0.03	0.03–0.25	–	–	–
Cefditoren	0.06–0.25	–	–	0.016–0.12	–	–	–
Cefepime	0.5–2	–	0.016–0.06	0.03–0.25	–	–	–
Cefetamet	0.5–2	–	0.016–0.25	0.5–2	–	–	–
Cefixime	0.12–1	–	0.004–0.03	–	–	–	–
Cefmetazole	2–16	–	0.5–2	–	–	–	–
Cefonicid	–	0.06–0.25	–	–	–	–	–
Cefotaxime	0.12–0.5	–	0.015–0.06	0.03–0.12	–	–	–
Cefotetan	–	–	0.5–2	–	–	–	–
Cefoxitin	–	–	0.5–2	–	–	–	–
Cefpirome	0.25–1	–	–	–	–	–	–
Cefpodoxime	0.25–1	–	0.03–0.12	0.03–0.12	–	–	–
Cefprozil	–	1–4	–	0.25–1	–	–	–
Ceftazidime	0.12–1	–	0.03–0.12	–	–	–	–
Ceftibuten	0.25–1	–	–	–	–	–	–
Ceftizoxime	0.06–0.5	–	0.008–0.03	0.12–0.5	–	–	–
Ceftriaxone	0.06–0.25	–	0.004–0.016	0.03–0.12	–	–	–
Cefuroxime	–	0.25–1	0.25–1	0.25–1	–	–	–
Cephalothin	–	–	–	0.5–2	–	–	–
Chloramphenicol	0.25–1	–	–	2–8	–	–	–
Ciprofloxacin	0.004–0.03	–	0.001–0.008	–	–	0.12-1	0.06-0.5
Clarithromycin	4–16	–	–	0.03–0.12	0.016–0.12	–	–
Clinafloxacin	0.001–0.008	–	–	0.03–0.12	–	–	–
Clindamycin	–	–	–	0.03–0.12	–	–	–
Daptomycin ^c	–	–	–	0.06–0.5	–	–	–
Dirithromycin	8–32	–	–	0.06–0.25	–	–	–
Doxycycline	–	–	–	–	–	0.5–2	0.25–2
Enoxacin	–	–	0.016–0.06	–	–	–	–
Ertapenem	–	0.016–0.06	–	0.03–0.25	–	–	–
Erythromycin	–	–	–	0.03–0.12	–	1–8	1–4
Fleroxacin	0.03–0.12	–	0.008–0.03	–	–	–	–
Garenoxacin	0.002-0.008	–	–	0.016–0.06	–	–	–
Gasfloxacin	0.004–0.03	–	0.002–0.016	0.12–0.5	–	–	–
Gemifloxacin	0.002–0.008	–	–	0.008–0.03	–	–	–
Gentamicin	–	–	–	–	–	0.5–2	0.5–4
Grepafloxacin	0.002–0.016	–	0.004–0.03	0.06–0.5	–	–	–
Imipenem	–	0.25–1	–	0.03–0.12	–	–	–
Levofloxacin	0.008–0.03	–	–	0.5–2	–	–	–
Linezolid	–	–	–	0.5–2	–	–	–
Lomefloxacin	0.03–0.12	–	0.008–0.03	–	–	–	–
Loracarbef	–	0.5–2	–	2–8	–	–	–
Metronidazole	–	–	–	–	64–256	–	–
Meropenem	–	0.03–0.12	–	0.06–0.25	–	0.004–0.015	0.008–0.03
Moxifloxacin	0.008–0.03	–	–	0.06–0.25	–	–	–

Table 3A. (Continued)

Antimicrobial Agent	<i>Haemophilus influenzae</i> ATCC® 49247 ^a	<i>Haemophilus influenzae</i> ATCC 49766	<i>Neisseria gonorrhoeae</i> ATCC® 49226	<i>Streptococcus pneumoniae</i> ATCC® 49619	<i>Helicobacter pylori</i> ATCC® 43504	<i>Campylobacter jejuni</i> ATCC® 33560 ^b 36 °C/48 hours	<i>Campylobacter jejuni</i> ATCC® 33560 ^b 42 °C/24 hours
Nitrofurantoin	–	–	–	4–16	–	–	–
Norfloxacin	–	–	–	2–8	–	–	–
Ofloxacin	0.016–0.06	–	0.004–0.016	1–4	–	–	–
Penicillin	–	–	0.25–1	0.25–1	–	–	–
Piperacillin-tazobactam	0.06/4–0.5/4	–	–	–	–	–	–
Quinupristin-dalfopristin	2–8	–	–	0.25–1	–	–	–
Rifampin	0.25–1	–	–	0.015–0.06	–	–	–
Sparfloxacin	0.004–0.016	–	0.004–0.016	0.12–0.5	–	–	–
Spectinomycin	–	–	8–32	–	–	–	–
Telithromycin	1–4	–	–	0.004–0.03	0.06–0.5	–	–
Tetracycline	4–32	–	0.25–1	0.12–0.5	0.12–1.0	–	–
Trimethoprim-sulfamethoxazole	0.03/0.59-0.25/4.75	–	–	0.12/2.4–1/19	–	–	–
Trospectomycin	0.5–2	–	1–4	1–4	–	–	–
Trovafoxacin	0.004–0.016	–	0.004–0.016	0.06–0.25	–	–	–
Vancomycin	–	–	–	0.12–0.5	–	–	–

Testing Conditions for Clinical Isolates and Performance of Quality Control

Organism	<i>Haemophilus influenzae</i>	<i>Neisseria gonorrhoeae</i>	<i>Streptococcus pneumoniae</i>	<i>Helicobacter pylori</i>	<i>Campylobacter</i> spp.
Medium	Broth dilution: Haemophilus Test Medium (HTM) broth	Agar dilution: GC agar base and 1% defined growth supplement. The use of a cysteine-free supplement is required for agar dilution tests with carbapenems and clavulanate. Cysteine-containing defined growth supplements <i>do not</i> significantly alter dilution test results with other drugs.	Broth dilution: Cation-adjusted Mueller-Hinton broth with lysed horse blood (2-5% v/v).	Agar Dilution: Mueller-Hinton agar with aged (≥ 2-week-old) sheep blood (5% v/v).	Agar dilution: Mueller-Hinton agar with 5% defibrinated sheep blood
Inoculum	Direct colony suspension, equivalent to a 0.5 McFarland standard	Direct colony suspension, equivalent to a 0.5 McFarland standard	Direct colony suspension, equivalent to a 0.5 McFarland standard	See footnote d, below.	Direct colony suspension, equivalent to a 0.5 McFarland standard
Incubation Characteristics	35 °C; ambient air; 20-24 hours	35 °C; 5% CO ₂ ; 20-24 hours	35 °C; ambient air; 20-24 hours	35 °C; 3 days; microaerobic atmosphere produced by gas-generating system suitable for campylobacters.	36 °C /48 hours or 42 °C/ 24 hours; 10% CO₂, 5% O₂ and 85% N₂ or a microaerophilic environment

NOTE 1: Information in boldface type is considered tentative for one year.

NOTE 2: For four-dilution ranges, results at the extremes of the acceptable range(s) should be suspect. Verify control validity with data from other control strains.

Footnotes

- ATCC is a registered trademark of the American Type Culture Collection.
- Since some isolates of *C. jejuni* ssp. *doylei*, *C. fetus* and *C. lari* may not grow at 42 °C, susceptibility testing of these isolates should be performed at 36 °C.**
- QC ranges reflect MICs obtained when Mueller-Hinton broth is supplemented with calcium to a final concentration of 50 µg/mL.
- The inoculum for testing of *Helicobacter pylori* should be as follows: a saline suspension equivalent to a 2.0 McFarland standard (containing 1x10⁷ to 1x10⁸ CFU/mL), to be prepared from a 72-hour-old subculture from a blood agar plate. The inoculum (1 to 3 µL per spot) is replicated directly on the antimicrobial agent-containing agar dilution plate

D5551**Interpretive Guidelines §493.1271(a)(1)**

The following table defines the frequency and the type of quality control to be performed for each container of antisera and reagent red cells use for immunohematology testing:

<u>Reagent</u>	<u>Positive Control</u>	<u>Negative Control</u>
ABO Antisera	Each day of use	N/A
Rh Antisera	Each day of use	Each day of use
Other Anti-sera	*Each day of use	Each day of use
*Anti-human globulin sera	*Each day of use	*Each day of use
ABO Reagent red cells	Each day of use	N/A
Antibody Screening cells	Each day of use	N/A

(at least one known antibody)

In daily quality control testing, it is sufficient to test antiglobulin serum for IgG only. Anticomplement activity can be checked, if desired, against complement coated RBC's but this need not be a routine procedure.

*This requirement is satisfied by checking the antihuman immune globulin (Coombs Serum) in one of the following ways:

- React anti-human globulin with a pre-sensitized reagent red blood cell which is either prepared commercially or by the laboratory;
- Perform the quality control for antibody detection using a known antibody which is demonstrated by the addition of antihuman globulin; or
- Add a pre-sensitized reagent red blood cell to all negative antiglobulin tests (direct antiglobulin, indirect antiglobulin, antibody detection and identification test) to indicate that antiglobulin serum present in the test was not inactivated by

Interpretive Guidelines §493.1271(a)(1)

unbound globulins or diluted by excess residual saline, and that the negative results reflect true absence of reactivity in the test. Using green antiglobulin serum does not substitute for this control.

D5683*Interpretive Guidelines §493.1276(b)(1)-(b)(3)*

<i>Culture Type</i>	<i>Minimum Number of Spreads Counted per Patient</i>	<i>Minimum Number of Cells Analyzed per Patient</i>
Amniotic Fluid		
<i>Flasks</i>	15 cells from at least 2 independent primary cultures	5 cells from at least 2 independent primary cultures
<u><i>in situ</i></u>	15 cells from at least 10 colonies from 2 independent primary cultures	5 cells from different colonies and split between different primary cultures

Many laboratories use a combination of the flask and *in situ* culture methods or use the flask method as a backup for the *in situ* method.

Chorionic Villus		
<i>Direct</i>	15 cells	5 cells
<i>Culture</i>	as in amniotic fluid, flask technique	
Peripheral Blood		
<i>Constitutional</i>	20 cells	5 cells
<i>Possible sex chromosome abnormality</i>	30 cells (total count)	5 cells

<i>Culture Type</i>	<i>Minimum Number of Spreads Counted per Patient</i>	<i>Minimum Number of Cells Analyzed per Patient</i>
<i>Blood (cancer)</i>	20 cells	20 cells
<i>Bone Marrow (cancer)</i>	20 cells	20 cells
<i>Tissue Fibroblasts</i>	15 cells from 2 independent cultures	5 cells split between 2 independent cell cultures

For confirmation of chromosomally abnormal amniotic fluid results, or familial chromosome abnormality, examination of fewer cells is permitted.

2. Manufacturers' Quality Assurance Procedure for Commercially Prepared Media

Medium	Atmosphere, Length of Incubation ¹	Control Organisms (ATCC No.) ²	Expected Results
Sheep blood and defibrinated horse blood agar media (non-reducing)	Anaerobic, 24–48 h	<i>B. fragilis</i> (25285) <i>C. perfringens</i> (13124) <i>F. nucleatum</i> (25586) <i>P. anaerobius</i> (27337)	Growth Growth, beta hemolysis Growth Growth
Broths - see separate medium			
Nonselective sheep blood agar media	Aerobic or CO ₂ , 24 h	<i>S. pyogenes</i> (19615) <i>S. pneumoniae</i> (6305) <i>S. aureus</i> (25923) <i>E. coli</i> (25922)	Growth, beta hemolysis Growth, alpha hemolysis Growth Growth
Sheep blood agar-CAMP with defibrinated horse blood only	Aerobic, 24 h	<i>S. aureus</i> (33862) or <i>S. aureus</i> (25923) <i>S. agalactiae</i> (12386) <i>S. pyogenes</i> (19615)	Positive reaction (arrowhead area of clearing) Negative reaction (no arrowhead formation)
Sheep blood agar-Selective sheep blood agar media (5% defibrinated horse blood, 10% Columbia CNA Agar, 10% phenylethyl alcohol agar)	Columbia CNA CO ₂ , 24–48h	<i>S. pyogenes</i> (19615) <i>S. pneumoniae</i> (6305) <i>S. aureus</i> (25923) <i>P. mirabilis</i> (12453)	Growth, beta hemolysis Growth, alpha hemolysis Growth Inhibition (partial)
	Phenylethyl alcohol agar CO ₂ , 24–48h	<i>S. pyogenes</i> (19615) <i>S. aureus</i> (25923) <i>P. mirabilis</i> (12453)	Growth Growth Inhibition (partial)
Blood culture media (includes BHI, TSB, and other blood-based media. Other blood culture media from user source testing provided that manufacturers certify additional organisms tested for their intended use.)	Anaerobic (nonvented) within 5 days	<i>B. fragilis</i> (25285) <i>S. pneumoniae</i> (6305)	Growth Growth
	Aerobic (vented) within 5 days	<i>P. aeruginosa</i> (27853) <i>S. pneumoniae</i> (6305)	Growth Growth
Microaerophilic bacterium agar (for quality control)	Reduced O ₂ , enriched with CO ₂ , 42 °C, 48 h	<i>C. jejuni</i> (33291) <i>E. coli</i> (25922)	Growth Inhibition (partial)

Table 2. Manufacturers' Quality Assurance Procedure for Commercially Prepared Media (Continued)

Medium	Atmosphere, Length of Incubation ¹	Control Organisms (ATCC No.) ²	Expected Results
...e agar	CO ₂ , 24 and 48 h	<i>N. gonorrhoeae</i> (43069 or 43070) <i>H. influenzae</i> (10211)	Growth Growth
	Aerobic, 24–48 h 25 °C	<i>Y. enterocolitica</i> (9610) <i>E. coli</i> (25922) <i>P. aeruginosa</i> (27853) <i>E. faecalis</i> (29212)	Growth; deep red center, transparent border (bull's eye) Inhibition (partial to complete) Inhibition (partial to complete) Inhibition (partial to complete)
...ar	Aerobic, 24–48 h	<i>E. coli</i> (25922) <i>P. vulgaris</i> (8427) <i>S. aureus</i> (25923)	Growth; yellow centers Growth; bluish, spreading inhibited (partial) Growth; uniform deep yellow
...E Agar	Aerobic, 48–72 h	<i>L. pneumophila</i> (33152) <i>L. bozemanii</i> (33217)	Growth; yellow-green fluorescence under long-wave u.v. light Growth; blue-white fluorescence under long-wave u.v. light
...nt broths for GN Broth, Broths)	Aerobic, up to 24 h	<i>S. typhimurium</i> (14028) <i>S. sonnei</i> (9290) <i>E. coli</i> (25922)	Growth on subculture Growth on subculture (may be inhibited by Selenite media) Inhibition (partial to complete) on subculture. Growth on subculture from GN broth
...ethylene blue media EMB Agar; EMB dified)	Aerobic, 24 h	<i>S. typhimurium</i> (14028) <i>E. coli</i> (25922) <i>E. faecalis</i> (29212)	Growth, colorless to amber colonies Growth, blue-black colonies w/green metallic sheen Inhibition (partial)
...enteric agar	Aerobic, 24 h	<i>S. typhimurium</i> (14028) <i>S. flexneri</i> (12022) <i>E. faecalis</i> (29212) <i>E. coli</i> (25922)	Growth, colonies blue to green-blue with black centers Growth, colonies green to blue-green Inhibition (partial; colonies yellow) Inhibition (partial to complete; colonies yellow to salmon colored)
...ey agar	Aerobic, 24 h	<i>E. coli</i> (25922) <i>P. mirabilis</i> (12453) <i>S. typhimurium</i> (14028) <i>E. faecalis</i> (29212)	Growth, pink colonies Growth, colorless colonies, inhibition of swarming (partial) Growth, colorless colonies Inhibition (partial)
...salt agar	Aerobic, 24 and 48 h	<i>S. aureus</i> (25923) <i>S. epidermidis</i> (12228) <i>P. mirabilis</i> (12453)	Growth, colonies have yellow zones at 48 h Growth, colonies have red zones at 48 h Inhibition (partial)

Table 2. Manufacturers' Quality Assurance Procedure for Commercially Prepared Media (Continued)

Medium	Atmosphere, Length of Incubation ¹	Control Organisms (ATCC No.) ²	Expected Results
...eria agar media ...ein–Jensen and ...ook)	CO ₂ up to 21 days	<i>M. tuberculosis</i> H37Ra (25177) <i>M. kansasii</i> Group I (12478) <i>M. scrofulaceum</i> Group II (19981)	Growth Growth Growth—May be inhibited on selective L-J and selective Middlebrook media

		<i>M. intracellulare</i> Group III (13950) <i>M. fortuitum</i> Group IV (6841) <i>E. coli</i> (25922)	Growth—May be inhibited on selective L-J and selective Middlebrook media Growth Inhibition (partial to complete)—Use only for selective mycobacteria media
d dextrose agar	Aerobic, up to 7 days 25–35 °C	<i>C. albicans</i> (60193 or 10231) <i>T. mentagrophytes</i> (9533)	Growth Growth
Shigella–Shigella ar	Aerobic, 24 h	<i>S. typhimurium</i> (14028) <i>S. flexneri</i> (12022) <i>E. faecalis</i> (29212) <i>E. coli</i> (25922)	Growth, colonies colorless with or without black centers Growth, colorless colonies Inhibition (complete) Inhibition (partial to complete; colonies pink to rose-red with precipitate)
mycology media containing imide and phenicol, excluding mold agar)	Aerobic, up to 7 days 25 °C	<i>A. niger</i> (16404) <i>C. albicans</i> (10231) <i>T. mentagrophytes</i> (9533) <i>E. coli</i> (25922)	Inhibition (partial to complete) on media containing cycloheximide Growth Growth Inhibition (partial to complete) on media containing chloramphenicol
media for ic <i>Neisseria</i> spp. (<i>Quality control required.</i>)	CO ₂ , 24–48 h	<i>N. gonorrhoeae</i> (43069 or 43070) <i>N. meningitidis</i> (13090) ³ <i>P. mirabilis</i> (43071) <i>E. coli</i> (25922) ³ <i>N. sicca</i> (9913) ³ <i>C. albicans</i> (60193) ³ <i>S. epidermidis</i> (12228)	Growth Growth Inhibition (partial)—use only for media containing trimethoprim Inhibition (partial) Inhibition (partial) Inhibition (partial) Inhibition (partial)
media for occi, with azide	Aerobic, 24 and 48 h	<i>E. faecalis</i> (29212) <i>S. pyogenes</i> (19615) <i>E. coli</i> (25922)	Growth, blackening around colonies Inhibition (partial to complete) Inhibition (partial)—Colorless colonies on bile esculin agar
media for occi, without azide	Aerobic, 24 and 48 h	<i>E. faecalis</i> (29212) <i>S. pyogenes</i> (19615)	Growth, blackening around colonies Inhibition (partial to complete)

Table 2. Manufacturers' Quality Assurance Procedure for Commercially Prepared Media (Continued)

Medium	Atmosphere, Length of Incubation ¹	Control Organisms (ATCC No.) ²	Expected Results
late medium, without indicator	Aerobic, 48 h (tightened cap)	<i>B. fragilis</i> (25285) <i>S. aureus</i> (25923)	Growth Growth
late medium, with vitamin K and	Aerobic, 48 h (tightened cap)	<i>P. anaerobius</i> (27337) <i>B. vulgatus</i> (8482) <i>C. perfringens</i> (13124)	Growth Growth Growth
edia (BHI and Tryptic h)	Aerobic, 24-48 h	<i>E. coli</i> (25922) <i>S. aureus</i> (25923)	Growth Growth
se lysine (holate) Agar	Aerobic, 24 h	<i>S. typhimurium</i> (14028) <i>S. flexneri</i> (12022) <i>E. faecalis</i> (29212) <i>E. coli</i> (25922)	Growth—Colonies red with black centers Growth—Colonies red Inhibition (partial) Inhibition (partial to complete; colonies yellow to yellow-red)

¹Temperature is 35 °C unless otherwise specified.

²ATCC is a registered trademark of the American Type Culture Collection.

³Required for commercial manufacturers; not necessary for testing by users.

CLIA DEFICIENCY NUMBER CONVERSION - EFFECTIVE 10/1/2003			
DEFICIENCY PREFIX = D		(Revised as of 10/7/03)	
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2007	2007	N	
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2015	2015	Y	
2015	3037	Y	
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4023	5411	N	Y			
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New Tags/New Requirements						
2132	Successful participation in Cytology PT					
3000	Lab performing non-waived testing meets 493.1101-493.1105					
3009	Federal State and Local Laws					
3045	Lab Closure - Record Retention					
5213	PT not evaluated					
5215	PT scores don't reflect					
5219	no comparative PT samples					
5309	transcribed data					
5803	Test report info in pt chart readily available to CMS or agent					
5455	molecular amplification					
5461	Run QC after reagent change, PM, critical part change					
5463	rotate QC among operators					
5467	Cal used as qc - different lot of cal					
5605	Neuromuscular - qualifies in Histo					
5761	Histocompatibility AB ID					

5980	PPM lab dir condition			
5981	PPM lab dir qualifications			
5983	PPM lab dir responsibilities			
5985	PPM lab dir directs no more than 5 labs			
5987	PPM lab dir assures test performed properly			
5990	PPM test personnel condition			
5991	PPM test personnel qualifications			
5993	PPM test personnel responsibilities			
5995	PPM test person use brightfield/phase contrast microscope			