COLLEGE of AMERICAN PATHOLOGISTS

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Microbiology Checklist

CAP Accreditation Program

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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES
Microbiology Checklist
12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged**:**
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

Requirement	Effective Date
MIC.22050	08/24/2023

REVISED Checklist Requirements

Requirement	Effective Date
MIC.11038	12/26/2024
MIC.11350	08/24/2023
MIC.11375	12/26/2024
MIC.11390	12/26/2024
MIC.13375	08/24/2023
MIC.19060	08/24/2023
MIC.21950	08/24/2023
MIC.22273	08/24/2023
MIC.22330	08/24/2023
MIC.22495	08/24/2023
MIC.22675	08/24/2023
MIC.22700	08/24/2023
MIC.31680	12/26/2024
MIC.31690	12/26/2024
MIC.32140	08/24/2023
MIC.42150	08/24/2023
MIC.42720	08/24/2023
MIC.52100	08/24/2023

DELETED/MOVED/MERGED Checklist Requirements

Requirement	Effective Date
MIC.19840	08/23/2023
MIC.20520	08/23/2023
MIC.21812	08/23/2023
MIC.21815	08/23/2023
MIC.22210	08/23/2023
MIC.22285	08/23/2023
MIC.22410	08/23/2023
MIC.22520	08/23/2023
MIC.42640	12/25/2024
MIC.63256	08/23/2023
MIC.63318	12/25/2024
MIC.63324	08/23/2023

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a microbiology laboratory section or department.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.


Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

GENERAL MICROBIOLOGY

Requirements in this section apply to ALL of the subsections in the microbiology laboratory (bacteriology, mycobacteriology, mycology, parasitology, molecular microbiology, and virology).

PROFICIENCY TESTING

MIC.00350 PT Extent of Testing **Phase II**

Organisms in proficiency testing specimens are identified to the same level as those from patient samples.

NOTE: If the laboratory's proficiency testing reports include incomplete identifications (eg, "Gram positive cocci" or "Mycobacterium species, not tuberculosis"), it must indicate that this matches the information produced by the laboratory's internal capabilities in patient reports. In other words, patient reports cannot be more specific than the identification level reporting in proficiency testing, unless the former contain more specific information provided by referral laboratories.

MIC.00375 PT for Susceptibility Testing **Phase II**

If any susceptibility testing is performed on-site, the laboratory participates in a proficiency testing program for the related subspecialty (eg, bacteriology, mycology).

Evidence of Compliance:

- ✓ Records of proficiency testing performance

QUALITY MANAGEMENT

QUALITY CONTROL - WAIVED TESTS

MIC.10060 QC - Waived Tests **Phase II**

The laboratory follows manufacturer's instructions for quality control, reviews results, and records acceptability prior to reporting patient results.

NOTE: Quality control must be performed according to manufacturer's instructions. Testing personnel or supervisory staff must review quality control data on days when controls are run prior to reporting patient results. The laboratory director or designee must review QC data at least monthly or more frequently if specified in the laboratory QC policy.

*With respect to internal controls, acceptable control results must be recorded, at a minimum, once per day of patient testing for each device.**

**Acceptable internal control results need not be recorded, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results.*

Evidence of Compliance:

- ✓ Records showing confirmation of acceptable QC results

MIC.10070 QC Corrective Action - Waived Tests **Phase II**

The laboratory performs and records corrective action when quality control results exceed the acceptable range.

QUALITY CONTROL - NONWAIVED TESTS

MIC.11005 Quality Control Organisms/Reference Cultures **Phase II**

The laboratory uses appropriate quality control organisms or reference cultures to check stains, reagents and susceptibility test methods.

NOTE:

1. *Quality control organisms may be ATCC strains or well characterized laboratory strains unless specified by the manufacturer*
2. *Quality control organisms are maintained in a manner to preserve their bioreactivity, phenotypic characteristics and integrity*

MIC.11015 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:

- ✓ Records reflecting that QC is run by the same personnel performing patient testing

MIC.11016 Commercial Product - QC **Phase II**

When using a commercial product, QC is performed according to the manufacturer's instructions or CAP Checklist requirements, whichever is more stringent.

MIC.11017 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:
- ✓ Records of control result approval

MIC.11018 QC Corrective Action **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. For example, evaluation could include comparison of patient results for the run or for the time period in question to historical averages, and/or review of selected patient results against previous results from the same patient to see if there may be evidence of a bias that could represent error.

The corrective action for tests that have an Individualized Quality Control Plan (IQCP) approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of corrective action for unacceptable control results

MIC.11020 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

MIC.11023 Direct Antigen Test QC - Nonwaived Tests **Phase II**

For nonwaived direct antigen tests performed on patient specimens, positive and negative controls are tested and recorded at least daily, or more frequently if specified in the manufacturer's instructions, laboratory procedure, or CAP Checklist.

NOTE: This requirement pertains to nonwaived tests with a protein, enzyme, or toxin which acts as an antigen. Examples include, but are not limited to: Group A Streptococcus antigen, C. difficile toxin, fecal lactoferrin and immunochemical occult blood tests. For panels or batteries, controls must be employed for each antigen sought in patient specimens.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

For each test system that requires an antigen extraction phase, as defined by the manufacturer, the system must be checked with an appropriate positive control that will detect problems in the extraction process. If an IQCP is implemented for the test, the laboratory's quality control plan must define how the extraction phase will be monitored, as applicable, based on the risk assessment performed by the laboratory and the manufacturer's instructions.

Evidence of Compliance:
- ✓ Records of QC results including external and electronic/procedural/built-in control systems **AND**
- ✓ Manufacturer's product insert or manual

MIC.11025 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- ✓ Records of alternative control procedures

CULTURE MEDIA

MIC.11035 Inspection of Media Shipments **Phase II**

Each shipment of purchased/acquired media is examined for breakage, contamination, appearance, and evidence of freezing or overheating. Unacceptable media is discarded, and problems identified during examination of media are recorded and reported to the manufacturer where indicated.

Evidence of Compliance:
- ✓ Records of media examination and action taken when unacceptable media is received

***REVISED** 12/26/2024*

MIC.11038 Media QC - Purchased/Acquired **Phase II**

An appropriate sample from each lot and shipment of each purchased/acquired medium for bacterial, mycobacterial, or mycologic culture is checked before or concurrent with initial use for each of the following:

1. **Sterility**
2. **Ability to support the growth of organisms intended to be isolated on the media by means of stock cultures or by parallel testing with previous lots and shipments**
3. **Biochemical reactivity, where appropriate**

NOTE: The laboratory must have records showing that all media are sterile, able to support growth, and are appropriately reactive biochemically. This checklist requirement does not apply to commercially prepared additives that are reconstituted when added to mycobacterial media.

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier. The media supplier's records must be retained and show that the QC performed meets the checklist requirements. Please refer to the IQCP section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

Problems with media deterioration or loss of reactivity in properly-stored media prior to the expiration date must be reported to the manufacturer, with records retained by the laboratory as part of corrective action.

Laboratories using media that have not implemented an IQCP must continue to test each lot and shipment of media and retain records of such testing.

Laboratories that supply uninoculated media to laboratories referring specimens to them are responsible for the quality control of the media and must provide media quality control records with each shipment. If the supplying laboratory uses an IQCP for media, it may instead provide a copy of the applicable IQCP or IQCP summary statement to the laboratory receiving the media (it is not necessary for the supplying laboratory to provide the data used to develop the IQCP). In this case, the director of the receiving laboratory must approve the IQCP and retain the record to show acceptance of the media QC processes.

Evidence of Compliance:

- ✓ Individualized quality control plan for the media approved by the laboratory director, as applicable **AND**
- ✓ Records of media quality control **AND**
- ✓ Records of reports of media problems/defects to manufacturers or referral laboratories supplying media

MIC.11045 Media QC - Laboratory Prepared **Phase II**

For culture media prepared by the laboratory, an appropriate sample of each medium is checked before or concurrent with initial use for each of the following:

1. **Sterility**
2. **Ability to support the growth of organisms intended to be isolated on the media by means of stock cultures or by parallel testing with previous batches**
3. **Biochemical reactivity (where appropriate)**

Evidence of Compliance:

- ✓ Records of media quality control

MIC.11055 Media Visual Examination **Phase II**

All media are in visibly satisfactory condition prior to use (within expiration date, plates smooth, adequately hydrated, uncontaminated, appropriate color and thickness, tubed media not dried or loose from sides).

GENERAL ISSUES - NONWAIVED TESTS

MIC.11060 Culture Result Reporting **Phase I**

If the laboratory is reporting culture results other than simply "growth/no growth," the laboratory has the ability to perform Gram stains as part of its bacterial identification process.

NOTE: The performance of a Gram stain on colonies from a culture plate may be a necessary procedure for guiding culture workup and in confirming the identification of organisms, especially when atypical findings are noted during the workup.

Personnel performing Gram stains for this purpose are subject to competency assessment. Requirements for proficiency testing must be met through participation in the bacterial culture proficiency testing programs.

MIC.11075 Smear Preparation and Stain Quality **Phase I**

The quality of smear preparation and staining is satisfactory for all microbiology stains (ie, proper smear thickness, free of precipitate, proper cell distribution, appropriate staining reactions, etc.).

NOTE: This can be evaluated by reviewing QC slides and random clinical slides.

*****REVISED** 08/24/2023***
MIC.11350 Morphologic Observation Evaluation **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing microscopic analysis (eg, stains or wet preparations) from direct specimens and cultured organisms at least annually.

NOTE: The laboratory must ensure the description and quantitation (if applicable) of microorganisms and human cells are reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:
1. *Circulation of a pre-graded set of organisms with defined staining characteristics.*
2. *Multi-headed microscopy*
3. *Use of photomicrographs with referee and participant identifications (eg, former CAP microbiology Surveys or other photomicrographs from teaching collections)*
4. *Use of digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation for Gram stains.*

The laboratory director or designee must determine acceptability criteria for agreement. The laboratory must maintain records of performance and record corrective actions taken for personnel demonstrating significant discrepancies from the group consensus.

Evidence of Compliance:
- ✓ Records of evaluation **AND/OR**
- ✓ Records of enrollment/participation of staff in an external assessment program

***REVISED** 12/26/2024*

MIC.11375 Review of Nomenclature **Phase I**

The laboratory maintains consistent nomenclature across testing platforms and considers use of contemporary nomenclature.

NOTE: The CAP does not require adoption of new or contemporary nomenclature for compliance with this requirement.

Nomenclature updates may impact the extent of work up in the laboratory, public health reporting, and/or interpretation of antimicrobial susceptibility testing results. The laboratory should take these factors into consideration when reviewing nomenclature updates to decide whether to adopt contemporary nomenclature.

The laboratory should be aware that multiple identification systems may generate conflicting names for the same organism and must mitigate or eliminate these inconsistencies.

Evidence of Compliance:

- ✓ Records showing that nomenclature updates for commercial identification test systems were reviewed by the laboratory and that the laboratory determined whether or not to adopt the updated nomenclature **AND**
- ✓ Records/examples of nomenclature consistency between testing systems if multiple identification systems are used by the laboratory

MIC.11380 Antimicrobial Susceptibility Test Interpretation Criteria **Phase II**

For antimicrobial susceptibility testing (AST) systems, there are written criteria for determining and interpreting minimal inhibitory concentration (MIC) or zone diameter sizes as susceptible, intermediate, resistant, non-susceptible, or susceptible dose-dependent. These criteria are reviewed annually.

NOTE: This checklist item applies to all antibacterial, antifungal, and antimycobacterial agents tested in the laboratory. The same criteria applied to clinical test results must be used for proficiency testing results.

The laboratory may use interpretive criteria from standards development organizations such as Clinical and Laboratory Standards Institute (CLSI) or European Committee on Antimicrobial Susceptibility Testing (EUCAST), the FDA, or in rare instances, validated institution-specific criteria.

The source of the breakpoints applied to interpret AST results must be documented for both manual and automated antimicrobial susceptibility testing methods, including the reference with the year it was published (eg, CLSI M100-S34, 2024). For automated susceptibility testing systems, laboratories may contact the manufacturer to understand the breakpoints applied by the automated expert rules programmed into the system for the test panels in use, if not already known.

Criteria must be reviewed by the laboratory and with the antimicrobial stewardship program in the institution (if applicable) annually. The records of the review must be available.

Evidence of Compliance:

- ✓ Listing of antimicrobial susceptibility test interpretive criteria applied to test results and the specific source document for these **AND**
- ✓ Patient reports with reporting of antimicrobial agents following written protocol **AND**
- ✓ Records of annual breakpoint review **AND**
- ✓ Proficiency testing susceptibility results following written policy

MIC.11385 Current Antimicrobial Susceptibility Test Interpretation Breakpoints **Phase I**

Effective January 1, 2024, the laboratory uses current breakpoints for interpretation of antimicrobial minimum inhibitory concentration (MIC) and disk diffusion test results. New breakpoints are implemented within three years of the date of publication by the FDA for laboratories subject to US regulations, or within three years of publication by CLSI, EUCAST or other standards development organization (SDO) for laboratories not subject to US regulations.

NOTE 1: For laboratories subject to US regulations, a breakpoint is considered obsolete three years after publication of an update by the FDA, though the laboratory may use currently accepted breakpoints from other SDOs with validation to support use. SDOs that develop breakpoints include the Clinical and Laboratory Standards Institute (CLSI) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST). Whether using breakpoints from the FDA or other SDOs, US laboratories must, at a minimum, adopt the change within three years of the official publication date of the updated breakpoint by the FDA.

NOTE 2: For laboratories not subject to US regulations, a breakpoint is considered obsolete three years after publication of an update by the SDO used by the laboratory. Laboratories must, at minimum, adopt the change within three years of the official publication date of the updated breakpoint by the SDO.

NOTE 3: Not all FDA-cleared susceptibility test systems apply current FDA-recognized breakpoints. Laboratories must determine if the breakpoints applied by their system are current and if they are not, validate changes to breakpoints as needed prior to use in patient result interpretation. Laboratories may also validate susceptibility test systems for use with alternative breakpoints (eg, those from SDOs or, more rarely, those that are institution-specific).

NOTE 4: Laboratories may choose to use CLSI, EUCAST, or FDA breakpoints. In rare instances, hospital-based laboratories may choose to use alternative breakpoints (eg, institution-derived breakpoints not recognized by SDOs or the FDA) that address unique patient and/or antimicrobial stewardship needs. In this case, the laboratory must have written documentation (eg, minutes from a pharmacy and therapeutic committee meeting, or a letter of approval signed by stakeholders) for the following:

- *Scientific and medical reasoning and institutional review/approval of institution-specific breakpoints*
- *Review and agreement to use alternative breakpoints by stakeholders (eg, chief medical officer, pharmacy, infectious diseases, and/or antimicrobial stewardship partners).*

Evidence of Compliance:

- ✓ Records of validation reports for breakpoints that differ from those included in the FDA-clearance of an instrument **AND**
- ✓ Records of the interpretive criteria used for antimicrobial susceptibility testing **AND**
- ✓ Source document (including year of publication) from which the interpretive criteria were derived **AND**
- ✓ Patient or LIS reports with interpretations matching the source document

*****REVISED** 12/26/2024***

MIC.11390 Susceptibility Testing - Pure Isolates **Phase II**

Antimicrobial susceptibility testing of bacterial, fungal, and mycobacterial isolates is performed using pure isolates or colonies (ie, susceptibility testing is not performed on mixed populations of organisms).

NOTE: A purity check must be performed by subculturing an aliquot of the inoculum onto a blood agar plate or other non-selective media at the same time the inoculum is used for susceptibility testing with the following exceptions:

- *A separate purity plate is not required for disk diffusion testing from isolated colonies, as long as the disk diffusion plate is carefully examined for a mixed culture.*

- *When testing by gradient diffusion methods, the manufacturer's instructions must be followed.*

MIC.11395 Referral of Isolates for Susceptibility Testing **Phase I**

If the laboratory is unable to perform susceptibility testing on-site, there is a mechanism to refer clinically significant isolates for which susceptibility testing is deemed necessary (eg, isolates obtained from blood or other sterile sites).

Evidence of Compliance:

✓ Records of referral of isolates for susceptibility testing

SPECIMEN COLLECTION AND HANDLING

Culture specimens are often collected by nurses or others outside the laboratory. An important aspect of quality control is the provision of adequate instructions to ensure proper collection and handling of specimens before they are received by the laboratory.

MIC.13200 Requisitions **Phase I**

Requests for analysis include source of specimen, test or tests requested and, when appropriate, type of infection and/or organism expected.

MIC.13250 Specimen Collection/Handling **Phase II**

There are written instructions for microbiology specimen collection and handling that include all of the following.

1. **Method for proper collection of culture specimens from different sources**
2. **Proper labeling of culture specimens**
3. **Use of appropriate transport media when necessary**
4. **Policies for safe handling of specimens (tightly sealed containers, no external spillage)**
5. **Need for prompt delivery of specimens to ensure minimum delay and processing (eg, CSF, wound cultures, anaerobes, viral culture specimens)**
6. **Method for preservation of specimens if processing is delayed (eg, refrigeration of urines)**

NOTE: Manufacturer's recommendations must be followed when there is a delay in delivery or processing of specimens for automated instruments (eg, blood culture instruments).

MIC.13275 Specimens for Molecular Amplification **Phase II**

The laboratory takes steps to prevent cross-contamination when handling specimens that will be tested using molecular amplification methods.

NOTE: Special precautions must be taken to avoid sample cross-contamination that may not affect culture-based methods but may lead to false positive results when tested using molecular amplification methods. For example, proper methods to prevent cross-contamination must be used when samples are processed in the same biological safety cabinet in which virus cultures are manipulated post-inoculation. Please refer to the Molecular Microbiology section of this checklist.

MIC.13375 **Rapid Detection of *Mycobacterium Tuberculosis* Complex - Laboratories Not Subject to US Regulations** **Phase I**

Appropriate testing is available, either in the laboratory or by a referral laboratory, for the rapid detection of *Mycobacterium tuberculosis* complex on at least one respiratory specimen submitted to the laboratory (preferably the first diagnostic specimen) for mycobacterial culture that includes a nucleic acid amplification test or follows an established testing algorithm for that country or region.

NOTE: The US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) algorithms for diagnosis of Mycobacterium tuberculosis complex infections recommend performing a diagnostic nucleic acid amplification test (NAAT) on the initial respiratory specimen from patients suspected of having pulmonary tuberculosis. This can include physician requests for patients with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered, but has not yet been established, and for whom the test result would alter case management or TB control activities (high index of clinical suspicion).

This requirement applies to any laboratory that may receive and/or process requests for mycobacterial culture on respiratory specimens.

Evidence of Compliance:

✓ Patient reports/worksheets with *M. tuberculosis* testing results **OR** referral laboratory reports with results, if available

REPORTING OF RESULTS

MIC.15000 **Preliminary Reports** **Phase I**

Preliminary reports are promptly generated, when indicated.

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

MIC.16550 **Adequate Incubators** **Phase I**

There are sufficient, clean, and well-maintained incubators available at specified temperature ranges.

LABORATORY SAFETY

Items in this section apply to ALL areas of the microbiology laboratory.

MIC.18968 **Agents of Bioterrorism** **Phase II**

The microbiology laboratory recognizes and safely handles isolates that may be used as agents of bioterrorism.

NOTE: Microorganisms likely to be utilized as biological weapons include Bacillus anthracis (anthrax), Brucella species (brucellosis), Clostridium botulinum (botulism), Francisella tularensis (tularemia), Yersinia pestis (plague) and variola major (smallpox).

As part of an institution-wide plan to prepare and respond to a bioterrorism event, the microbiology laboratory must have policies and procedures for the recognition of isolates that may be used as agents of bioterrorism.

Safe handling includes such activities as handling organisms under a certified biological safety cabinet, and not subjecting the isolates to identification utilizing automated instruments.

MIC.18976 Bioterrorism Response Plan **Phase I**

The laboratory is recognized in the institution's bioterrorism response plan and the role of the laboratory is outlined in the plan.

Evidence of Compliance:
- ✓ Organizational bioterrorism plan describing the role of the laboratory

MIC.18985 Spill Handling **Phase II**

The laboratory safely handles spills of infectious materials.

MIC.19010 Bench Top Decontamination **Phase II**

The laboratory decontaminates bench tops daily.

Evidence of Compliance:
- ✓ Records of daily bench top decontamination

MIC.19035 Safe Specimen Handling/Processing **Phase II**

The laboratory safely handles and processes specimens, including those suspected to contain highly infectious pathogens.

NOTE: Suggested topics to be considered in the policies and procedures include the need for tight sealing of containers, avoiding spills of hazardous materials, requirements for wearing gloves, the need for respirator protection, availability and use of vaccinations, and the hazards of sniffing plates.

For specimens suspected of containing highly infectious pathogens, laboratories must review national, federal, state (or provincial), and local guidelines for the handling of specimens from patients suspected to have high risk pathogens, such as Francisella tularensis, avian influenza, Ebola, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause disease in individuals and communities.

Evidence of Compliance:
- ✓ Records of universal precaution training for all personnel handling suspected infectious pathogens

*****REVISED** 08/24/2023***
MIC.19060 Biosafety Levels - Occupational Risk **Phase II**

The laboratory has minimized the occupational risk of exposure to infectious agents through the use of appropriate work practice controls in accordance with current recommendations on the biosafety levels (BSL) for working with different organisms.

NOTE: The laboratory director is responsible for defining and implementing work practice controls appropriate to the BSL of the laboratory and to minimize the risk of personnel infection. Work practice controls consist of combinations of equipment, processes and laboratory design that are appropriate for the type of laboratory, laboratory BSL (1 to 4), and infectious agents handled.

For bacterial, mycobacterial, mycologic, and virology processing and work performed in a biological safety cabinet (BSC):

- *Exhaust air from a class I or class II BSC must be filtered through high efficiency particulate air (HEPA) filters.*
- *Air from Class I and IIB cabinets is hard-ducted to the outside.*
- *Air from Class IIA cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least annually. It may also be exhausted through a dedicated stack that protects against backflow of air from adverse weather conditions or through the building exhaust air system in a manner (eg, thimble connection) that avoids any interference with the air balance of the biological safety cabinet or building exhaust system.*

The 6th edition of Biosafety in Microbiological and Biomedical Laboratories provides guidance for safe conduct of work from a biosafety perspective. It can be used as a tool for assessing and mitigating risk. Refer to Section IV - Laboratory Biosafety Level Criteria and Table 1. Summary of Laboratory Biosafety Levels (BSLs) for specific information.

Evidence of Compliance:

✓ Records of BSC HEPA filters and exhaust systems appropriate for the BSL and infectious agents handled

MIC.20530 Infectious Waste Disposal **Phase II**

Microbiology specimen residuals and contaminated media are disinfected, sterilized, and disposed of in a manner to minimize infectious hazards to personnel after completion of testing.

NOTE: Sterilization or decontamination within the microbiology section before disposal is preferred. If such material is transported before treatment, it must be placed into a leak-resistant rigid container, and appropriately labeled.

MIC.20540 Ether Safety - Parasitology **Phase II**

If a procedure uses ether, the diethyl ether is stored on open shelves in a well-ventilated room using the smallest can feasible (as shipped by manufacturer).

NOTE: The use of concentration techniques other than those requiring the use of ether is recommended.

BACTERIOLOGY

STAINS

MIC.21530 Direct Gram Stain Procedures **Phase I**

The laboratory follows defined criteria for using Gram stain results to provide a preliminary identification of organisms, evaluate specimen quality when appropriate, and guide culture work-up.

NOTE: The laboratory must have policies for the interpretation of the Gram stain, including the quantification, stain reaction, and morphotypes of organisms and cells (eg, neutrophils or squamous epithelial cells). Laboratories may correlate Gram stain results with the final culture results as a component of the quality management system.

This does not mean that interpretation of the Gram stain morphology suggesting a specific organism identification (eg, gram positive diplococci morphologically suggestive of pneumococcus) is required.

MIC.21540 Gram Stain QC **Phase II**

Quality control of Gram stain reagents is performed for intended reactivity for each new batch or lot, and shipment of stains and at least weekly against known gram-positive and gram-negative quality control organisms.

NOTE: Personnel who perform Gram stains infrequently must run a gram-positive and gram-negative control each day of testing. Control testing is not required during periods when patient testing is not performed.

Evidence of Compliance:
- ✓ Records of Gram stain QC

MIC.21560 Non-Immunofluorescent Stain QC **Phase II**

Quality control of all non-immunofluorescent, non-immunologic-based stains (other than Gram stains) is performed with a positive and negative quality control organism for intended reactivity each day of use, and for each new batch, lot number and shipment.

NOTE: Refer to MIC.51160 for requirement pertaining to parasitology permanent stains.

Evidence of Compliance:
- ✓ Records of non-immunofluorescent stain QC

MIC.21570 Fluorescent Stain QC **Phase II**

Quality control of fluorescent stains is performed for positive and negative reactivity each time of use.

Evidence of Compliance:
- ✓ Records of fluorescent stain QC

REAGENTS

MIC.21624 Reagent QC **Phase II**

Positive and negative controls are tested for each new batch, lot number, and shipment of reagents, disks/strips and stains.

NOTE: Reagents subject to this requirement include (but are not limited to) catalase, coagulase (including latex methods), oxidase and indole reagents; bacitracin, optochin, streptococcal latex agglutination grouping reagents, ONPG, X, V, and XV disks/strips. This does not include tests for antimicrobial susceptibility.

Evidence of Compliance:
- ✓ Records of reagent disk/strip, and stain QC

MIC.21626 Identification System QC **Phase II**

Appropriate positive and negative control organisms are tested for each new lot and shipment of reagents used in bacterial identification systems.

NOTE: An individualized quality control plan (IQCP) may be implemented by the laboratory to allow for the use of streamlined QC for commercial microbial identification systems (MIS). Refer to the IQCP section of the All Common Checklist for the requirements. The laboratory may use QC organisms in addition to those required for the streamlined QC. In order to qualify for streamlined QC, the user must fulfill initial and ongoing requirements as defined by the manufacturer and CLSI Guideline M50-A, Quality Control for Commercial Microbial Identification Systems, including the retention of test system verification and historical QC review as long as the streamlined QC is used, but in no case for less than two years.

For user-developed identification systems, commercial systems for which a streamlined QC process has not been developed, or any commercial system whose use is altered in any way from the manufacturer's instructions, all biochemical tests in each new lot number and shipment must be evaluated with known positive and negative control organisms.

Any test (eg, oxidase test) required for interpretation of MIS results that is not part of the MIS cannot be included in MIS streamlined QC procedures. QC requirements for such tests, including the use of positive and negative controls for each new batch, lot number and shipment are given in MIC.21624 (Reagent QC).

Evidence of Compliance:

- ✓ Individualized quality control plan for the MIS approved by the laboratory director, as applicable **AND**
- ✓ Records of MIS quality control

MIC.21632 Beta-Lactamase QC **Phase II**

Positive and negative controls are tested for beta-lactamase (other than Cefinase ®) tests on each day of use.

NOTE: Beta lactamase tests using Cefinase ® need be checked only with each batch, lot number and shipment.

Evidence of Compliance:

- ✓ Records of beta-lactamase QC

MIC.21813 CO_2 Incubator Levels **Phase I**

The laboratory checks CO_2 incubators daily for adequate CO_2 levels.

NOTE: It is acceptable to monitor and record CO_2 levels from digital readouts; however, the laboratory must verify that the readout is accurate (by initial calibration, Fyrite, or other calibrated CO_2 meter). The frequency of verification of the digital readout must be defined and should be performed, at minimum, at the frequency recommended by the manufacturer.

Evidence of Compliance:

- ✓ Records of daily CO_2 monitoring

BACTERIOLOGY SUSCEPTIBILITY TESTING

MIC.21835 Direct Identification and Susceptibility from Blood Culture Broth **Phase II**

If organism identification (ID) and/or antimicrobial susceptibility testing (AST) (phenotypic or genotypic) is performed directly from positive blood culture bottles, the broth from the bottle is inoculated onto solid media to assess for consistency with direct results.

NOTE: This checklist item is applicable to tests that detect bacteria and/or yeast in positive blood cultures that are culturable on standard bacteriological media such as sheep's blood agar and/or chocolate agar.

It is the responsibility of the laboratory director to determine the extent of confirmatory testing necessary by reviewing the manufacturer's recommendations and examining their verification/ validation data.

The accuracy of antimicrobial resistance markers or rapid phenotypic AST results performed directly from positive blood culture broth must, at a minimum, be confirmed by traditional AST methods following recovery on solid media during the internal verification/validation of the assay.

MIC.21910 Susceptibility Test QC Frequency **Phase II**

For antimicrobial susceptibility testing by either disk, gradient diffusion strips, or dilution (MIC) methods, quality control organisms are tested with each new lot number or shipment of antimicrobials or media before or concurrent with initial use, and each day the test is performed thereafter.

NOTE: The frequency of QC testing may be reduced to weekly (including the testing of new lots or batches of antimicrobials or media) if the laboratory director approves the use of an individualized quality control plan (IQCP), and the laboratory has records of satisfactory performance with daily QC tests as suggested by CLSI Standards. If multiple instruments are used for automated MIC testing, QC testing should be rotated equally among all testing instruments. Please refer to the IQCP section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP. For this purpose, satisfactory performance criteria are defined as follows:

1. *Records must show that all QC organisms are tested for 20 or 30 consecutive test days. For each drug/microorganism combination, no more than 1 of 20 or 3 of the 30 values may be outside the accepted QC ranges* ***OR***
2. *Records must show that all QC organisms are tested in triplicate (using separate inoculum suspensions) for 5 consecutive test days. For each drug/microorganism combination, no more than 1 of the 15 values may be outside the accepted QC ranges.*
   - *If 2 or 3 values are outside the accepted QC range during testing of 15 replicates, daily QC testing must be continued and performed in triplicate (using separate inoculum suspensions) for another 5 consecutive test days*
   - *For each drug/microorganism combination, no more than 4 of the 30 values may be outside the accepted QC range*

When a result is outside the accepted QC range during weekly QC testing, refer to the most recent CLSI Standards for the required corrective action.

If the laboratory performs QC on antimicrobial screening tests as defined by the CLSI Standard and manufacturer's instructions do not require QC on each day the test is performed, the laboratory must have an IQCP that meets all requirements defined in the All Common Checklist.

Evidence of Compliance:

✓ Records of susceptibility QC results at defined frequency and meeting defined acceptability criteria

MIC.21940 Standardized Inoculum **Phase II**

The inoculum used for antimicrobial susceptibility testing (ie, inoculum size) is controlled using a turbidity standard or other acceptable method.

NOTE: Antibiotic susceptibility may be substantially affected by inoculum size.

MIC.21943 Selection of Antimicrobial Agents to Report **Phase II**

The laboratory ensures that only antimicrobial agents appropriate for the organism and body site are routinely reported.

NOTE: The microbiology department may consult with the medical staff and pharmacy to develop a list of antimicrobial agents to be reported for specific organisms isolated from various body sites. These lists may be based on the CLSI recommendations provided in the M100 Table 1, which suggests those agents that might be reported routinely (Group A) and that might be reported selectively (Group B). Selective reporting of antimicrobial agents should help improve the clinical relevance of antimicrobial reporting and help minimize overuse of broad-spectrum agents that might result in selection of multi-resistant organisms.

The antimicrobial reporting policy should include antibacterial, antifungal, and antimycobacterial agents tested in the laboratory. Where applicable, policies should be reviewed with the stakeholders involved in the antimicrobial stewardship in the institution annually and records of the review should be available in the laboratory. The same policies should be used in reporting proficiency testing susceptibility results, particularly for isolates from cerebrospinal fluid and urine.

Evidence of Compliance:

- ✓ Patient reports with reporting of antimicrobial agents for different body sites following written policy **AND**
- ✓ Records of annual antimicrobial reporting policy review by the antimicrobial stewardship committee **AND**
- ✓ Proficiency testing susceptibility results following written policy

MIC.21944 Testing and Reporting Supplemental Antimicrobial Agents **Phase I**

The laboratory provides supplemental agent testing for organisms resistant to routinely tested antimicrobial agents, when necessary.

NOTE: The policy may include submission of isolates to an outside referral laboratory if testing is not performed onsite.

Evidence of Compliance:

- ✓ Patient testing reports demonstrating additional antimicrobial testing or referral

MIC.21946 Cumulative Susceptibility Data **Phase I**

For hospital-based microbiology laboratories, cumulative antimicrobial susceptibility test data are maintained and reported to the medical staff at least yearly.

*****REVISED** 08/24/2023***

MIC.21950 Inconsistent Antimicrobial Susceptibility Testing Results **Phase I**

The laboratory investigates unusual or inconsistent antimicrobial susceptibility testing results following a defined process.

NOTE: Acceptable results derived from testing QC strains do not guarantee accurate results with all patient isolates. Results from testing patient isolates must be reviewed and unusual or inconsistent results must be investigated to ensure accuracy. Expert software can identify unusual or inconsistent results that might be due to technical errors and to identify emerging resistance. Additional resources for determining which antimicrobial testing results are

unusual include the CLSI M100 Appendix A or the EUCAST Intrinsic Resistance and Unusual Phenotypes publication.

What is considered unusual (uncommonly found in the laboratory) antimicrobial susceptibility results may vary by local epidemiology. Examples of unusual antimicrobial susceptibility test results include:

1. *Escherichia coli resistant to carbapenems*
2. *Klebsiella spp. susceptible to ampicillin*
3. *Staphylococcus aureus resistant to vancomycin*

Actions must be taken to address unusual results. Actions may include consultation with a medical laboratory director, repeating antimicrobial susceptibility testing by the same or different method, confirming isolate identification, or referral of the isolate to a public health laboratory for confirmation. While confirming results, the laboratory must consider whether communication with treating clinicians is indicated to inform them that AST results are under investigation. In addition, laboratories may retrospectively review cumulative susceptibility testing data for unusual resistance patterns.

Evidence of Compliance:

✓ Records of investigation for unusual/inconsistent results

PROCEDURES AND TESTS

The requirements below define minimum standards for evaluation of routine bacterial cultures.

***NEW** 08/24/2023*

MIC.22050 Culture Media and Incubation Conditions **Phase II**

The laboratory uses defined media and incubation conditions to allow for the recovery of potential pathogens for each culture type, specimen, and/or body site.

NOTE: The media and incubation conditions must permit recovery of the bacteria expected for the specimen type, as clinically indicated or per laboratory protocol. This does not preclude the use of screening or surveillance cultures. At minimum, media and incubation conditions must allow for isolation and identification of potential pathogens for the following:

- *Respiratory specimens: Streptococcus pneumoniae and Haemophilus species*
- *Urine specimens: gram-positive and gram-negative bacteria (use of gram-positive selective media is not required)*
- *CSF and other sterile fluids: fastidious bacteria such as Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae*
- *Genital specimens for Neisseria gonorrhoeae: selective media designed for the recovery of N. gonorrhoeae, such as Thayer-Martin media*

RESPIRATORY SPECIMENS

MIC.22100 Sputum Gram Stain **Phase I**

A gram-stained smear is performed routinely on expectorated sputa to determine acceptability of a specimen for bacterial culture and as a guide for culture workup.

NOTE: An institution may define special policies to address patient needs at their institution in collaboration with providers. Examples include exceptions for patients with cystic fibrosis, suspected infection by legionellosis, and pediatric patients.

Evidence of Compliance:
- ✓ Records of sputum Gram stain results

MIC.22110 Unacceptable Sputum Specimens **Phase I**

Specimens deemed unacceptable by Gram stain review are not cultured for routine bacteria (or cultured only by special request) and the health care provider or submitting laboratory is notified so another specimen can be collected without delay, if clinically indicated.

NOTE: It is suggested that the laboratory notify an appropriate caregiver about an inadequate specimen even when specimens are submitted from an outpatient setting, or submitted to a referral laboratory. Notification can be by phone or computer report. The laboratory may implement written agreements with particular providers or submitting laboratories defining policies for handling sputum samples.

Evidence of Compliance:
- ✓ Records of specimen rejection such as rejection log or patient report

URINE SPECIMENS

MIC.22200 Urine Colony Count **Phase II**

Quantitative cultures (colony counts) are performed.

NOTE: Urine cultures must include an estimate of CFU/volume.

GENITAL SPECIMENS

*****REVISED** 08/24/2023***
MIC.22273 Group B Streptococcus Screen **Phase II**

Group B Streptococcus screens from pregnant women are collected and tested in accordance with the current guidelines.

NOTE: Universal prenatal screening for vaginal and rectal Group B streptococcal (GBS) colonization of all pregnant women at 36 to 38 weeks gestation is recommended. The optimum specimen for this test is a vaginal/rectal swab and results may be compromised if only a vaginal swab is submitted. Detection of GBS in urine cultures in this population should also be addressed.

Procedures for collecting and processing clinical specimens for GBS culture or molecular testing and performing susceptibility testing to clindamycin and erythromycin for highly penicillin allergic women are also included in the guidelines. Only the results of clindamycin should be reported. Erythromycin should not be reported and is tested only for the purpose of determination of possible inducible clindamycin resistance.

MIC.22280 Bacterial Vaginosis **Phase I**

Gram stains performed on vaginal specimens to make the laboratory diagnosis of bacterial vaginosis are scored and interpreted according to published criteria.

NOTE: Culture is not recommended for the diagnosis of bacterial vaginosis. Bacterial vaginosis (BV) is a syndrome involving a shift in the concentrations of aerobic and anaerobic flora of the genitourinary tract flora from a predominant presence of Lactobacillus sp. to that of a mixture of anaerobes, Gardnerella vaginalis and other gram-negative bacteria. Culturing for a particular organism, such as Gardnerella vaginalis, or any single organism or combination of organisms is not specific for the diagnosis of BV. Use of a scored Gram stain that demonstrates whether there has been a shift in the vaginal flora from predominantly gram-positive Lactobacillus to a gram-negative flora has been shown to correlate well with the Amsel criteria for the diagnosis of BV. The primary reason for performing a Gram stain on vaginal secretions is to diagnose bacterial vaginosis.

STOOL SPECIMENS

***REVISED** 08/24/2023*

MIC.22330 *Clostridioides (formerly Clostridium) difficile* **Phase II**

The laboratory defines criteria for the rejection of specimens for *C. difficile* and/or *C. difficile* toxin testing in stool.

NOTE: The laboratory, in collaboration with institutional stake holders (eg, infection prevention and control, antimicrobial stewardship, infectious disease physicians), must develop criteria for rejection of inappropriate specimens submitted to the laboratory for C. difficile testing. For example, these criteria may include stool consistency (eg, test only unformed stool), repeat testing (eg, do not perform repeat testing during the same episode of diarrhea), and any exceptions. Reference or commercial laboratories may not have the ability to collaborate with stakeholders, but still need to define rejection criteria.

Evidence of Compliance:

- ✓ Records of specimen rejection such as rejection log or patient report

MIC.22336 Stool Culture Reporting **Phase I**

The final report for stool cultures submitted for routine bacterial pathogen examination lists the organisms for which the specimen was cultured (eg, Salmonella, Shigella, Vibrio).

NOTE:

1. *It is inappropriate to report "No enteric pathogens isolated." The report should list the organisms whose presence was specifically sought (eg, No Salmonella, Shigella, or Campylobacter isolated).*
2. *When indicated, tests to detect Shiga toxin-producing E. coli (STEC) should be available at a referral laboratory if not performed onsite.*

MIC.22440 Stool Specimen Number/Timing **Phase I**

The laboratory defines the appropriate number and/or timing of collection of stool specimens submitted for routine bacterial testing.

NOTE: The laboratory may develop policies with its clinicians for the number and/or timing of collection of stool specimens submitted for routine bacterial testing. Suggestions made by the authors of a 1996 CAP Q-Probes study (Valenstein et al) include:

1. *Accept no more than two specimens/patient without prior consultation with an individual who can explain the limited yield provided by additional specimens*
2. *Do not accept specimens from inpatients after the third hospital day, without prior consultation*

3. *Test stool for Clostridiodes difficile toxin for all patients with clinically significant diarrhea and a history of antibiotic exposure. Consider C. difficile testing as an alternative to routine microbiologic studies for inpatients who have test requests for routine enteric pathogens*
4. *Positive test results for Clostridiodes difficile do not correlate well with disease in young children. Follow manufacturer's guidelines for guidance on the testing of pediatric patients.*

These recommendations are for diagnostic testing. Different policies may apply to tests ordered for follow-up.

CEREBROSPINAL & OTHER BODY FLUID SPECIMENS

***REVISED** 08/24/2023*

MIC.22495 Centrifugation of Body Fluids **Phase I**

If only plated media are used for sterile body fluids, fluid is centrifuged and the sediment used to inoculate media unless the entire specimen is plated.

NOTE: If insufficient specimen is received for centrifugation/concentration when specified in the procedure, the report must note that the culture results may be compromised by the limited volume of specimen received. Equivalent methods are acceptable, if validated by the laboratory.

MIC.22500 CSF Processing **Phase II**

CSF specimens are processed immediately on receipt.

NOTE: Bacterial meningitis is a critical condition that requires immediate attention. Samples must be processed upon receipt when meningitis is suspected. The laboratory may choose to handle surveillance cultures, eg, involving neurosurgical implants, differently.

Evidence of Compliance:

✓ Culture log or patient records

MIC.22550 CSF Back-Up Cultures **Phase II**

If bacterial antigen-detection methods are used, back-up cultures are performed on both positive and negative CSF specimens.

NOTE: Total dependence on a bacterial antigen test for the diagnosis of bacterial meningitis does NOT meet accreditation requirements. Meningitis may be caused by bacteria not detected by the antigen tests. Thus, culture is essential for proper evaluation of bacterial meningitis, and must be performed on the patient specimen - if not performed onsite by the laboratory, the inspector must seek evidence that culture is routinely performed in a referral laboratory if unable to be performed onsite.

Evidence of Compliance:

✓ Records of back-up CSF cultures performed on-site **OR** records indicating that cultures are performed at another location **OR** records that the order for CSF bacterial antigen was blocked by the computer due to no order for a culture

BLOOD CULTURES

MIC.22600 Blood Culture System **Phase II**

The blood culture system is capable of detecting both aerobic and anaerobic organisms, when indicated.

NOTE: This criterion is not intended to imply that anaerobic cultures must be performed on all blood cultures, but be available when clinically indicated.

MIC.22610 Manual Blood Culture Systems **Phase II**

For non-automated systems, macroscopically negative aerobic blood cultures are stained and/or subcultured within 12-48 hours of incubation.

Evidence of Compliance:

- ✓ Records of staining and/or subculture of macroscopically negative cultures

MIC.22620 Blood Culture Examination **Phase II**

Blood cultures are examined (macroscopically if manual method) for evidence of growth at least twice daily for the first two days of incubation, then at least daily for the remainder of the incubation period.

NOTE: The time to detection of positive blood cultures, whether processed by manual or automated methods, depends on the schedule of inspection for evidence of growth. The means of the inspection may include visual examination, gram staining, subculturing, or electronic analysis by continuous monitoring instruments. Because most significant positive blood cultures may be detected within 48 hours of incubation, it is recommended that blood cultures be examined for evidence of growth at least two times on the first two days of incubation, then at least once daily through the remainder of the laboratory's routine incubation period.

Evidence of Compliance:

- ✓ Patient records/worksheet with result of examination for manual methods at defined frequency

MIC.22630 Blood Culture Collection **Phase II**

Sterile techniques for drawing and handling of blood cultures are defined, made available to individuals responsible for specimen collection and practiced.

MIC.22635 Blood Culture Contamination **Phase II**

The laboratory monitors blood culture contamination rates and has established an acceptable threshold.

NOTE: The laboratory must determine and regularly review the number of contaminated cultures. Tracking the contamination rate and providing feedback to units and persons drawing cultures has been shown to reduce contamination rates. Other measures for consideration in monitoring blood culture contamination include the types of skin disinfection used, line draws, and the use of diversion devices.

The threshold may be established in collaboration with other relevant institutional groups (eg, infection prevention). The laboratory must perform and record corrective action if the threshold is exceeded.

Evidence of Compliance:

- ✓ Records of contamination rates and corrective action if threshold is exceeded **AND**
- ✓ Records of feedback to responsible parties

MIC.22640 Blood Culture Volume **Phase I**

The laboratory monitors blood cultures from adults for adequate volume and provides feedback on unacceptable volumes to blood collectors.

NOTE: Larger volumes of blood increase the yield of true positive cultures. The volume collected must be in accordance with manufacturer instructions (in most systems it is 20 mL, but smaller volumes may be recommended in some systems).

Evidence of Compliance:
- ✓ Records of monitoring of volume at a defined frequency **AND**
- ✓ Records of feedback to responsible parties

ANAEROBIC CULTURES

***REVISED** 08/24/2023*

MIC.22675 Anaerobic Cultures Specimen Acceptability **Phase I**

The laboratory defines acceptability criteria for anaerobic culture specimens.

NOTE: The laboratory acceptance criteria must include acceptable and unacceptable sources for routine anaerobic culture, as well as acceptable types of specimen containers to support the viability of anaerobic bacteria during specimen transport.

If the laboratory does not perform anaerobic cultures on-site, there must be a process to refer specimens to a referral laboratory for anaerobic culture when indicated or by request. Specimen acceptance criteria (including transport requirements) for the referral laboratory must be followed.

***REVISED** 08/24/2023*

MIC.22700 Cultures for Anaerobic Organisms and/or Organisms Which Grow Under Microaerophilic Conditions **Phase II**

Specimens submitted for anaerobic and/or microaerobic culture are inoculated promptly and incubated in proper conditions using media which support the recovery of the intended organisms.

NOTE: Culture for anaerobic organisms must include media to enable recovery of both anaerobic gram-negative and gram-positive organisms. For non-sterile sources, selective (eg, LKV and PEA) and/or differential agar (eg, BBE) must be used in addition to non-selective media. For sterile sources, it is acceptable for laboratories that identify organisms directly from primary cultures (such as identification performed by MALDI-TOF MS) to use only non-selective media.

When organisms which grow under microaerophilic conditions (eg, H. pylori or Campylobacter) are sought in culture, appropriate media for recovery must be used.

Adequate anaerobic incubation conditions must be ensured through monitoring of the anaerobic environment. This can be accomplished by the use of methylene blue strips, fastidious anaerobic QC organisms, or other methods. Microaerobic conditions, when used, must be monitored using QC organisms or other methods to ensure that environmental conditions are adequate to support growth of microaerophilic organism(s).

If specimens are referred to another laboratory, they must be transported in an expeditious fashion under defined conditions to successfully culture the intended organisms through the referral process.

Evidence of Compliance:
- ✓ Records of incubation condition monitoring

MYCOBACTERIOLOGY

QUALITY CONTROL

SPECIMEN HANDLING

MIC.31100 Specimen Collection/Transport **Phase I**

Specimens for mycobacterial testing are collected appropriately, in sealed leak-proof containers, and transported to the laboratory without delay.

NOTE: Collection of three sputum specimens at 8-24 hour intervals and including at least one first morning specimen is recommended for acid-fast smears and culture in patients with clinical and chest x-ray findings compatible with tuberculosis. Specimens must be delivered to the laboratory promptly; specimens that cannot be processed within one hour of the time of collection should be refrigerated during transport to and storage in the laboratory prior to processing. This will decrease overgrowth with contaminating organisms likely to be present.

Laboratories are encouraged to process acid-fast specimens in their laboratory or obtain results from referral laboratories as soon as possible so that smear results can be available within 24 hours of collection (see MIC.31200 below).

MIC.31120 Centrifuge Safety **Phase II**

Sealed screw-capped tubes are enclosed in sealed safety centrifuge carriers (ie, a double closure system) to minimize aerosol hazards when centrifuging specimens.

REPORTING OF RESULTS

MIC.31200 Acid Fast Stain Results **Phase I**

When clinically indicated, results of acid-fast stains are reported within 24 hours of specimen receipt by the testing laboratory.

Evidence of Compliance:
- ✓ Patient reports for acid-fast stain results

MIC.31220 Susceptibility Test Results **Phase I**

Susceptibility test results for *M. tuberculosis* are available in a timely manner.

NOTE: The rapid recognition of drug-resistant organisms is essential to the control of multidrug-resistant tuberculosis. For isolates of M. tuberculosis complex, the CDC and Prevention Laboratory work group recommends that laboratories use methods that may allow susceptibility test results to be available within 28 days of specimen receipt. From a CAP accreditation perspective, 28 days is a goal, not a requirement.

Evidence of Compliance:
- ✓ Patient reports for susceptibility test results

CONTROLS AND STANDARDS

MIC.31640 AFB Stain QC **Phase II**

Acid-fast bacillus stains are checked each day of use with appropriate positive and negative controls.

Evidence of Compliance:
- ✓ Records of stain QC

MIC.31650 Fluorescent Stain QC **Phase II**

Fluorescent stains are checked with positive and negative controls each time of use.

Evidence of Compliance:
- ✓ Records of stain QC

MIC.31670 Nucleic Acid Probe QC **Phase II**

If nucleic acid probes are used for identification of mycobacteria grown in culture, appropriate positive and negative controls are tested on each day of use.

Evidence of Compliance:
- ✓ Records of nucleic acid probe QC at defined frequency

***REVISED** 12/26/2024*

MIC.31680 Susceptibility QC - MTB **Phase II**

If the laboratory performs susceptibility testing of *Mycobacterium tuberculosis complex*, a control strain susceptible to all antimycobacterial agents is run each week of patient testing, and with each new batch/lot number of media and each new batch/lot number of antimycobacterial agents.

Evidence of Compliance:
- ✓ Records of routine and new lot QC results at defined frequency

***REVISED** 12/26/2024*

MIC.31690 Susceptibility QC - NTM **Phase II**

If the laboratory performs susceptibility testing of nontuberculous mycobacterial isolates, a control strain with established ranges is run each week of patient testing, and with each new batch/lot number of media and each new batch/lot number of antimycobacterial agents.

Evidence of Compliance:
- ✓ Records of routine and new lot QC results at defined frequency

PROCEDURES AND TESTS

RAPID METHODS

The College of American Pathologists encourages laboratories in areas with an increased incidence of tuberculosis or increased rate of recovery of mycobacteria to utilize the most rapid and reliable methods available for detection and identification of mycobacteria, especially M. tuberculosis, and the most rapid and reliable methods available for susceptibility testing of isolates of M. tuberculosis.

MIC.32100 Fluorochrome Stain **Phase II**

Fluorochrome staining is performed on mycobacterial smears prepared from primary respiratory specimens, either in the laboratory or by the referral laboratory.

NOTE: Such smears are easier to read than those stained with a conventional carbol-fuchsin based stain. Fluorescing organisms stand out prominently against the background of the smear, and the smears can be examined at a lower power than conventionally-stained smears, so that a larger amount of material can be examined in a given period of time. As with the interpretation of Ziehl-Neelsen- and Kinyoun-stained smears, expertise is needed for interpretation of smears stained with a fluorescent stain; not everything that fluoresces in such a stain is necessarily a mycobacterium. Particularly when only a few organism-like structures are seen, it is important to pay careful attention to their morphology before interpreting them as mycobacteria.

This requirement does not apply to laboratories outside of the United States where local regulations prevent fluorochrome staining.

Evidence of Compliance:

- ✓ Patient reports/worksheets with fluorochrome stain results **OR** referral laboratory reports with results

*****REVISED** 08/24/2023***

MIC.32140 Mycobacterial Identification Methods **Phase I**

The laboratory performs initial identification of mycobacterial isolates from the primary culture growth, when possible.

NOTE: The timely identification or exclusion of M. tuberculosis complex or definitive identification of nontuberculous mycobacteria can be accomplished through methods including nucleic acid probes, matrix assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry, nucleic acid amplification, or sequencing.

CONCENTRATION, INOCULATION, INCUBATION

MIC.32200 AFB Concentration **Phase II**

The laboratory defines specimen types requiring concentration before AFB smear examination and culture (eg, sputum).

MIC.32250 Specimen Inoculation **Phase I**

Specimens (other than blood) are routinely inoculated on media that support optimal growth of the majority of clinically relevant mycobacterial species.

NOTE: The use of two types of media (for specimens other than blood), including one liquid medium (when possible) or a comparable culture method, is recommended for optimal isolation of mycobacteria.

MYCOLOGY

QUALITY CONTROL

CONTROLS AND STANDARDS

MIC.41270 Nucleic Acid Probe/Exo-antigen QC **Phase II**

If nucleic acid probes or exo-antigen tests are used for identification of fungi isolated from culture, appropriate positive and negative controls are tested on each day of use.

Evidence of Compliance:
- ✓ Records of nucleic acid probe or exo-antigen QC at defined frequency

MIC.41370 Direct Smear Stain QC **Phase II**

Direct patient specimen stains (eg, acid fast, PAS, Giemsa, Gomori's methenamine silver, India ink) are checked with positive and negative controls on each day of patient sample testing.

NOTE: For certain stains such as GMS and Giemsa, the slide itself serves as the negative control. Controls for KOH preparations are not required.

Evidence of Compliance:
- ✓ Records of stain QC at defined frequency

MIC.41390 Fluorescent Stain QC **Phase II**

Fluorescent stains (such as calcofluor white) are checked with positive and negative controls each time of use.

Evidence of Compliance:
- ✓ Records of stain QC

MIC.41400 Lactophenol Cotton Blue QC **Phase II**

Lactophenol cotton blue is checked for intended reactivity with a control organism with each new batch, lot number, and shipment of reagent.

Evidence of Compliance:
- ✓ Records of QC at defined frequency

PROCEDURES AND TESTS

The intent of this series of requirements is to ensure the use of an appropriate variety of media and growth conditions to isolate the significant pathogens with minimal interference from contaminants.

MIC.42050 Selective Media **Phase II**

Suitable selective media are used for the growth and isolation of dermatophytes and/or systemic fungi.

MIC.42100 Selective Media **Phase II**

Media with antimicrobial agents are used to suppress the growth of contaminants.

NOTE: Antimicrobial agents may inhibit some yeasts and the yeast phase of dimorphic organisms. Both types of media (with and without antimicrobials) should be available and used when indicated.

MIC.42110 Mycology Plate Culture Media Safety **Phase II**

If plate culture media is used in mycology, appropriate safety precautions are taken (such as taping lid to plate on both sides when not in use or other appropriate measures) to prevent the accidental opening of a plate.

NOTE: Some authorities recommend the transfer of growing colonies from plate to tubed media, if the former is routinely used for initial inoculation.

MIC.42120 Mycology Culture Safety **Phase II**

When working with a colony exhibiting mycelial growth, all transfers are performed within a biologic safety cabinet, and the use of slide culture techniques is limited, whenever possible, to work with low virulence organisms.

MIC.42130 Mycology Teased Preparation Safety **Phase II**

When preparing teased preparations or "scotch" tape preps, mycelia are always submerged in liquid medium (such as lactophenol cotton blue).

*****REVISED** 08/24/2023***
MIC.42150 Incubation Temperature **Phase II**

Mycology cultures for dermatophytes and systemic fungi are maintained at suitable temperatures.

NOTE: The optimal incubation temperature for most mycology specimens is 30°C+/-2°C. Room temperature incubation (25°C) is also acceptable for dermatophytes but is not optimal for other fungi.

Evidence of Compliance:
- ✓ Temperature records

MIC.42200 Incubation Temperature **Phase II**

If cultures are incubated at room temperatures, actual ambient temperature (22 to 26°C) is recorded daily to determine if proper growth conditions are being maintained.

MIC.42250 Differential Tests **Phase II**

The laboratory differentiates fungi following a defined process appropriate for the extent of testing, including biochemical tests (eg, urease, carbohydrate assimilation and/or fermentation) and slide cultures, when appropriate.

NOTE: Laboratories offering full identification must have sufficient procedures and methods to do so. Smaller laboratories with limited services should have an arrangement with an approved referral laboratory for back-up and complete identification of mycology specimens.

MIC.42550 Dimorphic Fungi **Phase I**

The identification of dimorphic fungal isolates is confirmed by exo-antigen, molecular, yeast-mold conversion, MALDI-TOF mass spectrometry (MS), or tissue phase detection tests.

NOTE: Exo-antigen tests, DNA probes, DNA sequencing, or MALDI-TOF MS are recommended. Laboratories must ensure adequate inactivation prior to testing by methods that occur outside a biological safety cabinet and have risk for aerosol generation (eg, MALDI-TOF MS).

MYCOLOGY SUSCEPTIBILITY TESTING

MIC.42600 Susceptibility Testing QC Frequency **Phase II**

For antifungal susceptibility testing by either disk, gradient diffusion strips, or broth dilution (MIC) methods, appropriate quality control organisms are tested with each new lot number or shipment of susceptibility test reagents and media before or concurrent with initial use, and each day the test is performed thereafter.

NOTE: The frequency of QC testing may be reduced to weekly (and whenever any reagent component of the test is changed) if the laboratory director approves the use of an individualized quality control plan (IQCP), including all required elements of IQCP, and the laboratory has records of satisfactory performance with daily QC tests as suggested by CLSI Standards and Guidelines (M27, M44, and M38). Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

Evidence of Compliance:

- ✓ Records of susceptibility QC results recorded at defined frequency and meeting defined acceptability criteria

MIC.42660 Standardized Inoculum **Phase II**

The inoculum size of both QC strains and test organisms is standardized using a turbidity standard or another acceptable method.

MIC.42700 Antifungal Agents to Test/Report **Phase II**

The laboratory ensures that only antifungal agents appropriate for the organism and body site are routinely tested and reported.

NOTE: The microbiology department may consult with the medical staff and pharmacy to develop a list of antifungal agents to be reported for specific organisms isolated from certain body sites, instead of indiscriminate susceptibility testing and reporting of all fungal isolates or reporting of all antifungal agents that might be included on a test panel. Isolates from body sites for which susceptibility might be routinely tested and reported include Candida spp. isolates from blood cultures.

Evidence of Compliance:

- ✓ Patient records showing selection and testing of fungal isolates and reporting of fungal agents for certain body sites **AND**
- ✓ Records of review of antimicrobial reporting policies on an annual basis **AND**
- ✓ Proficiency testing susceptibility reporting following policy

*****REVISED** 08/24/2023***

MIC.42720 Inconsistent Antifungal Susceptibility Testing Results **Phase I**

The laboratory investigates unusual or inconsistent antifungal susceptibility testing results following a defined process.

NOTE: Acceptable results derived from testing QC strains do not guarantee accurate results on patient isolates. Results from testing of patient isolates must be reviewed, and unusual or inconsistent results must be investigated to ensure accuracy. For yeasts and molds, the time of endpoint reading (particularly for the echinocandins) and the effect of trailing growth (particularly for the azoles and flucytosine) can be significant factors impacting susceptibility results. Examples of inconsistent antifungal testing results include:

1. *Candida albicans resistant to all azoles*
2. *Candida spp. susceptible to azoles but resistant to echinocandins*
3. *Candida albicans resistant to echinocandins*

Actions must be taken to address unusual results. Actions may include consultation with a medical laboratory director, repeating antifungal susceptibility testing by the same or different method, confirming isolate identification, or referral of the isolate to a public health laboratory for confirmation. While confirming results, the laboratory must consider whether communication with treating clinicians is indicated to inform them that AST results are under investigation. In addition, laboratories may retrospectively review cumulative susceptibility testing data for unusual resistance patterns.

Evidence of Compliance:

- ✓ Records of investigation for unusual or inconsistent results

PARASITOLOGY

QUALITY CONTROL

MIC.51000 Reference Materials **Phase I**

Reference materials, such as permanent mounts, photomicrographs, CLSI documents M15-A and M28-A2, or printed atlases are available at the work bench to assist with identifications.

REAGENTS

MIC.51120 Reagents **Phase II**

If zinc sulfate is used, the solution is stored in a tightly-stoppered bottle and checked for specific gravity (1.18 for fresh specimens and 1.20 for formalin-fixed specimens) with a hydrometer whose scale is large enough to differentiate the two values.

Evidence of Compliance:
- ✓ Records for specific gravity checks on the zinc sulfate solution

MIC.51160 Permanent Stool Parasitology Stain QC **Phase II**

All permanent parasitology stains (eg, trichrome, iron hematoxylin) are checked for intended reactivity with controls or reference materials at least monthly (or with each test if performed less frequently than every month).

NOTE: PVA fixative solutions thoroughly mixed with fresh fecal material that has been seeded with buffy coat leukocytes usually provides reliable controls for permanent stains.

Evidence of Compliance:
- ✓ Records of permanent stain QC at defined frequency

MIC.51170 Special Stain QC **Phase II**

Stains that are used to detect specific parasites (eg, acid fast, fluorescent, Giemsa) are checked with appropriate control organisms each time of use.

NOTE: Laboratories may check stains used for blood parasites (eg, Giemsa, Wright-Giemsa) by confirming the intended reactivity of the stain on the cellular elements on the slide (eg, WBC, RBC, platelets). A slide prepared from a normal specimen can be used in lieu of a positive parasite slide.

Evidence of Compliance:
- ✓ Records of special stain QC each time of use

PROCEDURES AND TESTS

STOOLS FOR OVA AND PARASITES

*****REVISED** 08/24/2023***
MIC.52100 Ova/Parasite Exam **Phase II**

The microscopic examination of all stools submitted for an ova and parasite (O&P) examination includes a concentration procedure and a permanent stain.

NOTE: When a stool specimen is submitted fresh, the usual approach would be to perform a direct wet preparation (looking for motility), a concentration (helminth eggs/larvae/protozoan cysts), and the permanent stained smear (identification of protozoa missed by concentration and confirmation of suspect organisms). As a minimum (and certainly if the stool is submitted in preservatives), the standard O&P examination would include the concentration procedure and

a permanent stained smear. The main point is to ensure that the permanent stained smear is performed on all stool specimens, regardless of what was or was not seen in the concentration wet preparation. Often, intestinal protozoa will be seen in the permanent stained smear, but may be missed in the concentration examination. If the laboratory does not perform both a concentration procedure and a permanent stain, it must refer the testing that is not completed to a referral laboratory so that testing may be completed.

Laboratories in geographic regions that evaluate stool specifically for helminth ova as part of a general health asymptomatic screening program are not required to perform a permanent stain on screening specimens. Laboratories must have a mechanism to identify specimens received for asymptomatic screening, such as through a separate orderable test.

Evidence of Compliance:
- ✓ Patient reports/worksheets with concentration and permanent stain results **OR**
- ✓ Separate ova and parasite exam order for asymptomatic helminth ova screening

MIC.52190 Stool Number/Timing **Phase I**

The laboratory defines the appropriate number and/or timing of collection of stool specimens submitted for routine parasitology testing.

NOTE: The laboratory may develop policies with its clinicians for the number and/or timing of collection of stool specimens submitted for routine parasitology testing.

Suggestions made by the authors of a 1996 CAP Q-Probes study (Valenstein et al) include:
1. *Accept no more than two or three specimens/patients without prior consultation with an individual who can explain the limited yield provided by additional specimens*
2. *Do not accept specimens from inpatients after the fourth hospital day, without prior consultation*

These recommendations are for diagnostic testing. Different policies may apply to tests ordered for follow-up.

VIROLOGY

QUALITY CONTROL

CONTROLS AND STANDARDS

MIC.61380 Reagent Verification **Phase II**

Each new lot and shipment of reagents that detect multiple viruses are verified for each individual virus component prior to patient testing

NOTE: A pool reagent cannot be verified using only a pool control, as the reactivity of each virus specific component cannot be individually assessed. After initial verification, pool controls can be used for daily quality control of the pool reagent.

Evidence of Compliance:
- ✓ Records of reagent verification, as applicable

TESTS AND PROCEDURES

MIC.62400 Test Order and Reporting Information **Phase I**

For viral screening tests by direct antigen detection (direct immunofluorescence or EIA), rapid cell culture, or molecular methods, reports and test order information indicates the specific viruses sought/detected by the assay.

NOTE: For example, if the rapid cell culture method is used to detect seven different respiratory viruses, then the report must specifically indicate which viruses are included in the screening. While the cell lines in use may permit the growth of other viruses, such as enterovirus, these need not be specifically enumerated in the report, unless detected in a given sample.

MIC.62500 Viral Testing Algorithms **Phase I**

The laboratory incorporates criteria such as specimen source, diagnosis, suspected virus(es) and season into viral testing algorithms.

NOTE: Testing algorithms can vary depending on specimen type, virus(es) suspected, immune status of the patient, and season. For example, routine rapid EIA testing for influenza is not recommended outside of the respiratory virus season due to low specificity.

MOLECULAR MICROBIOLOGY

All requirements in this checklist section apply to nonwaived molecular-based infectious disease testing, with the exception of next generation sequencing (NGS). The Molecular Pathology checklist is used to inspect infectious disease testing performed by NGS.

The following requirements apply to waived molecular-based infectious disease testing: MIC.63252, MIC.65620, and MIC.66100.

Laboratories that use this section of the checklist must also comply with all applicable requirements included in the General section of the Microbiology checklist.

QUALITY MANAGEMENT

MIC.63252 Quality Monitoring **Phase I**

The laboratory monitors for the presence of false positive results (eg, due to nucleic acid contamination) for all molecular microbiology tests.

NOTE: Examples include review of summary statistics (eg, monitoring percentage of results that are positive for Chlamydia trachomatis and/or Neisseria gonorrhoeae for an increase above historical positive rate within a run or over multiple runs), unexpected increase in positive results for seasonal pathogens outside of the standard epidemiology, performance of wipe testing, and review and investigation of physician complaints on false positive results. Based on

monitoring data, the laboratory may implement additional mitigation strategies to minimize risk of contamination, such as process controls.

Evidence of Compliance:

- ✓ Records of data review, wipe testing, statistical data, and evaluation and corrective action if indicated

SPECIMEN HANDLING & PROCESSING

MIC.63327 Derivative Material Identification **Phase II**

There is a system to positively identify derivative material (eg, nucleic acid extracts) from patient specimens from nucleic acid extraction through all phases of subsequent testing and storage.

MIC.63328 Specimen Processing/Storage **Phase II**

Patient samples are processed promptly or stored appropriately to minimize degradation of nucleic acids.

NOTE: Frost-free freezers may not be used to store patient samples unless freezer temperature is monitored by a continuous monitoring system, or a maximum/minimum thermometer.

MIC.63340 Extracted Nucleic Acid Specimens **Phase II**

If extracted nucleic acid is accepted as a specimen type, the laboratory ensures that isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS. This policy is clearly displayed to ordering clients.

NOTE: All clinical testing must be performed in CLIA-certified laboratories or laboratories meeting equivalent requirements (refer to GEN.41350). This includes all components of testing that may impact the quality of the test result, including isolation or extraction of nucleic acids. Laboratories may choose to have referring clients formally attest that extracted nucleic acid submitted for testing has been isolated or extracted in an appropriately qualified laboratory.

Evidence of Compliance:

- ✓ Written statement on the test requisition, test catalog, or policy available to referring clients stating that the laboratory only accepts isolated or extracted nucleic acids for which extraction or isolation is performed in an appropriately qualified laboratory

ASSAY VALIDATION AND VERIFICATION - NONWAIVED TESTS

Additional requirements and details for validation and verification of nonwaived methods are found in the Test Method Validation and Verification - Nonwaived Test section of the All Common Checklist.

For waived tests, refer to the Waived Test Implementation section of the All Common Checklist.

MIC.64770 Validation Studies - Specimen Type/Collection Device **Phase II**

If the laboratory tests specimen types or uses collection devices other than those listed in the package insert, the laboratory performs validation studies to document adequate performance of the test with those specimen types or collection devices.

NOTE: Any change to the manufacturer's supplied or recommended specimen collection devices, solutions, or reagents or modifications to the assay as set forth in the manufacturer's labeling and instructions is considered a modification. It may include a change to specimen type, instrumentation or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results. Refer to the section Test Method Validation and Verification in the All Common Checklist for additional details.

Results from tests performed on specimen types not listed in the package insert may be reported without complete validation only if the specimen type is encountered rarely, precluding an adequate number for validation studies. Under these circumstances, the test report must include a disclaimer stating that the specimen type has not been validated

Evidence of Compliance:

- ✓ Records of validation studies for modified FDA-cleared/approved assays for different specimen types and collection devices

MIC.64790 Validation of Specimen Pooling **Phase II**

If the laboratory chooses to pool specimens for tests performed using test systems that have not been FDA-cleared/approved for that purpose (eg, *Chlamydia trachomatis/ Neisseria gonorrhoeae* NAAT on pooled urine specimens), the laboratory validates the testing procedure for pooled specimens, including limit of detection (sensitivity), reproducibility, and accuracy (method comparison).

NOTE: As part of the method comparison, the results for pooled specimens must be compared to the single (non-pooled) results using an adequate number of clinical specimens covering the entire range of organism concentration seen in clinical specimens (ie, low and high positive specimens).

Any clinical claim regarding the efficacy of pooling must be validated (see COM.40640).

MIC.64960 Validation or Verification Studies - Specimen Selection **Phase II**

Validation or verification studies were performed with an adequate number and representative (reasonable) distribution of samples for each type of specimen (eg, blood, fresh/frozen tissue, paraffin-embedded tissue).

NOTE: The number of specimens to be included in a verification study for each specimen type is to be determined by the laboratory director. Verification studies must include the following:

- *Evaluation of adequate numbers of positive and negative specimens across the specimen types to be used in the assay (eg, urine, genital swabs, rectal swabs, pharyngeal swabs), even if they are obtained with the same collection device*
- *Evaluation of local specimens representing the strains or genotypes, as appropriate, if geographic variations are known or expected in the strains or genotype of organisms tested*

Validation studies, by definition, are more rigorous assessments of non-FDA cleared/approved tests or specimens, requiring multiple positive and negative specimens representing all specimen types and strain/genotype variations.

For qualitative tests, a verification or validation study includes comparison of positive and negative test results to a comparable test method. For quantitative tests, the manufacturer's limit of detection, reportable range and precision must be validated or verified by the laboratory, as well as a comparison of patient test results across the reportable range of the test. Specimens for the validation or verification study can include quantitative external control material, cultured organisms (quantified) and proficiency testing material, and must include patient specimens.

Refer to the section "Test Method Validation and Verification" in the All Common Checklist for additional details.

Evidence of Compliance:

- ✓ Records of validation and verification studies

MIC.64975 Modified Cut-Off **Phase II**

If the laboratory has modified the manufacturer's cut off-value for a positive result, the new cut-off value has been validated.

Evidence of Compliance:

- ✓ Records of cut-off validation when different cut-off values are utilized

QUALITY CONTROL - NONWAIVED TESTS

Controls are samples that act as surrogates for patient/client specimens. They are processed like a patient/client sample to monitor the ongoing performance of the entire analytic process in every run.

Qualitative molecular tests typically include positive and negative controls and, in some instances, a sensitivity control to show that low level target is detectable. Quantitative tests typically include a negative control and at least two levels of control at relevant decision points to verify that calibration status is maintained within acceptable limits.

For waived tests, refer to the Quality Control - Waived Tests section of the checklist.

MIC.65200 Daily QC - Molecular-based Testing - Nonwaived Tests **Phase II**

The laboratory performs controls for molecular-based quantitative and qualitative tests each day of testing, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, and when changes occur that may impact patient results.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.

Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate.

Daily quality control must be run as follows:

- *Quantitative tests - three controls at least daily, including a negative control, a low-positive control and a high-positive control, except where a specific exception is given in this checklist*
- *Qualitative tests - a positive and negative control at least daily*

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

Controls must assess adequacy of extraction and amplification, eg, positive and negative controls that go through the entire testing process.

- *Laboratories performing tests using an IQCP may define their own quality control procedures to monitor the extraction and amplification phases based on the risk assessment performed by the laboratory and the manufacturer's instructions.*
- *If an IQCP is not in place that monitors the extraction and amplification processes, the following must be followed:*
  - *An extraction control must be used for each run with the positive control(s).*
  - *If the samples from an extraction batch are tested over multiple amplification runs, each amplification run must have its own amplification control. A single extraction control need only be tested in one of the amplification runs.*
  - *If samples from multiple extraction batches are tested in a single amplification run, each extraction batch needs an extraction control. All extraction controls must be tested in a single amplification run. A single amplification control is sufficient.*

Evidence of Compliance:

- ✓ *Records of QC results including external and electronic/procedural/built-in control systems* ***AND***
- ✓ *Manufacturer's product insert or manual*

MIC.65220 Multiplex QC - Nonwaived Tests **Phase II**

For multiplex tests, controls for each analyte are either included in each run or rotated so that all analytes are tested periodically.

NOTE: If an internal quality control process (eg, electronic/procedural/build-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

See also MIC.65200 Daily QC - Molecular-based Testing.

Evidence of Compliance:

- ✓ Records of multiplex test QC

MIC.65230 Control and Standard Acceptability Limits **Phase II**

Acceptability limits are defined for all control procedures, control materials, and standards.

NOTE: These controls must be appropriate for the range of sensitivities tested and should, ideally, focus on result ranges that are near clinical decision points.

MIC.65260 Isolation/Preparation **Phase II**

The laboratory evaluates the adequacy of nucleic acid isolation/preparation procedures.

NOTE: Adequacy of nucleic acid isolation/preparation procedures (manual or automated) must be evaluated with each assay by the use of positive and negative controls run in parallel with patient samples. To the extent possible, controls must be processed through all steps of the assay, including the extraction phase.

Evidence of Compliance:

- ✓ Records of controls used to assess adequacy

MIC.65270 Cut-Off for Qualitative Laboratory-Developed Tests **Phase II**

For qualitative tests that use a quantitative cut-off value to distinguish positive from negative results, the cut-off value is established initially, and verified with every change in lot or at least every six months.

NOTE: The limit of detection that distinguishes a positive from a negative result must be established or verified when the test is initially placed in service, and verified with every change in lot (eg, new master mix), instrument maintenance, or at least every six months thereafter. Note that a low-positive control that is close to the limit of detection can satisfy this checklist requirement, but must be external to the kit (eg, weak-positive patient sample or reference material prepared in appropriate matrix).

Evidence of Compliance:

- ✓ Records of initial establishment and verification at defined frequency

REAGENTS

For waived tests, refer to the Reagents section of the All Common Checklist.

MIC.65300 Reagent Storage **Phase II**

All test reagents and controls are stored properly and in a manner which minimizes target DNA/RNA contamination and degradation.

NOTE: Pre- and post-amplification reagents and controls must be stored under appropriate temperature and conditions in designated pre- and post-amplification areas. Temperature-sensitive reagents and/or controls may not be stored in frost-free freezers, unless either of the following conditions are met: 1) Reagent/control materials are kept in thermal containers and the laboratory can demonstrate that the function of these materials is not compromised; or 2) Freezer temperature is monitored by a continuous monitoring system, or a maximum/minimum thermometer.

Patient samples may be stored in a frost-free freezer only if the temperature is monitored in accordance with (2), above.

MIC.65320 New Reagent Lot - Multiplex Tests **Phase II**

For multiplex tests, at least two analytes are individually verified for each new shipment and lot, and the analytes verified are periodically rotated.

NOTE: A multiplex test simultaneously detects a defined set of analytes (eg, two or more pathogen-specific nucleic acid sequences) from a single run or cycle of the assay. Although a sample of analytes (at least two) may be used to verify each lot and shipment, the analytes verified must be rotated periodically as defined in laboratory procedure to assess all analytes in the multiplex test over time.

Evidence of Compliance:

- ✓ Records of new lot and shipment verification

PROCEDURES & TESTS

MIC.65500 Carryover **Phase II**

Nucleic acid amplification procedures (eg, PCR) use appropriate physical containment and procedural controls to minimize carryover (false positive results).

NOTE: This item is primarily directed at ensuring adequate physical separation of pre- and post-amplification samples to avoid amplicon contamination. The extreme sensitivity of amplification systems requires that the laboratory take special precautions. For example, pre- and post-amplification samples should be manipulated in physically separate areas; gloves must be worn and frequently changed during processing; dedicated pipettes (positive displacement type or with aerosol barrier tips) must be used; and manipulations must minimize aerosolization. Enzymatic destruction of amplification products is often helpful, as is real-time measurement of products to avoid manual manipulation of amplification products.

MIC.65520 Temperature Range Defined **Phase II**

For each step of the procedure all incubation temperatures are defined and recorded.

NOTE: For some instruments, this function is performed automatically by software provided by the manufacturer.

MIC.65530 Incubations - Manufacturer's Specifications **Phase II**

Incubations (reactions) performed using baths/blocks/instruments meet manufacturer's specifications.

NOTE: Bath/blocks/instruments must be able to maintain the appropriate temperature throughout the incubation (reaction) within the range specified by the manufacturer of the assay.

MIC.65540 Nucleic Acid Extraction/Isolation/Purification **Phase II**

Nucleic acids are extracted, isolated, and purified by methods reported in literature, by an established commercially available kit or instrument, or by a validated method developed by the laboratory.

Evidence of Compliance:

- ✓ Records to support nucleic acid extraction/isolation/purification is performed by a validated method

RESULTS REPORTING

MIC.66100 Final Report **Phase I**

The final report includes a summary of the test method and information regarding clinical interpretation if appropriate.

NOTE: For example, when a test may be performed by either direct antigen or PCR, including the test method in the report is important information for interpreting the results.