COLLEGE of AMERICAN PATHOLOGISTS

Al Hammadi Hospital Al Suwaidi
Laboratory Department

Microbiology Checklist

CAP Accreditation Program

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

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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
None

REVISED Checklist Requirements

Requirement	Effective Date
MIC.11038	12/26/2024
MIC.11350	08/24/2023
MIC.11375	12/26/2024
MIC.19060	08/24/2023
MIC.22330	08/24/2023
MIC.22495	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.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

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).

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

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

PROCEDURES AND TESTS

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

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

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.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.

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.