

December 2024 Changes

Microbiology Checklist

CAP Accreditation Program



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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text. **Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a “Revised” flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a “Revised” flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2024 CHECKLIST EDITION CHANGES NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
MIC	21820	Moved	MIC	11390
MIC	42640	Merged	MIC	11390
MIC	63318	Merged	COM	06250
		New	MIC	65610

*Deleted – Removed the requirement from the checklist edition

*Merged – Combined the requirement with a similar requirement in the same or different checklist

*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists ~~from the CAP website (cap.org)~~ 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.

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

QUALITY CONTROL - NONWAIVED TESTS

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

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1046[42CFR493.1282(b)(2)]

CULTURE MEDIA

****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 ~~for media listed as "exempt" in the CLSI Standard M22-A3, Quality Control for Commercially Prepared Microbiological Culture Media.~~ The media supplier's records must be retained and show that the QC performed meets the ~~CLSI standard and~~ checklist requirements. Please refer to the IQCP section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP. ~~End user quality control must be performed on the following, regardless of the exempt status:~~

- ~~• Campylobacter agar;~~
- ~~• Chocolate agar;~~
- ~~• Media for the selective isolation of pathogenic Neisseria;~~
- ~~• Other media not listed on Table 2 of M22-A3 (eg, dermatophyte test medium);~~
- ~~• Media used for the isolation of parasites, viruses, Mycoplasmas, Chlamydia;~~
- ~~• Mueller-Hinton media used for antimicrobial susceptibility tests; or~~
- ~~• Media commercially prepared and packaged as a unit or system consisting of two or more different substrates, primarily used for microbial identification.~~

~~Laboratories receiving media from media suppliers must have records showing that the quality control activities performed by the media supplier meet the CLSI Standard M22-A3, or are otherwise equivalent.~~ 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 ~~exempt~~ media that have not implemented ~~an IQCP or are using media that do not qualify for~~ an IQCP must continue to test each lot and shipment of media and retain records of such testing.

Laboratories that supply uninoculated media to ~~referring~~ laboratories referring specimens to them are responsible for the quality control of the media. ~~The laboratory and~~ must provide ~~records or certification of~~ 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 ~~approved~~ IQCP or IQCP summary statement must be available to the referring to the laboratory receiving the media (it is not necessary for the supplying laboratory upon request. Records 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 media quality control or the manufacturer's certificates of quality for each shipment must be available to the recipient 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

REFERENCES

- 1) Clinical and Laboratory Standards Institute. *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard*; 3rd ed. CLSI document M22-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2004.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Disk Susceptibility Tests*. ~~43th~~ 14th ed. CLSI standard M02. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~ 2024.
- 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988, final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(e)]
- 4) Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Detection of Fungi in Clinical Specimens-Direct Examination and Culture*. 2nd ed. CLSI guideline M54. Clinical and Laboratory Standards Institute, Wayne, PA; 2021.

GENERAL ISSUES - NONWAIVED TESTS

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

MIC.11375 **Taxonomy Changes** Review of Nomenclature

Phase I



The laboratory ~~reviews taxonomic changes~~ maintains consistent nomenclature across testing platforms and incorporates clinically relevant changes into patient reports considers use of contemporary nomenclature.

*NOTE: The laboratory must have a process to ensure that clinically relevant taxonomic changes are reviewed at least annually by the laboratory in collaboration with prescribers, antimicrobial stewardship teams and infection control committees, as appropriate, and incorporated into reporting patient and proficiency testing results even when commercial identification systems have not been updated. The genus and/or species names of microorganisms may change as new methods are applied to their taxonomy. This can impact the antimicrobials that should be reported for that organism and may also impact which breakpoints are used for reporting. For example, *Actinobacillus actinomycetomcomitans* was moved to the genus *Haemophilus* in 1985 and then to the new genus *Aggregatibacter* in 2006. The antimicrobials differ for *Haemophilus* species (CLSI M100, Table 2E) versus *Aggregatibacter* species (CLSI M45, Table 7).*

Bacterial taxonomic nomenclature is not valid until published in the International Journal of Systematic & Evolutionary Microbiology (IJSEM). For laboratories participating in the CAP's proficiency programs for microbiology, the Participant Summary Report Final Critique is a good source of information as the Microbiology Committee provides periodic updates in taxonomy through educational challenges.

Additional information for specific specialties may be found through the mini-reviews published in the Journal of Clinical Microbiology (January 2019, Vol 57, No 2) or on-line using web sites, such as the following:

For bacteriology

- ~~http://www.dsmz.de/bacterial-diversity/prokaryotic-nomenclature-up-to-date.html~~
- ~~http://enews.patricbrc.org/~~

For mycology:

- ~~http://mycobank.org~~
- ~~http://www.mycology.adelaide.edu.au~~
- ~~http://www.fungaltaxonomy.org~~
- ~~https://www.clinicalfungi.org/page/Home~~

For parasitology:

- ~~http://www.cdc.gov/dpdx/~~

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 ~~clinically relevant taxonomic changes~~ nomenclature updates for commercial identification test systems were reviewed ~~and incorporated~~ by the laboratory in collaboration with prescribers, antimicrobial stewardship teams and infection control committees 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

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria*; Approved Guideline; 3rd ed. CLSI document M45-ED3. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing*; 33rd ed. CLSI supplement M100. Clinical and Laboratory Standards Institute, Wayne, PA; 2023.
- 3) Kraft CS, McAdam AJ, Carroll KC. A Rose by Any Other Name: Practical Updates on Microbial Nomenclature for Clinical Microbiology. *J Clin Microbiol.* 2017; 55(1):3-4.
- 4) Munson E, Carroll KC. What's in a Name? New Bacterial Species and Changes to Taxonomic Status from 2012 through 2015. *J Clin Microbiol.* 2017; 55(1):24-42. Erratum in: *J Clin Microbiol.* 2017; 55(5): 1595.
- 5) Simner PJ. Medical Parasitology Taxonomy Update: January 2012 to December 2015. *J Clin Microbiol.* 2017; 55(1):43-47.
- 6) Loeffelholz MJ, Fenwick BW. Taxonomic Changes and Additions for Human and Animal Viruses, 2012 to 2015. *J Clin Microbiol.* 2017; 55(1):48-52.
- 7) Warnock DW. Name Changes for Fungi of Medical Importance, 2012 to 2015. *J Clin Microbiol.* 2017; 55(1):53-59.
- 8) Mathison BA, Pritt BS. Medical Parasitology Taxonomy Update, 2016–2017. *J Clin Microbiol.* 2019; 57(2): e01067-18.
- 9) Munson E, Carroll KC. An Update on the Novel Genera and Species and Revised Taxonomic Status of Bacterial Organisms Described in 2016 and 2017. *J Clin Microbiol.* 2019(2); 57: e01181-18.
- 10) Warnock, DW. Name Changes for Fungi of Medical Importance, 2016–2017. *J Clin Microbiol.* 2019(2); 57: e01183-18
- 11) Loeffelholz MJ, Fenwick BW. Taxonomic Changes for Human and Animal Viruses, 2016 to 2018. *J. Clin. Microbiol.* 2019(2); 57: e01457-18.

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-~~S33~~, ~~2023~~[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

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Disk Susceptibility Tests*. ~~43th~~[14th](#) ed. CLSI standard M02. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~[2024](#).
- 2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing*; ~~33rd~~, [34th](#) ed. CLSI supplement M100. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2023~~[2024](#).
- 3) Clinical and Laboratory Standards Institute (CLSI). *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*. ~~44th~~[12th](#) ed. CLSI standard M07. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~[2024](#).
- 4) Clinical and Laboratory Standards Institute (CLSI). *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*. 9th ed. CLSI standard M11. Clinical and Laboratory Standards Institute, Wayne, PA, 2018.

- 5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1263(b)(1)].
- 6) Clinical and Laboratory Standards Institute (CLSI). *Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts*. 4th ed. CLSI standard M27. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.
- 7) Clinical and Laboratory Standards Institute (CLSI). *Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi*. 3rd ed. CLSI standard M38. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.
- 8) Clinical and Laboratory Standards Institute (CLSI). *Reference Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts*. 3rd ed. CLSI guideline M44. Clinical and Laboratory Standards Institute, Wayne, PA, 2018.

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

MIC.2182011390 Susceptibility Testing - Pure **Cultures** Isolates

Phase II

RENUMBERED



Antimicrobial susceptibility testing of bacterial, fungal, and mycobacterial isolates must be performed using pure isolates or colonies (ie, susceptibility testing is not performed on mixed cultures 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.

BACTERIOLOGY GENITAL SPECIMENS

MIC.22273

Group B Streptococcus Screen

Phase II



Group B Streptococcus screens from pregnant women are collected and identified 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.

REFERENCES

- 1) Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. American Society for Microbiology Clinical and Public Health Microbiology Committee, Subcommittee on Laboratory Practices. Guidelines for the Detection and Identification of Group B *Streptococcus*. March 10, 2020.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing*; ~~33rd~~ 34th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2023~~ 2024.

MYCOBACTERIOLOGY CONTROLS AND STANDARDS

****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

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3708 [42CFR493.1262(b)]

****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 ~~included with~~ run each ~~batch~~ week of patient ~~isolates tested~~ 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

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Susceptibility Testing for Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes*. 3rd ~~2nd~~ ed. CLSI ~~standard M24~~ supplement M24S. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~ 2023.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes*. 4th ~~2nd~~ ed. CLSI ~~supplement M62~~ M24S. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~ 2023.
- 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988, final rule. *Fed Register*. 2003(Jan 24):3708 [42CFR493.1262(b)].

MYCOLOGY

MYCOLOGY SUSCEPTIBILITY TESTING

MIC.42640
Merged with
MIC.11390

Susceptibility Testing -- Pure Cultures**Phase II**

~~Only isolated colonies or pure cultures are used for performance of antifungal susceptibility testing (ie, susceptibility testing is not performed on mixed cultures).~~

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.63318~~, 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.

SPECIMEN HANDLING & PROCESSING

MIC.63318
Merged with
COM.06250



Specimen Handling

Phase II

~~The laboratory uses appropriate processes to prevent specimen loss, alteration, or contamination during collection, transport, processing and storage.~~

~~NOTE: Specimen collection, processing and storage must follow manufacturer's instructions and limit the risk of preanalytical error.~~

~~If residual samples are used for amplification-based testing, the laboratory ensures absence of cross-contamination of samples. For example, there must be a procedure to ensure absence of cross-contamination of samples during processing/testing for amplified molecular testing (such as C. trachomatis or N. gonorrhoeae tests) using liquid based cervical cytology (LBC) specimens. Alternatively, an aliquot can be removed for amplified molecular testing prior to LBC processing.~~

REAGENTS

MIC.65340

Probe or Primer Characteristics - Laboratory-Developed Test

Phase II



Information regarding the nature of any probe or primer used in a laboratory-developed test is sufficient to permit interpretation and troubleshooting of test results.

NOTE: Sequence and size data may not be available for commercially-obtained tests when this information is considered proprietary.

Evidence of Compliance:

- ✓ Records of probe or primer characteristics, such as oligonucleotide sequence, target, concentration, or purity, as applicable

PROCEDURES & TESTS

****NEW**** 12/26/2024

MIC.65610

Primary HPV Screening/Reflex Testing

Phase I



For laboratories performing primary HPV screening, the laboratory follows established professional recommendations or guidelines, and has a defined process for notifying providers when appropriate reflex testing or clinical follow-up is advised.

NOTE: Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing as necessary. This requirement does not apply to HPV/PAP co-testing where both tests are performed together.

If additional testing after a primary screening test is needed, the laboratory provides guidance to providers on submission of additional specimens.

REFERENCES

- 1) Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. *J Low Genit Tract Dis.* 2020;24(2):102-131.
- 2) The American College of Obstetricians and Gynecologists. Updated Cervical Cancer Screening Guidelines. ACOG. April 2021. Accessed January 30, 2024. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines>

MIC.65620

HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing

Phase I



The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or
- Sends additional testing to a referral laboratory if the specimen is suitable, or
- Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the [CDC](#) and [APHL](#) websites.

This checklist item does not apply to the testing of individuals from whom human-derived products for therapeutic use are being derived or other types of testing performed for the monitoring of HIV infection (eg, viral load, CD4 counts). Reporting HIV results to public health is not within the scope of this checklist item.

Evidence of Compliance:

- ✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES

- 1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at <http://stacks.cdc.gov/view/cdc/23447>. Published June 27, 2014. Accessed 11/19/2019.
- 2) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US). Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available at: <https://stacks.cdc.gov/view/cdc/50872>. Published January 2018. Accessed 4/2/2023.
- 3) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at [APHL Publications](#). Accessed 11/19/2019.

SANGER SEQUENCING AND PYROSEQUENCING

The requirements in this section apply to ~~a variety of methods that can be used for sequencing (eg, Sanger sequencing, pyrosequencing, methods other than~~ next generation sequencing (NGS). ~~If NGS methods are used for infectious disease-related testing (eg, sequences for specific organisms or taxonomic groups, assignment of drug resistance sequences, assignment of pathogenicity markers, or assignment of host response markers), the requirements in the Next Generation Sequencing section of the~~ The Molecular Pathology Checklist ~~must be used in conjunction with these requirements for inspection~~ is used to inspect infectious disease testing performed by NGS.