COLLEGE of AMERICAN PATHOLOGISTS

Microbiology: Key to the Individualized Quality Control Plan (IQCP) Option vs. Default CLIA/CAP Requirements

The table below compares the IQCP option with the default quality control required if an IQCP is not implemented. For some microbiology reagents or tests, quality control requirements have not changed and the use of an IQCP is not needed because the QC required is already compliant with regulatory requirements. Refer to the checklist requirements listed for the complete requirements.

NOTE: QC may not be performed less frequently than indicated in the manufacturer's instructions.

Type of Testing	Requirement Number	Default CAP/CLIA QC frequency	IQCP Option	Comments
Microbiology Media (exempt only)	MIC.21240 LSV.45390 MIC.31380 (Mycobact.) MIC.41200 (Mycology)	End user must check each lot and shipment of media before or concurrent with initial use for the following where appropriate: • Sterility • Ability to support growth • Biochemical reactivity	Implement an IQCP to allow for acceptance of manufacturer's QC in lieu of end user QC, except as specified in MIC.21240. Perform visual inspection upon receipt.	• Media not listed as exempt in the CLSI M22-A3 guideline are not eligible for CAP IQCP – end user QC is required • Media where end user quality control is specified in MIC.21240 (eg, Campylobacter, chocolate agar) are not eligible for CAP IQCP
Antimicrobial Susceptibility Testing (Manual or automated)	MIC.21910	All appropriate quality control organisms for the drug/bug combinations being tested must be completed each day of patient testing.	Implement an IQCP to reduce frequency of quality control to weekly.	• Applies to Kirby Bauer and e-tests as well as to automated MIC systems
Microbiology ID Systems with two or more substrates (non-molecular)	MIC.21626	Use positive and negative control organisms to check reactivity of all biochemical substrates in each new lot number and shipment of reagents for ID systems.	Implement an IQCP to perform streamlined QC as defined by the manufacturer. Quality control plan must be followed as approved.	• Applies to automated methods and manual biochemical methods where two or more substrates are used to provide an identification
MALDI-TOF	MIC.16605	Appropriate control organisms or calibrators are tested on each day of patient testing.	Not eligible for IQCP	• Current MALDI-TOF platforms are not eligible for IQCP, as they do not have internal controls.
Direct antigen with internal Controls testing (non-waived)	MIC.14583 IMM.41850 LSV.45676 LSV.48410	Use positive and negative external quality control material (organism or antigen) each day of testing. The positive control must detect	For non-waived testing, implement an IQCP to meet daily QC requirements. Quality control plan must be followed as approved.	• Examples include rapid Strep, Flu, RSV, Legionnaires' • Direct antigen testing that does not include an internal control process

Type of Testing	Requirement Number	Default CAP/CLIA QC frequency	IQCP Option	Comments
		problems in the extraction process.	External QC must be performed with each new lot and shipment.	is not eligible for CAP IQCP
Direct antigen testing with no internal controls	MIC.14616 IMM.41860 LSV.45702 LSV.48420	Use positive and negative external quality control material each day of testing. If there is an antigen extraction phase, use a positive control that will detect problems in the extraction process.	Not eligible for IQCP	• Direct antigen testing that does not include an internal control process is not eligible for CAP IQCP • Examples include CSF meningitis antigen and some Cryptococcal antigen kits
Molecular infectious disease testing with internal controls	MIC.63262	Use of positive and negative external control material on each day of testing. For quantitative tests, use three external control materials (negative, low-positive, and high positive) except where specified.	Implement an IQCP to meet daily QC requirements	• IQCP may be implemented for laboratory-developed and modified FDA- cleared/approved test systems that have internal controls
Gram stain	MIC.21540 LSV.45810	Weekly QC with known gram-positive and gram-negative QC organisms and QC with each new batch of stains.	Not eligible for IQCP	
Beta-lactamase	MIC.21632	Use positive and negative controls each day of use. QC by lot and shipment only if using Cefinase™.	Not eligible for IQCP	
Microbiology antisera	MIC.21628	Use positive and negative controls for each new batch, lot number, and shipment and at least every six months thereafter.	Not eligible for IQCP	• Examples include Salmonella/Shigella typing antisera
Microbiology reagents with no controls, for use in culture work-up	MIC.21624	Use positive and negative controls for each new batch, lot number, and shipment of reagents, disks/strips and stains.	Not eligible for IQCP	• Examples include PYR, indole, catalase, latex coagulation tests, optochin, bacitracin, Streptococcal grouping reagents