

MICROBIOLOGY – IQCP ELIGIBILITY of TESTS

Test	Default CMS/CLIA CAP		QC Frequency of Default	Eligible for IQCP
Direct Antigen	493.1261(a)	MIC.14583	Each day of patient testing	Yes
Molecular-Based Quantitative and Qualitative Test	493.1261(a) 493.1256(d)(3)(v)	MIC.65200	Each day of patient testing/run daily	Yes
Culture media (<u>Exempt</u> media as defined in CLSI M22)	493.1256(e)(4)(i) 493.1256(e)(4)(ii) 493.1256(e)(4)(iii)	MIC.21240 MIC.31380 MIC.41200	Each new batch, lot # and shipment check before or concurrent with initial use for: <ul style="list-style-type: none"> • Sterility • Ability to support growth and, as appropriate, select or inhibit specific organisms or produce biochemical response • Document physical characteristics of media when compromised, and report any deterioration in media to manufacturer 	Yes, may be done on exempt media (eg Blood agar, MacConkey, CNA) as defined in CLSI M22
Culture media (<u>Non-Exempt</u> media as defined in CLSI M22)	493.1256(e)(4)(i) 493.1256(e)(4)(ii) 493.1256(e)(4)(iii)	MIC.21240 MIC.31380 MIC.41200	Each new batch, lot # and shipment check before or concurrent with initial use for: <ul style="list-style-type: none"> • Sterility • Ability to support growth and, as appropriate, select or inhibit specific organisms or produce biochemical response • Document physical characteristics of media when compromised, and report any deterioration in media to manufacturer 	No (eg Chocolate, Campy agar, Thayer Martin and others)

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Antimicrobial Susceptibility testing	493.1261(b)(1)	MIC.21910	Each day tests are performed, must use appropriate control organisms to check procedure. Each batch of media AND each lot# and shipment of antimicrobial agents before, or concurrent with initial use	Yes, using CLSI M100
Antifungal Susceptibility tests (Disk, strips or MIC Method)	493.1263(b)(1) 493.1263(b)(2)	MIC.42620 MIC.42600	Each day tests are performed, must use appropriate control organisms to check procedure. Each batch of media AND each lot# and shipment of antifungal agents before, or concurrent with initial use	Yes
Gram stain	493.1261(a)(2)	MIC.21540	Perform weekly	No
AFB Stain (eg Kinyoun)	493.1256(e)(2)	MIC.31640	Each day of use	No
Fluorescent stain (includes fluorochrome)	493.1256(e)(3)	MIC.21570 MIC.31650	Each time of use	No
Beta Lactamase other than Cefinase™	493.1261	MIC.21632	Each day of use	No

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Bacitracin	493.1256(e)(1)	MIC.21624	Each new batch, Lot # and shipment	No
Catalase				
Cefinase™				
Coagulase Plasma				
Staph latex				
Germ Tube				
ONPG				
Optochin				
Oxidase				
Spot Indole				
X & V factor strips/disks				
Other reagents, disks/ strips/ stains (eg PYR, Mcat disk and others)				
MALDI TOF				
Salmonella and Shigella antisera, streptococcal serotyping systems	493.1261(a)(3)	MIC.21628	Each lot # and shipment, and once every 6 months. (NOTE: CAP for streptococcal grouping reagents MIC.21624 frequency is each new lot number and shipment)	No
LactoPhenol Cotton Blue	493.1263(a)	MIC.41400	Each lot number (commercially prepared), and shipment	No
Special stains used to detect Parasites (e.g. acid fast, fluorescent)	493.1256(e)(3)	MIC.51170	Each time of use	No
Parasitology permanent stain(s)	493.1264(c)	MIC.51160	Each month of use, laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics	No

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Antimycobacterial susceptibility test	493.1262(b)	MIC.31380	Each week tests are performed, laboratory must use the appropriate control organism(s) to check the procedure. Each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s)	No
Continuous monitoring blood culture instruments	Examples: BD FX, bioMerieux BacTAlert, Trek		Instrument is NOT ELIGIBLE	Media in Blood culture bottles meeting CLSI M22 criteria are eligible.
Continuous monitoring AFB instruments	Examples: BD MGIT, bioMerieux BacTAlert		Instrument is NOT ELIGIBLE	Media in AFB tube or bottle meeting CLSI M22 criteria are eligible
Automated ID / Susceptibility Instruments	Examples: Beckman MicroScan, BD Phoenix, bioMerieux Vitek 2		Instruments are NOT ELIGIBLE	ID Cards/Panels, ID Combo Panels using CLSI M50 Streamline QC are eligible
Automated ID / Susceptibility Instruments	Examples: Beckman MicroScan, BD Phoenix, bioMerieux Vitek 2		Instruments are NOT ELIGIBLE	MIC panels, Combo ID/MIC panels, sensitivity cards using CLSI M100 are eligible