

CMS Standards – Microbiology Tests that do NOT need IQCP

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CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC	
		Pos	Neg
QC Frequency: Each <u>day</u> of use			
D5473 493.1256	AFB Stains (eg Kinyoun, Ziehl-Neelsen)	Yes	Yes
D5501 493.1261	Beta-lactamase other than Cefinase	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC	
		Pos	Neg
QC Frequency: Each <u>time</u> of use			
D5475 493.1256	Fluorescent stains (includes fluorochrome AFB) and immunohistochemical stains	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC	
		Pos	Neg
QC Frequency: Each <u>new batch, lot #, and shipment</u>			
D5471 493.1256 (e)(1)	Bacitracin	Yes	Yes
	Catalase	Yes	Yes
	Cefinase	Yes	Yes
	Coagulase plasma	Yes	Yes
	Germ Tube test	Yes	No

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CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing

QC

Pos

Neg

QC Frequency: Each new batch, lot #, and shipment

D5471 493.1256 (e)(1)	ONPG	Yes	Yes
	Optochin	Yes	Yes
	Oxidase	Yes	Yes
	Spot indole	Yes	Yes
	X and V factor strips and disks	Yes	No

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC	
		Pos	Neg
QC Frequency: Each <u>week</u> of use			
D5503 493.1261 (a)(2)	Gram stain	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos Neg	
QC Frequency: Each <u>lot # and shipment, and once every 6 months</u>			
D5505 493.1261 (a)(3)	Salmonella and Shigella antisera, streptococcal serotyping systems	Yes	Yes
*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015			