SUMMARY OF MICROBIOLOGY QC REQUIREMENTS

Note: all procedures listed are eligible for the IQCP option described in S&C 16-02-CLIA (effective 1/4/2016)

TEST/PROCEDURE	QUALITY CONTROL	Reg. Cite	D TAG
BACTERIOLOGY			
Media; Commercially Prepared	Check each batch/lot/shipment for: • Sterility; • Ability to support growth; • As appropriate, selectivity/inhibition or biochemical response; and • Document deteriorated physical characteristics of media and report to manufacturer	493.1256(e)(4)(i-iii)	D5477
Gram Stain	Each week of use, check for positive and negative reactivity.	493.1261(a)(2)	D5503
Methylene Blue stain	Each day of use, check for positive and negative reactivity.	493.1256(e)(2)	D5473
Non-culture identification systems, i.e., direct antigen tests	Each day of patient testing: • For each qualitative procedure, include a negative and positive control. • For test systems with an extraction phase, include 2 controls, including one that is capable of detecting errors in extraction phase.	493.1256(d)(3)(ii) and/or 493.1256(d)(3)(iv)	D5449 and/or D5453
Molecular Amplification	Each day of patient testing, include 2 control materials. • If reaction inhibition is significant, include a control capable of detecting inhibition for false negative results.	493.1256(d)(3)(v)	D5455
Bacitracin, Catalase, Cefinase™ (beta-lactamase), Coagulase, ONPG, Optochin, Oxidase, and X, V and XV	Check each batch/lot/shipment when prepared/opened for positive and negative reactivity.	493.1256(e)(1)	D5471
Other Beta-Lactamases (i.e. acidometric, iodometric or non-Cefinase™ chromogenic based)	Each day of use, check for positive and negative reactivity.	493.1261(a)(1)	D5501
Reagents used with biochemical tests and other test procedures for bacteriological identification (e.g., hippurate, indole, LAP, PYR)	Check each batch/lot/shipment when prepared or opened for positive and negative reactivity.	493.1256(e)(1)	D5471
Identification systems (two or more substrates or two or more reagents, or a combination)	For each batch/shipment, check each media using control organisms to verify positive and negative reactivity of each substrate.	493.1256(e)(1)	D5471
Primary isolation media used for presumptive identification (e.g. MAC, EMB, CLED)	Check each batch/lot/shipment when prepared/opened: • Ability to support growth and as appropriate, selectivity/inhibition or biochemical response.	493.1256(e)(4)	D5477
Antisera (used for serotyping)	Check with a positive and negative control: • Each batch/lot/shipment when prepared or opened; and • Once every 6 months thereafter	493.1261(a)(3)	D5505

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TEST/PROCEDURE	QUALITY CONTROL	Reg. Cite	D TAG
BACTERIOLOGY contd.			
Antimicrobial Susceptibility	• Check each batch of media and each lot/shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms; • Each day tests are performed, use appropriate control organism(s) to check the procedure; • Zone sizes or MICs within established limits before reporting patient results; and • Ensure proper standardization of the inoculum (e.g., use a 0.5 McFarland standard or its optical equivalent, or follow manufacturer's instructions for a commercially available system).	493.1261(b)(1)-(b)(2) 493.1255(a)(2)(i)	D5507 D5437
MYCOBACTERIOLOGY			
Fluorochrome Acid-Fast Stain	Each time of use, check for positive and negative reactivity.	493.1256(e)(3)	D5475
Acid –Fast Stains	Each day of use, check for positive and negative reactivity. Previously confirmed AFB, such as M. tuberculosis, for positive reactivity and E.coli for negative reactivity are acceptable.	493.1256(e)(2)	D5473
Molecular Amplification	Each day of patient testing, include 2 control materials. • If reaction inhibition is significant, include a control capable of detecting inhibition for false negative results.	493.1256(d)(3)(v)	D5455
All reagents or test procedures for identification (e.g., niacin test)	Each day of use, check with a positive and negative acid-fast organism.	493.1262(a)	D5511
Antimycobacterial Susceptibility	• Check, each batch of media and each lot/shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using approved control organism(s); • Establish limits for acceptable control results; • Each week tests are performed, use appropriate control organism(s) to check the procedure; and • Results for control organism(s) within established limits before reporting patient results.	493.1262(b)(1-3)	D5513

SUMMARY OF MICROBIOLOGY QC REQUIREMENTS

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TEST/PROCEDURE	QUALITY CONTROL	Reg. Cite	D TAG
MYCOLOGY			
Lactophenol Cotton Blue Stain	Check each batch/lot/shipment when prepared or opened for intended reactivity. Can use Aspergillus species or mycelial type fungus to check staining.	493.1263(a)	D5517
Modified AFB stain or Lactofuchsin	Each day of use, check for positive and negative reactivity.	493.1256(e)(2)	D5473
Calcofluor stain	Each time of use, check for positive and negative reactivity.	493.1256(e)(3)	D5475
Non-culture identification systems, i.e., direct antigen	Each day of patient testing: • For each qualitative procedure, include a negative and positive control. • For test systems with an extraction phase, include 2 controls, including one that is capable of detecting errors in extraction phase.	493.1256(d)(3)(ii) and/or 493.1256(d)(3)(iv)	D5449 and/or D5453
Germ tube test	Check each batch/lot/shipment when prepared or opened for positive reactivity.	493.1256(e)(1)	D5471
Nitrate reagent used in auxanographic medium for nitrate assimilation	Check each batch/lot/shipment when prepared or opened for positive and negative reactivity.	493.1256(e)(1)	D5471
Reagents used with biochemical tests and other test procedures for mycological identification	Check each batch/lot/shipment when prepared or opened for positive and negative reactivity.	493.1256(e)(1)	D5471
Antifungal Susceptibility	• Check each batch of media and each lot/shipment of antifungal agent(s) before, or concurrent with, initial use, using approved control organism(s); • Establish limits for acceptable control results; • Each day tests are performed, use appropriate control organism(s) to check the procedure; and • Results for control organism(s) within established limits before reporting patient results.	493.1263 (b)(1-3)	D5519
PARASITOLOGY			
Non-culture identification systems, i.e., direct antigen	Each day of patient testing: • For each qualitative procedure, include a negative and positive control. • For test systems with an extraction phase, include 2 controls, including one that is capable of detecting errors in extraction phase.	493.1256(d)(3)(ii) and/or 493.1256(d)(3)(iv)	D5449 and/or D5453
Parasite identification	• Have available a reference collection of slides or photographs and, if available, gross specimens for identification. • If size is a critical parameter, calibrate and use an ocular micrometer for determining ova and parasite size. ○ Instructions for ocular micrometer calibration and criteria for use of micrometer in determining size	493.1264(a) 493.1264(b) 493.1251(b)(5) 493.1251(b)(3)	D5523 D5525 D5403 D5403
Iodine solution	Working iodine solution stable for approximately 2 weeks	493.1252(d)	D5417
Zinc sulfate concentrations	Specific gravity of zinc sulfate: 1.18 for fresh stool, & 1.20 for formalized	493.1101(b) and/or 493.1252(a)	D3007and/ or D5411
Permanent stains	Each month of use, check using a fecal sample control material that will demonstrate staining characteristics.	493.1264(c)	D5527

SUMMARY OF MICROBIOLOGY QC REQUIREMENTS

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TEST/PROCEDURE	QUALITY CONTROL	Reg. Cite	D TAG
VIROLOGY			
Fluorescent stains	Each time of use, check for positive and negative reactivity. • Virus-infected cells for a positive control and uninfected cells for a negative control may be used.	493.1256(e)(3)	D5475
Non-culture identification systems, i.e., direct antigen	Each day of patient testing: • Positive and negative controls are required to evaluate the detection phase, if such controls are available. • For test systems with an extraction phase, include 2 controls, including one that is capable of detecting errors in extraction phase. Previously extracted viral antigen as the positive control plus a previously confirmed negative control of the same matrix as the patient sample may be used. A positive organism control must be subjected to the extraction process.	493.1256(d)(3)(ii) 493.1256(d)(3)(iv) 493.1256(h) 493.1256(d)(3)(iv)	D5449 D5453 D5485 D5453
Molecular amplification	Each day of patient testing, include 2 control materials. • If reaction inhibition is significant, include a control capable of detecting inhibition for false negative results.	493.1256(d)(3)(v)	D5455
Commercial cell culture media	Each shipment/lot, visual check for sterility and ability to sustain cell life.	493.1256(e)(4)	D5477
Laboratory prepared/produced cell culture media	For each batch: • Check each component of cell culture media for sterility; • Check toxicity of fetal bovine serum; • Check the combined product for sterility and the ability to propagate growth with cell cultures; and • Check for mycoplasma contamination at regular intervals.	493.1256(e)(4)	D5477
Cell culture for virus isolation or identification	Simultaneously incubate a cell substrate control or uninoculated cells as negative control material.	493.1265(a)	D5531
Uninoculated cell cultures	Prior to cell culture inoculation, check: 1. Age of the cell culture (no more than 7-10 days post "seeding"); 2. Maintenance media is free from inhibitory substances; and 3. Sterility (visual observation for turbidity).	493.1252(d) 493.1256(e)(4)(ii) 493.1256(e)(4)(i)	D5417 D5477 D5477

SUMMARY OF MICROBIOLOGY QC REQUIREMENTS

Note: all procedures listed are eligible for the IQCP option described in S&C 16-02-CLIA (effective 1/4/2016)

TEST/PROCEDURE	QUALITY CONTROL	Reg. Cite	D TAG
VIROLOGY contd.			
Neutralization test	Dilution of the viral isolate and control virus is standardized to the appropriate Tissue Culture Dose 50 or equivalent; and The optimum dilution of the antisera is determined to assure maximum sensitivity and specificity. Check each new lot of anti-serum or serum pool for toxicity.	493.1255(a)(2)(i) 493.1256(e)(4)(ii) and/or 493.1256(e)(5)	D5437 D5477 and/or D5479
Hemagglutination Inhibition Test	The optimum dilution of the antisera is determined to assure maximum sensitivity and specificity. Check how lab determines the working dilution of viral isolate and that working dilution is correct for isolates and controls. A serum/cell/buffer control and a cell/buffer control is included at laboratory determined frequencies. Include one known virus or viral antigen specific to each antisera.	493.1255(a)(2)(i) 493.1253(b)(1) or 493.1253(b)(2) 493.1253(b)(3) 493.1256(d)(3)(ii)	D5437 D5421 or D5423 D5425 D5449
Direct FA Immunofluorescence Test	Check if lab determined specificity of the conjugate and ruled out non-specific reactivity for each conjugate used.	493.1253(b)(1) or 493.1253(b)(2)	D5421 or D5423
Indirect FA Immunofluorescence Test	For individually purchased components, check if laboratory determined optimum dilution of its anti-species and virus specific immune serum. Check for positive and negative reactivity using: 1. Uninoculated cells + immune serum + anti-species conjugate (negative control); and 2. Viral antigen or known virus infected cells plus immune serum + anti-species conjugate (positive control). Each new batch or shipment of conjugate is checked using known virus infected cells plus PBS plus anti-species conjugate.	493.1253(b)(1) or 493.1253(b)(2) 493.1256(e)(3) 493.1256(e)(1)	D5421 or D5423 D5475 D5471