

MICROBIOLOGY <i>(For Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology Testing)</i>		
Tag #	Standard	Guidance
	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
MB1	<p>Microbiology Standard 1</p> <p>The laboratory procedure manual shall include flow charts and/or similar identification schemes which indicate all steps to be employed to isolate and identify organisms and all tests, media, reagents, etc.</p>	
MB2	<p>Microbiology Standard 2</p> <p>Daily log or worksheets that include all tests and test results which led to the identification of microorganisms shall be maintained by the laboratory.</p>	<p>Documentation on worksheets is not needed when growth is not observed on the media.</p> <p>Worksheets should include identification of the plating media or host systems used and the corresponding observations for each medium as well as biochemical test reactions where appropriate.</p>
MB3a MB3b	<p>Microbiology Standard 3</p> <p>The laboratory shall:</p> <p>a) maintain stock cultures for all quality control procedures; and,</p> <p>b) establish the reactivity for each organism if in-house isolates are used as control material.</p>	<p>Maintenance of stock cultures should be standardized in a manner that will minimize the opportunity for contamination or alteration of any characteristics.</p> <p>Validated patient isolates, proficiency testing specimens, or commercially prepared controls may be used. American Type Culture Collection (ATCC) controls are not required, except for use in susceptibility testing.</p>

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MB8a	<p>and practices related to their activities as a Laboratory Response Network (LRN) sentinel (formerly level A) laboratory, if applicable, including:</p> <p>a) maintaining updated LRN guidelines and protocols related to the testing, identification and reporting of select and emergent agents including information regarding special handling and safety practices to be employed;</p>	<p>Only, are currently considered LRN sentinel (formerly Level A) laboratories, unless designated as a LRN reference laboratory.</p>
MB8b	<p>b) providing staff with information regarding the biosafety level(s) (BSL) recommended for the microbiological testing being performed and identifying the highest BSL available for each category of microbiological testing;</p>	<p>Information regarding laboratory testing for critical and emergent agents is available to all laboratories on the CDC website. LRN sentinel laboratories holding NYS clinical laboratory permits are advised to regularly access the NYSDOH HPN for updated information related to testing, identification and reporting of these agents. Information regarding NYS HPN accounts can be obtained at 1-866-325-7743. Laboratories serving NYC should also access the NYC Department of Health and Mental Hygiene's Health Alert Network (HAN); for information, contact 1-888-NYCMED9 or nycmed@health.nyc.gov.</p>
MB8c	<p>c) identifying the LRN reference laboratory for their facility and contact information for individual(s) to be contacted if a select agent is suspected; and,</p>	<p>The Wadsworth Center may define the levels of testing (e.g. rule out only) and identification (e.g. presumptive only) and the reporting pathway for a particular agent. The Wadsworth Center's LRN distributes this information as needed to sentinel laboratories by fax and/or electronic copy to the laboratory director and posts these announcements on the HPN.</p>
MB8d	<p>d) distributing information to health care providers regarding specimen collection and submission instructions that should be followed when infection with a select agent or other infectious agent requiring special handling is suspected.</p>	<p>NYS and NYC LRN reference laboratory contacts and other LRN information is available on the NYSDOH LRN website which is accessed through the HPN. The Wadsworth Center LRN program staff can be contacted at LRNexec@health.state.ny.us.</p> <p>Biosafety levels and associated recommendations and practices are described in the CDC publication "<i>Biosafety in Microbiological and Biomedical Laboratories</i>" (BMBL) and on the CDC website at www.cdc.gov.</p> <p>Laboratories must comply with infectious disease reporting</p>

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		<p>requirements as outlined in the Public Health SS1: Reporting standard.</p> <p>Laboratories must comply with pertinent items of USA Patriot Act and the Select Agent Rule (e.g. disposal/transfer of select rule—see Microbiology Standard 9).</p>
MB9	<p>Microbiology Standard 9</p> <p>The laboratory shall establish and implement an inventory and tracking system that ensures that all samples and their derivatives suspected or confirmed to contain select agents are accounted for until laboratory findings establish the absence of a select agent. If a select agent is confirmed then documentation of its transfer including record of appropriate packing and shipping or destruction within seven days must be completed.</p>	<p>A list of select agents (Biological Diseases/Agents List) can be found at the federal Centers for Disease Control and Prevention website at http://www.bt.cdc.gov/agent/agentlist.asp. Inventory and tracking documentation shall include the identity of all individuals accessing such materials, as well as completion of CDC form 0.1318- "Report of the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory" for organisms and toxins isolated from clinical specimens. This tracking system includes select agents used as control material and for those specimens that are suspected to be positive for a select agent. Tracking will begin at the time it is suspected that a specimen contains a select agent.</p>
Molecular Testing		
Molecular standards have been moved to General Standards 35-44 except as noted below.		
MB10	<p>Microbiology Standard 10</p> <p>Assays using molecular methods shall indicate the method used on the patient report.</p>	

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	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
	<p>Bacteriology Standard 1</p> <p>The laboratory shall check positive and negative reactivity with control organisms as follows:</p>	
BT1a	a) each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents, DNA probes, direct antigen identification methods and all stains other than Gram stain.	a) For anaerobic bacteriology, the catalase reagent need only be checked with a control organism that produces a positive reaction.
BT1b	b) each week of use for Gram stain,;	d) In addition to Salmonella and Shigella antisera, antisera used for serotyping of homologous organisms, e.g., streptococcal serotyping systems, should be checked for positive and negative reactivity. Polyvalent antisera should be tested with at least one organism from each polyvalent group.
BT1c	c) each month of use for bacitracin, optochin, ONPG, X and V discs or strips;	e) All systems must be checked with both positive and negative organisms, regardless of the recommendation of the manufacturer.
BT1d	d) each month of use for antisera (except for direct antigen identification methods which shall be checked each day of use);	Non-automated screening tests for bacterial contamination of blood components, such as pH or glucose, are covered under the permit category of Blood Services Transfusion or Collection. Identification of the organism requires a Bacteriology permit.
BT1e	e) at the frequency recommended by the manufacturer of manual, automated, or semi-automated identification systems but not less frequently than with each new lot number or shipment received, except for automated systems used exclusively to screen for bacterial contamination of blood components, in which case only a positive control is required; and,	
BT1f	f) each new lot or each new batch prepared or received for all reagents not specified elsewhere in the New York State Laboratory Standards.	
	<p>Bacteriology Standard 2</p>	

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BT2	Non-disposable urine loops shall be calibrated monthly.	Calibration may be performed using a blue-dye methodology or by using a calibrated drill bit.
BT3	<p>Bacteriology Standard 3</p> <p>The environmental conditions of anaerobic bags, jars, and glove boxes shall be monitored and documented each day of use.</p>	An oxygen sensitive indicator such as methylene blue, resazurine, or a control culture of Clostridium novyi B should be placed in anaerobic jars or chambers to ensure anaerobic conditions are met.
BT4	<p>Bacteriology Standard 4</p> <p>Reports shall indicate methodology used.</p>	For example, reports for direct testing of Streptococcus Group A from throat swabs should indicate that a screening method was used. <input type="checkbox"/> Negative by antigen detection <input type="checkbox"/> or other appropriate wording should be included on the report.
BT5	<p>Bacteriology Standard 5</p> <p>Macroscopically negative aerobic blood cultures shall be stained and/or subcultured at some point before discarding.</p>	Subcultures and/or stains need not be done on blood cultures performed by radiometric methods or automated non-radiometric methods if the bottles are monitored for five days.
BT6	<p>Bacteriology Standard 6</p> <p>Laboratories that test for aerobic actinomycetes shall maintain:</p> <p>a) a diagnostic stain; and</p> <p>b) diagnostic identification tests.</p>	<p>Examples of suitable media are as follows (Note: the listed examples are not all-inclusive):</p> <p>a) Modified acid-fast stain;</p> <p>b) Casein, tyrosine, xanthine, lysosome, urea, or other similar media. These may be available as dehydrate to be prepared as needed.</p>
	<p>ANTIMICROBIAL SUSCEPTIBILITY TESTING: DISK DIFFUSION AND MINIMAL INHIBITORY CONCENTRATION</p>	
	<p>General</p>	
	<p>Bacteriology Standard 7</p>	

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BT7	Antibiotic panels appropriate to the specimen source and organism isolated shall be defined.	Guidelines should be established for the number and type of antibiotics tested and/or reported for organisms isolated from different sources. It is recommended that, in a hospital setting, the laboratory periodically reviews the most current formulary established by the pharmacy and/or the Infection Control Committee.
	Disk diffusion methods (standards 8-13)	
BT8	<p>Bacteriology Standard 8</p> <p>Each batch of media used for antimicrobial susceptibility testing shall be checked with the appropriate control strains before, or concurrent with, initial use utilizing approved reference organisms.</p>	
BT9	<p>Bacteriology Standard 9</p> <p>Using known reference organisms, the laboratory shall check each new lot of antimicrobial disks before, or concurrent with, initial use.</p>	
BT10	<p>Bacteriology Standard 10</p> <p>Antibiotic disks shall be evenly distributed over the culture plate not less than 15mm from the outer edge of the plate and no closer than 24mm from center to center.</p>	Generally, no more than 12 disks should be distributed on a 150mm petri plate and no more than 5 disks on a 100mm plate. For Haemophilus species, Neisseria gonorrhoeae, and Streptococcus species (including Streptococcus pneumoniae), no more than 9 disks per 150mm plate and no more than 4 disks per 100mm plate should be used.
BT11	<p>Bacteriology Standard 11</p> <p>A barium sulfate turbidity standard or equivalent shall be used to standardize the inoculum density for disk susceptibility testing.</p>	The turbidity standard should be equivalent to a 0.5 McFarland standard or its optical Alternate.
	Bacteriology Standard 12	Zone sizes may be measured using a ruler, sliding

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BT12	Zone sizes shall be recorded for each antimicrobial control test and accuracy control limits shall be established by the laboratory.	<p>calipers, or templates prepared for this purpose.</p> <p>The accuracy control limit is the acceptable range of zone diameters for that drug-microorganism combination.</p> <p>The laboratory may establish accuracy control limits or the laboratory may use the accuracy control limits provided in the current NCCLS Approved Standards, Performance Standards for Antimicrobial Disk Susceptibility Tests.</p>

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BT13a	<p>Bacteriology Standard 13</p> <p>For antimicrobial susceptibility disk diffusion testing, the laboratory shall:</p> <p>a) use the appropriate control organism(s) to check the procedure each day of testing; or,</p>	<p>Appropriate control strains for antimicrobial disk diffusion susceptibility include <i>Staphylococcus aureus</i> ATCC 25923, <i>Escherichia coli</i> ATCC 25922, <i>Pseudomonas aeruginosa</i> ATCC 27853, and <i>Enterococcus faecalis</i> ATCC 29212 (or 33186). <i>Escherichia coli</i> ATCC 35218 is recommended only for β-lactamase inhibitor combinations containing clavulanic acid, sulbactam, or tazobactam. An Alternate strain which demonstrates reactivity similar to an ATCC strain and for which limits have been established is acceptable. Organisms that manufacturers recommend or require for use in their systems are acceptable strains for control organisms.</p> <p>If susceptibility tests on fastidious organisms, such as <i>Haemophilus influenzae</i>, <i>Streptococcus pneumoniae</i>, <i>Moraxella catarrhalis</i>, and <i>Neisseria gonorrhoeae</i> are performed, the laboratory should follow specialized procedures which have been generally accepted by leading authorities in the Microbiology field. Control strains include <i>Haemophilus influenzae</i> ATCC 49247 and 49766, <i>Streptococcus pneumoniae</i> ATCC 49619, and <i>N. gonorrhoeae</i> ATCC 49226.</p> <p>b) The following requirements should be met if the laboratory performs weekly quality control testing:</p>
BT13b	<p>b) test each appropriate control strain a minimum of once each week during which patients are tested, provided the laboratory demonstrates satisfactory performance for this weekly quality control testing.</p>	<p>i) The laboratory should document that appropriate control strains were tested for twenty (20) or thirty (30) consecutive test days. For each drug-microorganism combination, no more than three of the thirty zone diameters may be outside the laboratory's established accuracy control limits.</p> <p>In addition, for each drug-microorganism combination, none of the six (6) zone ranges (obtained from grouping the 30 control test results into 6 groups of 5 consecutive tests) may be greater than the maximum allowable range for precision which has been defined by the laboratory.</p> <p>ii) Generally, one out of every twenty (20) tests in a series of tests might be out of control or three out of 30 zone diameters. Two consecutive tests out-of-control, or any more than two out-of-control results in 20 consecutive control tests requires corrective action. However, one zone diameter beyond four standard deviations above or below the midpoint between the stated limits also requires corrective action.</p> <p>iii) If a zone diameter is observed outside the established accuracy control limits during weekly quality control testing, the following control checks are necessary:</p>

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	For minimal inhibitory concentration (MIC) (standards 14-16)	
BT14	<p>Bacteriology Standard 14</p> <p>Each batch of macrodilution tubes, microdilution plates, and agar dilution plates used for antimicrobial susceptibility testing shall be checked with the appropriate control strains before, or concurrent with, initial use using approved reference organisms.</p>	
BT15	<p>Bacteriology Standard 15</p> <p>MIC's shall be recorded for each control test.</p>	
BT16a BT16b	<p>Bacteriology Standard 16</p> <p>For MIC antimicrobial susceptibility testing, the laboratory shall:</p> <p>a) use the appropriate control organism(s) to check the procedure each day of testing; or,</p> <p>b) test each appropriate control strain a minimum of once each week during which patients are tested, provided the laboratory demonstrates satisfactory performance for this weekly testing.</p>	<p>Escherichia coli ATCC 25922, Pseudomonas aeruginosa ATCC 27853, Enterococcus faecalis ATCC 29212, and Staphylococcus aureus ATCC 29213 are the recommended reference strains for both agar and broth methods. Escherichia coli ATCC 35218 is recommended only for beta-lactam-□-lactamase inhibitor combinations.</p> <p>If susceptibility tests on fastidious organisms, such as Haemophilus influenzae, Streptococcus pneumoniae, Moraxella catarrhalis, and Neisseria gonorrhoeae are performed, the laboratory should follow specialized procedures which have been generally accepted by leading authorities in the Microbiology field. Control strains include Haemophilus influenzae ATCC 49247 and 49766; Streptococcus pneumoniae ATCC 49619; and Neisseria gonorrhoeae ATCC 49226.</p> <p>b) The following requirements should be met if the laboratory performs weekly quality control testing:</p> <p>i) the laboratory should document that appropriate control strains were tested for a minimum of 20 or 30 consecutive test days. For each drug-microorganism combination, no more than one out of 20 or three out of 30 of the MIC</p>

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		<p>values may be outside the laboratory's established accuracy control limits.</p> <p>ii) generally, one out of every 20 tests in a series of tests might be out-of-control. Two consecutive tests out-of-control, or any more than two out-of-control results in 20 consecutive control tests requires corrective action.</p> <p>iii) whenever a MIC value is observed outside the established accuracy control limits during weekly quality control testing, the following control checks are necessary:</p> <p>Appropriate control strains should be tested for 5 days, during which time, all of the MIC values should be within established accuracy control limits for each drug-microorganism combination; and, if one MIC value is observed outside the established accuracy control limits, the laboratory should continue daily control testing for a minimum of another 30 consecutive days and meet all requirements stated above before weekly testing can resume.</p> <p>=====</p> <p>Automated equipment using an algorithm system to determine antibiotic susceptibility qualifies for testing each appropriate control organism once each week, provided the stated requirements are met.</p>

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	ALL CATEGORIES	
	<p>The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.</p>	
TB1a TB1b	<p>Mycobacteriology Standard 1</p> <p>For mycobacteriological staining, a positive and negative control shall be run with each new shipment or lot of stain and:</p> <p>a) for fluorochrome stains, each time of use; and,</p> <p>b) for stains other than fluorochrome, each day of use.</p>	
TB2	<p>Mycobacteriology Standard 2</p> <p>To minimize the possibility of specimen cross-contamination, slides shall be stained individually.</p>	Batch staining with jars or dishes is not permitted.

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<p>TB3a</p> <p>TB3b</p>	<p>Mycobacteriology Standard 3</p> <p>Each shipment or lot of commercial test system or test reagent(s) shall be tested with:</p> <p>a) at least one organism which produces the expected biochemical reaction (positive control); and,</p> <p>b) one organism which shows that the expected biochemical reaction does not occur (negative control).</p>	<p>a) During the decontamination of patient specimens, the positive control should be removed from the batch. False positive results have been reported due to contamination with a control that contained a high concentration of organisms (i.e. TB or NTM culture).</p>
<p>TB4</p>	<p>Mycobacteriology Standard 4</p> <p>Acid-fast stain results, both positive and negative, shall be reported to the ordering physician or other authorized person within 24 hours of the receipt of the specimen.</p>	<p>Reporting time should be periodically monitored to ensure compliance.</p>
<p>TB5</p>	<p>Mycobacteriology Standard 5</p> <p>The laboratory shall have documentation that positive fluorochrome stains in newly diagnosed patients:</p> <p>a) are confirmed by carbol fuchsin stain; or,</p> <p>b) are independently interpreted as positive by a second qualified person.</p>	
<p>TB6</p>	<p>Mycobacteriology Standard 6</p> <p>Negative acid-fast stained slides shall be retained until the final culture report has been issued.</p>	<p>The laboratory should implement a quality assurance monitor to assess proficiency with microscopy. This might include an independent review of a percentage (as determined by the laboratory director) of negative slides, or as a minimum, review of all smears from smear-negative, culture-positive specimens.</p>

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TB7	<p>Mycobacteriology Standard 7</p> <p>Positive acid-fast stained slides shall be retained for one year.</p>	<p>Fluorochrome slides will fade with time, so they should be retained in the dark. The slides may be restained with a carbol-fuchsin method if necessary.</p>
TB8	<p>Mycobacteriology Standard 8</p> <p>All respiratory specimens which test acid-fast smear positive and are from patients who have not previously been diagnosed with tuberculosis shall have nucleic acid amplification testing performed.</p>	<p>Specimens from patients with a past history of NTM infection and without clinical suspicion of tuberculosis (e.g., cystic fibrosis patients) do not need nucleic acid amplification testing performed.</p> <p>If the laboratory does not have the capability to perform nucleic acid amplification testing, an additional respiratory specimen shall be immediately requested and sent to a New York State permitted laboratory that performs nucleic acid amplification.</p>
TB9	<p>Mycobacteriology Standard 9</p> <p>For initial smear and culture positive respiratory specimens, the time elapsed between the date the specimen is taken and the date the susceptibility testing results for rifampin are reported shall be less than four weeks for 80% of these specimens.</p>	<p>This applies only to isolates identified or suspected of being <i>Mycobacterium tuberculosis</i> complex.</p> <p>This should be an ongoing quality assurance monitor.</p>
	SMEARS ONLY	
TB10a	<p>Mycobacteriology Standard 10</p> <p>Due to limited sensitivity, microscopy reports shall indicate that:</p> <p>a) the smear result shall be used as an adjunct in evaluating a patient's tuberculosis status; and,</p> <p>b) cultural examination is highly recommended for laboratory diagnosis.</p>	
TB10b		

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TB11	RESTRICTED, RESTRICTED-S, GENERAL, GENERAL-S	
	<p>Mycobacteriology Standard 11</p> <p>A biological safety cabinet (BSC) shall be used.</p>	Refer to Safety Standard SSP9 for operational guidelines.
TB12a TB12b	<p>Mycobacteriology Standard 12</p> <p>For all mycobacteriology procedures that use centrifuges:</p> <p>a) aerosol-free centrifuge cups shall be used; and,</p> <p>b) specimens shall be spun for a minimum of 15 min at greater than or equal to 3000 x g.</p>	
TB13	<p>Mycobacteriology Standard 13</p> <p>When performing patient testing, laboratories shall label initial and subsequent testing materials with:</p> <p>a) the specimen's accession number;</p> <p>b) the last name or other personal identifier that is not numerical; and</p> <p>c) the date of implementation of each phase of testing.</p>	<p>Errors have been attributed to mislabeling or misidentifying specimen material through the testing process.</p> <p>b) Since numbers can be easily transposed/misread, the use of the patient's last name may prevent errors in identification.</p> <p>c) The date of implementation may be the date that labels are generated. In the case of a small vial and the test is completed the same day and the date is captured on a work sheet, the name and the accession number may be sufficient.</p>

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TB14	<p>Mycobacteriology Standard 14</p> <p>At least one solid and one liquid medium shall be inoculated for culturing AFB (except for blood specimens processed with the BACTEC system using 13A bottles or Myco/F Lytic medium).</p>	<p>Solid media might include, but are not limited to: Lowenstein-Jensen, Lowenstein-Jensen Gruft, Lowenstein-Jensen with Iron, Lowenstein-Jensen with Pyruvic Acid, Middlebrook 7H10, Selective Middlebrook 7H10, Middlebrook 7H11, and Selective Middlebrook 7H11.</p> <p>Liquid media might include, but are not limited to, BACTEC 12B, Septi-Chek AFB, MGIT, ESP Myco, MB/BacT, BACTEC 9000MB.</p> <p>If a laboratory is using Septi-Chek with the paddle, an additional solid medium should be used.</p>
TB15	<p>Mycobacteriology Standard 15</p> <p>The purity of a positive acid-fast culture in liquid media shall be verified.</p>	
TB16	<p>Mycobacteriology Standard 16</p> <p>If susceptibility cannot be performed in-house, the culture should be referred in 24 hours to a New York State permitted laboratory for testing.</p>	<p>The laboratory that recovers initial <i>M. tuberculosis</i> complex isolates is responsible for assuring that susceptibility testing is performed.</p> <p>Whenever possible, the primary isolation media (i.e., 3-ml broth aliquot or slant) should be immediately submitted and a subculture should be retained in the originating laboratory.</p> <p>The laboratory should periodically monitor the time period from initial identification to the receipt of culture by the reference laboratory in order to assess the adequacy of isolate transport/shipping.</p>

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TB17	<p>Mycobacteriology Standard 17</p> <p>All initial isolates of <i>M. tuberculosis</i> complex shall be submitted to either the Wadsworth Center or NYC Public Health Laboratories, as appropriate, for DNA typing within 24 hours of a positive test result for <i>M. tuberculosis</i> complex. All other isolates must be saved for 12 months.</p>	<p>Laboratories located within New York City submit isolates to the NYC Public Health Laboratories; laboratories outside of New York City (upstate and out-of-state) submit isolates to the Wadsworth Center in Albany, NY.</p> <p>For all laboratories, <i>M. tuberculosis</i> complex isolated by the New York State Fast-Track Program do not need to be resubmitted to either public health laboratory by the original submitter. Isolates may be retained on appropriate media and stored at 4-8 degrees C or may be frozen at -70 degrees C to -80 degrees C.</p> <p>To expedite the genotyping testing, an aliquot of at least 3ml of the primary broth medium is recommended rather than waiting for a mature subculture on a slant.</p>
TB18	RESTRICTED, RESTRICTED-S	<p>Identification of these two taxons by use of biochemical reactions is not satisfactory.</p>
	<p>Mycobacteriology Standard 18</p> <p>The laboratory shall identify <i>M. avium</i> complex or <i>M. gordonae</i> by use of AFB morphology and genetic probe.</p>	
TB19	RESTRICTED-S, GENERAL-S	<p>This requirement can be met by in-house testing under the appropriate subcategory or by referral of the specimen to an appropriate NYS permitted laboratory.</p> <p>All <i>M. tuberculosis</i> complex- not <i>M. tuberculosis</i> isolates shall be referred to Wadsworth Center for final identification.</p> <p>Only <i>M. tuberculosis</i> identification should be performed in a Restricted-S laboratory.</p>
	<p>Mycobacteriology Standard 19</p> <p>Laboratories performing susceptibility testing of <i>M. tuberculosis</i> complex for first-line tuberculosis drugs shall identify <i>M. tuberculosis</i> and are responsible for ensuring a final identification in the event of <i>M. tuberculosis</i> complex- not <i>M. tuberculosis</i> isolate.</p>	

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TB20	<p>Mycobacteriology Standard 20</p> <p>A commercial liquid-based test system shall be used for <u>indirect</u> susceptibility testing.</p>	<p><u>Direct</u> susceptibility testing is not recommended when using liquid-based test systems for first- and second-line drugs.</p>
TB21	<p>Mycobacteriology Standard 21</p> <p>For susceptibility tests performed on <i>M. tuberculosis</i> complex isolates, the laboratory shall include a fully susceptible strain of <i>M. tuberculosis</i> at least once per week of use.</p>	<p>The laboratory can determine the MIC of each drug tested in order to quickly recognize problems with the test system.</p>
TB22	<p>Mycobacteriology Standard 22</p> <p>All initial isolates of <i>M. tuberculosis</i> complex shall be tested against the following first-line tuberculosis drugs:</p> <ul style="list-style-type: none"> - Rifampin (RMP) - Isoniazid (INH) - Pyrazinamide (PZA) - Ethambutol (EMB) - Streptomycin (SM) 	
TB23	<p>Mycobacteriology Standard 23</p> <p>If the laboratory does not have the capability to perform PZA susceptibility testing, the isolate shall be immediately sent to a New York State permitted laboratory that performs PZA testing.</p>	<p>The laboratory should periodically monitor the time period from initial identification to the receipt of culture by the reference laboratory in order to assess the adequacy of isolate transport/shipping.</p>

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TB24	<p>Mycobacteriology Standard 24</p> <p>For all initial isolates of <i>M. tuberculosis</i> complex, if resistance is found to one or more first-line drugs, additional susceptibility shall be performed using second-line drugs with the exception of mono-PZA resistance.</p>	<p>If second-line drug susceptibility cannot be performed in-house, the culture should be immediately referred to a New York State permitted laboratory for testing. Whenever possible, the primary isolation media (i.e., 3-ml broth aliquot or slant) should be immediately submitted and a subculture should be retained in the originating laboratory.</p> <p>Initial test results should not be held pending the additional testing, and should be reported immediately noting the additional testing being performed</p> <p>The laboratory should periodically monitor the time period from reporting first-line drugs to the receipt of culture by the reference laboratory in order to assess the adequacy of means of isolate transport/shipping.</p>
TB25	<p>Mycobacteriology Standard 25</p> <p>Susceptibility results for all initial isolates of <i>M. tuberculosis</i> complex showing resistance to one or more first-line drugs and for all isolates that change drug susceptibility patterns shall be confirmed at the NYC Public Health Laboratories or at the Wadsworth Center, as appropriate.</p> <p>While performing confirmatory testing, all first line drugs shall be repeated in addition to second-line drug testing.</p>	<p>Initial test results should not be held pending the additional testing, and should be reported immediately noting the additional testing being performed.</p> <p>Laboratories located within New York City submit isolates to the NYC Public Health Laboratories; laboratories outside of New York City (upstate and out-of-state) submit isolates to the Wadsworth Center in Albany, NY. The laboratory should maintain records of confirmation studies.</p>

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TB26	<p>Mycobacteriology Standard 26</p> <p>For antimycobacterial susceptibility tests, the laboratory must check 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).</p> <p>(1) The laboratory must establish limits for acceptable control results;</p> <p>(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure;</p> <p>(3) The results for the control organism(s) must be within established limits before reporting patient results;</p> <p>(4) The laboratory must document all control procedures performed.</p>	

Mycology		
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	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
MY1	<p>Mycology Standard 1</p> <p>A biological safety cabinet shall be used for processing specimens.</p>	<p>The use of at least a Class II BSC is recommended.</p> <p>Refer to Safety Standard SSP9 for operational guidelines.</p>
MY2	<p>Mycology Standard 2</p> <p>For all mycology procedures that require centrifugation, aerosol-free centrifuge cups shall be used.</p>	
MY3	<p>Mycology Standard 3</p> <p>The mycology laboratory shall have a 30 degrees C incubator and other incubators needed to maintain temperatures for the isolation and growth of pathogenic fungi.</p>	<p>If cultures are incubated at room temperature (22-26 degrees C), the temperature should be documented each day of testing to ensure that proper growth conditions are maintained.</p>
MY4a MY4b MY4c	<p>Mycology Standard 4</p> <p>Laboratories shall maintain media for:</p> <p>a) the isolation of antibiotic-sensitive zoopathogenic fungi;</p> <p>b) the initial isolation of cycloheximide-sensitive fungal pathogens and the elimination of bacterial contamination; and,</p> <p>c) the initial isolation of fungal pathogens and elimination of bacterial and fungal contaminants;</p>	<p>Examples of suitable media are as follows (Note: The listed examples are not all-inclusive):</p> <p>a) Sabouraud dextrose agar - no antibacterial or antifungal agents;</p> <p>b) Sabouraud dextrose agar - with antibacterial agents, or inhibitory mold agar;</p> <p>c) Sabouraud dextrose agar - with antibacterial and antifungal agents (e.g., Mycosel);</p>

Mycology		
Tag #	Standard	Guidance
<p>MY5a</p> <p>MY5b</p>	<p>Mycology Standard 5</p> <p>Laboratories shall maintain:</p> <p>a) a medium for the assessment of morphologic features of yeast-like pathogens; and,</p> <p>b) a commercial diagnostic system for the identification of yeast-like pathogens.</p>	<p>a) Cornmeal or cream of rice medium with Tween 80;</p> <p>b) Commercial yeast identification kit, either carbohydrate assimilation or enzyme based (e.g., API 20C AUX, MicroScan, Vitek).</p>
<p>MY6</p>	<p>Mycology Standard 6</p> <p>Laboratories with a Mycology General permit shall maintain a diagnostic medium to stimulate conidial formation required in the identification of zoopathogenic molds.</p>	<p>Examples of suitable media and stains are as follows (Note: The listed examples are not all-inclusive):</p> <p>Malt extract agar, potato dextrose agar, potato flake agar, or cornmeal;</p>
<p>MY7</p>	<p>Mycology Standard 7</p> <p>Primary clinical specimens and primary isolates of molds and yeasts shall be examined by direct microscopy using an appropriate mounting medium or stain.</p>	<p>Based upon clinical history and nature of the primary specimen, a direct examination is required with one of the following reagents or stains: potassium hydroxide, India ink, or Cellufluor mounts, or Gram, Giemsa or Methenamine silver stain, or other appropriate methods.</p> <p>Primary isolates may be examined with Lactophenol cotton blue, Cellufluor, India ink, Giemsa stain, or other appropriate methods.</p>

Mycology		
Tag #	Standard	Guidance
	<p>Mycology Standard 8</p> <p>The laboratory shall check positive and negative reactivity with control organisms as follows:</p>	
MY8a	a) each day of use for DNA probes; and fluorescent antibody stains;	<p>b) Reagents and test procedures used for identification purposes (including, but not limited to, germ tube, yeast and mold morphology media) should be tested with an organism that produces a positive reaction.</p> <p>c) Includes commercial yeast identification kits. See Microbiology Standard 4 guidance.</p>
MY8b	b) each week of use for all other stains; all reagents used with biochemical tests and other test procedures for mycological identification;	
MY8c	c) as recommended by the manufacturer of manual, automated, or semi-automated identification systems but not less frequently than with each new lot or shipment received;	
MY8d	d) for lactophenol cotton blue each batch when prepared in-house, each lot when commercially prepared and each shipment.	
	ANTIFUNGAL TESTING: YEAST ONLY	
	Laboratories holding this permit category should follow Mycology Standards 1 and 2 in addition to the applicable standards outlined below:	

Mycology		
Tag #	Standard	Guidance
MY9	<p>Mycology Standard 9</p> <p>For susceptibility testing, laboratories shall only report results for those drugs where published standards for interpreting results exist, or where ranges have been established by the laboratory and approved by the department.</p>	<p>Guidelines for selection of appropriate drugs to be tested against pathogenic yeast are provided in Rex et al (Clinical Microbiology Reviews, October, 2001 and other recent publications). NCCLS document provides guidelines for the following drugs:</p> <ul style="list-style-type: none"> Amphotericin B Fluconazole Flucytosine Itraconazole Ketoconazole <p>Additional drugs, including recently approved entities such as caspofungin, voriconazole, etc., can be tested by providing validation data to the department for review and approval before commencing patient testing.</p> <p>Similarly, newly described testing methods can be adapted for antifungal susceptibility testing by proper validation of test results.</p>
MY10	<p>Mycology Standard 10</p> <p>Reports for yeast susceptibility testing shall include a statement on the limitations and reliability of the interpretative guidelines.</p>	<p>The limitations should indicate the basis for establishing susceptibility ranges such as specific diseases, animal models and the reliability of break points. Protocols based on the NCCLS M27-A method, including commercial products, should use the interpretative guidelines in that document.</p>
MY11	<p>Mycology Standard 11</p> <p>Laboratories shall maintain an incubator at 35° C for susceptibility testing.</p>	

Mycology		
Tag #	Standard	Guidance
MY12	<p>Mycology Standard 12</p> <p>For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).</p> <p>(1) The laboratory must establish limits for acceptable control results.</p> <p>(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.</p> <p>(3) The results for the control organism(s) must be within established limits before reporting patient results.</p> <p>(c) The laboratory must document all control procedures performed.</p>	<p>Appropriate control strains (QC strains) for antifungal susceptibility testing of yeasts include <i>Candida parapsilosis</i> ATCC 22019 and <i>Candida krusei</i> ATCC 6258 using the NCCLS 27-A guidelines. Other strains where QC ranges have been previously described in peer-reviewed journal may be used.</p> <p>Recent publications from NCCLS document (M27-A, M38-A, M27-A2, and M23-A2) describe daily or weekly quality control standards.</p>
DISK DIFFUSION METHODS (Standards 13-14)		
MY13	<p>Mycology Standard 13</p> <p>Each batch of media used for antifungal susceptibility testing by disk diffusion shall be checked for the expected zone size using known reference organisms before or concurrent with initial use.</p>	
MY14	<p>Mycology Standard 14</p> <p>When using the disk diffusion method, the laboratory shall check each new lot of antifungal agents for the expected zone size using known reference organisms before or concurrent with initial use.</p>	<p>The relevant literature is available in the NCCLS document M27-A2.</p>
MACRODILUTION TUBES, MICRODILUTION PLATES, OR AGAR DILUTION PLATES METHODS (Standards 15-18)		

Mycology		
Tag #	Standard	Guidance
MY15	<p>Mycology Standard 15</p> <p>Before or concurrent with initial use, each batch of macrodilution tubes, microdilution plates, or agar dilution plates used for antifungal susceptibility testing shall be checked for MIC values that fall within range using appropriate control strains.</p>	<p>Antifungal standards or reference powders should not be from pharmacy stock or other clinical preparations.</p>
MY16	<p>Mycology Standard 16</p> <p>For each reference organism, the MIC determined by the laboratory shall be verified as consistent with expected values or the run shall be deemed invalid.</p>	<p>All QC data shall be recorded.</p>
MY17	<p>Mycology Standard 17</p> <p>For susceptibility testing, standardization of inoculum for both QC strains and test organisms shall be performed using one of the following methods:</p> <p style="padding-left: 40px;">Spectrophotometer with sterile cuvettes; MacFarland Standards for inoculum preparation; or Hemocytometer.</p>	<p>A number of publications describe interlaboratory validation of inoculum preparation by a variety of methods.</p>
MY18	<p>Mycology Standard 18</p> <p>Each broth dilution series shall include a growth control of basal medium without antifungal agent to assess viability of the test organisms.</p>	<p>Series that fail to show viability of the test organism should be repeated.</p>
MY19	<p>Mycology Standard 19</p> <p>Susceptibility testing shall be performed on pure cultures.</p>	<p>A sample of each inoculum should be streaked on a suitable agar plate and incubated overnight. This plate will also provide freshly isolated colonies in the event retesting proves necessary.</p>

Mycology

Tag #	Standard	Guidance
MY20	Mycology Standard 20 Laboratories holding this category shall maintain a commercial system for detection of fungal antigen.	Cryptococcal antigen detection systems include Meridian Diagnostics Cryptococcal LA system, Meridian Diagnostics Premier Cryptococcal Ag, Remel Cryptococcus Antigen Latex Test, Wampole Crypto-LA Test, Immuno-Mycologics Latex-Crypto

Parasitology		
Tag #	Standard	Guidance
	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
PS1a PS1b	<p>Parasitology Standard 1</p> <p>Reports on stool specimens shall:</p> <p>a) include the methodology(ies) used; and,</p> <p>b) indicate whether or not a diagnostic test for <i>Cryptosporidium parvum</i> was performed.</p>	Methodologies might include wet mount, permanent stains (such as trichrome and modified acid-fast), ELISA, MFA, etc.
PS2	<p>Parasitology Standard 2</p> <p>The laboratory shall have the ability to test for all reportable parasites.</p>	<p>Reportable parasites and acceptable diagnostic tests include:</p> <p><i>Cryptosporidium parvum</i> - Enzyme ImmunoAssay (EIA), Fluorescent Antibody (FA), <i>Cyclospora cayetanensis</i> - AF, Safranin</p> <p><i>Entamoeba histolytica</i>—wet mount, Iron Haematoxylin (IH), Trichrome</p> <p><i>Giardia duodenalis</i> - wet mount, FA, EIA, IH, Trichrome</p> <p><i>Plasmodium falciparum</i> - Giemsa or Wright's blood stain</p> <p><i>Taenia</i> species, <i>Trichinella spiralis</i>, <i>Enterobius vermicularis</i> - ova, whole mount</p>
PS3	<p>Parasitology Standard 3</p> <p>The parasitology laboratory shall use an acid-fast stain when reporting of <i>Isospora belli</i>.</p>	<p>The following stains or tests are recommended but not required for a Parasitology permit:</p> <p>Modified Trichrome Stain - for microsporidia (now classified as a fungus).</p>

Parasitology

Tag #	Standard	Guidance
PS4a PS4b	<p>Parasitology Standard 4</p> <p>For positive stool specimens, the laboratory shall retain, for a minimum of one year:</p> <p>a) permanently stained slides; or,</p> <p>b) a portion of the sample, properly preserved and stored.</p>	<p>The staining method used is the choice of the laboratory, but the stain should be appropriate for the organism. Common permanent stains include modified acid-fast, trichrome, and iron hematoxylin.</p>
PS5	<p>Parasitology Standard 5</p> <p>Permanent stains shall be checked using a positive and negative control, as a minimum, with each new shipment or lot, and once per month of use.</p>	<p>Controls may be obtained commercially or the laboratory may use validated patient or proficiency testing specimens.</p>
PS6	<p>Parasitology Standard 6</p> <p>Each antigen detection kit shall be tested with at least one known positive and one known negative control each time the test is performed.</p>	
PS7a PS7b PS7c	<p>Parasitology Standard 7</p> <p>A calibrated ocular micrometer shall be:</p> <p>a) used for determining the size of ova and parasites, where size is a critical factor; and;</p> <p>b) calibrated at least annually and each change in optics; and</p> <p>c) checked for each person using the microscope to insure consistency of results.</p>	<p>The SOPM should contain instructions for calibration, figures to show how each objective (high, oil, and low) has been calibrated, criteria for the use of the micrometer for determining the size of the ova and parasites and the maximum amount of variation acceptable between users of the microscope before individual calibration figures should be used.</p> <p>c) The calibration figures should be checked for each new person hired.</p>

Parasitology

Tag #	Standard	Guidance
PS8	<p>Parasitology Standard 8</p> <p>Blood films for malaria shall meet the laboratory's pre-established criteria.</p>	<p>Giemsa stain is recommended; however, Wright's stain or a Wright-Giemsa combination stain may also be used. Controls are generally not available for this staining, but the laboratory should check the quality and preparation of its differential smears. An adequate number of fields [e.g., 300 oil immersion (10x100)] should be examined under oil immersion. Specimen collection time should be indicated on the report. If a single sample is submitted for testing, reports should also indicate that one negative specimen does not rule out the possibility of a parasitic infection.</p>
PS9a PS9b	<p>Parasitology Standard 9</p> <p>Fresh stool specimens shall:</p> <p>a) be examined immediately after collection or preserved; and,</p> <p>b) not be refrigerated for more than three hours without proper fixation.</p>	<p>The laboratory should choose the fixative that is most appropriate for its testing purposes.</p>
PS10	<p>Parasitology Standard 10</p> <p>A current reference collection of slides, photographs, or gross specimens of identified parasites shall be readily available in the laboratory for comparison with diagnostic specimens.</p>	<p>Textbooks with photographs, previously stained slide preparations, preserved specimens, or slides from proficiency testing programs are examples of acceptable reference material.</p>

Parasitology

Tag #	Standard	Guidance
PS11	<p>Parasitology Standard 11</p> <p>The parasitology laboratory shall have available all the appropriate reagents, stains, and controls which are required to perform the procedures offered by the laboratory.</p>	<p>If the laboratory uses zinc sulfate for the concentration of fecal specimens, the specific gravity of the solution should be determined (1.18 for fresh specimens and 1.20 for formalin fixed specimens).</p> <p>Concentration is highly recommended.</p> <p>Direct microscopic exam (wet mounts) of fecal specimens may include both saline and iodine preparations. If iodine is used, the iodine solution should be that of D'Antoni's or Dobell and O'Connor (1%), or a 1:5 dilution of Lugol's iodine. Full strength Gram's iodine is not acceptable. A mechanism should exist to ensure that the iodine solution in use has not deteriorated.</p>

Virology		
Tag #	Standard	Guidance
	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
VR1	<p>Virology Standard 1</p> <p>Staining materials shall be tested each day of use for intended reactivity to ensure predictable staining characteristics.</p>	If the laboratory is performing antibody serologic tests, refer to the Diagnostic Immunology Standards.
VR2	<p>Virology Standard 2</p> <p>Quality control shall be performed on all cell culture media.</p>	<p>For commercially purchased cell culture media, the requirement for quality control checks is satisfied by visually examining the media for sterility and assuring the ability of the media to sustain cell life.</p> <p>For media prepared or produced in the laboratory, each component of cell culture media should be checked for sterility using bacterial culture techniques. In addition, fetal bovine serum should be checked for toxicity using cell culture systems.</p> <p>Cell culture systems should be checked for mycoplasma contamination at least annually.</p>
VR3	<p>Virology Standard 3</p> <p>For laboratories holding a subcategory "General" permit, the laboratory shall have available host systems for the isolation of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.</p>	<p>The laboratory should have the appropriate media available for all virology testing that is performed in the laboratory.</p> <p>"Host systems" is defined as the animal, egg or cell culture model that supports the propagation of viruses. The cell culture host system is most frequently used.</p>

Virology		
Tag #	Standard	Guidance
VR4	<p>Virology Standard 4</p> <p>In test systems for the identification of viruses, with each run of patient samples, the laboratory shall simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.</p>	<p>Uninoculated cell substrate controls are used to insure the absence of morphological change in the absence of a viral agent and to the appropriate confluence of the monolayer before and during the culture time period. Additionally, in test systems utilizing specific antibodies directed to a specific virus, the uninoculated cell substrate is used to determine that the reaction observed (whether fluorescence, agglutination, or lysis) is a result of the specific antibody-virus reaction and not a nonspecific binding of serum components and cell substrate.</p>
VR5	<p>Virology Standard 5</p> <p>Prior to the inoculation of the cell cultures, the laboratory shall check the cell culture systems for the age of the cell culture monolayer (no more than 7-10 days post “seeding”).</p>	<p>Greater than 7-10 days is acceptable if either so stated by the supplier or the uninoculated control culture does not exhibit deterioration over the test period.</p>
VR6	<p>Virology Standard 6</p> <p>For tests such as hemagglutination and viral neutralization in which antisera shall be standardized, the laboratory shall determine the optimum dilution of each lot of antisera to ensure maximum sensitivity and specificity.</p>	
VR7	<p>Virology Standard 7</p> <p>For neutralization tests, the laboratory shall standardize its dilution of the viral isolate and control virus to the appropriate Tissue Culture Dose 50 or Alternate, each time the test is performed.</p>	
VR8	<p>Virology Standard 8</p> <p>For Hemagglutination Inhibition Tests, the laboratory shall include one known virus or viral antigen specific to each antisera used in the test procedure.</p>	

Virology		
Tag #	Standard	Guidance
<p>VR9a</p> <p>VR9b</p>	<p>Virology Standard 9</p> <p>For Indirect Immunofluorescence Tests, positive and negative reactivity shall be determined using:</p> <p>a) uninoculated cells plus immune serum plus anti-species conjugate (negative control); and,</p> <p>b) viral antigen or known virus infected cells plus immune serum plus antispecies conjugate (positive control).</p>	
<p>VR10</p>	<p>Virology Standard 10</p> <p>Laboratory records shall indicate cell types, passage number, source, and media used for their growth and maintenance.</p>	
<p>VR11</p>	<p>Virology Standard 11</p> <p>Inoculated cultures shall be checked at least every second or third day for cytopathic effect.</p>	
<p>VR12</p>	<p>Virology Standard 12</p> <p>In house prepared diluents shall be checked for sterility and pH initially and before placing into routine use.</p>	
<p>VR13</p>	<p>Virology Standard 13</p> <p>All specimens that test negative for influenza by nonculture methods shall be sent to a laboratory with a Virology – General permit for confirmation by culture or have a disclaimer on the report that cell culture testing should be considered to confirm the results and to assist in detecting other viruses that can produce similar clinical symptoms.</p>	<p>The intent of the disclaimer is to inform the physicians that direct tests for influenza virus can have low sensitivity and produce false negative test results.</p>

Virology		
Tag #	Standard	Guidance
VR14	<p>Virology Standard 14</p> <p>Laboratories shall use a Class II Biological Safety Cabinet for all procedures involving the inoculation of diagnostic specimens into cell culture, as well as the harvesting and manipulation of cell culture amplified material.</p>	Refer to Safety Standard SSP9 for operational guidance.
VR15	<p>Virology Standard 15</p> <p>For sample preparation of highly pathogenic respiratory viruses performed in the absence of a class II BSC, personal protective equipment (PPE) shall include an N-95 mask or battery-powered air purifying respirator and the procedure should be performed in a laboratory space separate from unprotected personnel.</p>	As described in Safety Standard SSP12, sample preparation should be performed in such a manner as to minimize splashing, spraying and creation of aerosols. Use of a BSC Class II is highly recommended for molecular assays but if this is not possible, appropriate personal protective equipment (PPE) including solid front gowns, gloves and face shields should be used.
Wet Mounts		
	All laboratories shall comply with the applicable requirements for quality management systems and sustaining standards of practice.	