NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of Proposed Revision to Mycobacteriology Standards
Comment Period from March 13, 2018 to May 1, 2018

Any Mycobacteriology standards not addressed here remain in effect.
(changes are underlined)

Current Standard	Current Guidance	Proposed Standard	Proposed Guidance
Mycobacteriology Sustaining Standard of Practice 8 (TB S8): Smears Only Permit Category - Specimen Submission and Result Notification Laboratories testing under the Smears Only permit category shall: a) submit specimens for culture to a laboratory holding a New York State permit in the appropriate Mycobacteriology category; and b) notify the reference laboratory if the specimen being sent is the first smear positive specimen from the patient.	Part (a) of the standard is to be followed regardless of the smear result. b) This notification is essential so that the reference laboratory can comply with Mycobacteriology Sustaining Standard of Practice 15 (TB S15). b) The patient smear history can be reviewed in the LIMS system of the referring laboratory.	**Mycobacteriology Sustaining Standard of Practice 8 (TB S8): Laboratories testing only Smears- Specimen Submission and Result Notification** Laboratories testing only smears shall: a) <u>submit specimens to a laboratory holding a New York State clinical laboratory permit in Mycobacteriology</u>; and b) notify the reference laboratory if the specimen being sent is the first smear positive specimen from the patient.	Part (a) of the standard is to be followed regardless of the smear result. b) This notification is essential so that the reference laboratory can comply with Mycobacteriology Sustaining Standard of Practice 15 (TB S15). b) The patient smear history can be reviewed in the LIMS system of the referring laboratory.

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Mycobacteriology Sustaining Standard of Practice 14 (TB S14): Identifying *M. avium* complex and *M. gordonae* Laboratories shall use only AFB morphology and NYS or FDA approved ~~molecular~~ methods to identify *M. avium* complex and *M. gordonae*.	Identification of *M. avium* complex or *M. gordonae* by biochemical methods is not satisfactory. However, ~~mass spectroscopy, HPLC, and~~ new technologies are acceptable as long as they are appropriately validated and approved by NYS Clinical Laboratory Reference System or cleared by the FDA.	**Mycobacteriology Sustaining Standard of Practice 14 (TB S14): Identifying *M. avium* complex and *M. gordonae*** Laboratories shall use only AFB morphology and NYS or FDA approved methods to identify *M. avium* complex and *M. gordonae*.	Identification of *M. avium* complex or *M. gordonae* by biochemical methods is not satisfactory. However, new technologies <u>may be</u> acceptable as long as they are appropriately validated and approved by NYS Clinical Laboratory Reference System or cleared by the FDA.
Mycobacteriology Sustaining Standard of Practice 15 (TB S15): Submission of Isolates to a Public Health Laboratory Laboratories shall submit to either the Wadsworth Center or the NYC Public Health Laboratories: a) all initial isolates of *Mycobacterium tuberculosis* complex	Isolates recovered from patients residing in New York City should be submitted to the NYC Public Health Laboratories; isolates from patients residing outside of NYC (upstate and out-of-state) should be submitted to the Wadsworth Center in Albany, NY. Refer to the latest version of the Laboratory Reporting and Specimen Submission	**Mycobacteriology Sustaining Standard of Practice 15 (TB S15): Submission of Isolates to a Public Health Laboratory** Laboratories shall submit to either the Wadsworth Center or the NYC Public Health Laboratories: a) all initial isolates of *Mycobacterium tuberculosis* complex	Isolates recovered from patients residing in New York City should be submitted to the NYC Public Health Laboratories; isolates from patients residing outside of NYC (upstate and out-of-state) should be submitted to the Wadsworth Center in Albany, NY. <u>If a TB culture positive report has been received from either public health</u>

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from newly diagnosed patients within the next business day of a positive identification of *M. tuberculosis* complex; b) all *M. tuberculosis* complex isolates presenting a change in susceptibility pattern. The initial isolate and the subsequent isolate demonstrating an altered susceptibility pattern shall both be submitted.	Requirements for Communicable Diseases available at: http://www.wadsworth.org/labcert/regaffairs/clinical/commdiseaseguide.pdf ~~For all laboratories, *M. tuberculosis* 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.~~ a) To expedite genotype testing, an aliquot of at least 1 ml of the primary broth medium should be sent rather than waiting for a mature subculture on a slant. b) A change in drug susceptibility may be identified by the health care provider or through the patient's history. ~~b) If an initial isolate has already been submitted, there is no need to re-submit that isolate with a subsequent isolate~~	from newly diagnosed patients within the next business day of a positive identification of *M. tuberculosis* complex; b) all *M. tuberculosis* complex isolates presenting a change in susceptibility pattern. The initial isolate and the subsequent isolate demonstrating an altered susceptibility pattern shall both be submitted.	laboratory, isolates do not need to be submitted. Refer to the latest version of the Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases available at: http://www.wadsworth.org/regulatory/clep/laws. a) To expedite genotype testing, an aliquot of at least 1 ml of the primary broth medium should be sent rather than waiting for a mature subculture on a slant. b) A change in drug susceptibility may be identified by the health care provider or through the patient's history.

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	~~demonstrating an altered susceptibility pattern.~~		
Mycobacteriology Sustaining Standard of Practice 17 (TB S17): Susceptibility Testing Susceptibility testing shall be performed using the indirect testing method.	Indirect susceptibility testing utilizes a pure ~~isolate~~ as inoculum. Using a specimen as inoculum (direct susceptibility method) is not acceptable.	**Mycobacteriology Sustaining Standard of Practice 17 (TB S17): Susceptibility Testing** Susceptibility testing shall be performed using the indirect testing method.	Indirect susceptibility testing utilizes a pure <u>culture</u> as inoculum. Using a specimen as inoculum (direct susceptibility method) is not acceptable.

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Mycobacteriology Sustaining Standard of Practice 18 (TB S18): First-Line Tuberculosis Drugs All initial isolates of *M. tuberculosis* complex shall at a minimum be tested against the following first-line tuberculosis drugs: - Rifampin (RMP) - Isoniazid (INH) - Pyrazinamide (PZA) - Ethambutol (EMB)	For all isolates identified as *M. tuberculosis* complex: If the laboratory does not perform pyrazinamide (PZA) susceptibility testing, the isolate should be submitted within 24 hours to a New York State permitted laboratory for PZA testing.	**Mycobacteriology Sustaining Standard of Practice 18 (TB S18): First-Line Tuberculosis Drugs** All initial isolates of *M. tuberculosis* complex shall, at a minimum, be tested for <u>susceptibility to</u> the following first-line tuberculosis drugs: <u>Rifampin, Isoniazid, Pyrazinamide, Ethambutol using culture or nucleic acid based methods.</u> <u>All isolates predicted to be resistant by nucleic acid based methods shall be confirmed by culture-based susceptibility testing.</u> <u>Isolates predicted to be susceptible by nucleic acid methods other than whole genome sequencing shall be confirmed by culture-based susceptibility testing.</u>	For all isolates identified as *M. tuberculosis* complex: If the laboratory does not perform pyrazinamide susceptibility testing, the isolate should be submitted within 24 hours to a New York State permitted laboratory for pyrazinamide testing.

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Mycobacteriology Sustaining Standard of Practice 19 (TB S19): Verification of Reagents for Susceptibility Testing For anti-mycobacterial susceptibility tests, the laboratory shall check each batch of media and each lot number and shipment of anti-mycobacterial agent(s) before or concurrent with initial use, using an appropriate control organism(s) and a) establish limits for acceptable control results; b) use the appropriate control organism(s) to check the procedure each week tests are performed; c) use a control strain of *M. tuberculosis* that is fully susceptible to first line drugs for	It is recommended that laboratories performing susceptibility testing have access to the latest CLSI guideline, M24.	**Mycobacteriology Sustaining Standard of Practice 19 (TB S19): Verification of Reagents for <u>Culture-Based</u> Susceptibility Testing** For anti-mycobacterial <u>culture-based</u> susceptibility tests, the laboratory shall check each batch of media and each lot number and shipment of anti-mycobacterial agent(s) before or concurrent with initial use, using an appropriate control organism(s) and a) establish limits for acceptable control results; b) use the appropriate control organism(s) to check the procedure each week tests are performed; c) use a control strain of *M. tuberculosis* that is fully susceptible to first	

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susceptibility tests performed on *M. tuberculosis* complex isolates; d) verify that the results for the control organism(s) are within established limits before reporting patient results; and e) document the results of all control procedures performed.		line drugs for susceptibility tests performed on *M. tuberculosis* complex isolates; d) verify that the results for the control organism(s) are within established limits before reporting patient results; and e) document the results of all control procedures performed.	
~~**Mycobacteriology Sustaining Standard of Practice 20 (TB S20): Identification of the members of the *M. tuberculosis* complex**~~ ~~Laboratories performing susceptibility testing of *M. tuberculosis* complex for first-line tuberculosis drugs shall ensure a final identification of all members of the *M. tuberculosis* complex.~~	~~The requirement for identification can be met by in-house testing or by submission of the isolate to an appropriate New York State permitted laboratory.~~	**STANDARD DELETED**	

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Mycobacteriology Sustaining Standard of Practice 21 (TB S21): Second-Line Drugs Additional susceptibility testing shall be performed using second-line drugs for all initial positive cultures of *M. tuberculosis* complex from newly diagnosed patients if resistance is detected for one or more first-line drugs, with the exception of mono-PZA resistance. If second-line drug susceptibility cannot be performed in-house, the isolate shall be referred within 24 hours to a New York State permitted laboratory for testing.	Whenever possible, the initial positive culture (i.e., 3 ml broth aliquot or slant) should be immediately submitted and a subculture should be retained in the originating laboratory.	**Mycobacteriology Sustaining Standard of Practice 21 (TB S21): Second-Line Drugs** Additional culture or nucleic acid based susceptibility testing shall be performed for second-line drugs for all initial positive cultures of *M. tuberculosis* complex from newly diagnosed patients if culture-based resistance is detected for one or more first-line drugs, with the exception of mono-resistance to pyrazinamide. If second-line drug susceptibility cannot be performed in-house, the isolate shall be referred within 24 hours to a New York State permitted laboratory for testing. All isolates predicted to be resistant by nucleic acid based methods shall be confirmed by culture-based susceptibility testing. Isolates predicted to be susceptible by nucleic acid based methods other than whole genome sequencing shall be confirmed by culture	Whenever possible, the initial positive culture (i.e., 3 ml broth aliquot or slant) should be immediately referred and a subculture should be retained in the originating laboratory.

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Mycobacteriology Sustaining Standard of Practice 22 (TB S22): Reporting First-Line Drugs Susceptibility test results for first-line drugs shall be reported within 24 hours of findings. If applicable, the report shall specify that second line drug susceptibility testing is being performed.	Test results for susceptibility to first line drugs should not be held pending the results of the additional testing.	**Mycobacteriology Sustaining Standard of Practice 22 (TB S22): Reporting First-Line Drugs** Susceptibility test results for first-line drugs shall be reported within 24 hours of findings. If applicable, the report shall specify that second line drug susceptibility testing is being performed.	Test results for susceptibility to first line drugs should not be held pending the results of the additional testing.

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Mycobacteriology Sustaining Standard of Practice 23 (TB S23): Turn Around Time for Susceptibility Testing The turn-around time between receipt of the primary specimen and reporting of susceptibility results for first line drugs shall not exceed 28 days for 80% of such specimens.	The lab receiving the primary specimen is responsible for ensuring that the turn around time requirement is met. This standard applies to laboratories performing smear only and laboratories performing susceptibility testing.	**Mycobacteriology Sustaining Standard of Practice 23 (TB S23): Turn Around Time for Susceptibility Testing** For initial diagnostic specimens, the average time from identification of *M. tuberculosis* complex from culture to reporting of susceptibility results for first line drugs shall not exceed 17 days for 70% of such specimens.	The laboratory receiving the primary specimen is responsible for ensuring that the turn around time requirement is met. This standard applies to laboratories performing smears only and laboratories performing susceptibility testing.