NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program
Biggs Lab – Wadsworth Center
Empire State Plaza
Albany, NY 12237

E-mail: CLEPCQ@health.ny.gov
Web: www.wadsworth.org/regulatory/clep

Certificate of Qualification Questionnaire

Mycobacteriology

Instructions:	Complete in full for testing you personally performed, supervised and/or directed. Obtain all appropriate signatures and submit this form along with any applicable letters of documentation to the NYS Department of Health at the address listed above.

Name _____ CQ Code (if known)_____

Name of facility _____ PFI/CLIA#_____

Test	Specimen Source	Dates (MM/YY-MM/YY)	Volume for dates listed	Instrument/ platform	Method/chemistry	FDA-Approved* Yes/No
Direct Smear Examination						
AFB Culture						
TB drug susceptibility testing						
Molecular Detection and/or Identification of *Mycobacteria* species						
Other (list):						

*FDA-Approved assays include those cleared (510k), approved (PMA), exempted, or with Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) that have not been modified to change the procedure or the intended use. Investigational Use Only (IUO)-labeled tests are ONLY included when utilized under a specific FDA Investigational Device Exemption (IDE).

The applicant and supervisor/director must print and sign their names below to attest that the testing above was performed by and/or under direct supervision by the applicant.

Print applicant name _____ Applicant signature _____ Date _____

Print supervisor/director name _____ Supervisor/director signature _____ Date _____

Supervisor/director's relationship to applicant (e.g. direct supervisor) and how this allows attestation of the applicant's training and/or experience