

NEW YORK STATE DEPARTMENT OF HEALTH

Clinical Laboratory Evaluation Program

E-mail: CLEPCQ@health.ny.govWeb: www.wadsworth.org/regulatory/clep**Technical Director
Certificate of Qualification
Questionnaire****Bacteriology**

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/organism	Specimen source (if applicable)	Dates MM/YY-MM/YY	Volume for dates listed	Instrument/platform	Method/chemistry	FDA- Approved* Yes/No
Antigen Detection (specify organism and add additional page(s) if needed)						
Gram Stains						
Aerobic Cultures						
Anaerobic Cultures						
Chlamydia and Gonorrhea Testing						
Molecular Testing (specify organism or target and add additional page(s) if needed)						
Susceptibility Testing						
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 _____