NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program
E-mail: CLEPCQ@health.ny.gov
Web: www.wadsworth.org/regulatory/clep

Technical Director Certificate of Qualification Questionnaire

Virology

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/virus	Specimen source (if applicable)	Dates (MM/YY-MM/YY)	Volume for dates listed	Instrument/platform	Method/chemistry#	FDA-Approved* Yes/No
Antigen Detection (specify virus and add additional page(s) if needed)						
Virus Culture (specify virus and add additional page(s) if needed)#						
Molecular Detection and Characterization (specify virus or target and add additional page(s) if needed)						

#List method used for confirmation in Method/chemistry column.
*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