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

Hematology

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	Dates (MM/YY-MM/YY)	Volume for dates listed	Instrument/platform (if applicable)	Method/chemistry (if applicable)	FDA-Approved* Yes/No
Cellular Hematology					
WBC count					
RBC count					
Hemoglobin					
Hematocrit					
Platelet					
WBC Diff - automated					
WBC Diff - manual					
Coagulation					
APTT					
PT					
Fibrinogen					

*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