

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

Hematology

Name of facility _____ PFI/CLIA# _____

*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).

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