**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

## Cellular Immunology

| 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/analyte | Specimen source | Dates (MM/YY-MM/YY) | Volume for dates listed | Instrument/platform | Method/chemistry | FDA-Approved* Yes/No |
|---|---|---|---|---|---|---|
| Leukocyte Function (add additional page(s) if needed) | | | | | | |
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| Malignant Leukocyte Immunophenotyping (add additional page(s) if needed) | | | | | | |
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| Non-malignant Leukocyte Immunophenotyping (add additional page(s) if needed) | | | | | | |
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*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).

Is/Was all testing listed in the above table performed under your direct supervision? ☐ Yes ☐ No

If No, what percentage was under your direct supervision? _____

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