

Fetal Defect Markers
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E-mail: CLEPCQ@health.ny.gov
 Web: www.wadsworth.org/regulatory/clep

Instructions: Complete in full for testing you personally performed, supervised and/or directed. Obtain all appropriate signatures on page 2 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# _____

Analyte	Dates (MM/YY-MM/YY)	Volume for dates listed	Instrument/ platform	Method/chemistry				FDA- Approved* Yes/No
				Lumin- escence	EIA	RIA	Other	
AFP								
uE3								
Total hCG								
Beta (β)-hCG								
Inhibin-A								
PAPP-A								
Other (list below)								

*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).

Select birth defects screening software used:

1. Alpha
2. Benetech
3. Robert Maciel (RMA)
4. "In-house"
5. Other (proprietary)
Please specify:

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Select all screens you personally performed, supervised, and/or directed:

1. Combined testing: 1st Trimester NT plus PAPP-A, hCG
2. Double testing: 2nd Trimester AFP, and total hCG or β -hCG
3. Triple testing: 2nd Trimester AFP, uE3, and total hCG or β -hCG
4. Quad testing: 2nd Trimester AFP, uE3, Inhibin-A, and total hCG or β -hCG
5. Integrated test: 1st Trimester (10-13 weeks) NT plus PAPP-A and 2nd Trimester (14-20 weeks) Quad testing
6. Serum Integrated: 1st Trimester (10-13 weeks) PAPP-A (non-NT) and 2nd Trimester (14-20 weeks) Quad testing (a single result only)

*NT = Nuchal translucency

Describe any modifications of the above screens you have personally performed, supervised, and/or directed:

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