Fetal Defect Markers

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Revised and effective July 14, 2014	

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Standard	Guidance
Fetal Defect Markers Standard 1 (FEDM S1) The laboratory shall establish weekly gestational age dependent reference intervals for each marker tested based on in-house generated data which: a) include weekly gestational analyte marker concentration versus gestational age correlations each first and/or second trimester week for which the laboratory reports risk assessments; b) include a minimum of 100 samples for each marker per gestational weeks 11,12,13 for first trimester screening, and 15,16,17,18 for second trimester screening; 75 samples for week 19; and 50 samples for the border weeks 10.6 and 13.9 for the first trimester, and 14.0, 20, and 20.9 for the second trimester; c) addresses marker values for all specimen matrices accepted by the laboratory; d) includes the number of "normal" specimens employed for each weekly gestational age interval to determine cutoff percentile values or multiples of the median (MOM); e) is periodically updated by inclusion of each new determination performed in the laboratory; f) indicates the date of last recalculation; and g) is verified through follow-up of results by monitoring pregnancy outcomes, results of medical procedures (e.g., sonography) performed subsequent to testing, or epidemiological monitoring by comparison of in-house statistics with global databases.	Reference intervals may not be obtained or derived from manufacturer's inserts or published values from other laboratories. a) Weekly analyte concentrations for first trimester border weeks 10.6 and 13.9 and second trimester weeks 14.0 and 20.9 may be extrapolated from log linear plots of median vs. gestational age until sufficient data are accumulated. b) Samples should be representative of the routine regional patient population tested by the laboratory. c) There should be separate curves for serum and amniotic fluid. d) There should be separate values for each individual analyte marker.

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Standard	Guidance
Fetal Defect Markers Standard 2 (FEDM S2) Laboratories performing supplemental testing for abnormal alpha-fetoprotein (AFP) results from amniotic fluid shall confirm by inhibition all AChE diagnostic bands detected in gels run on amniotic fluid prior to reporting of the AFP test results.	Laboratories may choose to refer supplemental testing of amniotic fluid to another New York State permitted laboratory.
Fetal Defect Markers Standard 3 (FEDM S3) Reports shall contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is an individual who holds a valid New York State certificate of qualification in Fetal Defect Markers.	Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).