Fetal Defect Markers	
Former Standard and Guidance	***Proposed Standard and 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. Effective July 14, 2014	
Fetal Defect Markers Sustaining Standard of Practice 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;	**Fetal Defect Markers Standard of Practice 1 (FDM S1): Marker Reference Ranges** The laboratory must establish weekly gestational age dependent reference ranges 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) are based on minimum of: i. one-hundred (100) specimens for each marker per gestational weeks eleven (11), twelve (12), and thirteen (13) for first trimester screening, and fifteen (15), sixteen (16), seventeen (17), and eighteen (18) for second trimester screening; ii. seventy-five (75) specimens for week nineteen (19); iii. fifty (50) specimens for the border weeks 10.6 and 13.9 for the first trimester, and fourteen (14), twenty (20), and 20.9 for the second trimester; and

Fetal Defect Markers	
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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. **Guidance –** 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 weeks10.6 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.	c) address marker values using separate curves for serum and amniotic fluid and for all specimen matrices accepted by the laboratory; d) include separate values for each individual analyte marker and 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) indicate 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. **Guidance –** 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 fourteen (14) and 20.9 may be extrapolated from log linear plots of median vs. gestational age until sufficient data are accumulated. b) Specimens should be representative of the routine patient population tested by the laboratory.

Fetal Defect Markers	
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Fetal Defect Markers Sustaining Standard of Practice 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. **Guidance –** Laboratories may choose to refer supplemental testing of amniotic fluid to another New York State permitted laboratory.	**Fetal Defect Markers Standard of Practice 2 (FDM S2): Alpha-fetoprotein Confirmation** Laboratories performing supplemental testing for abnormal alpha- fetoprotein (AFP) results from amniotic fluid must confirm by inhibition all acetylcholinesterase (AChE) diagnostic bands detected in gels run on amniotic fluid prior to reporting of the AFP test results. **Guidance –** Laboratories may choose to refer supplemental testing of amniotic fluid to another New York State laboratory holding a permit in the category.
Fetal Defect Markers Sustaining Standard of Practice 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. **Guidance –** 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).	**Standard deleted**