

| <b>Fetal Defect Markers (FDM)</b> |   |   |
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| <b>Tag #</b>                      | <b>Standard</b>   | <b>Guidance</b>   |
|                                   | 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.  |   |
| FDM1                              | <p><b>Fetal Defect Markers Standard 1</b></p> <p>The laboratory shall request clinical information necessary for proper initiation of test procedures and interpretation of test results, including gestational dating and an indication of whether the specimen submitted is an initial or follow-up specimen.</p> | The laboratory should request information related to maternal factors (e.g., ethnicity and weight) and other critical values applicable to its algorithm for determining fetal defect risk factors. |
| FDM2                              | <p><b>Fetal Defect Markers Standard 2</b></p> <p>The laboratory shall have a system to distinguish specimen types to assure proper processing, handling and analysis, and to facilitate quality assurance review.</p>   | An accessioning/labeling procedure should code sera differently from amniotic fluids.   |
| FDM3                              | <p><b>Fetal Defect Markers Standard 3</b></p>   | Standard has been deleted. Number reserved for future use.  |

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|                                   | <p><b>Fetal Defect Markers Standard 4</b></p> <p>The laboratory shall establish <b>weekly</b> gestational age dependent cutoff values for each marker tested based on in-house generated data which:</p>                                  |   |
| FDM4a                             | a) includes <b>weekly</b> gestational <b>analyte</b> marker concentration versus gestation age for the <b>first trimester range of 10.6 to 13.6 weeks and second trimester range of 15.0 to 20.9 weeks</b> ;                              | <p>Cutoff values may not be obtained or derived from manufacturer's inserts or published values from other laboratories.</p> <p>a) Weekly analyte concentrations for first trimester border weeks 10.0 and 13.6 and second trimester weeks 15.0 and 20.9 may be derived from log linear plots of median vs. gestational age until sufficient data (100 samples) are accumulated.</p> <p>b) Samples should be representative of the routine <b>regional</b> patient population tested by the laboratory.</p> <p>c) There should be separate curves for serum and amniotic fluid.</p> <p>d) There should be separate values for each individual analyte marker.</p> |
| FDM4b                             | b) includes a minimum of 100 samples for each marker per gestational week;  |   |
| FDM4c                             | c) addresses marker values for all specimen matrices accepted by the laboratory;  |   |
| FDM4d                             | 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);  |   |
| FDM4e                             | e) is periodically updated by inclusion of each new determination performed in the laboratory; and,   |   |
| FDM4f                             | f) indicates the date of last recalculation.  |   |
|                                   | <p><b>Fetal Defect Markers Standard 5</b></p>   | Standard has been deleted. Number reserved for future use.  |
| FDM6                              | <p><b>Fetal Defect Markers Standard 6</b></p> <p>The laboratory shall establish critical limits for turn-around-times which minimally include a requirement that results are reported within seven days in at least 90% of the cases.</p> | <p>The laboratory should have a policy to ensure that later gestational age specimens are given priority so that results are released prior to the 25<sup>th</sup> week of gestation in order to allow patient decisions regarding pregnancy termination.</p>   |

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|                                   | <p><b>Fetal Defect Markers Standard 7</b></p> <p>In addition to the general requirements, the SOPM shall include:</p>   |  |
| FDM7a                             | a) the international reference preparation used for calibration;  | <p>b) The laboratory shall have the ability to convert mass units (i.e. IU/ml to ng/ml).</p> <p>c) The laboratory should attempt follow-up of all results by monitoring pregnancy outcomes or results of medical procedures (e.g., sonography) performed subsequent to testing OR epidemiological monitoring by comparison of in-house statistics with global databases.</p> |
| FDM7b                             | b) the conversion formula applicable to the procedure(s) in use;  |  |
| FDM7c                             | c) algorithms for monitoring of clinical performance; and,  |  |
| FDM7d                             | d) procedures for reporting results specific to specimens taken outside the 14 – 22 week window.  |  |
|                                   | <p><b>Fetal Defect Markers Standard 8</b></p> <p>Laboratories performing supplemental testing for abnormal alpha-fetoprotein (AFP) results from amniotic fluid shall:</p>   |  |
| FDM8a                             | a) establish a documented protocol for supplemental testing of amniotic fluid for fetal hemoglobin (HbF) and acetylcholinesterase (AChE), which includes a prohibition against release of abnormal AFP results prior to supplemental testing; | <p>Laboratories may choose to refer supplemental testing of amniotic fluid to another New York State permitted laboratory.</p>   |
| FDM8b                             | b) establish and implement procedures for HbF analysis of both centrifuged and uncentrifuged specimens; and,  |  |
| FDM8c                             | c) confirm by inhibition all AChE diagnostic bands detected in gels run on amniotic fluid prior to reporting of the AFP test results.   |  |

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| FDM9a<br>FDM9b<br>FDM9c           | <p><b>Fetal Defect Markers Standard 9</b></p> <p>For rocket electroimmunodiffusion:</p> <p>a) the calibration curve shall be based on a minimum of four standards;</p> <p>b) three levels of control shall be run; and,</p> <p>c) parallel testing of samples shall be performed monthly, using a WHO standardized procedure which employs a method based on different chemical and physical principles.</p> | <p>a) A zero value may be counted as one of the four.</p> <p>b) Controls should include "high", "medium", and "low" AFP values.</p> <p>c) e.g., EIA, RIA or chemiluminescence</p>  |
| FDM10                             | <p><b>Fetal Defect Markers Standard 10</b></p> <p>Reports shall contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is a director or designated assistant director who holds a valid New York State certificate of qualification in Fetal Defect Markers</p>  | <p>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).</p> <p>All information used to generate results including, but not limited to, raw data and/or worksheets, instrument readings, personal observations, clinical information related to maternal factors (e.g., ethnicity and weight), critical values applicable to the algorithm for determining fetal defect risk factors, and normative data should be reviewed.</p> |
| FDM11a<br>FDM11b<br>FDM11c        | <p><b>Fetal Defect Markers Standard 11</b></p> <p>In addition to the requirements of Part 58, reports shall include:</p> <p>a) the results in mass units and derived units;</p> <p>b) the gestational dating, weight and ethnicity used in calculations; and,</p> <p>c) recommendations for follow-up.</p>   |  |

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| FDM12                             | <p><b>Fetal Defect Markers Standard 12</b></p> <p>In addition to the information required in Part 58, the laboratory test request for maternal serum and/or amniotic fluid shall include the designation of the diagnostic center to which elevated results will be reported.</p> | <p>This may be indicated by the referring physician or, in the absence of such designation, this will be indicated by the laboratory. Laboratories not directly linked to such centers should document, by written statements, prearranged referral mechanisms to such diagnostic centers. This is to insure that patients with abnormal results are not lost to follow-up.</p> |

| <b>Oncology</b> |  |  |
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|                 | 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. |  |
|                 | <b>SERUM OR SOLUBLE TUMOR MARKERS</b>  |  |
|                 | <b>Oncology Standard 1</b>   |  |
|                 | Reports shall include:   |  |
| OC1a            | a) a quantitative mass unit accompanied by the normal range;   |  |
| OC1b            | b) the name of the manufacturer and the testing methodology used;  | c) Refer to manufacturer's instructions.   |
| OC1c            | c) a statement indicating that values obtained with different assay methods or kits cannot be used interchangeably;  |  |
| OC1d            | d) a statement indicating that results cannot be interpreted as absolute evidence of the presence or absence of malignant disease; and,  | d) The laboratory should refer to the manufacturer's instructions for the limitations of the test. |
| OC1e            | e) if AFP is the analyte, a statement indicating that the test is not interpretable in pregnant females.   |  |

| <b>Oncology</b>                          |  |  |
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| Tag #                                    | Standard   | Guidance   |
| <b>ONCOLOGY – CELLULAR TUMOR MARKERS</b> |  |  |
|  | <b>GENERAL STANDARDS</b>   |  |
|  | <p><b>Oncology Standard 2</b></p> <p>Reports shall:</p> <p>OC2a a) indicate the testing methodology used;</p> <p>OC2b b) indicate the limits of sensitivity (both diagnostic and technical limits) of the method used;</p> <p>OC2c c) include an interpretation of findings; and</p> <p>OC2d d) contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is a director or assistant director who holds a valid New York State certificate of qualification in the Oncology – Cellular Tumor Markers subcategory.</p> | <p>b) i) Technical limits: the amount of target DNA/RNA that needs to be present to obtain a positive signal; e.g., one tumor cell in 10<sup>6</sup> normal cells.</p> <p>ii) Diagnostic limits: Given the technical limitation, what is the diagnostic sensitivity.</p> <p>c) 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).</p> |
| OC3                                      | <p><b>Oncology Standard 3</b></p> <p>The laboratory shall include a sensitivity control in each patient run.</p>   | <p>For this control, it is suggested that a small amount of a positive sample be mixed with an excess of a negative sample, e.g., 1:20 for a 5% sensitivity.</p>   |