# NEW YORK STATE DEPARTMENT OF HEALTH
## CLINICAL LABORATORY EVALUATION PROGRAM

## Crosswalk of Adopted Revision to Oncology Standards

### SOLUBLE TUMOR MARKERS

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<tr>
<td>Oncology Standard 1 (OC S1) Reports shall include:</td>
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<td>a) a quantitative mass unit accompanied by the normal range;</td>
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<td>b) the name of the manufacturer and the testing methodology used;</td>
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<td>c) a statement indicating that values obtained with different assay methods or kits cannot be used interchangeably;</td>
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<td>d) a statement indicating that results cannot be interpreted as absolute evidence of the presence or absence of malignant disease; and,</td>
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<td>e) if AFP is the analyte, a statement indicating that the test is not interpretable in pregnant females.</td>
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<td>c) Refer to manufacturer’s instructions.</td>
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<td>d) if AFP or hCG is the analyte, a statement indicating that the test is not interpretable in pregnant females.</td>
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**MOLECULAR AND CELLULAR TUMOR MARKERS**

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<td>Oncology Standard 2 (OC S2)</td>
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<td>Reports shall:</td>
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<td>a) indicate the testing methodology used;</td>
<td>b) i) <strong>Technical limits:</strong> the amount of target DNA/RNA that needs to be present to obtain a positive signal; e.g., one tumor cell in 10⁶ normal cells.</td>
<td>Oncology Standard 2 (OC S2)</td>
<td>b) i) <strong>Analytical sensitivity:</strong> generally the number of tumor cells in a background of normal cells that needs to be present to obtain a positive signal; e.g., five tumor cells in 100 normal cells, or 20%.</td>
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<td>b) indicate the limits of sensitivity (both diagnostic and technical limits) of the method used;</td>
<td>ii) <strong>Diagnostic limits:</strong> given the technical limitation, what is the diagnostic sensitivity</td>
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<td>ii) <strong>Diagnostic sensitivity:</strong> given the <strong>analytical sensitivity</strong>, what is the diagnostic sensitivity; e.g., that assay is able to detect a variant in 95% of patients with variants in this region of the genome.</td>
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<td>c) include an interpretation of findings; and</td>
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<td>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.</td>
<td>d) 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).</td>
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<td><strong>2008 Standard</strong></td>
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<td><strong>2014 Standard</strong></td>
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<td><strong>Oncology Standard 3 (OC S3)</strong></td>
<td><em>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.</em></td>
<td><strong>OC S3 Standard deleted.</strong></td>
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<td>Please refer to proposed Quality Control Sustaining Standard of Practice 1: Design of Individualized Quality Control Plan and proposed Quality Control Sustaining Standard of Practice 2a: Minimum Requirements.</td>
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