Oncology

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	
SOLUBLE TUMOR MARKERS	
Oncology Standard 1 (OC S1) Reports shall include: a) the name of the manufacturer and the testing methodology used; b) a statement indicating that values obtained with different assay methods or kits cannot be used interchangeably; c) a statement indicating that results cannot be interpreted as absolute evidence of the presence or absence of malignant disease; and, d) if AFP or hCG is the analyte, a statement indicating that the test is not interpretable in pregnant females.	c) The laboratory should refer to the manufacturer's instructions for the limitations of the test.

Oncology

MOLECULAR AND CELLULAR TUMOR MARKERS

Oncology Standard 2 (OC S2)

Reports shall:

a) indicate the testing methodology used;

b) indicate the limits of sensitivity (both analytic and diagnostic) of the method used;

c) include an interpretation of findings; and

d) contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is an individual holding a valid New York State certificate of qualification in the Oncology – Cellular Tumor Markers subcategory.

b) i) Analytical sensitivity: 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%

ii) Diagnostic sensitivity: given the analytical sensitivity, 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.

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).