NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of Adopted Revision to Oncology Standards

SOLUBLE TUMOR MARKERS			
Current Standard	**Current Guidance**	**Revised Standard**	**Revised Guidance**
Oncology Standard 1 (OC S1): Reporting 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.	No change to the current standard.	

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MOLECULAR AND CELLULAR TUMOR MARKERS			
Current Standard	**Current Guidance**	**Proposed Standard**	**Proposed Guidance**
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).	**Oncology Standard 2 (OC S2): Reporting** 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; 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. e) if the report contains results from **FISH** testing, it shall include: i) use of the current International System for Human Cytogenetic Nomenclature (ISCN); i) number of cells analyzed i) probe target and vendor i) cutoff values for interphase FISH	b) i) Analytical sensitivity: generally the number of tumor cells or alleles in a background of normal cells that need to be present to obtain a positive signal; e.g., five tumor cells in 100 normal cells; or 5% minor allele frequency; or similar. ii) Diagnostic sensitivity: given the analytical sensitivity, what is the diagnostic sensitivity; e.g., the 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). e,i) Results may be reported in other formats **in addition** to ISCN

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NEW STANDARDS:

Standard	Guidance
Oncology Standard 3 (OC S3): FISH testing For **FISH** testing, method validation, result reporting, patient testing and any other procedure or operation must comply with all applicable cytogenetics requirements.	
Oncology Standard 4 (OC S4): FISH Hybridization Acceptability Laboratories must establish criteria to determine the acceptability of each FISH hybridization and document the acceptability of each hybridization prior to reporting. Such criteria must include: a) signal intensity b) background/noise c) appropriate internal (normal homolog and/or control probe) and/or external controls	
Oncology Standard 5 (OC S5): Laboratory-Developed FISH Analysis The laboratory shall analyze a number of cells appropriate to the specimen type, reason for referral, and aberrations expected. At a minimum, the laboratory must analyze for interphase FISH: i) suspension culture – 100 cells ii) tissue section – 50 tumor cells.	Unexpected results may require analysis of more cells. FDA-approved/cleared tests should be analyzed as described in the package insert or its equivalent.

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Oncology Standard 6 (OC S6): Ongoing Verification of Examination Accuracy for FISH testing A representative sample of all probes used in your laboratory must be regularly verified on a rotating schedule through e.g. proficiency testing or similar mechanisms.	The representative sample must minimally contain examples for each procedure, test design (fusion, breakapart, enumeration, etc) and specimen type (suspension, smear/touch, fixed tissue section, etc) used in the laboratory.