Oncology – Soluble Tumor Markers

Oncology	
Soluble Tumor Markers	
Standard	***Guidance***
Laboratories performing fluorescence in situ hybridization (FISH) analysis for molecular and cellular tumor markers must follow Cytogenetics Standards of Practice, as applicable.	
Oncology Standard of Practice 1 (OC S1): Soluble Tumor Marker Report Requirements In addition to the requirements in Reporting Standard of Practice 2, reports for soluble tumor markers must 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 alpha-fetoprotein (AFP) or human chorionic gonadotropin (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	
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Standard	***Guidance***
Oncology Standard of Practice 2 (OC S2): Molecular and Cellular Tumor Markers Report Requirements In addition to the requirements in Reporting Standard of Practice 2, reports for molecular and cellular tumor markers must: a) indicate the testing methodology used; b) indicate the limits of sensitivity (both analytical and clinical) of the method used; c) if the report contains results from fluorescence in situ hybridization (FISH) testing, it must include: i. use of the current International System for Human Cytogenetic Nomenclature (ISCN); ii. number of cells analyzed; iii. probe target and vendor; and iv. cutoff values for interphase FISH.	b) 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 (5) tumor cells in one hundred (100) normal cells; or five (5) percent minor allele frequency; or similar. b) Clinical sensitivity: given the analytical sensitivity, what is the likelihood to detect a variant in a patient with the targeted disease.
Oncology Standard 3 (OC S3): Fluorescence in situ Hybridization (FISH) Testing For fluorescence in situ hybridization (FISH) testing, method validation, result reporting, patient testing and any other procedure or operation must comply with all applicable cytogenetics requirements.	