NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED ONCOLOGY STANDARDS

The Proposed Standards in the areas of Oncology – Molecular and Cellular Tumor Markers were circulated for comment on July 13, 2017. The announcement was sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended August 25, 2017. Three comments were received from two commenters.

The standards are adopted and effective as of October 1, 2017.

Standard	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. 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

Comment 1:
Does NY require the summarized ISCN interpretation, or will a granular, detailed list of signal patterns also work?

RESPONSE 1:

The New York state Clinical Laboratory Evaluation Program requires that all FISH results be reported using ISCN. Laboratories may also report the same results in other formats.

Comment 2:

I propose that NYS exempt UroVysion and HER2 FISH testing from reporting using ISCN guidelines. Of all the various FISH assays, these 2 FDA-cleared assays are not typically reported with ISCN nomenclature, nor does the CAP or the package insert require this. There are specific CAP/ASCO guidelines for HER2 reporting that are universally accepted and additional nomenclature will be confusing to oncologists. With respect to UroVysion, reporting via the ISCN will only serve to make the report difficult to interpret for urologists. I see no value added here, as well as a potential downside.

RESPONSE 2:

The New York state Clinical Laboratory Evaluation Program requires that all FISH results be reported using ISCN. Laboratories may also report the same results in other formats. ISCN provides clinicians and laboratorians with the data used to make interpretations such as "positive" and "negative."

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Standard	Guidance
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.

Comment 1:
We would like clarification on what they envision for probes/tests that are not included in CAP Proficiency Surveys. Would a blinded review of archived specimens suffice for this requirement (for tests/probes not offered as part of CAP PT)? May we perform a blinded repeat test for correlation, or is NY requiring correlation with an outside institution?

RESPONSE 1:

The New York State Clinical Laboratory Standard of Practice Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy requires "…a system for verifying the reliability and accuracy of test results…at least semiannually." A blinded review of archived specimens would not meet the intent of QA S3 or OC S6. The laboratory may perform internal testing on previously tested samples, split samples with another laboratory, or compare FISH results to other test results for the same sample.