

NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED CLINICAL TOXICOLOGY STANDARDS

The Proposed Standards in the areas of Toxicology – Clinical Toxicology were circulated for comment on April 1, 2016. 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 May 27, 2016. Two comments were received.

The standards are considered to be accepted and will be adopted and effective as of August 5, 2016.

Standard	Guidance
Clinical Toxicology Standard 1 (CT S1) Laboratories holding a Toxicology - Clinical Toxicology - Comprehensive permit shall either: a) maintain the ability to confirm presumptive positive results on-site by a quantitative confirmatory method; or b) report the presumptive positive result as unconfirmed; or c) refer the specimen to another laboratory holding a New York State permit in Toxicology - Clinical Toxicology – Comprehensive for confirmation by a quantitative method.	

Comment 1:

We currently perform confirmation testing by LCMS and report the confirmation qualitatively as POS or NEG. A positive confirmation result will include the cutoff of the compound that it tested positive for. (EX: Oxycodone Present (cut-off 50 ng/mL)). Could you please define "Quantitative" for the proposed changes. Is our current practice acceptable with these proposed changes?

RESPONSE 1:

For the purposes of the proposed CT S1, "Quantitative" refers to the ability of the method to confidently determine the concentration of the analyte with reasonable accuracy, selectivity and reproducibility.

The proposed CT S1 standard is referring to the method being quantitative, but not the reporting requirements.

The chosen confirmatory method of LC-MS would be considered "quantitative" if it is validated to reproducibly determine the analyte concentration and identity with good accuracy, and the analyte concentration derived from the method is then numerically compared with a cutoff value to produce the reported qualitative result of "positive" or "negative". A simple observation of the presence of an analyte by LC-MS would not be considered sufficient under the proposed CT S1 standards, because it does not confirm the analyte's concentration with relation to the cutoff used for the screen (or a separate confirmatory method cutoff being reported).

**Please note that although this meets the standards of the proposed CT S1 standard for NYDOH CLEP, qualitative reporting may not meet the requirements of other regulatory or accrediting groups.*

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Standard	Guidance
<p>Clinical Toxicology Standard 2 (CT S2)</p> <p>Laboratories holding a Toxicology - Clinical Toxicology – Qualitative Testing Only permit shall either:</p> <ul style="list-style-type: none">a) clearly state on the report that all presumptive positive findings are unconfirmed; orb) refer the specimen to a laboratory holding a New York State permit in Toxicology - Clinical Toxicology – Comprehensive for confirmation by a quantitative confirmatory method.	

Comment 2:

Does the new standard precluded laboratories holding a “Toxicology - Clinical Toxicology – Qualitative Testing Only permit” from referring to another Clinical Toxicology – Qualitative Testing Only permit. An example of this scenario is the case where the laboratory did not offer a particular assay or it was down.

RESPONSE 2:

This standard applies to specimens that are actually tested at the laboratory. A laboratory that does not perform testing for a particular analyte/ target may refer a specimen, or a portion thereof, to another NYS permitted laboratory holding Toxicology - Clinical Toxicology - Qualitative Testing Only.