

**Consensus Standards Development Board
Proposed Tentative Interim Amendment #1. April, 2009**

- a. the section(s) of the standard that should be amended;

V3 10.3, V3 10.3.1, V3 10.3.2, V3 10.3.3, V3 10.3.4, V3 10.3.5, V3 10.3.6

- b. the rationale for the Tentative Interim Amendment:

The TIA will correct an implementation problem that was discovered during LASC review.

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

These sections contain an error or omission that was overlooked during regular standard development, the language in these sections conflicts with other language in related PT modules and the proposed amendment will correct a circumstance that will result in an adverse impact to laboratories if the amendment is not made.

- d. the proposed change to the standard, including suggested wording is as follows:

10.3 Evaluation of Individual Participant Results

10.3.1 If the assigned value is greater than "0" and the acceptance limits are calculated per section 10.2; a reported value shall be evaluated as "Acceptable" if it falls within the acceptance limits. If a reported value falls outside of the acceptance limits it shall be evaluated as "Not Acceptable" unless the reported value meets the conditions of 10.3.2 or 10.3.3 in which case, the reported value shall be evaluated as per the requirements given in these sections.

10.3.2 If an assigned value set to less than (<) the PTRL, any value reported with a less than (<) sign or a reported value of "0" or if the reported numerical value is less than the PTRL, the reported value shall be evaluated as "Acceptable".

Examples are as follows:

A) If the assigned value is set to "< 10", any value reported with a "<" i.e.: <5, <10, < 100 shall be evaluated as "Acceptable".

B) If the assigned value is set to "< 10", and the reported value of "0" shall be evaluated as "Acceptable".

C) If the assigned value is set to "< 10", and the reported value is "5" the data point shall be evaluated as "Acceptable".

D) If the assigned value is set to "< 10", and the reported value is "11" the data point shall be evaluated as "Not Acceptable".

10.3.3 If the assigned value is greater than "0", any value reported with a less than (<) sign shall be evaluated as "Acceptable", if the value reported with the less than sign is greater than the lower acceptance limit.

Examples as follows:

A) If the assigned value is set to "10" with a lower acceptance limit of "5", if the reported value is "< 4" the data point shall be evaluated as the "Not Acceptable".

B) If the assigned value is set to "10" with a lower acceptance limit of "5", if the reported value is "< 7" the data point shall be evaluated as the "Acceptable".

10.3.4 A result shall be evaluated as "No Evaluation" if it cannot be evaluated (e.g. alpha characters for a quantitative test).

10.3.5 Analytes not reported by the laboratory, but included in a PT sample received from the PT Provider shall be evaluated as "Not Reported".

10.3.6 If the PT Provider invalidates an analyte in a PT study, all evaluations for data reported for that analyte shall be "No Evaluation" and a discussion of the situation leading to the invalidation shall be included in the final report to participant labs and ABs.