LDMS Pharmacology Censor Codes for CPQA

This document describes how LDMS censor codes should be used across CPQA proficiency data and how the censored record is scored. LDMS utilizes two types of censor codes: user-defined censor codes and system-generated censor codes. User-defined censors are assigned by the user in the Assay module of LDMS after the assay results have been entered into LDMS. System-generated censors are automatically assigned by LDMS in the Assay module during the algorithm/ calculation processes. The user is unable to remove a system-generated censor code. There are two types of user and system censors: Specimen censors is a censor for a single specimen on a run; other specimens on the run are unaffected. Run censors censor the results of the entire assay run. They indicate something went wrong with the entire test.

User-defined censor codes

Censor	Description	Result Score
B	Below quantification limit or no peak	If the run lower limit is above the lower bound of *acceptable* (within 20% of final target value), the result is scored as *acceptable*, otherwise it is scored as *unacceptable*.
D	Drug not required to be assayed	Not scored if the analyte is not expected. If the analyte is expected, the result is scored as *unacceptable*.
O	QC out of range—repeat	If a result for the repeated test is present, it is scored according to the reported value. If there is no subsequent result, the laboratory will have a missing result which will be scored as *unacceptable*.
P	Not able to interpret results	Not scored. Note: The laboratory must contact CPQA prior to applying this censor code for final submitted results.
U	Sample Diluted	Result scored as *acceptable*.
X	Per laboratory, sample must be repeated	If a result for the repeated test is present, it is scored according to the reported value. If there is no subsequent result, the laboratory will have a missing result which will be scored as *unacceptable*. Note: The laboratory must contact CPQA prior to applying this censor code for final submitted results.
Z	No result; laboratory issue	Not scored. Note: The laboratory must contact CPQA prior to applying this censor code for final submitted results.

System-generated censor codes

Censor	Description	Result Score
A	Invalid. Greater than the upper limit—Dilute and repeat	If a result for the repeated test is present, it is scored according to the reported value. If there is no subsequent result, the laboratory will have a missing result which will be scored as *unacceptable*.
B	Below quantifiable limit	If the run lower limit is above the lower bound of *acceptable* (within 20% of final target value), the result is scored as *acceptable*, otherwise it is scored as *unacceptable*.
L	Lower limit adjusted up for this run	Result will be scored as *acceptable*
R	Repeat (with L system censor only)	If a result for the repeated test is present, it is scored according to the reported value. If there is no subsequent result, the laboratory will have a missing result which will be scored as *unacceptable*.

Example censor code scenarios on next page »

Example usage scenarios

1. A laboratory is measuring darunavir by its CPQA approved LCMS method. The upper-most calibrator is 10,000 ng/mL. Sample #3 of Panel A result is 12,000 ng/mL. Sample #3 of panel A will automatically be assigned the "A" system censor code. If the laboratory goes on to dilute and re-assay sample #3, the new result requires a user-defined censor code application of "U".

2. A laboratory is measuring ritonavir by its CPQA approved HPLC-UV method. Sample #1 of panel A is below its limit of quantitation. The system censor will apply a B censor automatically.

3. Laboratory C has not elected rilpivirine as an analyte for PT reporting and is using a multiple analyte HPLC method which measures rilpivirine, lopinavir and ritonavir. Each PT sample Rilpivirine result requires a user-defined censor code application of "D".

4. A laboratory is measuring darunavir by its CPQA approved LCMS method. The quality controls are out of range and the run must be repeated. . The entire run requires a censor code of "O".

5. A laboratory is measuring lopinavir by its CPQA approved HPLC-UV method. A peak interfering the lopinavir peak is observed in sample #4 of panel A, but not in samples 1, 2, 3, or 5. Sample #4 of panel A requires the "P" user-defined censor code.

6. A laboratory is measuring atazanavir by its CPQA approved LCMSMS method. The round blank measures a false positive for atazanavir within its quantifiable range. Each PT sample result that cannot be interpreted requires a user-defined censor code application of "P". If more than three of the samples are affected, the laboratory should contact cpqasupport@fstrf.org for guidance if this censor will be applied to their final submitted result.

7. A laboratory has measured etravirine by its CPQA approved method. Sample #5 of the panel with etravirine is observed to contain twice the expected response of internal standard. Sample #5 requires a user-defined censor of "X". Sample analysis must be repeated. If a subsequent result is not submitted the laboratory will receive an unsatisfactory score for its result. The laboratory is responsible to contact cpqasupport@fstrf.org if it is determined that "X" is the final censor for a submitted result.

8. A laboratory has measured ritonavir in panel A using its CPQA approved method. Upon quality review it is discovered that the calibration standards had expired one month prior to the analysis. If it will not be possible for the laboratory to report results by the round due date, each PT sample ritonavir result requires a user-defined censor code application of "Z". Alternately the laboratory may "unselect" the analyte(s) from the Panel Participation Utility provided it is done before the drop/add deadline. The laboratory is responsible to contact cpqasupport@fstrf.org to inform them that results will not be available and the use of the "Z" censor is needed.