



Standard Practice for Determination of a Pooled Limit of Quantitation for a Test Method¹

This standard is issued under the fixed designation D6259; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This practice covers the use of standard regression techniques and data from an interlaboratory study to determine a lower quantitative limit for a test method. This determined lower limit represents the numerical limit at or above which the test results are considered to be quantitatively meaningful for commerce or regulatory activities by this practice. It is defined by this standard as the *pooled limit of quantitation (PLOQ)* for the test method.

1.2 This practice is applicable to test methods that are capable of producing numerical test results close to zero. Examples are those test methods that determine quantitatively the concentration of analyte(s) near zero.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- D6300 Practice for Determination of Precision and Bias Data for Use in Test Methods for Petroleum Products, Liquid Fuels, and Lubricants
- E456 Terminology Relating to Quality and Statistics
- E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

¹ This practice is under the jurisdiction of Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants and is the direct responsibility of Subcommittee D02.94 on Coordinating Subcommittee on Quality Assurance and Statistics.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3. Terminology

3.1 Definitions:

3.1.1 *repeatability conditions*, *n*—conditions under which test results are obtained with the same test method in the same laboratory by the same operator with the same equipment in the shortest practical period of time using test units or test specimens taken at random from a single quantity of material that is as nearly homogeneous as possible.

NOTE 1—By *in the shortest practical period of time* is meant that the test results, at least for one material, are obtained in a time period not less than in normal testing and not so long as to permit significant change in test material, equipment, or environment. See Terminology E456.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *pooled limit of quantitation (PLOQ)*, *n*—level of property or concentration for a test method at which the ratio: [10× pooled repeatability standard deviation of results for a concentration level/concentration level] = 1.

3.2.1.1 *Discussion*—Quantitative test results obtained using a test method at or below its PLOQ is expected to have an uncertainty of ±30 % or greater at the 95 % confidence level.

3.2.2 *pooled repeatability standard deviation*, *n*—the statistically pooled standard deviation for results obtained under repeatability conditions over multiple operators/laboratories for a sample that is obtained in accordance with Practice D6300 or other equivalent Interlaboratory Study (ILS) analysis (for example, Practice E691, ISO 4259).

3.2.3 *laboratory limit of quantitation (LLOQ)*, *n*—level of property or concentration for a test method at which the ratio: [10× repeatability standard deviation of results for a concentration level determined in a single laboratory/concentration level] = 1.

3.2.3.1 *Discussion*—Quantitative test results obtained by this single laboratory at or below its LLOQ is expected to have an uncertainty of ±30 % or greater at the 95 % confidence level.

3.3 Acronyms:

3.3.1 *ILS*, *n*—interlaboratory study.

*A Summary of Changes section appears at the end of this standard