

Designation: E2489 - 16 E2489 - 21

An American National Standard

Standard Practice for Statistical Analysis of One-Sample and Two-Sample Interlaboratory Proficiency Testing Programs¹

This standard is issued under the fixed designation E2489; 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 (\$\epsilon\$) indicates an editorial change since the last revision or reapproval.

1. Scope-Scope*

- 1.1 This practice describes methods for the statistical analysis of laboratory results obtained from interlaboratory proficiency testing programs. As in accordance with Practice E1301, proficiency testing is the use of interlaboratory comparisons for the determination of laboratory testing or measurement performance. Conversely, collaborative study (or collaborative trial) is the use of interlaboratory comparisons for the determination of the precision of a test method, as covered by Practice E691.
- 1.1.1 Method A covers testing programs using single test results obtained by testing a single sample (each laboratory submits a single test result).
- 1.1.2 Method B covers testing programs using paired test results obtained by testing two samples (each laboratory submits one test result for each of the two samples). The two samples should be of the same material or two materials similar enough to have approximately the same degree of variation in test results.
- 1.2 Methods A and B are applicable to proficiency testing programs containing a minimum of 10 participating laboratories.
- 1.3 The methods provide direction for assessing and categorizing the performance of individual laboratories based on the relative likelihood of occurrence of their test results, and for determining estimates of testing variation associated with repeatability and reproducibility. Assumptions are that a majority of the participating laboratories execute the test method properly and that samples are of sufficient homogeneity that the testing results represent results obtained from each laboratory testing essentially the same material. Each laboratory receives the same instructions or protocol.
- 1.4 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety safety, health, and health environmental practices and determine the applicability of regulatory limitations prior to use.
- 1.5 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

¹ This practice is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.20 on Test Method Evaluation and Quality Control.

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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.



- E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
- E178 Practice for Dealing With Outlying Observations
- E456 Terminology Relating to Quality and Statistics
- E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
- E1301 Guide for Proficiency Testing by Interlaboratory Comparisons (Withdrawn 2012)³
- E2586 Practice for Calculating and Using Basic Statistics

3. Terminology

- 3.1 *Definitions*—The terminology defined in Terminology—Unless otherwise noted in this E456 applies to this practice unless modified herein.standard, all terms relating to quality and statistics are defined in Terminology E456.
- 3.1.1 *collaborative study, n*—interlaboratory study in which each laboratory uses the defined method of analysis to analyze identical portions of homogeneous materials to assess the performance characteristics obtained for that method of analysis.

Horwitz⁴

- 3.1.2 collaborative trial, n—see collaborative study.
- 3.1.3 *interlaboratory comparison*, *n*—organization, performance, and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions.
- 3.1.4 *median*, X^{\sim} , n—the 50^{th} percentile in a population or sample.

E2586

- 3.1.4.1 Discussion—
- The sample median is the [(n + 1)/2] order statistic if the sample size n is odd and is the average of the [n/2] and [n/2 + 1] order statistics if n is even.
- 3.1.5 outlier, n—see outlying observation.

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- 3.1.6 *outlying observation*, *n*—observation that appears to deviate markedly in value from other members of the sample in which it appears.
- 3.1.7 proficiency testing, n—determination of laboratory testing performance by means of interlaboratory comparisons.
- 3.1.8 repeatability standard deviation (S_r), n—standard deviation of test results obtained under repeatability conditions. E177
- 3.1.9 reproducibility standard deviation (S_R), n—standard deviation of test results obtained under reproducibility conditions. **E177**
 - 3.2 Definitions of Terms Specific to This Standard:
- 3.2.1 hinge (upper or lower), n—median of the upper or lower half of a set of data when the data is arranged in order of size.

3.2.1.1 Discussion—

When there is an odd number of items in the data set, the middle value is included in both the upper and lower halves. The upper hinge is an estimate of the 75th percentile; the lower hinge is an estimate of the 25th percentile.

- 3.2.2 *inner fence (upper or lower)*, *n*—value equal to the upper or lower hinge of a data set plus (upper) or minus (lower) 1.5 times the difference between upper and lower hinges.
- 3.2.3 interquartile range, n—distance between the upper and lower hinges of a data set.
- 3.2.4 *outer fence (upper or lower)*, *n*—value equal to the upper or lower hinge of a data set plus (upper) or minus (lower) three times the difference between upper and lower hinges.

4. Summary of Practice

4.1 This practice describes methods of displaying interlaboratory data that visually show individual laboratory results.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Horwitz, W., "Protocol for the Design, Conduct and Interpretation of Collaborative Studies," Pure and Applied Chemistry, Vol 60, No. 6, 1988, pp. 855–864.

- 4.2 The methods described in this practice can be applied to large and small sample populations from any distribution expected to have a general mound shape. It is recommended that in cases in which it is suspected that the data may be highly unsymmetrical or very unusual in some other manner a statistician should be consulted regarding the applicability of the analysis method.
- 4.2.1 The median is used as the "consensus" value of the measured test property.
- 4.2.2 The interquartile range (IQR) is used as the basis for estimating the spread in the data. Because the median and the interquartile range are not affected by the magnitude of extreme values of a data set, the analysis approach presented in this practice effectively eliminates the need to identify outlying observations (outliers).
- 4.3 Laboratory results are categorized according to how far the results lie outside of the interquartile range.
- 4.4 The upper and lower ends of the interquartile range are referred to as the hinges. The limits for categorizing laboratory results lying outside of the interquartile range are determined by multiplying the extent of the interquartile range by the fixed factors of 1.5 and 3.0. The upper and lower limits lying a distance of 1.5 times the range of the IQR beyond the hinges are referred to as the inner fences. The upper and lower limits for results lying at 3.0 times the range of the IQR beyond the hinges are referred to as the outer fences.
- 4.5 Guidance is provided for proficiency testing programs wishing to establish additional limits (or fences). The user is directed to Guide E1301 for additional guidance.
- 4.6 When using the methods in this practice, the number of participating laboratories should be at least ten. Since the degree of confidence is lower for analyses performed on small sample populations, caution should be used in applying statistics obtained from small sample populations.
- 4.7 When possible, it is generally desirable to have 30 or more participants when estimating the precision of test methods.
- 4.8 Estimates of the repeatability standard deviation and the reproducibility standard deviation are determined by dividing the interquartile ranges of appropriate data sets by a factor of 1.35.
- 4.8.1 The number 1.35 used in determining the repeatability and reproducibility standard deviations is based on an assumption of similarity to a normal distribution. Therefore, the estimate of the standard deviation using the methods described in this practice may not supply the desired accuracy if the distribution differs too much from the general shape of a normal curve. It is beyond the scope of this practice to describe procedures for determining when the analysis methods described in this practice are not applicable.

5. Significance and Use

- 5.1 This practice is specifically designed to describe simple robust statistical methods for use in proficiency testing programs.
- 5.2 Proficiency testing programs can use the methods in this practice for the purpose of comparing testing results obtained from a group of participating laboratories. The laboratory comparisons can then be used for practice describes evaluation of individual laboratory performance.results using the interquartile range and Tukey inner and outer fences.
- 5.3 In addition, the data obtained in proficiency testing programs may contain information regarding repeatability (within-lab) and reproducibility (between-lab) testing variation. Repeatability information is possible only if the program uses more than one sample. See Method B. Proficiency testing programs often have a greater number of participants than might be available for conducting an interlaboratory study to determine the precision of a test method (such as described in Practice E691). Precision estimates obtained for the larger number of participants in a proficiency testing program, along with the corresponding wider variation of test conditions, can provide useful information to standards developers regarding the precision of test results that can be expected for a test method when in actual use in the general testing community.
- 5.4 To estimate the precision of a test method, the participants must use the same test method to obtain their test results, and testing must be performed under the conditions required for repeatability and reproducibility. The precision estimates are applicable to the

TABLE 1 Original Data for a One-Sample Program

l ab	Test Decult
Lab	Test Result
1	1.22
2	1.62
3	1.82
4	0.60
5	2.75
6	1.55
7	1.17
8	1.76
9	1.35
10	1.18
11	1.19
12	1.71
13	2.03
14	1.10
15	1.84
16	1.39
17	1.13
18	1.66
19	1.28
20	1.24
21	0.69
22	1.54
23	1.43
24	0.84
25	0.98
26	1.97
27	4.89
28	1.85
29	1.09
30	1.07
• 7 7 7 7 7 7 7	

property levels and material types included in the testing program. The precision of a test method may vary considerably for different material types and at different property levels.

- 5.5 This practice may be useful to proficiency testing program administrators and provides examples of statistical methods along with explanations of some of the advantages of the suggested methods of analysis. The analyses resulting from the application of methods described in this practice may be used by laboratories as part of their quality control procedures, accrediting bodies to assist in the evaluation of laboratory performance, and ASTM International technical committees (and other organizations charged with the task of writing, maintaining, or improving test methods) to obtain information regarding reproducibility and repeatability.
- 5.6 There are many types of proficiency testing programs in existence and many methods exist for analyzing the data resulting from the interlaboratory testing. It is not the intention of this practice to call into question the integrity of programs using other methods of analysis. Testing programs using replicate testing of one or more samples (each laboratory submits two or more results for each sample) are directed to Practice E691 or other practices for the description of a method of analysis that may be more suitable to that type of program.

6. Analysis of a One-Sample Program (Method A)

- 6.1 Display of Data:
- 6.1.1 When possible, display the data in a table to show the actual results submitted by each laboratory. This may not be practical if the number of participants is too large.
- 6.1.1.1 To assist in maintaining confidentiality, give each laboratory an identification number if one does not already exist.
- 6.1.1.2 List the laboratory results in increasing order by laboratory identification number to make it easy to locate the results for a particular laboratory. See Table 1.
- 6.1.2 Sort the laboratory results in decreasing order by test result to show the range and distribution of the test results. See Table 2. Besides the laboratory identification number and corresponding test results, Table 2 contains columns of additional information that will be explained in the following sections of this practice.

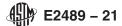


TABLE 2 Data in Descending Order for One-Sample Program

Count of Labs	Lab	Test Result	Number of Occurrences	Category
	27	4.89	1	Extremely Unusual
	5	2.75	1	Unusual
	13	2.03	1	Typical
	26	1.97	1	Typical
	28	1.85	1	Typical
	15	1.84	1	Typical
	3	1.82	1	Typical
8th from Top	8	1.76	_ 1	Typical
	12	1.71	_ 1	Typical
	18	1.66	1	Typical
	2	1.62	1	Typical
	6	1.55	1	Typical
	22	1.54	1	Typical
	23	1.43	1	Typical
15th from Top	16	1.39	1	Typical
16th from Top	9	1.35	1	Typical
	19	1.28	1	Typical
	20	1.24	1	Typical
	1	1.22	1	Typical
	11	1.19	1	Typical
	10	1.18	1	Typical
	7	1.17	1	Typical
8th from Bottom	17	1.13	1	Typical
-	14	1.10	1	Typical
	29	1.09	1	Typical
	30	1.07	1	Typical
	25	0.98	1	Typical
	24	0.84	1	Typical
	21	0.69	1	Typical
	4	0.60	on Hor	Typical

Shown Below Is Determination of "Fences" for Data Above

Median of All Test Results = 1.37
Upper hinge (Median of Top Half) = 1.76
Lower Hinge (Median of Bottom Half) = 1.13
Interquartile Range (IQR) = (1.76 - 1.13) = 0.63

(3 × IQR) = 1.89
Outer Fence (Upper) = (1.76 + 1.89) = 3.65
Outer Fence (Lower) = (1.13 - 1.89) = -0.76

https://standards.iteh.ai/catalog/standards/sist/276 (1.5 × IQR) = 0.945498b-8473-208766719b64/astm-e2489-21 Inner Fence (Upper) = (1.76 + 0.945) = 2.705

Inner Ferice (Opper) = (1.76 + 0.945) = 2.705Inner Fence (Lower) = (1.13 - 0.945) = 0.185

Reproducibility Standard Deviation = (IQR / 1.35) = 0.467

6.1.3 Display the data in a dot diagram to show the location of each laboratory's test result in the distribution of all test results. For each test result, plot occurrence number of that test result value versus the value of the test result. As points are plotted from the top of Table 2 to the bottom, the first time a test value occurs assign it an occurrence of "one." The next time that test result value occurs, assign it an occurrence of "two." If the test result value appears a third time, assign it an occurrence of "three" and so forth. If a test result value appears three times in the data, plot the test result value three times, once with an occurrence of "one," once with an occurrence of "two." and once with an occurrence of "three." The consequence is that each laboratory's test result will be plotted as an individual dot and no dots will be concealed by being plotted on top of one another.

6.1.3.1 Fig. 1 shows the dot diagram for the data in Table 2. There are no repeat values in the test results, so Column 3 of Table 2 shows that the number of occurrences is "one" for each test result and the dots in Fig. 1 appear in a single horizontal row. The dot diagram in Fig. 1 also shows that the test result for Laboratory 5, at (2.75, 1), is slightly removed from the rest of the data. The test result for Laboratory 27, at (4.89, 1), is farther removed.

6.1.3.2 A dot diagram with a different appearance can be obtained by classifying the results into multiple contiguous size classes such that each class contains a portion of the data, but together, the classes cover the entire data range. Table 3 shows the number of occurrences in each size class when the range of each class is 0.10. When the numbers of occurrences in each size class are plotted versus the corresponding values of the lower ends of each size class (see Fig. 2), the display has the advantage of being

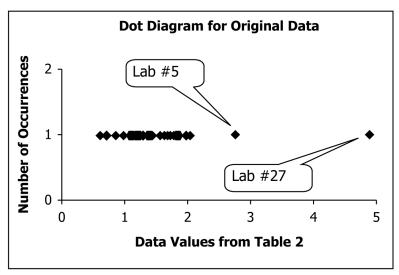


FIG. 1 Dot Diagram for Original Data

TABLE 3 Data Classified by Tenths

				-		
Toot		Size Class Range			- Number of	
Lab Test - Result	Lower End		Upper End	Occurrences		
27	4.89	4.80	≤ X <	4.90	1	
5	2.75	2.70	≤ X <	2.80	<u> </u>	
13	2.03	2.00	≤ X <	2.10	S 1	
26	1.97	1.90	≤ X <	2.00	1	
28	1.85	1.80	≤ X <	1.90	_ 1	
	1.84	1.80	≤ X <	1.90	to 201	
15	1.82	1.80	≤ X <	1.90		
8	1.76	1.70	≤ X <	1.80	1	
12	1.71	1.70	≤ X <	1.80	2	
18	1.66	1.60	_ ≤ X <	1.70		
2	1.62	1.60	≤ X <	1.70	2	
6	1.55	1.50	≤ X <	1.60	1	
22	1.54	1.50	≤ X <	1.60	2	
23	1.43	1.40	≤ X <	9-2 1.50	1	
16	1.39	1.30	≤ X < 0	1.40	0472 10076	
9	1.35	1.30	≤ X <	1.40	-04/3-2200/0	
19	1.28	1.20	≤ X <	1.30	1	
20	1.24	1.20	≤ X <	1.30	2	
1	1.22	1.20	≤ X <	1.30	3	
11	1.19	1.10	≤ X <	1.20	1	
10	1.18	1.10	≤ X <	1.20	2	
7	1.17	1.10	≤ X <	1.20	3	
17	1.13	1.10	≤ X <	1.20	4	
14	1.10	1.10	≤ X <	1.20	5	
29	1.09	1.00	≤ X <	1.10	1	
30	1.07	1.00	≤ X <	1.10	2	
25	0.98	0.90	≤ X <	1.00	1	
24	0.84	0.80	≤ X <	0.90	1	
21	0.69	0.60	≤ X <	0.70	1	
4	0.60	0.60	≤ X <	0.70	2	

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more compact, and it is more apparent how test results are clustered. The dot diagram in Fig. 2 still shows that the test result for Laboratory 5 is slightly removed from the rest of the data and that the test result for Laboratory 27 is farther removed.

6.1.3.3 Other ranges for the size classes are permitted to be used to classify the test results. For example, each size class could have a range of 0.20 or 0.05. The corresponding dot diagrams will each have a different appearance.

6.1.3.4 The range of the size classes used for grouping the laboratory test results should be chosen carefully to show as much information (regarding individual laboratory test results and the overall distribution of the test results) as possible in the dot diagram. One consideration should be the number of test results that must be plotted. Generally, it is desirable to limit the number of classes to be plotted along the *x*-axis of the dot diagram. For larger data sets, the range of each of the classes must be wider

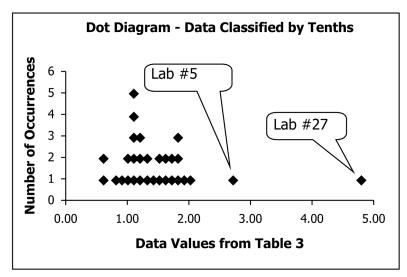


FIG. 2 Dot Diagram—Data Classified by Tenths

to contain a larger number of test results. Another consideration should be the overall range of the test results in the data set. All size classes should have the same width and each size class must be sufficiently wide to limit the number of classes to be plotted along the *x*-axis of the dot diagram.

6.1.3.5 Various computer software programs can be used to generate similar types of diagrams. When other types of diagrams are used, it is generally preferable to choose one in which each individual laboratory's result is displayed as a single point on the diagram. For example, Fig. 2 is similar in appearance to a histogram, but a typical histogram does not show individual data points. Another example is a stem-and-leaf plot.

6.2 Steps for Evaluating Laboratory Performance:

- 6.2.1 Visually examine the dot plot (or graphic of the data) to confirm that the distribution is approximately mound shaped and unimodal. If either condition is not met, the analysis prescribed may not be appropriate. See 4.2.
- 6.2.2 The steps for evaluating a laboratory's performance are to determine the median and interquartile range (IQR), locate the inner and outer fences, and then categorize the laboratories according to where their results lie relative to the fences.
- 6.2.3 The method for determining the median depends on whether there is an odd or even number of results in the data set.
- 6.2.3.1 Sort the data set into ascending or descending order. If there is an odd number of results in the data set, after the results are placed in ascending or decreasing order, the median is the middle number of the data set. For example, consider the five results in the data set 9, 1, 5, 4, 5. When placed in ascending order, the result is 1, 4, $\underline{5}$, 5, 9. The middle number, or median, is the underlined $\underline{5}$. It does not matter that one of the numbers is repeated.
- 6.2.3.2 If there is an even number of results in the data set, after the results are placed in ascending or descending order, the median is the average of the middle two numbers in the data set. For example, consider the eight results in the data set 2, 8, 5, 11, 4, 6, 9, 4. When placed in ascending order, the result is 2, 4, 4, 5, 6, 8, 9, 11. The middle two numbers are 5 and 6. The average is (5 + 6)/2 or 5.5, so the median is 5.5.
- 6.2.4 The method for determining the interquartile range is to determine the middle number (or median) of the top and bottom halves of the data set.
- 6.2.4.1 If there are an odd number of results in the data set, the median of the entire data set is included in both halves. For example, consider again the data set 1, 4, $\underline{5}$, 5, 9. The underlined $\underline{5}$ is included in both halves. So, the middle number (or median) of the top half of the data set, 5, 5, 9, is 5. The median of the top half of the data set is referred to as the upper hinge. The middle number (or median) of the bottom half of the data set, 1, 4, 5, is 4. The median of the bottom half of the data set is referred to as the lower hinge.