EP Evaluator®

Clinical Chemistry -- Labonovum Lab Services

Complex Precision Summary

Instrument	Analyte	Sample	Days (Tot/Excl)	No. Runs with Outliers	Within Run SD/CV	Total SD/CV
Dimension	✔ Albumine	NUCC lvl 1	20 / 0	None	0,22 / 0,9	0,31 / 1,3
	✔ Albumine	NUCC lvl 2	20 / 0	None	0,19 / 0,6	0,31 / 1,0

⚠ Required parameters are missing.   ✖ Experiment 'fails' (or not enough results).

✔ Experiment 'passes' (or adequate number of results).   ⬤ Experiment has outliers.

	Source	Lot Number	Expiration	Analytes
Reagents	Siemens	FA3266		Albumine
Calibrators	Siemens	2JD001		Albumine

Alternate Precision

Claim Evaluation

User's Concentration: 24,25   **Claim Concentration: --**

	df	User's % CV	Standard Deviation			Pass/Fail
			User's	Claim	Verification Value (95%)	
Within Run	40	0,9	0,22	0,50	0,59	Pass
Between Run		0,7	0,17			
Between Day		0,6	0,14			
Total	58	1,3	0,31	0,72	0,828	Pass
Medical Reqd	58	1,3	0,31	--	--	--

The calculated value passes if it does not exceed the verification value.

Precision Plot
(Different plotting symbols represent different runs)
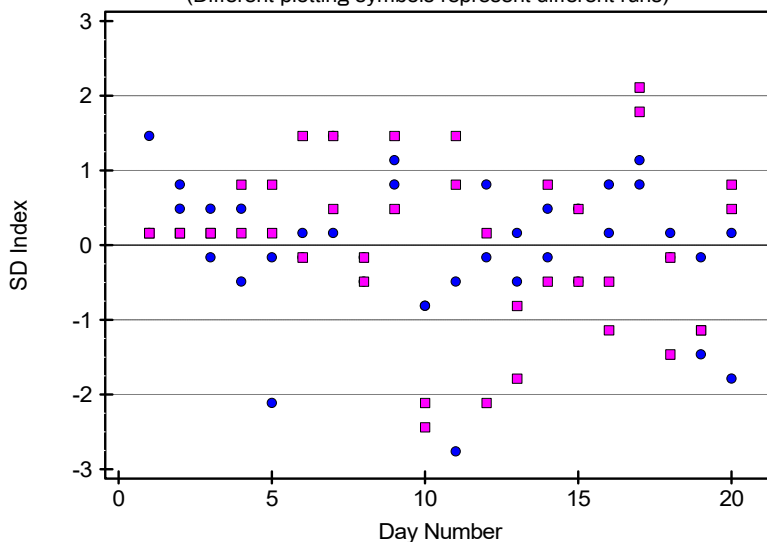
Upper 95% tolerance limit for 95% of user estimates

df for user's experiment	within run SD	total SD
10	0,29	0,42
20	0,27	0,38
30	0,26	0,37
40	0,26	0,36
50	0,25	0,36
60	0,25	0,35
70	0,25	0,35
80	0,25	0,35
90	0,24	0,34
100	0,24	0,34

This table provides data for a manufacturer to include in published materials for users.

Supporting Data

Analyst	Labonovum
Analysis Date	24 mrt 2023 to 01 mei 2023
Days (Tot/Excl)	20 / 0
Runs per Day	2
Reps per Run	2
Critical Value	95%
Units	g/l
Verify Mode	Verify Vendor Claim
TEa	--
Random Error Budget	--
Allow Rand. Err.	--
Control	--
Reagent	Siemens FA3266
Calibrators	Siemens 2JD001
Comment	

Accepted by: _____   _____

Signature   Date

Alternate Precision

Experimental Results

Date	Results		Date	Results		Date	Results	
24 mrt 2023	24,7	24,3	04 apr 2023	24,2	24,1	18 apr 2023	24,4	24,1
	24,3	24,3		24,1	24,2		24,4	24,1
27 mrt 2023	24,5	24,4	05 apr 2023	24,5	24,6	21 apr 2023	24,3	24,5
	24,3	24,3		24,7	24,4		23,9	24,1
28 mrt 2023	24,2	24,4	06 apr 2023	24,0	24,0	24 apr 2023	24,6	24,5
	24,3	24,3		23,6	23,5		24,9	24,8
29 mrt 2023	24,4	24,1	07 apr 2023	23,4	24,1	26 apr 2023	24,2	24,3
	24,5	24,3		24,5	24,7		23,8	24,2
30 mrt 2023	23,6	24,2	11 apr 2023	24,5	24,2	28 apr 2023	23,8	24,2
	24,3	24,5		23,6	24,3		23,9	23,9
31 mrt 2023	24,3	24,2	13 apr 2023	24,3	24,1	01 mei 2023	23,7	24,3
	24,2	24,7		23,7	24,0		24,4	24,5
03 apr 2023	24,7	24,3	14 apr 2023	24,2	24,4			
	24,7	24,4		24,1	24,5			

"X" indicates an excluded run, "O" indicates an outlier run, and "S" indicates a day that does not
have a full complement of results. In all of these cases, the entire day is excluded from the calculations.

Alternate Precision

Claim Evaluation

|			Standard Deviation			
User's Concentration: 33,00			Claim Concentration: --			
	df	User's % CV	User's	Claim	Verification Value (95%)	Pass/Fail
Within Run	40	0,6	0,19	0,50	0,59	Pass
Between Run		0,5	0,16			
Between Day		0,6	0,19			
Total	47	1,0	0,31	0,72	0,84	Pass
Medical Reqd	47	1,0	0,31	--	--	--

The calculated value passes if it does not exceed the verification value.

Precision Plot
(Different plotting symbols represent different runs)
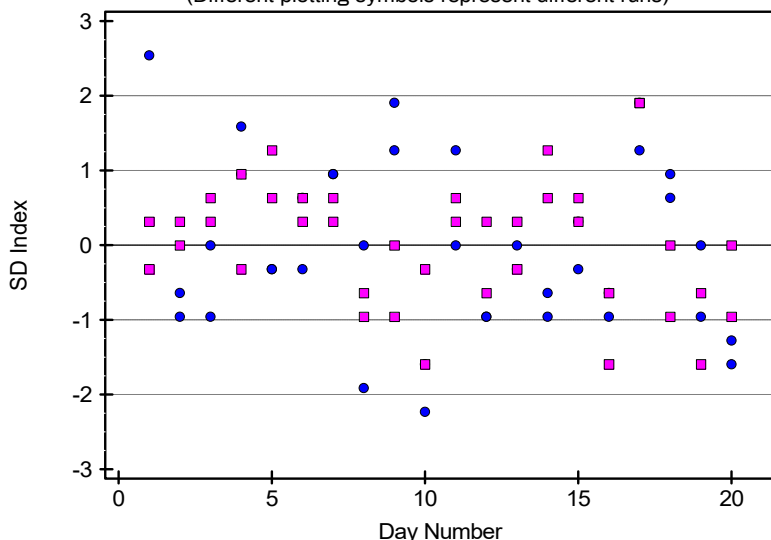
Upper 95% tolerance limit for 95% of user estimates

df for user's experiment	within run SD	total SD	
10	0,26	0,42	
20	0,24	0,39	
30	0,23	0,38	This table provides data for a manufact- urer to include in published materials for users.
40	0,23	0,37	
50	0,22	0,36	
60	0,22	0,36	
70	0,22	0,36	
80	0,22	0,36	
90	0,22	0,35	
100	0,21	0,35	

Supporting Data

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Analysis Date	24 mrt 2023 to 01 mei 2023
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TEa	--
Random Error Budget	--
Allow Rand. Err.	--
Control	--
Reagent	Siemens FA3266
Calibrators	Siemens 2JD001
Comment	

Accepted by: _____

Signature   Date

Alternate Precision

Experimental Results

Date	Results		Date	Results		Date	Results	
24 mrt 2023	33,8 32,9	32,9 33,1	04 apr 2023	32,4 32,8	33,0 32,7	18 apr 2023	33,1 33,2	32,9 33,1
27 mrt 2023	32,8 33,1	32,7 33,0	05 apr 2023	33,4 32,7	33,6 33,0	21 apr 2023	32,8 32,5	32,7 32,8
28 mrt 2023	33,0 33,2	32,7 33,1	06 apr 2023	32,3 32,9	32,5 32,5	24 apr 2023	33,6 33,6	33,4 33,6
29 mrt 2023	33,3 33,3	33,5 32,9	07 apr 2023	33,4 33,2	33,0 33,1	26 apr 2023	33,3 33,0	33,2 32,7
30 mrt 2023	32,9 33,4	32,9 33,2	11 apr 2023	32,7 33,1	32,7 32,8	28 apr 2023	33,0 32,8	32,7 32,5
31 mrt 2023	32,9 33,2	33,2 33,1	13 apr 2023	32,9 33,1	33,0 32,9	01 mei 2023	32,5 32,7	32,6 33,0
03 apr 2023	33,3 33,2	33,3 33,1	14 apr 2023	32,7 33,2	32,8 33,4			

"X" indicates an excluded run, "O" indicates an outlier run, and "S" indicates a day that does not
have a full complement of results. In all of these cases, the entire day is excluded from the calculations.

Complex Precision
Report Interpretation Guide

The Complex Precision Module is used in three situations:

- A manufacturer wants to calculate precision statistics using a statistically rugged procedure recognized in the industry, for use in official documents which may then be submitted to regulatory bodies.

- A user wants to determine whether an instrument meets the manufacturer's claim for precision using a statistically valid approach.

- A user wants to determine both within-run and total precision.

Experiment Procedure

- Define the number of replicates per run, runs per day, and number of days for the experiment. CLSI:EP5 recommends 2 replicates per run, 1 or 2 runs per day, for a minimum of 20 days.

- Collect data for a preliminary run of 8-20 results. The preliminary run is used to detect outliers. This step is optional, but strongly recommended. (It is required for EP5 compliance.)

- Collect data for the full duration of the experiment. The number of replicates per run and runs per day must be the same for all days.

Definitions

Precision. Ability to obtain the same result upon repeated measurement of a specimen.

User's Concentration. Grand mean, computed by adding the results (across all days, replicates, and runs) and dividing the total by the number of results.

Claim Concentration. Concentration at which the manufacturer's SD claims were determined. Laboratorians often think of precision in terms of CV, which is somewhat constant across concentrations. However, the statistical calculations in this module are intended to verify SD. Thus the sample tested should be at approximately the manufacturer's claim concentration. In the report summary, the CV is provided in addition to the SD.

Standard Deviation (SD). SD is the primary measure of Precision (variation of the individual results about the mean). The point of the Complex Precision experiment is either 1) to determine whether the SD meets the manufacturer's claim, or 2) to compute within-run and total SDs to establish such a claim.

SD Components: The experimental results are analyzed by a random-effects Analysis of Variance (ANOVA) procedure to partition the SD into separate components. The two

components usually cited in precision claims are within-run and total SD. The intent of the following definition of the components is to be intuitive, NOT to be mathematically correct.

- **Within-run SD.** Measures the "average" SD computed over replicates that occur within the same run

- **Between-run SD.** SD computed from the means of the results for each run.

- **Between-day SD.** SD computed from the means of the results for each day.

- **Total SD.** A composite of within-run, between-run, and between-day SDs. This is not the answer you would get if you computed an ordinary SD on all the data, ignoring replicate number, day number, and run number.

Claim Value (of SD). Two kinds of claims may be verified: Manufacturer's claims and Medical Requirements. A manufacturer will typically provide separate values for within-run and total SD. A medical requirement is for Total SD only.

Verification Value. You can pass the precision test even if your measured SD is greater than the claim, as long as the difference is not statistically significant. The Verification Value is the largest SD that is not significantly different from the claim. It varies with sample size -- the larger the sample, the closer the Verification Value is to the claim value.

The precision test passes if the computed SD does not exceed the Verification Value.

Critical Value. The confidence level on which the Verification Value is based. Normally the Critical Value is 95%. This means that the Verification Value is equivalent to a 95% confidence limit -- the observed SD meets the manufacturer's claim if its lower 95% confidence limit does not exceed the claim value.

Coefficient of Variation (CV). SD expressed as a percent of the mean.

Degrees of Freedom (df). df is like an "effective N" for an SD component. As df gets larger the confidence limit around the computed SD narrows, and the verification value gets closer to the claimed value.

Outlier. A result so far from the others as to arouse suspicion that it was generated by a different mechanism.

Outlier Rejection

The program first calculates the SD of the preliminary run. This preliminary SD is multiplied by a user-defined Multiplier (usually 5.5) to compute the Maximum Acceptable Difference between Replicates. Any run whose range exceeds this

Complex Precision
Report Interpretation Guide

maximum is declared an outlier, and the entire day is excluded from analysis.

Report Labeling

The Report title is "EP5 Precision" if the experiment meets all requirements of the CLSI:EP5 guideline. Specifically:

- Two replicates per run, either one or two runs per day, for at least 20 days.

- Uses a preliminary run of at least 8 results to establish a preliminary SD. Excludes a replicate pair if the difference between the duplicates exceeds 5.5 times this preliminary SD.

Reports that use other numbers of replicates per run, runs per day, or duration are labeled "Alternate Precision".

An option in Preferences/Reports can change the Report Summary sort order to be by sample name rather than by analyte name.

Pass or Fail?

The Complex Precision experiment "passes" as long as neither the within-run or total SD exceeds its verification value. However, the experiment might warrant further review if more than 5% of the runs were rejected as outliers.

Preliminary Report

The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing. Causes:

- Less than 3 days.

- Less than 6 runs.

References

1. CLSI Document EP5-A. Evaluation of precision performance of quantitative measurement methods; Approved guideline. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 1999. (References to this document will be to CLSI:EP5)