EP Evaluator®

Method Comparison Report

Semi-Annual

1/5/2018

Prepared for

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Signature

Name / Title

Date

EP Evaluator®

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Linearity Summary

Instrument	*Analyte*	*Linearity*	*Accuracy*	*Reportable Range*	*Precision*
ASSAYER	✔ AMMONIA	–	–	–	–
	✘ GLUCOSE	1 of 6 Fail	1 of 6 Fail	–	–
ASSAYER2	✘ GLUCOSE	1 of 6 Fail	1 of 6 Fail	1 of 2 Fail	Pass
ATOM-ABSORB	✔ CALCIUM	Pass	–	–	–

⚠ Required parameters are missing.
✘ Experiment 'fails' (or not enough results).
✔ Experiment 'passes' (or adequate number of results).

Linearity

	Assigned	N	Est	Mean	Residual	Percent Recovery
CalKit-1	1.0	4	1.61	0.97	-0.64	97.5
CalKit-2	4.0	4	4.16	4.17	0.01	104.4
CalKit-3	7.0	4	6.71	7.08	0.36	101.1
CalKit-4	12.0	4	10.97	11.88	0.91	99.0
CalKit-5	20.0	4	17.77	17.13	-0.64	85.6

Linearity Summary

	Reg. Regression
Slope	0.850 ± 0.052
Intercept	0.76 ± 0.57
SEE	0.77
N	5

Experimental Results

CalKit-1	0.7	0.9	1.2	1.1
CalKit-2	4.6	4.1	3.2	4.8
CalKit-3	6.5	6.9	7.2	7.7
CalKit-4	11.0	12.2	11.7	12.6
CalKit-5	18.2	17.5	16.8	16.0

X: Excluded from calculations

User's Specifications

Allowable Total Error	–
Systematic Error Budget	–
Allowable Systematic Error	–

Supporting Data

Analyst	Ellen Doe
Date	01 Jun 2000
Value Mode	Pre-Assigned
Units	mg/dl
Controls	–
Reagent	–
Calibrators	–
Comment	

Evaluation of Results

The Linearity of AMMONIA was analyzed on ASSAYER over a measured range of 0.97 to 17.13 mg/dl.

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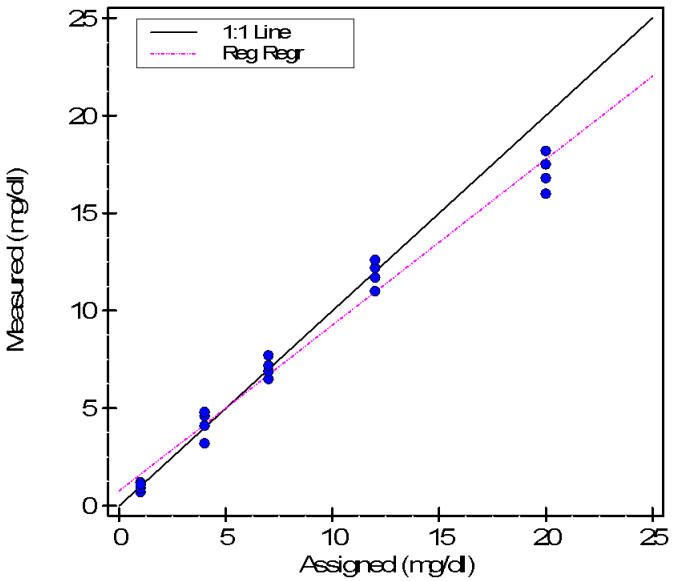
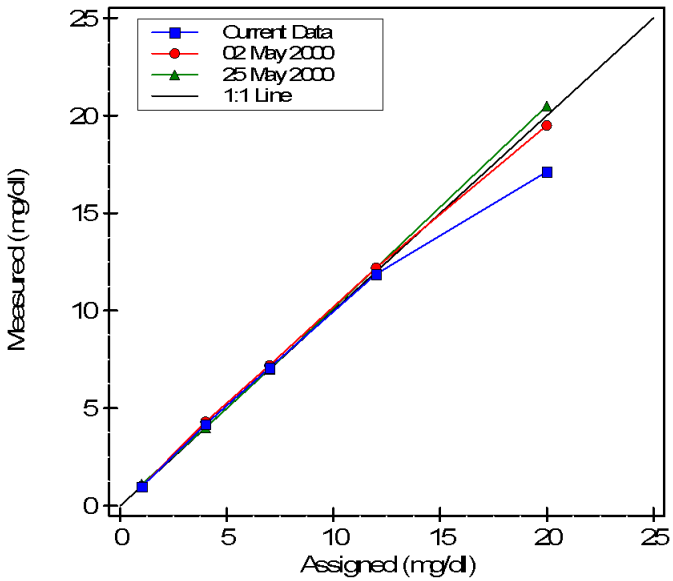
Linearity

Scatter Plot



History Plot



Accuracy and Linearity

	Assigned	N	Accuracy & Recovery			Linearity		
			Mean	% Rec	Status	Estimate	Residual	Status
CalKit-1	25.0	4	25.5	102.0	Pass	26.4	-0.9	Pass
CalKit-2	100.0	4	101.5	101.5	Pass	101.4	0.1	Pass
CalKit-3	250.0	4	249.5	99.8	Pass	251.4	-1.9	Pass
CalKit-4	400.0	4	407.8	101.9	Pass	401.3	6.5	Pass
CalKit-5	700.0	4	690.3	98.6	Pass	701.2	-10.9	Pass
CalKit-6	*1000.0*	*4*	*938.0*	*93.8*	*Fail*	*1001.1*	*-63.1*	*Fail*

See User's Specifications for Pass/Fail criteria

Linearity Summary

	Overall	*w/o Outliers*
Slope	0.971	1.000
Intercept	3.6	1.5
Obs Err	2.33 mg/dl or 3.9%	0.95 mg/dl or 1.6%
N	6	5

NON-LINEAR within Allowable Systematic Error of 1.5 mg/dl or 2.5%

Experimental Results

CalKit-1	24	26	25	27
CalKit-2	101	102	100	103
CalKit-3	243	252	248	255
CalKit-4	400	410	409	412
CalKit-5	690	696	680	695
CalKit-6	930	940	945	937

X: Excluded from calculations

User's Specifications

Allowable Total Error	6 mg/dl or 10.0%
Systematic Error Budget	25%
Allowable Systematic Error	1.5 mg/dl or 2.5%

Supporting Data

Analyst	Kate Doe
Date	01 Jun 2000
Value Mode	Pre-Assigned
Units	mg/dl
Controls	–
Reagent	–
Calibrators	–
Comment	

Evaluation of Results

The Accuracy and Linearity of GLUCOSE were analyzed on ASSAYER over a measured range of 25.5 to 938.0 mg/dl. Reportable Range was not verified. This analysis assumes accurate assigned values. Allowable systematic error (SEa) was 1.5 mg/dl or 2.5%. The accuracy test FAILED. The maximum deviation for a mean recovery from 100% was 6.2%. 5 of 6 mean recoveries were accurate within the SEa. 24 of 24 results were accurate within the allowable total error (TEa) of 6 mg/dl or 10.0%. The results are NON-LINEAR.

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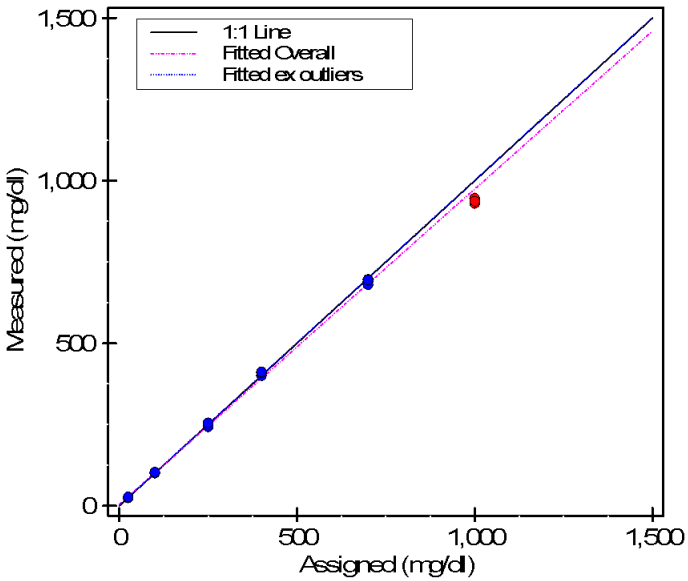
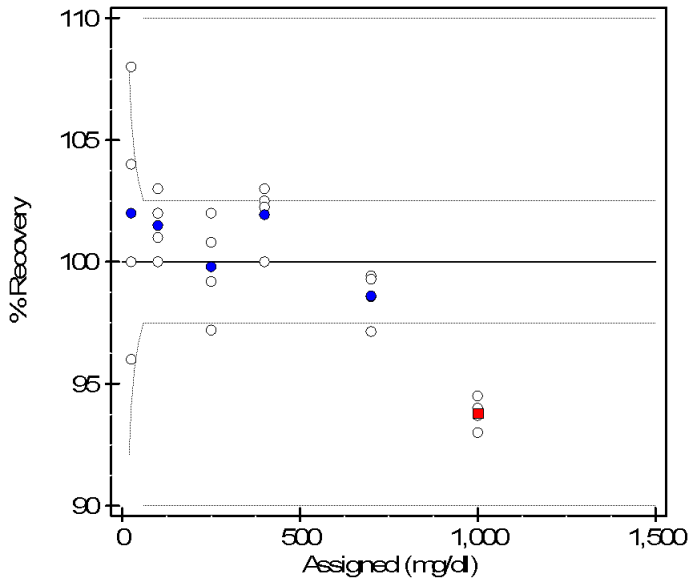
Accuracy and Linearity

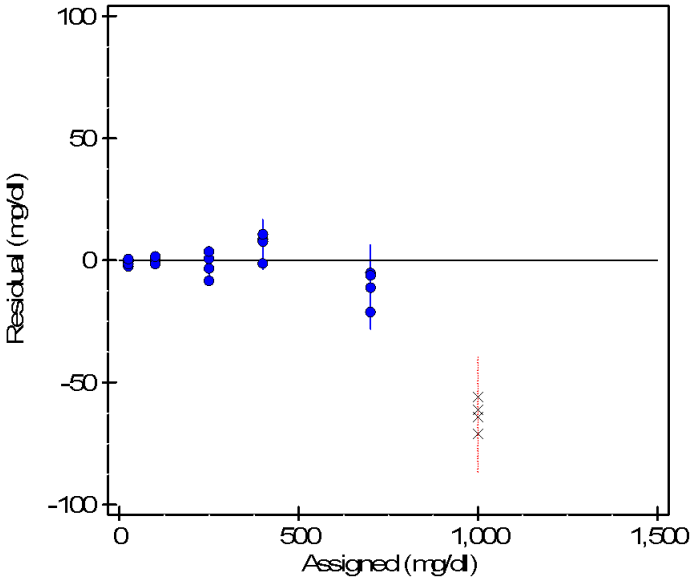
Scatter Plot



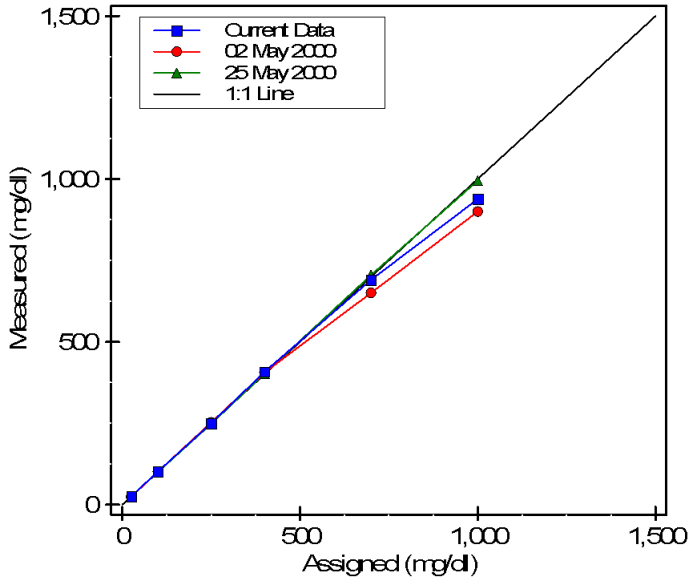
Percent Recovery



Residual Plot



History Plot



Probability of Failure in Proficiency Testing

	User's QC Statistics		PT Limits	
	Mean	SD		
Control 1	70	3	Pct	10
Control 2	150	5	Units	6
Control 3	300	6		

Reference:

Reference:

PT Analysis

	Concentration Units		Percent of PT Limits			Probability Result is Outside Limits	
	Assigned Conc'ns	PT Limits	Est. SD	Linear Bias	Recovery Bias	for Linearity	for Recovery
CalKit-1	25.0	6.0	31%	16%	8%	0.2%	0.1%
CalKit-2	100.0	10.0	38%	1%	15%	0.5%	1%
CalKit-3	250.0	25.0	23%	7%	2%	<0.01%	<0.01%
CalKit-4	400.0	40.0	17%	16%	19%	<0.01%	<0.01%
CalKit-5	700.0	70.0	12%	16%	14%	<0.01%	<0.01%
CalKit-6	1000.0	100.0	11%	63%	62%	0.02%	0.02%

Linear bias based on Clinical Linearity

Failure Relationships

Probability Failure Outside Limits	Probability Failure Next Event	Probability Failure 1 of Next 2	Probability Failure 2 of Next 3
0.1%	0.001%	0.002%	0.0000%
0.2	0.005	0.01	0.0000
0.5	0.02	0.05	0.0000
1	0.1	0.2	0.0005
2	0.5	1	0.005
5	2	5	0.2
10	10	15	2
20	30	45	20
50	80	95	90

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GLUCOSE
Instrument ASSAYER2

Precision, Accuracy, Reportable Range, and Linearity

	Assigned	N	Accuracy & Recovery			Precision				Linearity	Rpt Range
			Mean	% Rec	Status	SD	95% CI	%CV	Status		
CalKit-1	25.0	3	25.0	100.0	Pass	–	–	–	–	Pass	Pass
CalKit-2	100.0	10	102.0	102.0	Pass	2.2	3.9	2.12	Pass	Pass	–
CalKit-3	250.0	3	247.7	99.1	Pass	–	–	–	–	Pass	–
CalKit-4	400.0	3	406.3	101.6	Pass	–	–	–	–	Pass	–
CalKit-5	600	10	600.4	100.1	Pass	13.8	25.2	2.30	Pass	Pass	–
CalKit-6	*750*	*3*	*713.3*	*95.1*	*Fail*	--	--	--	--	*Fail*	*Fail*

See User's Specifications for Pass/Fail criteria

Linearity Summary

	Overall	*w/o Outliers*
Slope	0.978	1.001
Intercept	2.4	0.5
Obs Err	1.89 mg/dl or 3.1%	0.78 mg/dl or 1.3%
N	6	5

NON-LINEAR within Allowable Systematic Error of 1.5 mg/dl or 2.5%

Experimental Results

CalKit-1	24	26	25				
CalKit-2	101	102	100	103	105	103	102
	98	105	101				
CalKit-3	243	252	248				
CalKit-4	400	410	409				
CalKit-5	590	596	580	595	615	598	585
	610	620	615				
CalKit-6	700	740	700				

X: Excluded from calculations

User's Specifications

Allowable Total Error	6 mg/dl or 10.0%
Systematic Error Budget	25%
Random Error Budget	25%
Allowable Systematic Error	1.5 mg/dl or 2.5%
Allowable Random Error	1.5 mg/dl or 2.5%
Reportable Range	25 to 700 mg/dl
RR-Low Range	22.5 to 27.5 mg/dl
RR-High Range	630.0 to 770.0 mg/dl

Supporting Data

Analyst	Kate Doe
Date	01 Jun 2000
Value Mode	Pre-Assigned
Units	mg/dl
Controls	–
Reagent	–
Calibrators	–
Comment	

Evaluation of Results

The Accuracy, Reportable Range, and Linearity of GLUCOSE were analyzed on ASSAYER2 over a measured range of 25.0 to 713.3 mg/dl. This analysis assumes accurate assigned values. Allowable systematic error (SEa) was 1.5 mg/dl or 2.5%. The accuracy test FAILED. The maximum deviation for a mean recovery from 100% was 4.9%. 5 of 6 mean recoveries were accurate within the SEa. 32 of 32 results were accurate within the allowable total error (TEa) of 6 mg/dl or 10.0%. The results are NON-LINEAR. The system FAILED reportable range tests. 1 of 2 specimens met accuracy requirements. Precision was analyzed at mean concentrations of 102.0 and 600.4 mg/dl. The precision test PASSED. The precision of 2 of 2 specimens was within the Allowable Random Error of 1.5 mg/dl or 2.5%.

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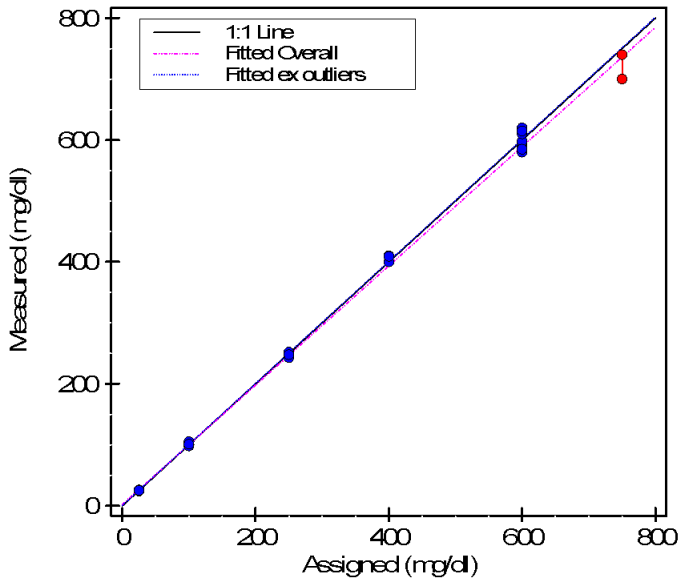
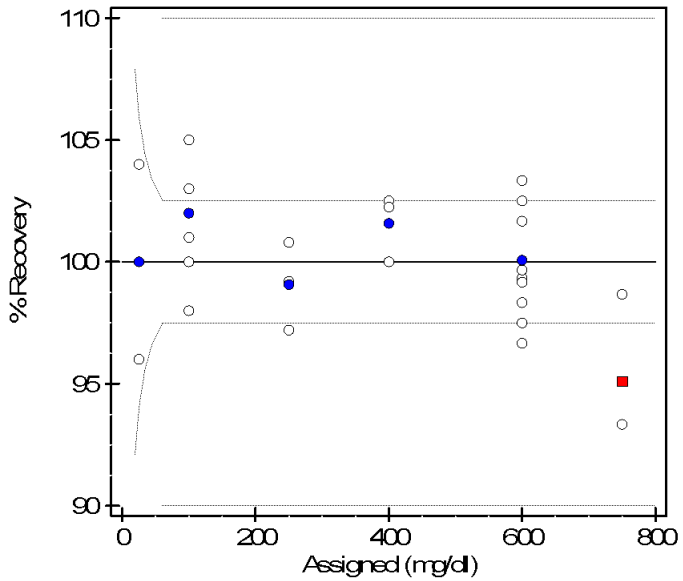
Precision, Accuracy, Reportable Range, and Linearity

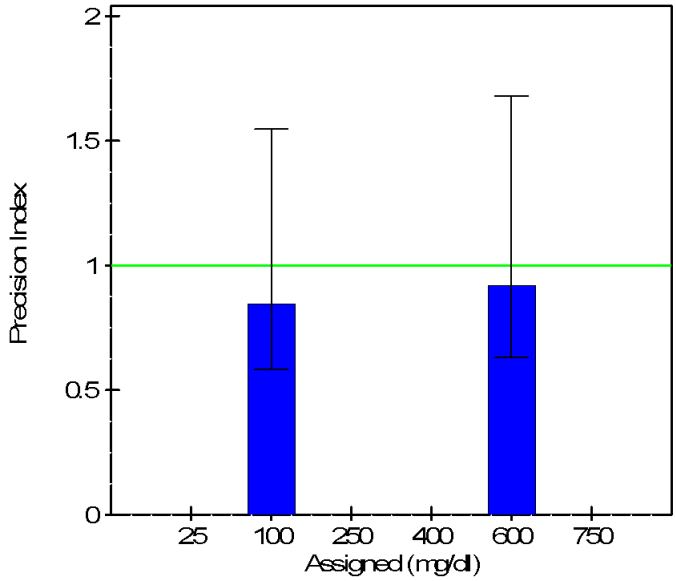
Scatter Plot



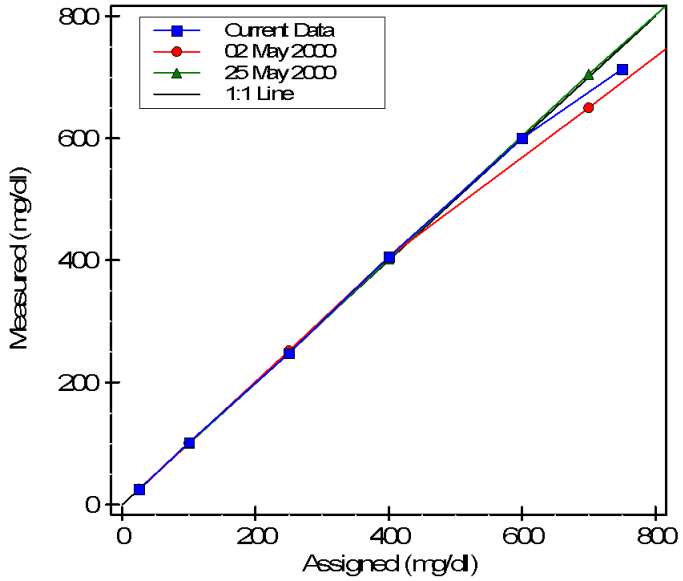
Percent Recovery



Precision Index



History Plot



Probability of Failure in Proficiency Testing

	User's QC Statistics		PT Limits	
	Mean	SD		
Control 1	70	3	Pct	10
Control 2	150	5	Units	6
Control 3	300	6		

Reference:

Reference:

PT Analysis

	Concentration Units		Percent of PT Limits			Probability Result is Outside Limits	
	Assigned Conc'ns	PT Limits	Est. SD	Linear Bias	Recovery Bias	for Linearity	for Recovery
CalKit-1	25.0	6.0	31%	10%	0%	0.1%	0.05%
CalKit-2	100.0	10.0	38%	13%	20%	1%	1%
CalKit-3	250.0	25.0	23%	13%	9%	<0.01%	<0.01%
CalKit-4	400.0	40.0	17%	13%	16%	<0.01%	<0.01%
CalKit-5	600	60.0	13%	2%	1%	<0.01%	<0.01%
CalKit-6	750	75.0	12%	51%	49%	<0.01%	<0.01%

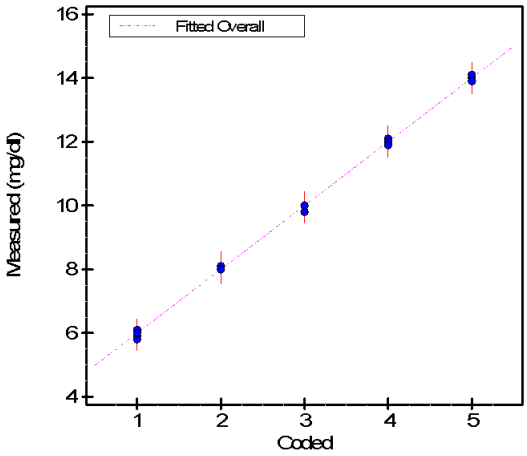
Linear bias based on Clinical Linearity

Failure Relationships

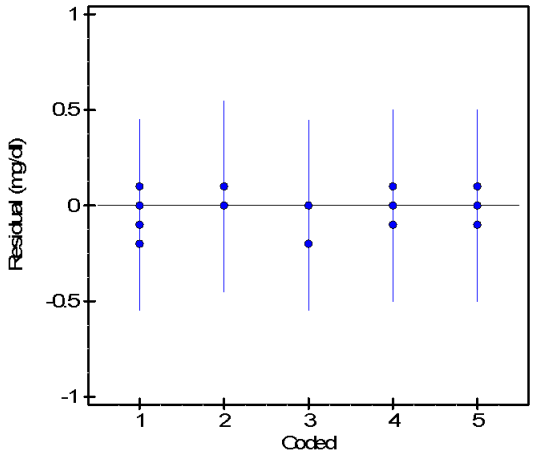
Probability Failure Outside Limits	Probability Failure Next Event	Probability Failure 1 of Next 2	Probability Failure 2 of Next 3
0.1%	0.001%	0.002%	0.0000%
0.2	0.005	0.01	0.0000
0.5	0.02	0.05	0.0000
1	0.1	0.2	0.0005
2	0.5	1	0.005
5	2	5	0.2
10	10	15	2
20	30	45	20
50	80	95	90

Linearity

Scatter Plot



Residual Plot



Linearity Summary

	N	Slope	Intercept	Error
Overall	5	2.000	4.00	0.05 mg/dl

LINEAR within Allowable Systematic Error of 0.5 mg/dl

Statistical Analysis and Experimental Results

	Coded	Est	Mean	Residual	Linear?	Measured Concentrations			
CalKit-1	1	6.00	5.95	-0.05	Pass	5.9	5.8	6.1	6.0
CalKit-2	2	8.00	8.05	0.05	Pass	8.0	8.1	8.1	8.0
CalKit-3	3	10.00	9.95	-0.05	Pass	10.0	10.0	10.0	9.8
CalKit-4	4	12.00	12.00	0.00	Pass	12.1	12.0	12.0	11.9
CalKit-5	5	14.00	14.00	0.00	Pass	14.0	14.0	14.1	13.9

See User's Specifications for Pass/Fail criteria

X: Excluded from calculations

User's Specifications

Allowable Total Error	1 mg/dl
Systematic Error Budget	50%
Allowable Systematic Error	0.5 mg/dl

Supporting Data

Analyst	Carol Doe
Date	01 Jun 2000
Value Mode	Coded
Units	mg/dl
Controls	–
Reagent	–
Calibrators	–
Comment	

Evaluation of Results

The Linearity of CALCIUM was analyzed on ATOM-ABSORB over a measured range of 5.95 to 14.00 mg/dl. Accuracy and Reportable Range were not verified. Allowable systematic error (SEa) was 0.5 mg/dl. The results are LINEAR.

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Linearity

Report Interpretation Guide

In EP Evaluator, Linearity experiments are experiments that use specimens with defined concentrations. The Linearity module can also evaluate Calibration Verification, Accuracy, Reportable Range and Precision. This means that you can verify three of the four major CLIA '88 requirements with one properly designed experiment.

User-selectable options determine which of these analytical properties the report verifies. Also, the user may request Pass/Fail flags against a specific allowable error criterion, or he/she may simply report selected statistical measures.

Experiment Procedure: Replicate measurements are made on 3-11 specimens, with (known) concentrations spread across the reportable range. Ideally, the lowest and highest specimens should challenge the limits of the range.

Accuracy (or Recovery)

Definition: The ability to recover the correct amount of analyte present in the specimen.

Verification process: Accuracy can be verified only when the "correct" amount of analyte **(the Assigned Value)** is known. While it is possible to evaluate recovery using a single replicate, assaying 2 to 4 replicates provides a more reliable estimate.

Key statistic: Recovery = 100 x Measured Mean / Assigned Value

Reportable Range

Definition: As used in CLIA, Reportable Range refers to the Analytical Range or Assay Range -- the maximum range of values that can be assayed accurately without dilution. The CAP term "Analytical Measurement Range" (AMR) is a synonym for Reportable Range.

Verification Procedure: Reportable Range is verified if two conditions are met: 1) the assigned values of the lowest and highest specimens are within proximity limits of the Reportable Range limits, and 2) these two specimens are acceptably accurate.

Proximity Limits: Proximity Limits define how close the lowest and highest specimens must be to the Reportable Range limits.

Calibration Verification

Calibration Verification verifies whether a method is properly calibrated, by verifying both Accuracy and Reportable Range. The report is titled to match the CAP and CLIA regulatory requirements.

CLIA requires a minimum of three specimens, each assayed in duplicate. Two specimens challenge the lower and upper limits of the reportable range. The third specimen is somewhere in between.

Linearity

Several definitions are in common use. Among them:

- **Traditional Linearity** (CAP Visual Inspection): Draw a scatter plot with assigned values on the X-axis and measured mean on the Y-axis. If it looks like a straight line, the method is linear.
- **Statistical Linearity** (CLSI EP6P and EP6-A): These procedures determine acceptability based on statistical significance (i.e., p-values) rather than medical significance. EP Evaluator does not compute Statistical Linearity.
- **Clinical Linearity:** The method is linear if it is possible to draw a straight line that passes within a user-defined allowable error of each specimen point.

Related concepts:

- **Best Fit Line:** If the user opts to verify Linearity, this line it is obtained using the Clinical Linearity algorithm. Otherwise it is a regular linear regression line.
- **Outliers:** When verifying Linearity, the program first tries to determine an acceptable line using all specimens. If it fails, it then tries to find some subset of at least three specimens that are linear within allowable error. Specimens not in this acceptable subset are classified as outliers.
- **Slope and Intercept:** Coefficients of the Best Fit Line. The ideal slope is 1.00; the ideal intercept is zero.
- **Observed Error:** For Clinical Linearity, this is the minimum allowable error that could be defined for a data set and still have it be linear.
- **Standard Error of Estimate:** For regular regression, this measures the dispersion of the data points around the Best Fit Line.
- **Residual:** The difference between the best fit line and either an individual result or a mean measured value, depending on context.

Precision

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

Verification Process: Measure the specimen many times. Compute the SD and CV, and verify that they are acceptably small. While 2-4 replicates are adequate for assessing accuracy, a minimum of 10 (and preferably 20 or more) is required to verify Precision.

Linearity

Report Interpretation Guide

The **Precision Index** is the ratio of SD to Allowable Random Error (defined below). The ideal -- and probably unattainable -- Precision Index is zero. A value of 1.00 indicates borderline acceptability. Any further increase in SD would exceed allowable error.

The **95% Confidence Interval** (CI) for the Precision Index indicates how much sampling variation might be expected. The CI narrows as the number of replicates increases.

Allowable Total Error (TEa), and the Error Budget

TEa states the laboratory's policy for how much error is medically (or administratively) acceptable. Regulatory requirements represent an upper limit. Example: the CLIA limit for Sodium is 4 mmol/L.

Total Error has two major components: **Systematic Error** (synonym Bias) and **Random Error** (synonym Imprecision). The **Error Budget** allocates a fraction of the Allowable Total Error for Systematic Error, and the remaining fraction for Random Error. Establishing an appropriate Error Budget allows the lab to control accuracy and precision separately, with reasonable confidence that Total Error will also remain in control. The recommended upper value for the Systematic Error Budget is 50%; for the Random Error Budget it is 25%.

Pass or Fail?

The program reports Pass/Fail for Accuracy and Linearity based on Allowable Systematic Error (SEa). Pass/Fail for Precision is based on Allowable Random Error (REa).

- A specimen passes Accuracy if its mean measured value is within SEa of the Assigned Value.
- The experiment passes Linearity if it is possible to draw a straight line (on the scatter plot of mean measured value vs. assigned value) that passes within +/- SEa of each specimen point.
- A specimen passes Precision if SD does not exceed REa.
- The experiment passes Reportable Range if 1) the assigned values of the lowest and highest specimens are within proximity limits of the Reportable Range Limits, and 2) these two specimens also pass accuracy.

Preliminary Report

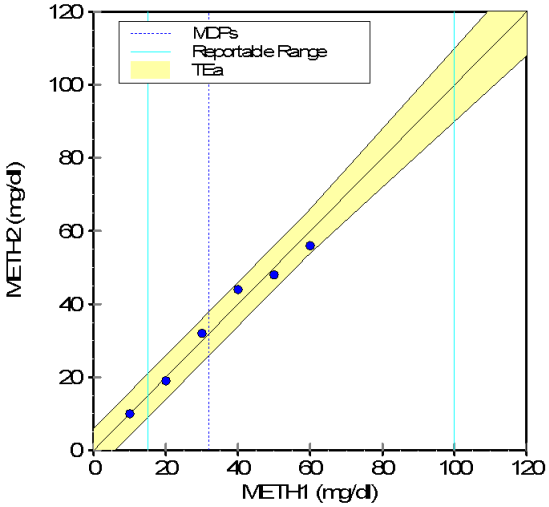
The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing.

The Linearity report is preliminary if there are less than three specimens.

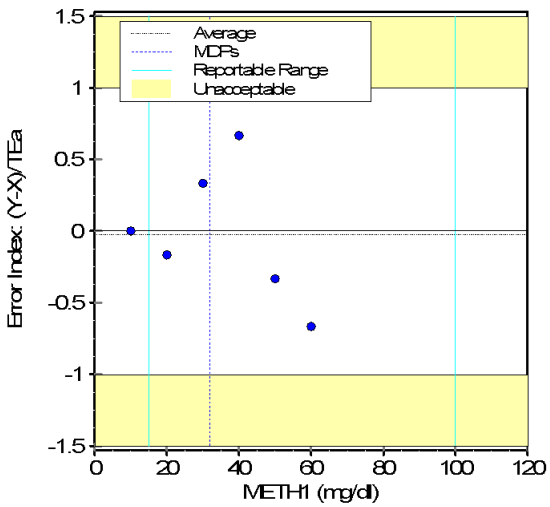
Two Instrument Comparison

X Method METH1 **Y Method METH2**

Scatter Plot



Error Index



Evaluation of Results

DEFAULT was analyzed by methods METH1 and METH2 to determine whether the methods are equivalent within Allowable Total Error of 6 mg/dl or 10%. 6 specimens were compared over a range of 10 to 60 mg/dl. The test Passed. The difference between the two methods was within allowable error for 6 of 6 specimens (100%). The average Error Index (Y-X)/TEa was -0.03, with a range of -0.67 to 0.67. The largest Error Index occured at a concentration of 40 mg/dl.

Key Statistics	
Average Error Index	-0.03
Error Index Range	-0.67 to 0.67
Coverage Ratio	53%
Evaluation Criteria	
Allowable Total Error	6 mg/dl or 10%
Reportable Range	15 to 100 mg/dl

Deming Regression Statistics	
Y = Slope * X + Intercept	
Correlation Coeff (R)	0.9890
Slope	0.950 (0.754 to 1.145)
Intercept	1.6 (-6.0 to 9.2)
Std Error Estimate	2.9
N	6 of 6

Experiment Description

	X Method	Y Method
Expt Date	01 Jun 2000	01 Jun 2000
Result Ranges	10 to 60	10 to 56
Mean ± SD	35.0 ± 18.7	34.8 ± 17.8
Units	mg/dl	mg/dl
Analyst	Fred Doe	Gina Doe
Comment		

Accepted by: _____ _____

Signature Date

Two Instrument Comparison

X Method METH1 **Y Method METH2**

Experimental Results

Specimen	X	Y	Error Index	Specimen	X	Y	Error Index	Specimen	X	Y	Error Index
SPEC1	10	10	0.00	SPEC3	30	32	0.33	SPEC5	50	48	-0.33
SPEC2	20	19	-0.17	SPEC4	40	44	0.67	SPEC6	60	56	-0.67

Values with an "X" were excluded from the calculations.

Two Instrument Comparison

Report Interpretation Guide

Two Instrument Comparison (2IC) is a simple, straight-forward procedure for comparing two methods without using linear regression. The pass-fail rule is easy to understand: two methods X and Y are the same within allowable error (i.e., are clinically identical) if the difference between the two does not exceed Allowable Total Error (TEa) for each specimen.

Clinical Equivalence vs. Statistical Equivalence

Traditional method comparison protocols test whether two methods are statistically equivalent. In contrast, 2IC tests whether the two methods are clinically equivalent. What's the difference?

Statistical Equivalence. Two methods are statistically equivalent if the difference between them is random. It does not matter how large the difference is.

The CLIA limit for Calcium is 1 mg/dL. However, two Calcium tests could differ by 3 mg/dL and still test as statistically identical -- if no bias is present. Suppose you constructed an experiment by arranging the specimens in increasing order by X, with a +3 mg/dL error at the even-numbered points and a -3 mg/dL error at the odd-numbered points. On average, the bias is zero. A regression-based comparison considers these methods "identical", even though the error is far greater than TEa.

Clinical Equivalence. Two methods are clinically equivalent if the difference between the two is less than allowable error for each specimen. It does not matter if there is a bias, as long as that bias is within allowable error.

For example, suppose Calcium for the Y method is, in every case, 0.2 mg/dL higher than for the X method. These methods are not statistically identical, because the difference is not random. However, they are clinically identical, since the difference is less than the allowable error of 1.0 mg/dL.

Data Quality

2IC gives a meaningful comparison with fewer data points than are required for traditional, regression-based procedures -- perhaps 5 to 10 specimens. However, it is important that the specimens cover the reportable range of the method, and include points near the Medical Decision Points.

Key Statistics and Evaluation Criteria

Allowable Total Error (TEa). TEa states the laboratory's policy for how much error is medically (or administratively) acceptable. Regulatory requirements represent an upper limit.

Examples: the CLIA limit for Sodium is 4 mmol/L; the CLIA limit for Glucose is 6 mg/dL or 10%, whichever is greater.

Error Index. The ratio of the difference Y-X to Allowable Total Error (evaluated at X). The Error Index is measured for each X-Y pair. An index greater than 1.00 or less than -1.00 is unacceptable -- it means the difference between the methods exceeds TEa. If an excessive number of specimens have an unacceptable Error Index (EI), the experiment fails. Excessive number of specimens occurs if the EI is unacceptable for at least one specimen if N<40 or if the EI for more than 5% of the specimens is unacceptable when N>= 40.

Reportable Range. The maximum range of values that can be measured accurately without diluting the specimen. Synonyms: Analytical Measurement Range, Assay Range, Analytical Range.

Coverage Ratio. The percent of the Reportable Range covered by the analysis. The ideal is 100%.

Coverage is computed as 100 x (Xhi - Xlo) / (Rhi - Rlo). Rlo and Rhi are the lower and upper limits of the Reportable Range. Xhi is the smaller of maximum X and the upper limit of the range. Xlo is the larger of minimum X and the lower limit of the range.

Example: Suppose the Reportable Range is 100 to 300, and the range of X values measured is 200 to 350. There is a 50% overlap between the X-range and the Reportable Range. The coverage ratio is 100 x (300 - 200) / (300 - 100) = 50%.

Deming Regression Statistics. The report shows the slope, intercept, standard error of estimate, and correlation coefficient for reference only. They are not used to determine whether the experiment passes or fails. Note that the slope and intercept are computed from Deming regression, assuming that the two methods have comparable precision (i.e., the same representative SD).

Plots

Scatter Plot. The Scatter plot shows the data points, together with the 1:1 (Y=X) line with Allowable Error bounds around it. Vertical lines mark the Reportable Range and Medical Decision Points (if these values were input). The plot does NOT show the regression line.

Error Index Plot. The Error Index plot shows the Error Index. Points that fall in the shaded area have an unacceptable Error Index (> 1.00 or < -1.00).

Logarithmic Scale. When the data covers a wide range and has a tight cluster of points at the low end, the scatter plot may be shown on a logarithmic scale instead of a linear scale. Using a log scale gives better visual separation of the points at the low end.

Two Instrument Comparison

Report Interpretation Guide

When the plots are shown on a log scale, the regression fit is computed for the logs of the data points, and the Standard Error of Estimate (SEE) represents percent variation around the regression line. (SEE of 0.10 means 10% variation.)

Pass or Fail?

The objective is to determine whether the two methods are clinically equivalent. The experiment passes if the Error Index is acceptable for a suitable number of specimens. See Error Index above for a complete discussion.

Preliminary Report

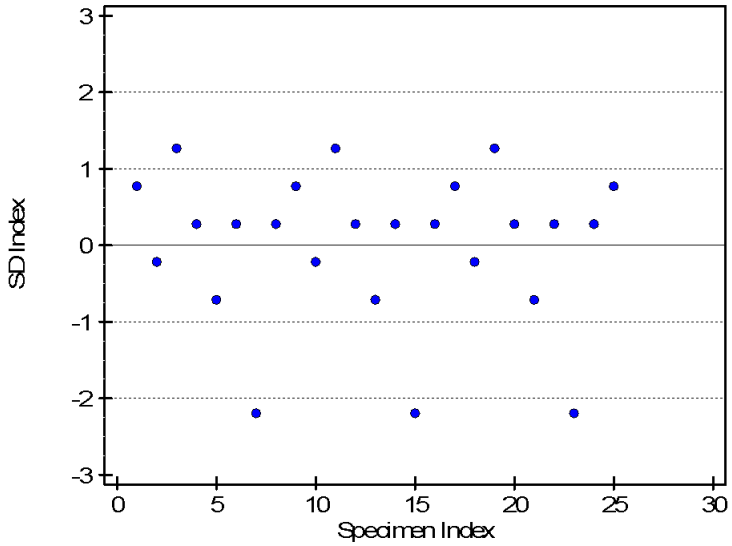
The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing.

The 2IC report is preliminary if there are less than 5 unexcluded data points.

Simple Precision

Precision Statistics			
Mean	19.4 mg/dL	95% CI for Mean	18.6 to 20.3
Standard Deviation (SD)	2.0	2 SD Range	15.4 to 23.5
95% Confidence for SD	1.6 to 2.8	Number of Specimens (N)	25 of 25
Coefficient of Variation (CV)	10.4%		

Precision Plot



Supporting Data

Analyst	Michael Doe
Expt Date	01 Jun 2000
Units	mg/dL
Control Lot	–
Reag Lot	–
Cal Lot	–
Comment	

Precision Data

Index	Results	Index	Results	Index	Results	Index	Results
1	21	8	20	15	15	22	20
2	19	9	21	16	20	23	15
3	22	10	19	17	21	24	20
4	20	11	22	18	19	25	21
5	18	12	20	19	22		
6	20	13	18	20	20		
7	15	14	20	21	18		

Accepted by: _____ _____

Signature Date

Simple Precision

Report Interpretation Guide

CLIA and CAP require periodic verification of Precision. The Simple Precision experiment is a quick and dirty way to fulfill the letter of this requirement. The procedure is to make repeated measurements of a single sample, and compute simple statistics like mean, SD, and CV. In addition, EP Evaluator offers an option to enter a precision goal (Allowable Random Error). When a goal is entered, the program will report that the test "passes" if the calculated SD does not exceed Allowable Random Error.

Definitions

Precision: Ability to obtain the same result upon repeated measurement of a specimen. Not necessarily the *correct* result, just the *same* result. (Ability to get the correct result is *Accuracy.)*

Mean: Average value, computed by adding the results and dividing the total by the number of results.

Standard Deviation (SD): The primary measure of dispersion or variation of the individual results about the mean. In other words, a measure of Precision. For many analytes, SD varies with sample concentration. Example: For Glucose, an SD of 10 for a 400 mg/dL sample represents very good precision. For a 40 mg/dL sample, an SD of 10 represents very poor precision.

Coefficient of Variation (CV): SD expressed as a percent of the mean. For analytes where error varies with concentration, CV is more likely to remain constant across the analytical range. Example: 2.5% CV for Glucose is good precision at any concentration.

Within-Run and Total SD: Manufacturers often publish these statistics in package inserts. They are computed from a more complex precision experiment that requires replicate measurements over several days. Total SD from this complex precision experiment is NOT comparable to EP Evaluator's Simple Precision SD.

Number of Specimens (N): A good precision study should include 20-50 replicates. Mathematically, it is possible to calculate SD and CV from only 3 replicates, but it is not a very reliable estimate. For example, suppose the true SD is 1.00. An estimate based on 3 replicates might easily be as low as 0.52 or as high as 6.29 (95% confidence). At N=20, the 95% confidence interval is much narrower: 0.76 to 1.46. At N=50 it narrows further: 0.84 to 1.24.

95% Confidence Interval for SD: In a sense, this measures the "precision of the precision". It shows how much the SD might vary if the precision experiment was repeated with different experimental results. The width of the confidence interval depends on two factors: N and the intrinsic SD of the system. The reliability of the precision estimate improves as N increases.

Allowable Total Error (TEa), and the Error Budget

TEa states the laboratory's policy for how much error is medically (or administratively) acceptable. Regulatory requirements represent an upper limit. Example: the CLIA limit for Sodium is 4 mmol/L.

Total Error has two major components: **Systematic Error** (synonym Bias) and **Random Error** (synonym Imprecision). The **Error Budget** allocates a fraction of the Allowable Total Error for Systematic Error, and the remaining fraction for Random Error. Establishing an appropriate Error Budget allows the lab to control accuracy and precision separately. Recommended ranges of values are 25-50% for the Systematic Error Budget and 16-25% for the Random Error Budget.

Pass or Fail?

The objective is to determine whether precision is acceptable, so the standard of comparison is Allowable Random Error. The test passes if the computed SD does not exceed Allowable Random Error.

Example: Suppose Allowable Total Error for Sodium is 4 mmol/L, with a Random Error Budget of 25%. Allowable Random Error is 25% x 4 or 1 mmol/L. The precision test passes when the computed SD is at or below 1 mmol/L.

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. The Simple Precision report is Preliminary if there are fewer than 3 unexcluded results.

Chart Interpretation

Levey-Jennings Chart: A scatter plot of Standard Deviation Index (SDI) on the Y-axis vs. specimen index on the X-axis. Specimen index reflects the order in which the results were typed into the program. SDI = (Result - mean) / SD.

Precision Goal: This chart appears only when Allowable Random Error is provided. It shows the observed SD and its 95% confidence interval in relation to allowable random error (the goal). The wide colored bar represents the SD. The fence marks above and below the top of the SD bar show the 95% confidence limits.

- The report calls the test a "pass" if the SD (top of the wide colored bar) does not exceed the goal. The bar is green if the test passes, or red if it fails.

Simple Precision

Report Interpretation Guide

- If you consider all points within the 95% confidence interval to be statistically identical, you might consider the test at least marginally acceptable if the lower confidence limit does not exceed the goal.
- The ideal situation is when the upper 95% confidence limit does not exceed the goal.