



Triglyceride

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Experiment Details

Units: mg/l

Comparison By	Error Allowance
Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95% REa (50% TEa): 7.5%
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

NPL100245 Reference Value: 5.5	Results 25	Mean and CV 5.464 4.8298%	Error Index -0.0873	Agreement 100 %	✓
NPL100234 Reference Value: 1.7	Results 25	Mean and CV 1.74 3.4310%	Error Index 0.3137	Agreement 100 %	✓
NPL1000435 Reference Value: 2.3	Results 25	Mean and CV 2.324 1.8675%	Error Index 0.1391	Agreement 100 %	✓

Precision
Passed

Samples
3

Results
75

Agreements
100 %





Triglyceride

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Sample Data for TAG Precision NPL100245

Run	R1	R2	R3	R4	R5	Within Run
Day 1	5.7	5.2	5.5	5.2	5.9	5/5
Day 2	5.6	5.2	5.8	5.3	5.7	5/5
Day 3	5.4	5.4	5.1	5.3	5.3	5/5
Day 4	5.2	5.3	5.3	5.6	5.2	5/5
Day 5	5.8	5.8	5.7	5.2	5.9	5/5

Sample Data for TAG Precision NPL100234

Run	R1	R2	R3	R4	R5	Within Run
Day 1	1.7	1.7	1.8	1.7	1.8	5/5
Day 2	1.8	1.8	1.8	1.8	1.8	5/5
Day 3	1.7	1.7	1.7	1.7	1.7	5/5
Day 4	1.8	1.8	1.7	1.7	1.8	5/5
Day 5	1.6	1.7	1.7	1.8	1.7	5/5

Sample Data for TAG Precision NPL1000435

Run	R1	R2	R3	R4	R5	Within Run
Day 1	2.3	2.3	2.4	2.3	2.3	5/5
Day 2	2.3	2.3	2.3	2.3	2.3	5/5
Day 3	2.3	2.4	2.4	2.3	2.3	5/5
Day 4	2.3	2.3	2.3	2.4	2.3	5/5
Day 5	2.4	2.3	2.3	2.4	2.3	5/5

Precision
Passed

Samples
3

Results
75

Agreements
100 %





Triglyceride

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Experiment Details

Units: mg/l

Acceptance Criteria	Days: 5 Replicates per Day: 5 LoB Reference Value: 0.05
Mean	0
Standard Deviation	0
1.65 SD	0

Limit of Blank
Passed

Mean
0

SD
0

LoB
0





Triglyceride

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Sample Data for TAG Limit of Blank

	Run	R1	R2	R3	R4	R5
1	Run 1	0	0	0	0	0
2	Run 2	0	0	0	0	0
3	Run 3	0	0	0	0	0
4	Run 4	0	0	0	0	0
5	Run 5	0	0	0	0	0

Limit of Blank
Passed

Mean
0

SD
0

LoB
0





Triglyceride

Quantitative Limit of Quantification

For reference on this experiment see link.cualia.io/docs-qnt-loq

Experiment Details

Units: mg/l

Acceptance Criteria	Days: 5 Replicates per Day: 5 LoQ Allowable Error % (k): 10%
LoQ Error Allowance	0.01
Bias	0
Overall mean	0.1
Overall SD	0
Total Error (TE)	0

Limit of Quantification
Passed

Mean
0.1

Bias
0

TE
0





Triglyceride

Quantitative Limit of Quantification

For reference on this experiment see link.cualia.io/docs-qnt-loq

Sample Data for TAG Limit of Quantification

	Run	R1	R2	R3	R4	R5
1	Run 1	0.1	0.1	0.1	0.1	0.1
2	Run 2	0.1	0.1	0.1	0.1	0.1
3	Run 3	0.1	0.1	0.1	0.1	0.1
4	Run 4	0.1	0.1	0.1	0.1	0.1
5	Run 5	0.1	0.1	0.1	0.1	0.1

Limit of Quantification	Mean	Bias	TE	
Passed	0.1	0	0	





Triglyceride

Quantitative Linearity

For reference on this experiment see link.cualia.io/docs-qnt-lin

Experiment Details

Units: mg/l

Acceptance Criteria	Levels: 5 Replicates per Level: 3 Regression Type: Pearson Correlation Coefficient (r) Min. Pearson Correlation Coefficient (r): 0.95 Range Extension (%): 5%
Levels	5
Allowable Range	110 to 200
Actual Range	110 to 190.5
Pearson Correlation Coefficient (r)	0.9999

Pearson Correlation Coefficient (r)	0.9999 $y = 0.9961x + 0.9258$ SEE: 0.5137
Coefficient of Determination (r^2)	0.9999

Linearity
Passed

Regression
 $y = 0.9961x + 0.9258$

Actual Range
110 to 190.5

Pearson Correlation
Coefficient (r)
0.9999



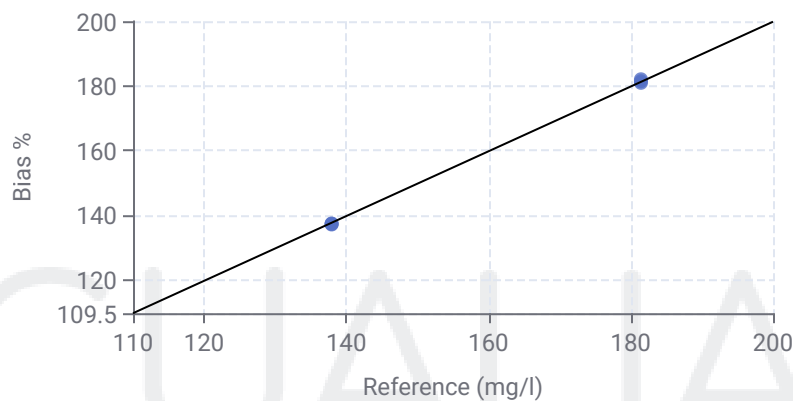


Triglyceride

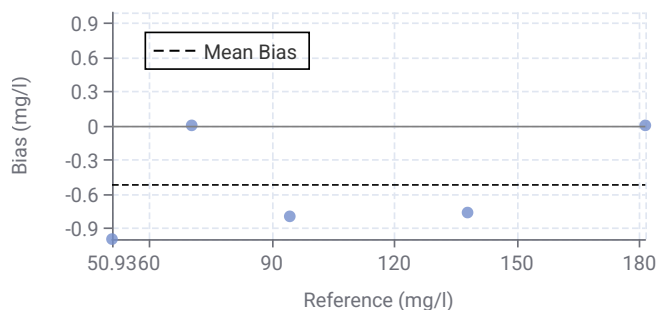
Quantitative Linearity

For reference on this experiment see link.cualia.io/docs-qnt-lin

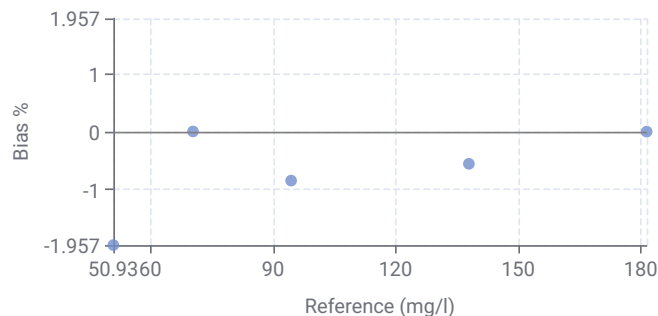
Scatter Plot



Bias % Chart



Bias Chart



Linearity
Passed

Regression
 $y = 0.9961x + 0.9258$

Actual Range
110 to 190.5

Pearson Correlation
Coefficient (r)
0.9999





Triglyceride

Quantitative Linearity

For reference on this experiment see link.cualia.io/docs-qnt-lin

Sample Data for TAG Linearity

Level	Reference Value	R1	R2	R3	Mean and Bias
1	70.43	70.4	70.3	70.6	$\bar{x} = 70.43$ 0.003 (0.00%)
2	50.93	49.8	50	50	$\bar{x} = 49.93$ -0.997 (-1.96%)
3	94.43	93.3	93.4	94.2	$\bar{x} = 93.63$ -0.797 (-0.84%)
4	137.93	137	137.3	137.2	$\bar{x} = 137.2$ -0.763 (-0.55%)
5	181.43	182	181.4	180.9	$\bar{x} = 181.4$ 0.003 (0.00%)

Linearity
Passed

Regression
 $y = 0.9961x + 0.9258$

Actual Range
110 to 190.5

Pearson Correlation
Coefficient (r)
0.9999





Triglyceride

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Experiment Details

Units: mg/l

Acceptance Criteria	Calculation Mode: Error Allowance Min. Samples: 5 Min. Agreement: 95% TEa: 15%
Agreement	5/5 (100%)
Range Tested	120.6 - 144
Mean Error Index	0.0249

Trueness
Passed

Samples

5

Range Tested

120.6 - 144

Agreement

100 %

Mean Error Index

0.0249



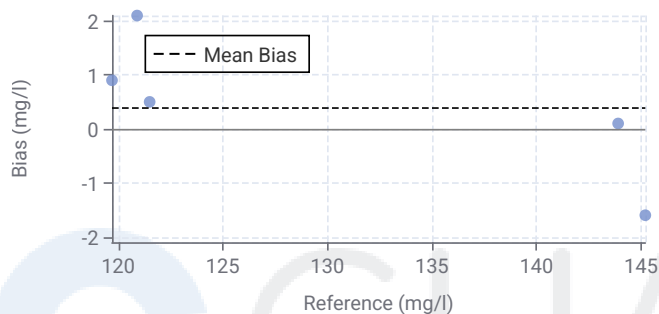


Triglyceride

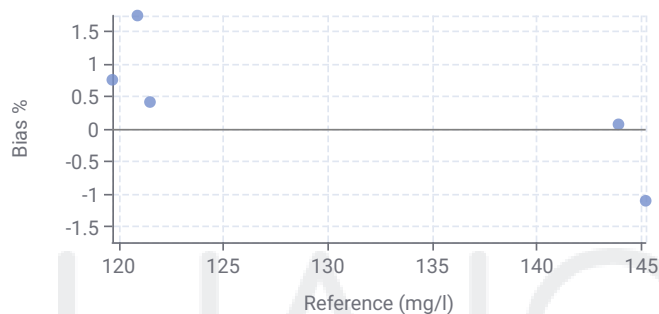
Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Bias % Chart



Bias Chart



Trueness
Passed

Samples

5

Range Tested

120.6 - 144

Agreement

100 %

Mean Error Index

0.0249





Triglyceride

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Sample Data for TAG Trueness

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
25I00035	119.7	120.6	0.9 (0.7519%)	0.0501	✓
25I00012	145.2	143.6	-1.6 (-1.1019%)	-0.0735	✓
25I00033	143.9	144	0.1 (0.0695%)	0.0046	✓
23I00009	120.9	123	2.1 (1.737%)	0.1158	✓
25I00045	121.5	122	0.5 (0.4115%)	0.0274	✓

Trueness
Passed

Samples

5

Range Tested

120.6 - 144

Agreement

100 %

Mean Error Index

0.0249





Cholesterol Total

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Experiment Details

Units: mg/l

Comparison By	Error Allowance
Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95% TEas: Exact Match
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

Sample 1 Reference Value: 2.5	Results 25	Mean and CV 2.5 0%	Error Index -	Agreement 100 %	
Sample 2 Reference Value: 2.5	Results 25	Mean and CV 2.5 0%	Error Index -	Agreement 100 %	
Sample 3 Reference Value: 2.5	Results 25	Mean and CV 2.5 0%	Error Index -	Agreement 100 %	

Precision
Passed

Samples
3

Results
75

Agreements
100 %





Cholesterol Total

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Sample Data for Tot Chol. Precision Sample 1

Run	R1	R2	R3	R4	R5	Within Run
Day 1	2.5	2.5	2.5	2.5	2.5	5/5
Day 2	2.5	2.5	2.5	2.5	2.5	5/5
Day 3	2.5	2.5	2.5	2.5	2.5	5/5
Day 4	2.5	2.5	2.5	2.5	2.5	5/5
Day 5	2.5	2.5	2.5	2.5	2.5	5/5

Sample Data for Tot Chol. Precision Sample 2

Run	R1	R2	R3	R4	R5	Within Run
Day 1	2.5	2.5	2.5	2.5	2.5	5/5
Day 2	2.5	2.5	2.5	2.5	2.5	5/5
Day 3	2.5	2.5	2.5	2.5	2.5	5/5
Day 4	2.5	2.5	2.5	2.5	2.5	5/5
Day 5	2.5	2.5	2.5	2.5	2.5	5/5

Sample Data for Tot Chol. Precision Sample 3

Run	R1	R2	R3	R4	R5	Within Run
Day 1	2.5	2.5	2.5	2.5	2.5	5/5
Day 2	2.5	2.5	2.5	2.5	2.5	5/5
Day 3	2.5	2.5	2.5	2.5	2.5	5/5
Day 4	2.5	2.5	2.5	2.5	2.5	5/5
Day 5	2.5	2.5	2.5	2.5	2.5	5/5

Precision
Passed

Samples
3

Results
75

Agreements
100 %





Cholesterol Total

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Experiment Details

Units: mg/l

Acceptance Criteria	Days: 5 Replicates per Day: 5 LoB Reference Value: 0.05
Mean	0
Standard Deviation	0
1.65 SD	0

Limit of Blank
Passed

Mean
0

SD
0

LoB
0





Cholesterol Total

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Sample Data for Tot Chol. Limit of Blank

	Run	R1	R2	R3	R4	R5
1	Run 1	0	0	0	0	0
2	Run 2	0	0	0	0	0
3	Run 3	0	0	0	0	0
4	Run 4	0	0	0	0	0
5	Run 5	0	0	0	0	0

Limit of Blank
Passed

Mean
0

SD
0

LoB
0





Cholesterol Total

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Experiment Details

Units: mg/l

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95% TEas: Exact Match
Agreement	20/20 (100%)
Range Tested	2 - 9
Pearson Correlation Coefficient (r)	1.0000
Mean Error Index	-

Pearson Correlation Coefficient (r)	1.0000 $y = 1x + 0$ SEE: 0
Coefficient of Determination (r^2)	1.0000

Method Comparison
Passed

Samples

20

Range Tested

2 - 9

Agreement

100 %

Mean Error Index

-



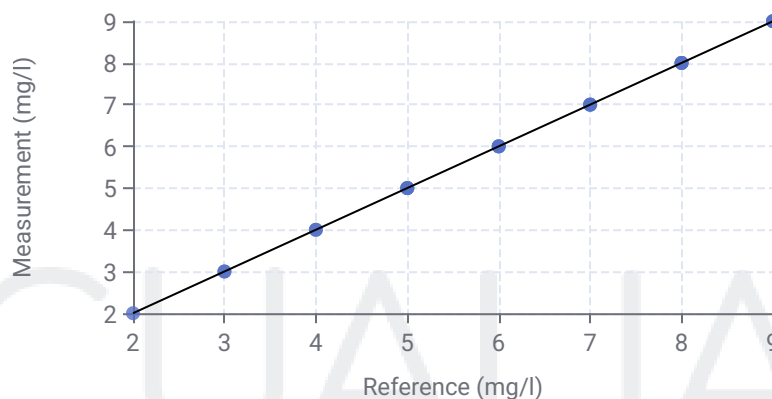


Cholesterol Total

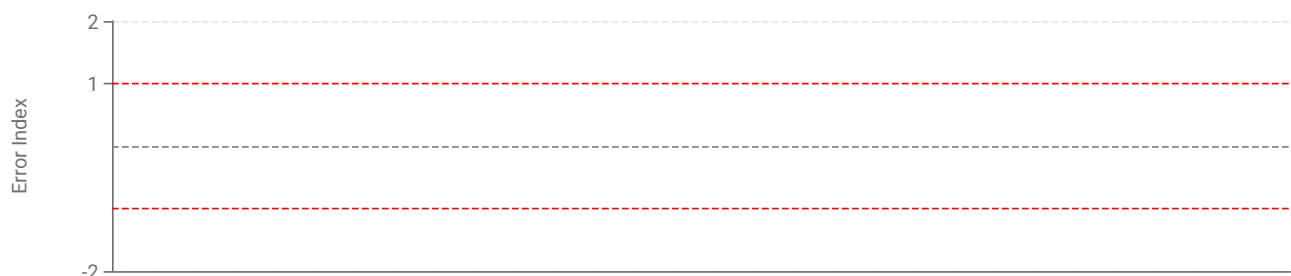
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Scatter Plot



Error Index Chart



Method Comparison
Passed

Samples

20

Range Tested

2 - 9

Agreement

100 %

Mean Error Index

-



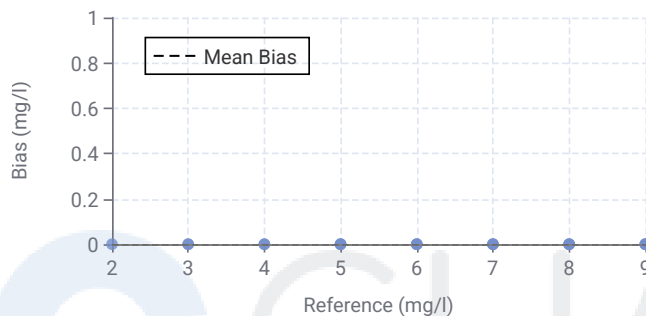


Cholesterol Total

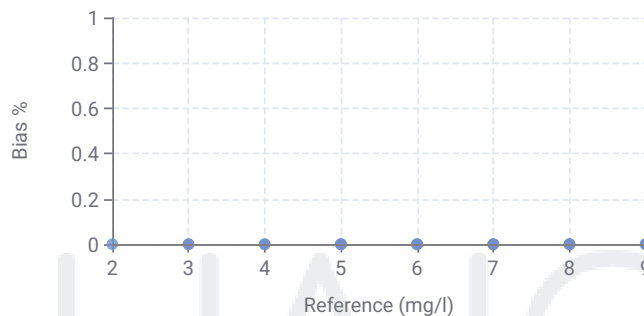
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Bias % Chart



Bias Chart



Method Comparison
Passed

Samples

20

Range Tested

2 - 9

Agreement

100 %

Mean Error Index

-





Cholesterol Total

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Sample Data for Tot Chol. Method Comparison

Label	Reference (X)	Measurement (Y)	Bias	Error Index
L1	5	5	0 (0%)	-
L2	6	6	0 (0%)	-
L3	7	7	0 (0%)	-
L4	8	8	0 (0%)	-
L5	9	9	0 (0%)	-
L6	2	2	0 (0%)	-
L7	3	3	0 (0%)	-
L8	4	4	0 (0%)	-
L9	5	5	0 (0%)	-
L10	6	6	0 (0%)	-
L11	7	7	0 (0%)	-
L12	8	8	0 (0%)	-
L13	9	9	0 (0%)	-
L14	3	3	0 (0%)	-
L15	4	4	0 (0%)	-
L16	5	5	0 (0%)	-
L17	6	6	0 (0%)	-
L18	7	7	0 (0%)	-
L19	8	8	0 (0%)	-

Method Comparison
Passed

Samples

20

Range Tested

2 - 9

Agreement

100 %

Mean Error Index

-





Cholesterol Total

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Label	Reference (X)	Measurement (Y)	Bias	Error Index
L20	9	9	0 (0%)	-



Method Comparison
Passed

Samples
20

Range Tested
2 - 9

Agreement
100 %

Mean Error Index
-





Cholesterol Total

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Experiment Details

Units: mg/l

Acceptance Criteria	Calculation Mode: Error Allowance Min. Samples: 5 Min. Agreement: 95% TEas: Exact Match
Agreement	5/5 (100%)
Range Tested	1 - 5
Mean Error Index	-

Trueness
Passed

Samples

5

Range Tested

1 - 5

Agreement

100 %

Mean Error Index

-



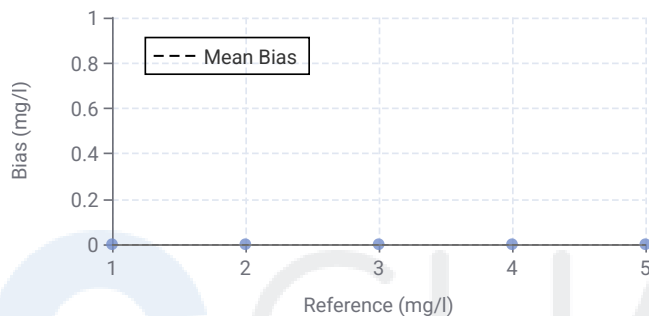


Cholesterol Total

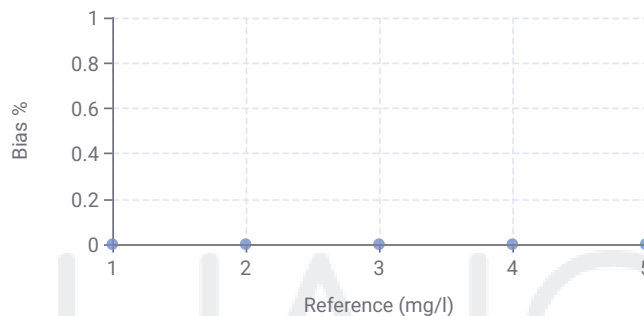
Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Bias % Chart



Bias Chart



Trueness
Passed

Samples

5

Range Tested

1 - 5

Agreement

100 %

Mean Error Index

-





Cholesterol Total

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Sample Data for Tot Chol. Trueness

Label	Reference (X)	Measurement (Y)	Bias	Error Index
T1	5	5	0 (0%)	-
T2	4	4	0 (0%)	-
T3	3	3	0 (0%)	-
T4	2	2	0 (0%)	-
T5	1	1	0 (0%)	-

Trueness
Passed

Samples

5

Range Tested

1 - 5

Agreement

100 %

Mean Error Index

-





Glucose

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Experiment Details

Units: mg/L

Comparison By	Error Allowance
Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95% REa (50% TEa): 5%
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

Sample 1 Reference Value: 5.97	Results 25	Mean and CV 5.9832 1.5610%	Error Index 0.0442	Agreement 96 %	✓
Sample 2 Reference Value: 9.4	Results 25	Mean and CV 9.4 1.0617%	Error Index 0	Agreement 100 %	✓
Sample 3 Reference Value: 12.7	Results 25	Mean and CV 12.704 0.8289%	Error Index 0.0063	Agreement 100 %	✓

Precision
Passed

Samples
3

Results
75

Agreements
98.67 %





Glucose

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Sample Data for GLUC Precision Sample 1

Run	R1	R2	R3	R4	R5	Within Run
Day 1	5.97	5.97	5.97	5.97	6.1	5/5
Day 2	6	5.9	5.8	5.9	5.9	5/5
Day 3	6.1	6	5.9	6	6	5/5
Day 4	6	6	6	6	6	5/5
Day 5	6.3	5.9	5.9	6	6	4/5

Sample Data for GLUC Precision Sample 2

Run	R1	R2	R3	R4	R5	Within Run
Day 1	9.3	9.3	9.3	9.3	9.4	5/5
Day 2	9.3	9.3	9.3	9.4	9.3	5/5
Day 3	9.5	9.4	9.4	9.4	9.4	5/5
Day 4	9.4	9.5	9.5	9.5	9.5	5/5
Day 5	9.4	9.4	9.4	9.7	9.4	5/5

Sample Data for GLUC Precision Sample 3

Run	R1	R2	R3	R4	R5	Within Run
Day 1	12.6	12.5	12.8	12.8	12.6	5/5
Day 2	12.6	12.7	12.6	12.6	12.5	5/5
Day 3	12.8	12.8	12.7	12.8	12.7	5/5
Day 4	12.8	12.7	12.8	12.8	12.8	5/5
Day 5	12.6	12.8	12.8	12.7	12.7	5/5

Precision
Passed

Samples
3

Results
75

Agreements
98.67 %





Glucose

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Experiment Details

Units: mg/L

Acceptance Criteria	Days: 5 Replicates per Day: 5 LoB Reference Value: 0.05
Mean	0.05
Standard Deviation	0
1.65 SD	0

Limit of Blank
Passed

Mean
0.05

SD
0

LoB
0.05





Glucose

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Sample Data for GLUC Limit of Blank

	Run	R1	R2	R3	R4	R5
1	Run 1	0.05	0.05	0.05	0.05	0.05
2	Run 2	0.05	0.05	0.05	0.05	0.05
3	Run 3	0.05	0.05	0.05	0.05	0.05
4	Run 4	0.05	0.05	0.05	0.05	0.05
5	Run 5	0.05	0.05	0.05	0.05	0.05

Limit of Blank
Passed

Mean
0.05

SD
0

LoB
0.05





Glucose

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Experiment Details

Units: mg/L

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95% TEas: 10%
Agreement	19/20 (95%)
Range Tested	70 - 221
Pearson Correlation Coefficient (r)	0.9932
Mean Error Index	-0.4643

Pearson Correlation Coefficient (r)	0.9932 $y = 0.9996x + -6.2872$ SEE: 5.6201
Coefficient of Determination (r^2)	0.9864

Method Comparison
Passed

Samples

20

Range Tested

70 - 221

Agreement

95 %

Mean Error Index

-0.4643



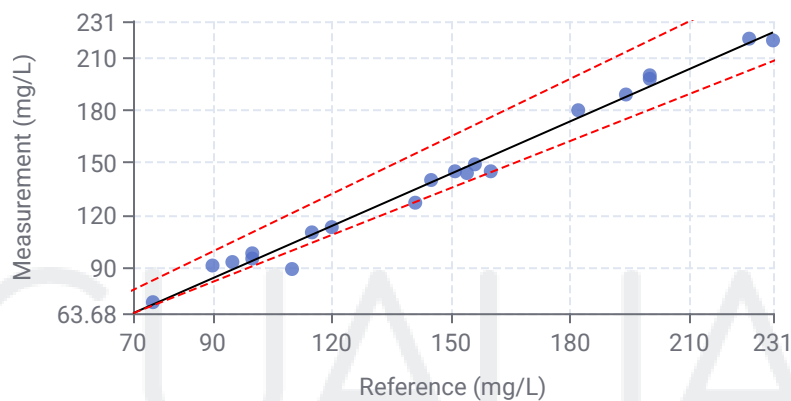


Glucose

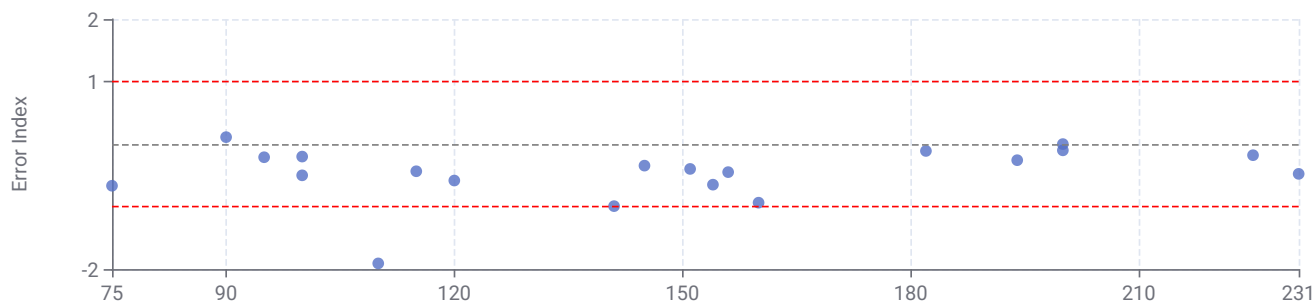
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Scatter Plot



Error Index Chart



Method Comparison
Passed

Samples

20

Range Tested

70 - 221

Agreement

95 %

Mean Error Index

-0.4643



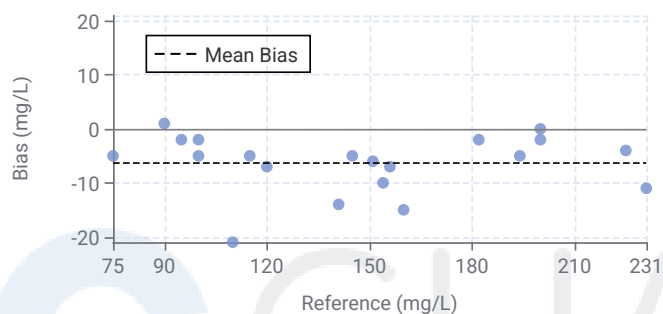


Glucose

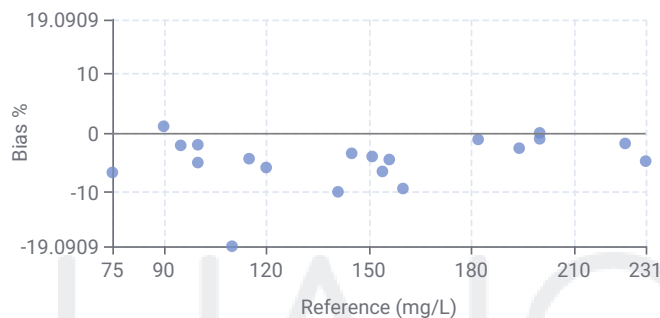
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Bias % Chart



Bias Chart



Method Comparison
Passed

Samples

20

Range Tested

70 - 221

Agreement

95 %

Mean Error Index

-0.4643





Glucose

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Sample Data for GLUC Method Comparison

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
MC7281	75	70	-5 (-6.6667%)	-0.6667	✓
MC7282	200	198	-2 (-1%)	-0.1	✓
MC7283	182	180	-2 (-1.0989%)	-0.1099	✓
MC7284	200	200	0 (0%)	0	✓
MC7285	231	220	-11 (-4.7619%)	-0.4762	✓
MC7286	225	221	-4 (-1.7778%)	-0.1778	✓
MC7287	115	110	-5 (-4.3478%)	-0.4348	✓
MC7288	90	91	1 (1.1111%)	0.1111	✓
MC7289	110	89	-21 (-19.0909%)	-1.9091	✗
MC7290	100	98	-2 (-2%)	-0.2	✓
MC7291	95	93	-2 (-2.1053%)	-0.2105	✓
MC7292	145	140	-5 (-3.4483%)	-0.3448	✓
MC7293	154	144	-10 (-6.4935%)	-0.6494	✓
MC7294	160	145	-15 (-9.375%)	-0.9375	✓
MC7295	194	189	-5 (-2.5773%)	-0.2577	✓
MC7296	141	127	-14 (-9.9291%)	-0.9929	✓
MC7297	156	149	-7 (-4.4872%)	-0.4487	✓
MC7298	151	145	-6 (-3.9735%)	-0.3974	✓
MC7299	100	95	-5 (-5%)	-0.5	✓

Method Comparison
Passed

Samples
20

Range Tested
70 - 221

Agreement
95 %

Mean Error Index
-0.4643





Glucose

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
MC7300	120	113	-7 (-5.8333%)	-0.5833	✓



Method Comparison
Passed

Samples

20

Range Tested

70 - 221

Agreement

95 %

Mean Error Index

-0.4643





Glucose

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Experiment Details

Units: mg/L

Acceptance Criteria	Calculation Mode: Error Allowance Min. Samples: 5 Min. Agreement: 95% TEa: 10%
Agreement	5/5 (100%)
Range Tested	5 - 9
Mean Error Index	0

Trueness
Passed

Samples
5

Range Tested
5 - 9

Agreement
100 %

Mean Error Index
0



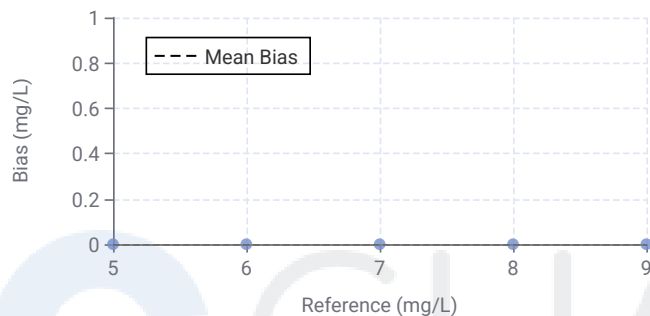


Glucose

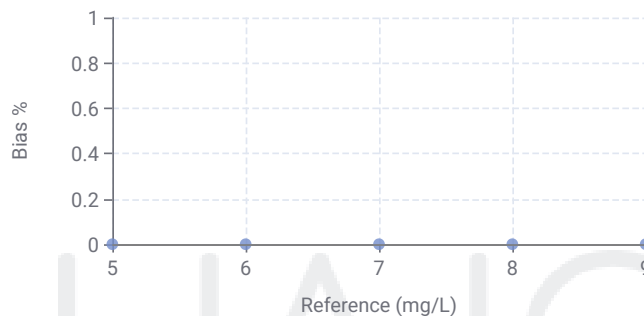
Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Bias % Chart



Bias Chart



Trueness
Passed

Samples

5

Range Tested

5 - 9

Agreement

100 %

Mean Error Index

0





Glucose

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Sample Data for GLUC Trueness

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
	5	5	0 (0%)	0	✓
	6	6	0 (0%)	0	✓
	7	7	0 (0%)	0	✓
	8	8	0 (0%)	0	✓
	9	9	0 (0%)	0	✓

Trueness
Passed

Samples
5

Range Tested
5 - 9

Agreement
100 %

Mean Error Index
0





Creatinine

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Experiment Details

Units: mg/dL

Comparison By	Error Allowance
Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95% REa (50% TEa): 0.25 or 5%
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

Sample 1 Reference Value: 0.6	Results 25	Mean and CV 0.6 0%	Error Index 0	Agreement 100 %	✓
Sample 2 Reference Value: 0.2	Results 25	Mean and CV 0.208 24.13%	Error Index 0.0320	Agreement 100 %	✓
Sample 3 Reference Value: 1.5	Results 25	Mean and CV 1.468 7.3093%	Error Index -0.1280	Agreement 96 %	✓

Precision
Passed

Samples
3

Results
75

Agreements
98.67 %





Creatinine

Quantitative Precision

For reference on this experiment see link.cualia.io/docs-qnt-precision

Sample Data for Crea Precision Sample 1

Run	R1	R2	R3	R4	R5	Within Run
Day 1	0.6	0.6	0.6	0.6	0.6	5/5
Day 2	0.6	0.6	0.6	0.6	0.6	5/5
Day 3	0.6	0.6	0.6	0.6	0.6	5/5
Day 4	0.6	0.6	0.6	0.6	0.6	5/5
Day 5	0.6	0.6	0.6	0.6	0.6	5/5

Sample Data for Crea Precision Sample 2

Run	R1	R2	R3	R4	R5	Within Run
Day 1	0.2	0.3	0.2	0.4	0.2	5/5
Day 2	0.2	0.2	0.2	0.2	0.2	5/5
Day 3	0.2	0.1	0.2	0.2	0.2	5/5
Day 4	0.2	0.2	0.2	0.2	0.2	5/5
Day 5	0.2	0.2	0.2	0.2	0.2	5/5

Sample Data for Crea Precision Sample 3

Run	R1	R2	R3	R4	R5	Within Run
Day 1	1.5	1.5	1.5	1	1.4	4/5
Day 2	1.5	1.5	1.5	1.3	1.5	5/5
Day 3	1.5	1.5	1.5	1.5	1.5	5/5
Day 4	1.5	1.5	1.5	1.5	1.5	5/5
Day 5	1.5	1.5	1.5	1.5	1.5	5/5

Precision
Passed

Samples
3

Results
75

Agreements
98.67 %





Creatinine

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Experiment Details

Units: mg/dL

Acceptance Criteria	Days: 5 Replicates per Day: 5 LoB Reference Value: 0.05
Mean	0
Standard Deviation	0
1.65 SD	0

Limit of Blank Passed	Mean 0	SD 0	LoB 0	
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Creatinine

Quantitative Limit of Blank

For reference on this experiment see link.cualia.io/docs-qnt-lob

Sample Data for Crea Limit of Blank

	Run	R1	R2	R3	R4	R5
1	Run 1	0	0	0	0	0
2	Run 2	0	0	0	0	0
3	Run 3	0	0	0	0	0
4	Run 4	0	0	0	0	0
5	Run 5	0	0	0	0	0

Limit of Blank
Passed

Mean
0

SD
0

LoB
0





Creatinine

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Experiment Details

Units: mg/dL

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95% TEas: 0.5 or 10%
Agreement	20/20 (100%)
Range Tested	1.8 - 2.5
Pearson Correlation Coefficient (r)	0.9621
Mean Error Index	-0.35

Pearson Correlation Coefficient (r)	0.9621 $y = 0.9144x + 0.0168$ SEE: 0.05
Coefficient of Determination (r^2)	0.9257

Method Comparison
Passed

Samples

20

Range Tested

1.8 - 2.5

Agreement

100 %

Mean Error Index

-0.35



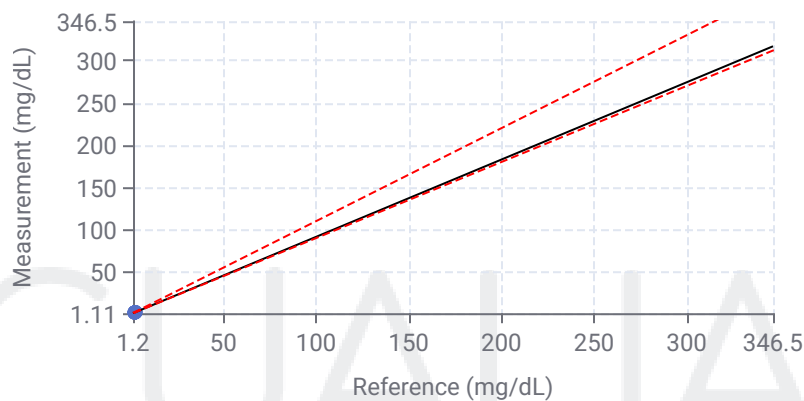


Creatinine

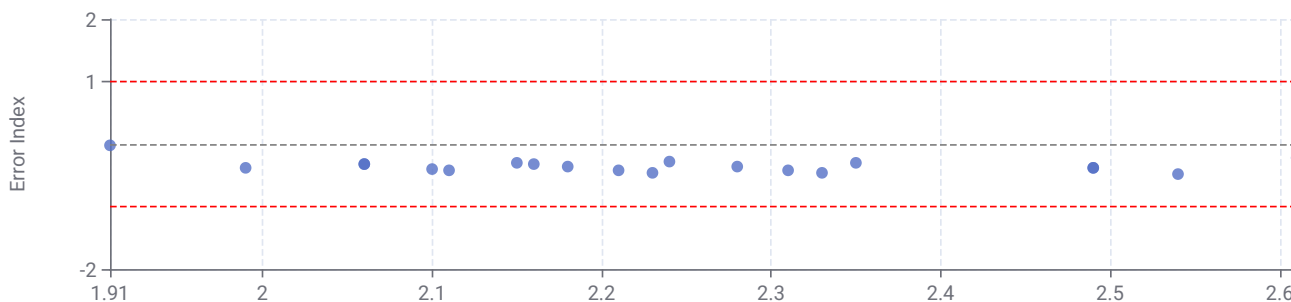
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Scatter Plot



Error Index Chart



Method Comparison
Passed

Samples

20

Range Tested

1.8 - 2.5

Agreement

100 %

Mean Error Index

-0.35



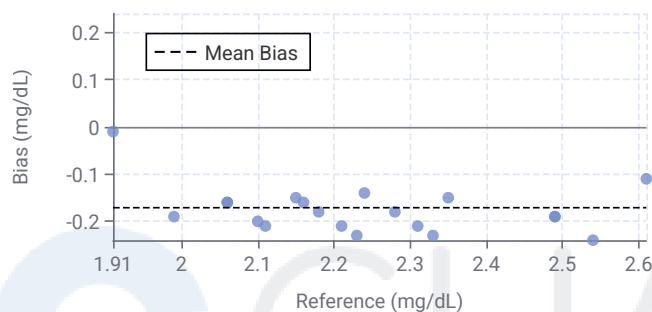


Creatinine

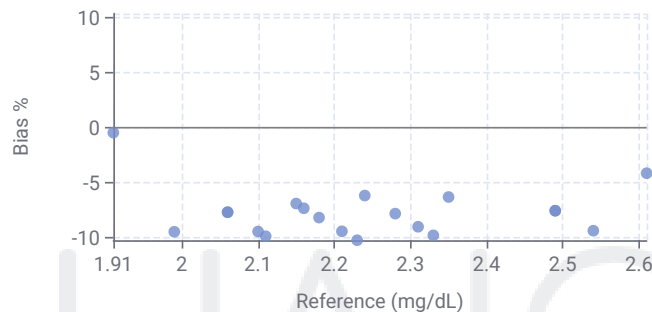
Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Bias % Chart



Bias Chart



Method Comparison
Passed

Samples
20

Range Tested
1.8 - 2.5

Agreement
100 %

Mean Error Index
-0.35





Creatinine

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Sample Data for Crea Method Comparison

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
MC7281	2.21	2	-0.21 (-9.5023%)	-0.42	✓
MC7282	2.15	2	-0.15 (-6.9767%)	-0.3	✓
MC7283	2.28	2.1	-0.18 (-7.8947%)	-0.36	✓
MC7284	2.16	2	-0.16 (-7.4074%)	-0.32	✓
MC7285	2.49	2.3	-0.19 (-7.6305%)	-0.38	✓
MC7286	2.18	2	-0.18 (-8.2569%)	-0.36	✓
MC7287	2.24	2.1	-0.14 (-6.25%)	-0.28	✓
MC7288	2.06	1.9	-0.16 (-7.767%)	-0.32	✓
MC7289	2.61	2.5	-0.11 (-4.2146%)	-0.22	✓
MC7290	2.11	1.9	-0.21 (-9.9526%)	-0.42	✓
MC7291	2.31	2.1	-0.21 (-9.0909%)	-0.42	✓
MC7292	2.49	2.3	-0.19 (-7.6305%)	-0.38	✓
MC7293	2.23	2	-0.23 (-10.3139%)	-0.46	✓
MC7294	2.06	1.9	-0.16 (-7.767%)	-0.32	✓
MC7295	2.1	1.9	-0.2 (-9.5238%)	-0.4	✓
MC7296	2.35	2.2	-0.15 (-6.383%)	-0.3	✓
MC7297	2.54	2.3	-0.24 (-9.4488%)	-0.48	✓
MC7298	1.91	1.9	-0.01 (-0.5236%)	-0.02	✓
MC7299	1.99	1.8	-0.19 (-9.5477%)	-0.38	✓

Method Comparison
Passed

Samples
20

Range Tested
1.8 - 2.5

Agreement
100 %

Mean Error Index
-0.35





Creatinine

Quantitative Method Comparison

For reference on this experiment see link.cualia.io/docs-qnt-mc

Label	Reference (X)	Measurement (Y)	Bias	Error Index
MC7300	2.33	2.1	-0.23 (-9.8712%)	-0.46 



Method Comparison
Passed

Samples

20

Range Tested

1.8 - 2.5

Agreement

100 %

Mean Error Index

-0.35





Creatinine

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Experiment Details

Units: mg/dL

Acceptance Criteria	Calculation Mode: Error Allowance Min. Samples: 5 Min. Agreement: 95% TEas: 0.5 or 10%
Agreement	5/5 (100%)
Range Tested	1.8 - 2.4
Mean Error Index	-0.4680

Trueness
Passed

Samples

5

Range Tested

1.8 - 2.4

Agreement

100 %

Mean Error Index

-0.4680



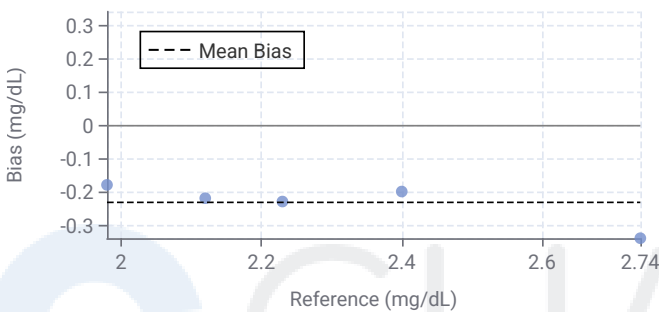


Creatinine

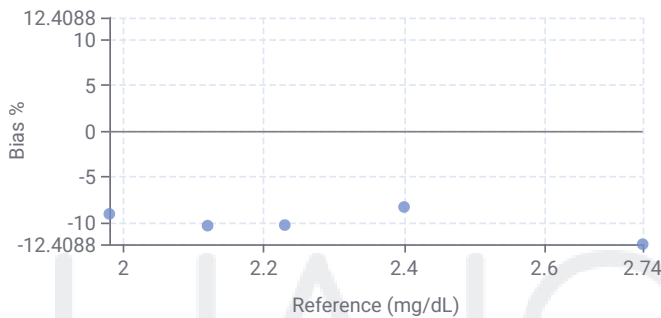
Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Bias % Chart



Bias Chart



Trueness
Passed

Samples

5

Range Tested

1.8 - 2.4

Agreement

100 %

Mean Error Index

-0.4680





Creatinine

Quantitative Trueness

For reference on this experiment see link.cualia.io/docs-qnt-trueness

Sample Data for Crea Trueness

Label	Reference (X)	Measurement (Y)	Bias	Error Index	
RSEQA01	1.98	1.8	-0.18 (-9.0909%)	-0.36	✓
RSEQA02	2.74	2.4	-0.34 (-12.4088%)	-0.68	✓
RSEQA03	2.23	2	-0.23 (-10.3139%)	-0.46	✓
RSEQA04	2.4	2.2	-0.2 (-8.3333%)	-0.4	✓
RSEQA05	2.12	1.9	-0.22 (-10.3774%)	-0.44	✓

Trueness
Passed

Samples

5

Range Tested

1.8 - 2.4

Agreement

100 %

Mean Error Index

-0.4680





Anti-Human Immunodeficiency virus

Qualitative Precision

Experiment Details

Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

Sample 1 Reference Value: Pos	Results 25	Agreement 100 %	✓
Sample 2 Reference Value: Neg	Results 25	Agreement 100 %	✓
Sample 3 Reference Value: Pos	Results 25	Agreement 100 %	✓

Precision Passed	Samples 3	Results 75	Agreement 100 %	✓
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Anti-Human Immunodeficiency virus

Qualitative Precision

Sample Data for Anti-HIV Precision Sample 1

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Sample Data for Anti-HIV Precision Sample 2

Run	R1	R2	R3	R4	R5	Status
Day 1	Neg	Neg	Neg	Neg	Neg	5/5
Day 2	Neg	Neg	Neg	Neg	Neg	5/5
Day 3	Neg	Neg	Neg	Neg	Neg	5/5
Day 4	Neg	Neg	Neg	Neg	Neg	5/5
Day 5	Neg	Neg	Neg	Neg	Neg	5/5

Sample Data for Anti-HIV Precision Sample 3

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Precision
Passed

Samples
3

Results
75

Agreement
100 %





Anti-Human Immunodeficiency virus
Qualitative Limit of Detection

Experiment Details

Acceptance Criteria	Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%
Description	This Limit of Detection experiment follows a 5 x 5 format of 25 replicates.

Limit of Detection Passed	Results 25	Agreement (%) 100%	
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Anti-Human Immunodeficiency virus

Qualitative Limit of Detection

Sample Data for Anti-HIV Limit of Detection

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Limit of Detection
Passed

Results
25

Agreement (%)
100%





Anti-Human Immunodeficiency virus

Qualitative Method Comparison

Experiment Details

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95 %
Samples	20
Agreement	19 / 20 (95 %)

Method Comparison
Passed

Samples
20

Agreement
95 %





Anti-Human Immunodeficiency virus

Qualitative Method Comparison

Sample Data for Anti-HIV Method Comparison

Label	Comment	Reference (X)	Measurement (Y)	Status
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✗
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓

Method Comparison
Passed

Samples
20

Agreement
95 %





Anti-Human Immunodeficiency virus

Qualitative Trueness

Experiment Details

Acceptance Criteria	Min. Samples: 5 Min. Agreement: 95 %
Samples	5
Agreement	5 / 5 (100 %)

Trueness
Passed

Samples
5

Agreement
100 %





Anti-Human Immunodeficiency virus

Qualitative Trueness

Sample Data for Anti-HIV Trueness

Label	Reference (X)	Measurement (Y)	Status
RSEQA01	Pos	Pos	✓
RSEQA02	Neg	Neg	✓
RSEQA03	Pos	Pos	✓
RSEQA04	Pos	Pos	✓
RSEQA05	Neg	Neg	✓

Trueness
Passed

Samples
5

Agreement
100 %





Anti Hepatitis B

Qualitative Precision

Experiment Details

Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates

Samples

Sample 1 Reference Value: Pos	Results 25	Agreement 96 %	✓
Sample 2 Reference Value: Neg	Results 25	Agreement 100 %	✓
Sample 3 Reference Value: Pos	Results 25	Agreement 96 %	✓

Precision Passed	Samples 3	Results 75	Agreement 97.33 %	✓
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Anti Hepatitis B

Qualitative Precision

Sample Data for AntiHB Precision Sample 1

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Neg	Pos	Pos	Pos	4/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Sample Data for AntiHB Precision Sample 2

Run	R1	R2	R3	R4	R5	Status
Day 1	Neg	Neg	Neg	Neg	Neg	5/5
Day 2	Neg	Neg	Neg	Neg	Neg	5/5
Day 3	Neg	Neg	Neg	Neg	Neg	5/5
Day 4	Neg	Neg	Neg	Neg	Neg	5/5
Day 5	Neg	Neg	Neg	Neg	Neg	5/5

Sample Data for AntiHB Precision Sample 3

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Neg	Pos	Pos	Pos	4/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Precision
Passed

Samples
3

Results
75

Agreement
97.33 %





Anti Hepatitis B
Qualitative Limit of Detection

Experiment Details

Acceptance Criteria	Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%
Description	This Limit of Detection experiment follows a 5 x 5 format of 25 replicates.

Limit of Detection Passed	Results 25	Agreement (%) 100%	
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Anti Hepatitis B

Qualitative Limit of Detection

Sample Data for AntiHB Limit of Detection

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Limit of Detection
Passed

Results
25

Agreement (%)
100%





Anti Hepatitis B

Qualitative Method Comparison

Experiment Details

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95 %
Samples	20
Agreement	19 / 20 (95 %)

Method Comparison
Passed

Samples
20

Agreement
95 %





Anti Hepatitis B

Qualitative Method Comparison

Sample Data for AntiHB Method Comparison

Label	Comment	Reference (X)	Measurement (Y)	Status
		Neg	Neg	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Neg	Neg	✗
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓

Method Comparison
Passed

Samples
20

Agreement
95 %





Anti Hepatitis B

Qualitative Trueness

Experiment Details

Acceptance Criteria	Min. Samples: 5 Min. Agreement: 95 %
Samples	5
Agreement	5 / 5 (100 %)

Trueness
Passed

Samples
5

Agreement
100 %





Anti Hepatitis B

Qualitative Trueness

Sample Data for AntiHB Trueness

Label	Reference (X)	Measurement (Y)	Status
	Pos	Pos	✓
	Pos	Pos	✓
	Pos	Pos	✓
	Neg	Neg	✓
	Neg	Neg	✓

Trueness
Passed

Samples
5

Agreement
100 %





Syphilis

Qualitative Precision

Experiment Details

Acceptance Criteria	Samples: 3 Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%		
Description	This precision experiment follows a 3 x 5 x 5 format of 75 replicates		
Samples			
Sample 1 Reference Value: Pos	Results 25	Agreement 100 %	
Sample 2 Reference Value: Neg	Results 25	Agreement 96 %	
Sample 3 Reference Value: Pos	Results 25	Agreement 100 %	

Precision Passed	Samples 3	Results 75	Agreement 98.67 %	✓
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Syphilis

Qualitative Precision

Sample Data for SYPH Precision Sample 1

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Sample Data for SYPH Precision Sample 2

Run	R1	R2	R3	R4	R5	Status
Day 1	Neg	Pos	Neg	Neg	Neg	4/5
Day 2	Neg	Neg	Neg	Neg	Neg	5/5
Day 3	Neg	Neg	Neg	Neg	Neg	5/5
Day 4	Neg	Neg	Neg	Neg	Neg	5/5
Day 5	Neg	Neg	Neg	Neg	Neg	5/5

Sample Data for SYPH Precision Sample 3

Run	R1	R2	R3	R4	R5	Status
Day 1	Pos	Pos	Pos	Pos	Pos	5/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Precision
Passed

Samples
3

Results
75

Agreement
98.67 %





Syphilis

Qualitative Limit of Detection

Experiment Details

Acceptance Criteria	Days: 5 Results per Day: 5 Min. Between Day Agreement (%): 95%
Description	This Limit of Detection experiment follows a 5 x 5 format of 25 replicates.

Limit of Detection
Passed

Results
25

Agreement (%)
96%





Syphillis

Qualitative Limit of Detection

Sample Data for SYPH Limit of Detection

Run	R1	R2	R3	R4	R5	Status
Day 1	Neg	Pos	Pos	Pos	Pos	4/5
Day 2	Pos	Pos	Pos	Pos	Pos	5/5
Day 3	Pos	Pos	Pos	Pos	Pos	5/5
Day 4	Pos	Pos	Pos	Pos	Pos	5/5
Day 5	Pos	Pos	Pos	Pos	Pos	5/5

Limit of Detection
Passed

Results
25

Agreement (%)
96%





Syphilis

Qualitative Method Comparison

Experiment Details

Acceptance Criteria	Min. Samples: 20 Min. Agreement: 95 %
Samples	20
Agreement	19 / 20 (95 %)

Method Comparison
Passed

Samples
20

Agreement
95 %





Syphilis

Qualitative Method Comparison

Sample Data for SYPH Method Comparison

Label	Comment	Reference (X)	Measurement (Y)	Status
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Pos	Pos	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Neg	Neg	✓
		Pos	Pos	✓
		Pos	Pos	✗
		Pos	Pos	✓

Method Comparison
Passed

Samples
20

Agreement
95 %





Syphilis

Qualitative Trueness

Experiment Details

Acceptance Criteria	Min. Samples: 5 Min. Agreement: 95 %
Samples	5
Agreement	5 / 5 (100 %)

Trueness
Passed

Samples
5

Agreement
100 %





Syphilis

Qualitative Trueness

Sample Data for SYPH Trueness

Label	Reference (X)	Measurement (Y)	Status
RSEQA01	Neg	Neg	✓
RSEQA02	Neg	Neg	✓
RSEQA03	Neg	Neg	✓
RSEQA04	Pos	Pos	✓
RSEQA05	Pos	Pos	✓

Trueness
Passed

Samples
5

Agreement
100 %

