ASSAYPROOF

Method Validation Report

Sample — copper assay by AAS

Study ID	11111111-2222-3333-4444-555555555555
Guideline	ICH Q2(R2)
Study status	draft
Generated	2026-11-01T14:22:26.901Z (UTC)
Generated by	AssayProof — https://assayproof.com

PASS

This report is generated from analyst-entered data. Acceptance criteria are defaults per guideline and were not independently verified.

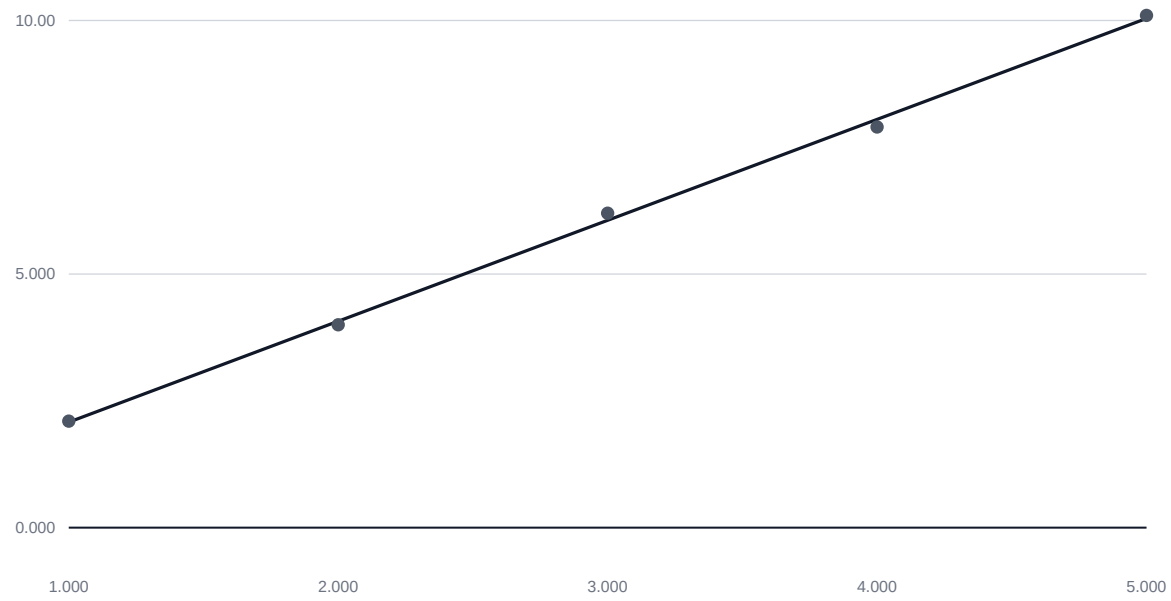
Linearity

Item	Value
Slope	1.990
Standard error of the slope	0.04123
Intercept	0.09000
Standard error of the intercept	0.1367
Residual standard deviation, S(y/x)	0.1304
Coefficient of determination (r^2)	0.998714
Calibration levels (n)	5
Degrees of freedom	3
sigma — SE of the y-intercept	0.1367
LOD (3.3 sigma/S) — SE of the y-intercept	0.2268
LOQ (10 sigma/S) — SE of the y-intercept	0.6872
sigma — Residual SD, S(y/x)	0.1304
LOD (3.3 sigma/S) — Residual SD, S(y/x)	0.2162
LOQ (10 sigma/S) — Residual SD, S(y/x)	0.6552
Back-calculated concentration — level 1 (nominal 1.000)	1.010
Back-calculated concentration — level 2 (nominal 2.000)	1.965
Back-calculated concentration — level 3 (nominal 3.000)	3.070
Back-calculated concentration — level 4 (nominal 4.000)	3.925
Back-calculated concentration — level 5 (nominal 5.000)	5.030

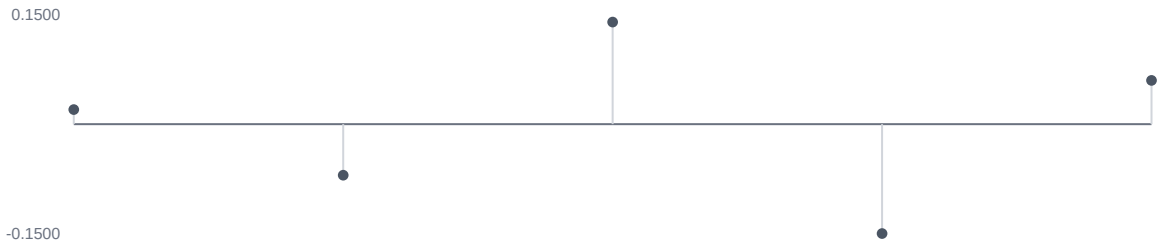
Linearity

Item	Value

Calibration curve



Residuals



Points are the recorded responses; the fitted line is drawn across the calibration range. Residuals are the recorded response minus the fitted response at each level.

Accuracy

Item	Value
Unspiked (native) result	10.00 ppm
Determinations (n)	4
Grand mean recovery (weighted)	99.69 %
Confidence level	95 %
Level 1 — amount added	40.00 ppm
Level 1 — n	2
Level 1 — mean recovery	99.50 %
Level 1 — %RSD	2.132 %
Level 1 — 95 % confidence bounds	80.44 – 118.6 %
Level 1 — AOAC expected range	80 – 110 % (10 ppm)
Level 2 — amount added	90.00 ppm
Level 2 — n	2
Level 2 — mean recovery	99.89 %
Level 2 — %RSD	2.045 %
Level 2 — 95 % confidence bounds	81.54 – 118.2 %
Level 2 — AOAC expected range	90 – 107 % (100 ppm)

Precision — repeatability

Item	Value
Determinations (n)	5
Mean	100.0
Standard deviation	0.5339
Relative standard deviation (%RSD)	0.5339 %
Standard error of the mean	0.2387
Degrees of freedom	4
Confidence level	95 %
Critical t (two-sided, tabulated)	2.776
Margin of error	0.6628
Lower confidence bound	99.34
Upper confidence bound	100.7
Minimum	99.20
Maximum	100.6

Excluded values

Determinations (n) above counts retained values only. A restored value is listed here and counts above.

Value	State	Method	Stat.	Critical	Justification	Recorded by
108.4	Excluded	Grubbs	2.022	1.887	Autosampler carryover confirmed against run log #12	Sample data

Detection and quantitation limits

Item	Value
sigma — SE of the y-intercept	0.1367
LOD (3.3 sigma/S) — SE of the y-intercept	0.2268
LOQ (10 sigma/S) — SE of the y-intercept	0.6872
sigma — Residual SD, S(y/x)	0.1304
LOD (3.3 sigma/S) — Residual SD, S(y/x)	0.2162
LOQ (10 sigma/S) — Residual SD, S(y/x)	0.6552

Acceptance criteria — ICH Q2(R2)

Criterion	Value	Required	Verdict
Coefficient of determination (r^2)	0.998714	>= 0.99	**PASS**
Detection and quantitation limits reported	2 sigma sources	>= 1 sigma sources	**PASS**
Mean recovery per level — level 1 (40 ppm added)	99.50	98–102 %	**PASS**
Mean recovery per level — level 2 (90 ppm added)	99.89	98–102 %	**PASS**
Repeatability (%RSD)	0.5339	<= 2 %	**PASS**

Audit trail

When (UTC)	Who	What
2026-08-26T09:00:00.000Z	Sample data	study-created
2026-08-26T09:00:00.000Z	Sample data	study-saved