Supplementary Table 1. The minimal number of replicates required to pass the ADL with a 95% probability in a linearity study of a measurement procedure showing a particular %CV (excerpted from Appendix D of EP06-ED2 [12])

ADL (%)	CV (%)	R
5	2.7	2
	3.4	3
	3.9	4
	4.3	5
	4.7	6
	5.0	7
	10.0	27
10	5.5	2
	6.7	3
	7.8	4
	8.7	5
	9.5	6
	10.0	7
	15.0	15
15	8.2	2
	10.1	3
	11.6	4
	13.0	5
	14.2	6
	15.0	7
	20.0	12
20	11.0	2
	13.4	3
	15.5	4
	17.3	5
	19.0	6
	20.0	7

Abbreviations: ADL, allowable deviation from linearity; CV, coefficient of variation; R, replicates.

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Supplementary Table 2. Adjustments for the high-level sample (A) and the low-level sample (B) (excerpted from Table 16 and 17 of EP06-ED2 [12])

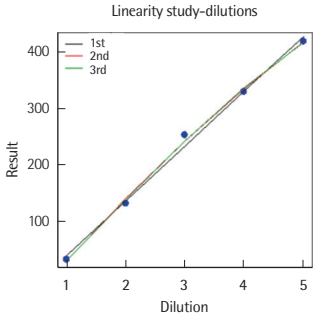
(A) Repeatability CV%	Adjustment for the high-level sample: Percent below the ULoQ
≤ 1	−2%
> 1 but ≤ 2	−4%
> 2 but ≤ 3	−5%
> 3 but ≤ 4	−7%
> 4 but ≤ 5	−10%
> 5 but ≤ 10	−15%
> 10 but ≤ 15	−20%

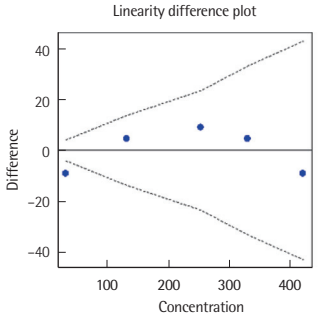
(B) Imprecision CV% for LLoQ	Adjustment for the low-level sample: Percent above the LLoQ
5	10%
10	15–20%
15	25–30%
20	30–40%

Abbreviations: CV, coefficient of variation; ULoQ, upper limit of quantitation; LLoQ, lower limit of quantitation.

DF	.90	.95	.99
6	1.943	2.447	3.707
7	1.895	2.365	3.500
8	1.860	2.306	3.355
9	1.833	2.262	3.250
10	1.812	2.228	3.169
11	1.794	2.201	3.106
12	1.782	2.179	3.054
13	1.771	2.160	3.012
14	1.761	2.145	2.977
15	1.753	2.132	2.947

A





B

Order	Coef. Symbol	Coef. Value	Coef. SE	t-test	DF	SE Reg.	Fitting
First	b0	-61.15	15.11	-4.05			
First	b1	98.95	4.56	21.72	8	20.37	
Second	b0	-115.4	23.2	-4.97			
Second	b1	145.45	17.68	8.23			
Second	b2	-7.75	2.89	-2.68	7	15.3	Best fit
Third	b0	-116.8	57.48	-2.03			
Third	b1	147.42	75.13	1.96			
Third	b2	-8.5	27.89	-0.3			
Third	b3	0.08	3.08	0.03	6	16.52	

C

Level	Rep #1	Rep #2	Mean	%CV	Predicted 1	Predicted 2	Diff	%Diff
1	26	25	25.5	2.72	37.8	22.3	-15.5	-41.01
2	135	128	131.5	3.67	136.75	144.5	7.75	5.67
3	267	275	271	2.12	235.7	251.2	15.5	6.58
4	325	333	329	1.74	334.65	324.4	7.75	2.32
5	425	418	421.5	1.16	433.6	418.1	-15.5	-3.57

D

Supplementary Fig. 1. An example of linearity evaluation. (A) t-table according to DF and confidence level (partly excerpted from Appendix B of EP06-A [11]). DF is determined by the formula: DF=L·R–R_{df} (L: No. of levels; R: No. of replicates; R_{df}: regression DF, 2 for the first-order, 3 for the second-order, and 4 for the third-order). For example, if a linearity study of L=5 and R=2 is conducted, the DF for the second-order is 5·2–3=7 and the DF for the third order is 5·2–4=6; (B) Graphs of the linearity study using Labostat (Laboratory Medicine Foundation, Seoul, Korea) software; (C) Results of linear and polynomial regression analysis and determination of the best-fit regression. Starting with a higher order, it the calculated *t*-test value exceeds 95% *t*-test value of DF of each order, the order is determined as the best-fit regression; (D) Differences of predicted values by between the best-fit and linear regression by sample levels. Predicted 1 is the predicted value obtained from the best-fit regression, and Predicted 2 is the predicted value obtained from the linear regression. Diff=(Predicted 1)–(Predicted 2), and %Diff=100·Diff/(Predicted 1).
Abbreviations: DF, degree of freedom; Diff, difference; Coef., coefficient; SE, standard error; Reg., regression; CV, coefficient of variation.

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