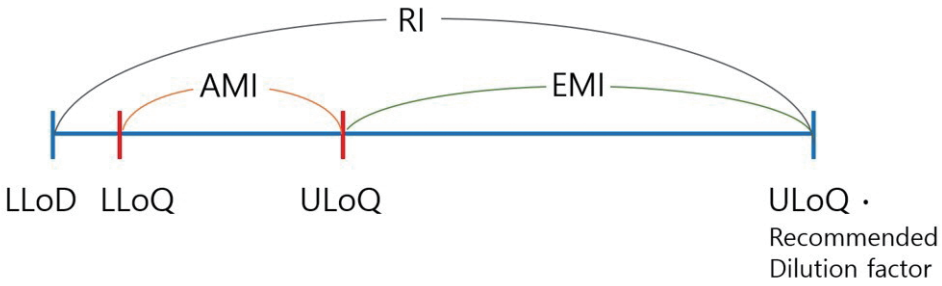
Supplementary Table 1. Boundaries for the observed proportion of results for the verification of the detection capabilities (modified from Linnet and Kondratovich [30] and excepted from EP17-A2 [13, 14])

No. of measurements	Observed proportion boundary (%)
20	85
30	87
40	88
50	88
60	90
70	90
80	90
90	91
100	91
150	92
200	92
250	92
300	93
400	93
500	93
1,000	94

Supplementary Table 2. The summary of the minimal experimental designs for validating and verifying the detection capabilities

Classic approach	Precision profile approach	Probit approach	Classic approach	Verification
LoB/LoD validation	LoD validation	LoB/LoD validation	LoQ validation	LoB/LoD/LoQ verification
Two reagent lots	Two reagent lots	Two reagent lots	Two reagent lots	One reagent lot
Three days	Five days	Three days	Three days	Three days
Four blank (low-level) samples	Five samples	Three positive samples and five dilutions per positive sample (totally 3 sets and 15 samples)	Four low-level samples	Two blank (low-level) samples
Two replicates per sample	Five replicates per sample	30 negative patient samples	Three replicates per sample	Two replicates per sample per day
60 total replicates per reagent lot	40 replicates per sample per reagent lot	20 replicates per dilution per positive sample per reagent lot Two replicates per negative sample per reagent lot	36 total replicates per reagent lot	20 total replicates

Abbreviations: LoB, limit of blank; LoD, limit of detection; LoQ, limit of quantitation.



Supplementary Fig. 1. The relationship between AMI, EMI, and RI. AMI refers to the interval where precision, linearity, and bias are within acceptable limits without dilution or pretreatment. As shown in this figure, the LLoD is the lower limit of the RI, and the LLoQ is the lower limit of the AMI. (Reprinted with permission from Clinical and Laboratory Standards Institute from: CLSI. Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed. CLSI guideline EP34. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. [5]).
Abbreviations: AMI, analytical measuring interval; EMI, extended measuring interval; RI, reportable interval; LLoD, lower limit of detection; LLoQ, lower limit of quantitation; ULoQ, upper limit of quantitation.

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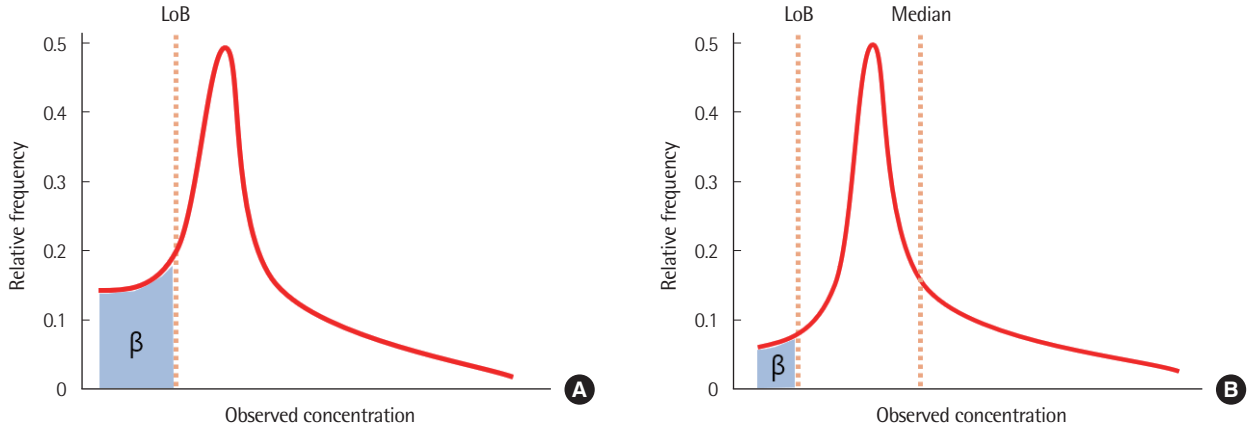
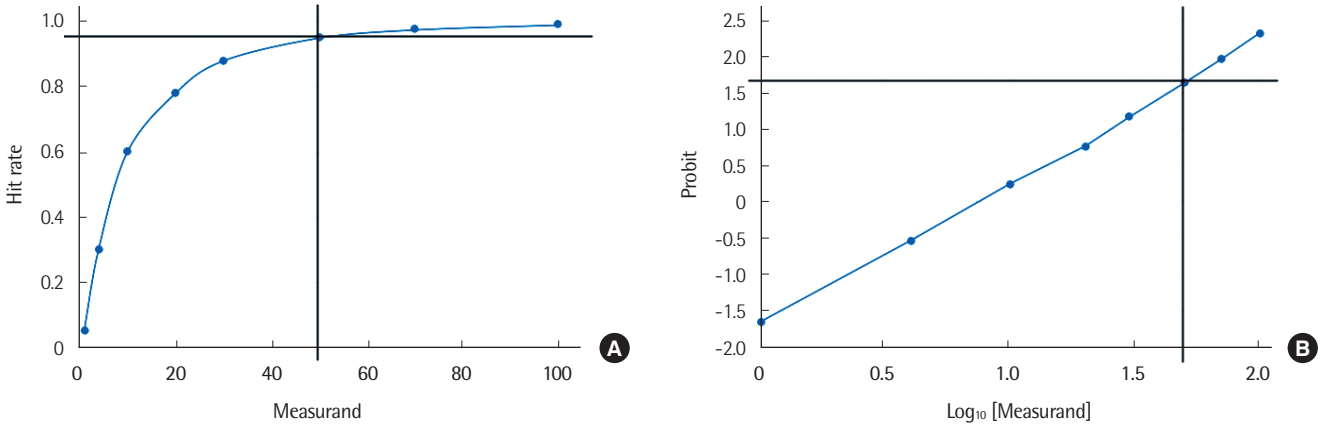


Supplementary Fig. 2. The LoD variant approach for non-parametric analysis. (A) If the β error excceds 5%, the LoD for that reagent lot cannot be obtained. (B) However, if the β error is equal to or less than 5% (more than 95% of the replicates are equal to or more than the LoB), the median value for these replicates can be considered as the LoD for that reagent lot.
Abbreviations: LoB, limit of blank; LoD, limit of detection.



Supplementary Fig. 3. The probit analysis using the hit rate (A) and the probit value (B). For (A), the LoD is the value of the X-axis corresponding to the Y-axis value of 0.95, and therefore the LoD=50. For (B), LoD is the value of the X-axis (after inverse log transformation) corresponding to the Y-axis value of 1.645 (95% hit rate=1.645 probit). Since the value of the X-axis corresponding to the Y=1.645 is 1.7, the LoD is calculated as $\log_{10}$[Measurand]=1.7. Therefore, [Measurand]=$10^{1.7} \fallingdotseq 50$.
Abbreviation: LoD, limit of detection.

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