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ORIGINAL ARTICLE

Procalcitonin Chemiluminescent Immunoassay - Bias Estimation on Multiplatform

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SUMMARY

Background: **Procalcitonin (PCT) is a useful biomarker for infection and especially useful for sepsis management. Multiple platforms, including the chemiluminescence immunoassay (CLIA), have been used for serum PCT analysis. However, the results from different analytical platforms should be evaluated to determine if they can be mutually substituted in the same laboratory.**
Methods: **The serum PCT were analyzed on the Mindray CL-6000i chemiluminescent immunoassay (candidate method), the Roche Elecsys, and the VIDAS PCT chemiluminescence immunoassay platforms (comparative measurements), and the results were evaluated and compared, following the CLSI EP09-A3 guidelines, by using patient samples with different PCT concentrations.**
Results: **The median of difference was 0.04 (95% CI: 0.038 - 0.045) between the candidate method and the comparative measurements for the concentration interval of < 0.5 ng/mL. The median of percentage difference was 6.6% (95% CI: 5.5% - 8.7%) for the concentration interval of 0.5 - 2.0 ng/mL, the median of difference was 0.11 (95% CI: 0.06 - 0.17) for the concentration interval of 2.0 - 10.0 ng/mL, and the median of percentage difference was -4.7% (95% CI: -6.1% - 2.4%) for the concentration interval of 10.0 - 100.0 ng/mL. The acceptable bias was ± 0.055 (± 10.4%) at 0.53 ng/mL (low value), and the acceptable bias was ± 0.83 (± 9.0%) at 9.34 ng/mL (high value). The bias between the candidate method and comparative measurements was acceptable for the full concentration ranges.**
Conclusions: **The bias between the PCT results from Mindray, Roche, and VIDAS was acceptable. Therefore, the results of the three analytical platforms were comparable, and they may be mixed-used in the same institution.**
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Supplementary Data

Table S1. General information on PCT sample distribution.

Concentration range	Hospital	Sample size
< 0.5 ng/mL	Guangzhou Thoracic Hospital	104
	Nanfang Hospital	400
	Sun Yat-sen Memorial Hospital	105
	Total	609
0.5 - 2 ng/mL	Guangzhou Thoracic Hospital	35
	Nanfang Hospital	250
	Sun Yat-sen Memorial Hospital	60
	Total	345
2 - 10 ng/mL	Guangzhou Thoracic Hospital	21
	Nanfang Hospital	250
	Sun Yat-sen Memorial Hospital	57
	Total	328
10 - 50 ng/mL	Guangzhou Thoracic Hospital	8
	Nanfang Hospital	86
	Sun Yat-sen Memorial Hospital	21
	Total	115
50 - 100 ng/mL	Guangzhou Thoracic Hospital	3
	Nanfang Hospital	14
	Sun Yat-sen Memorial Hospital	1
	Total	18
Total	Guangzhou Thoracic Hospital	171
	Nanfang Hospital	1,000
	Sun Yat-sen Memorial Hospital	244
	Total	1,415

Including 89 samples with values < 0.05 from Roche and 1 sample with value < 0.02 from Mindray left truncated data.

Table S2. Distribution of difference and percentage difference of PCT detection results between candidate method and comparative measurements (n = 1,325 *).

Statistics		Difference	Difference %
Mean		-0.1314	14.4701
Median		0.0460	8.9655
Standard deviation		2.51469	45.27421
Skewness		-10.803	14.578
Kurtosis		231.697	358.815
Minimum		-58.03	-86.84
Maximum		16.48	1,200.00
Percentiles	25	-0.0130	-1.4815
	50	0.0460	8.9655
	75	0.1400	23.6204

*** Excluding 89 samples with values < 0.05 from Roche and 1 sample with value < 0.02 from Mindray left truncated data (same below).**

Table S3. Bias estimation from difference or percentage difference between candidate method and comparative measurements.

Concentration	Sample	Median bias	95% CI for median bias *	
interval	size		lower	upper
< 0.5 ng/mL	519	0.040	0.038	0.045
0.5 - 2 ng/mL	345	6.62%	5.52%	8.72%
2 - 10 ng/mL	328	0.11	0.06	0.17
10 - 100 ng/mL	133	-4.69%	-6.05%	-2.41%

*** Based on 1,000 Bootstrap samples.**

Table S4. Weighted least squares (WLS) regression analysis results of PCT results from candidate method and comparative measurements (n = 1,325).

Outliers	Weight	R^2	Coefficient		95% CI for coefficient	
					lower bound	upper bound
Inclusion	$1/x_i^{1.5}$	0.931	intercept	0.0613	0.0543	0.0683
			slope	0.9821	0.9676	0.9966
Exclusion	$1/x_i^{1.4}$	0.944	intercept	0.0613	0.0538	0.0688
			slope	0.9824	0.9694	0.9953

Table S5. Bias estimates ($\widehat{B}_c$) and relative bias estimates ($\widehat{B}_c$%) of PCT at a specific concentration (X_c).

Outliers	X_c	$E\widehat{Y}_c$	95% CI of $E\widehat{Y}_c$		$\widehat{B}_c$ ($\widehat{B}_c$%) *	95% CI of $\widehat{B}_c$ ($\widehat{B}_c$%) *	
			lower limit	upper limit		lower limit	upper limit
Inclusion	0.5 (local infection)	0.5523	0.5447	0.5600	0.05 (10.47%)	0.04 (8.94%)	0.06 (12.00%)
	2.0 (systemic infection)	2.0255	1.9987	2.0522	0.03 (1.27%)	0.00 (-0.06%)	0.05 (2.61%)
	10 (critical value)	9.8821	9.7402	10.0240	-0.12 (-1.18%)	-0.26 (-2.6%)	0.02 (0.24%)
Exclusion	0.5 (local infection)	0.5525	0.5447	0.5602	0.05 (10.49%)	0.04 (8.94%)	0.06 (12.04%)
	2.0 (systemic infection)	2.0260	2.0021	2.0500	0.03 (1.30%)	0.00 (0.10%)	0.05 (2.50%)
	10 (critical value)	9.8852	9.7585	10.0118	-0.11 (-1.15%)	-0.24 (-2.42%)	0.01 (0.12%)

***** $\widehat{B}_c = E\widehat{Y}_c - X_c$, $\widehat{B}_c\% = 100 * \widehat{B}_c/X_c$.

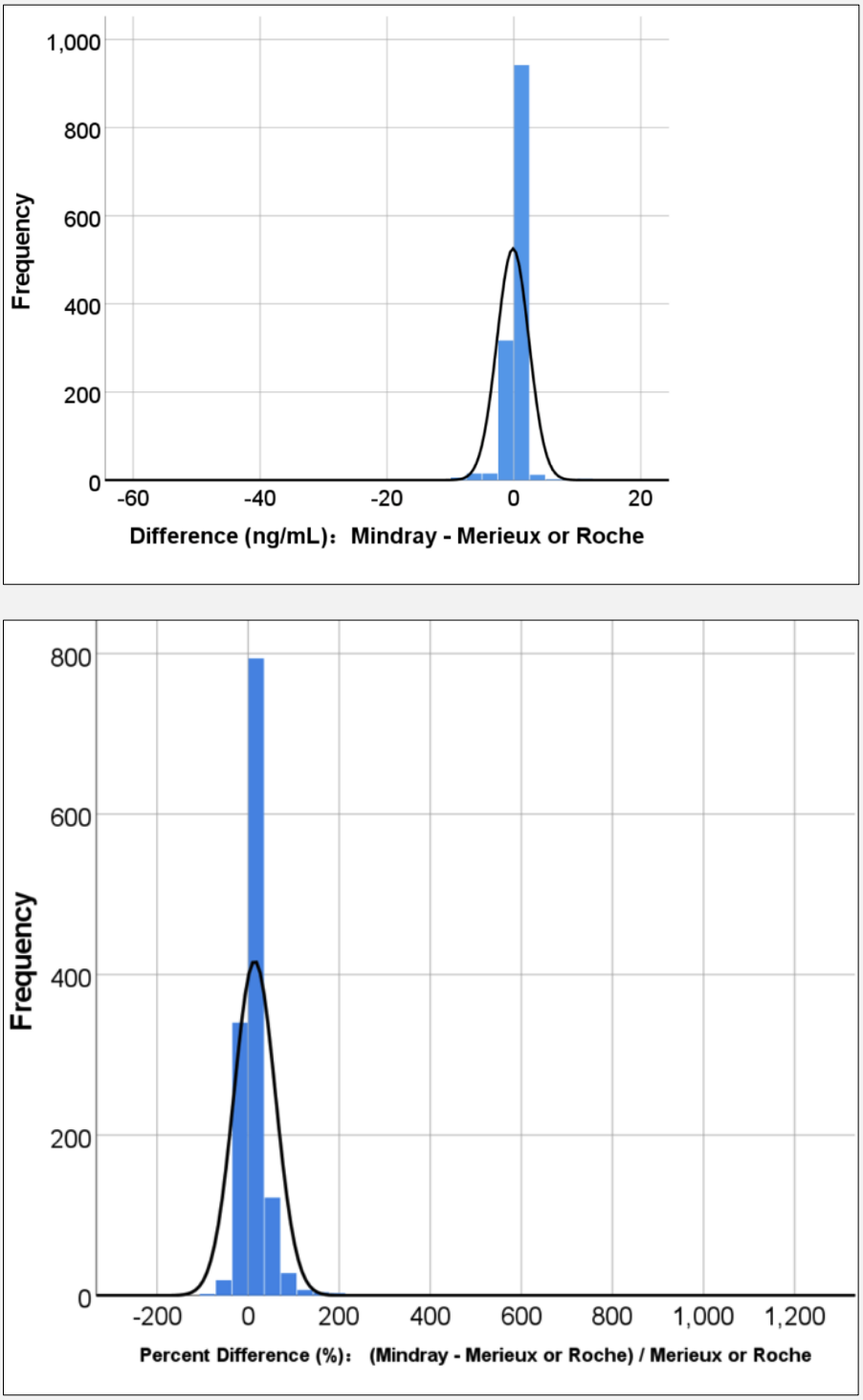

Figure S1. Distribution of difference and percent difference of PCT detection results between candidate method and comparative measurements.