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ORIGINAL ARTICLE

Application of Sigma Metrics for the Optimization of Quality Control Program in the Clinical Chemistry Laboratory

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SUMMARY

Background: **This study aimed to assess and optimize the quality control (QC) program in the clinical chemistry laboratory by addressing the errors after identification with Sigma metric.**
Methods: **All quality indicators from the internal and external quality control of 41 clinical analytes were collected in our laboratory in 2023. The Sigma metric imprecision and bias were calculated by using internal and external quality control data, respectively, then the Sigma metric and quality goal index (QGI) was calculated to assess and improve the performance of laboratory process system.**
Results: **Sigma levels from 21 clinical analytes were found ≥ 6, and the analytical performance of these analytes were at "world-class" level. The analytical performance of serum potassium, glucose, bicarbonate, β_2-MG, LDH, and direct bilirubin reached "excellent" level ($5 \leq \sigma < 6$ and QGI ≤ 0.8), and multiple rules of $1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1) with batch length of 450 patient samples were selected as QC schemes. The analytical performance of sodium and TBA also achieved "good" level ($4 \leq \sigma < 5$ and QGI ≤ 0.8), so multiple rules of $1_{3s}2_{2s}R_{4s}4_{1s}$ (N = 4, R = 1 or N = 2, R = 2) with batch length of 200 patient samples were selected as QC schemes. Sigma level of chloride, total protein, total bilirubin, and albumin was < 4 and ≥ 3 (QGI ≤ 0.8), so multiple rules of $1_{3s}2_{2s}R_{4s}4_{1s}8_x$ (N = 4, R = 2 or N = 2, R = 4) with batch length of 45 patient samples were selected as QC schemes. For the rest of the analytes, such as calcium and Urea, Sigma metric was found < 3, and they required more modification in quality control procedure.**
Conclusions: **Application of Sigma metric provided us an assessment of performance of laboratory process system and improvement of QC procedure for clinical analytes.**
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Supplementary Data

Supplementary Table 1. Assessment of performance using Sigma metrics and selection of control rules.

Test	Tea (%)	CV (%)	Bias (%)	Sigma	Performance	QC rule recommendation	QGI	Precision and/or accuracy
Ca^{2+}	5	1.37	1.89	2.27	poor	-	0.92	precision and accuracy
Urea	8	2.26	1.8	2.74	poor	-	0.53	precision
Cl	4	0.97	0.86	3.24	marginal	$1_{3s}2_{2s}R_{4s}4_{1s}8_x$ (N = 4, R = 2 or N = 2, R = 4)	0.59	precision
TP	5	1.21	0.63	3.61	marginal	$1_{3s}2_{2s}R_{4s}4_{1s}8_x$ (N = 4, R = 2 or N = 2, R = 4)	0.35	precision
TIBC	15	3.5	2.33	3.62	marginal	$1_{3s}2_{2s}R_{4s}4_{1s}8_x$ (N = 4, R = 2 or N = 2, R = 4)	0.44	precision
ALB	6	1.43	0.69	3.71	marginal	$1_{3s}2_{2s}R_{4s}4_{1s}8_x$ (N = 4, R = 2 or N = 2, R = 4)	0.32	precision
Na	4	0.81	0.27	4.6	good	$1_{3s}2_{2s}R_{4s}4_{1s}$ (N = 4, R = 1 or N = 2, R = 2)	0.22	precision
TBA	25	4.49	3.95	4.69	good	$1_{3s}2_{2s}R_{4s}4_{1s}$ (N = 4, R = 1 or N = 2, R = 2)	0.59	precision
K	6	1.08	0.58	5.02	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.36	precision
GLU	7	1.23	0.83	5.02	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.45	precision
HCO3-	25	4.3	3.42	5.02	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.53	precision
β2-MG	25	4.53	1.79	5.12	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.26	precision
LDH	11	1.73	0.81	5.89	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.31	precision
DBIL	20	2.82	3.31	5.92	excellent	$1_{3s}2_{2s}R_{4s}$ (N = 2, R = 1)	0.78	precision
HCY	20	2.98	2.11	6	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
P	10	1.57	0.57	6.01	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
Crea	12	1.71	0.8	6.55	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
AST	15	2.07	0.79	6.86	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
TG	14	1.81	1.41	6.96	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
GGT	11	1.27	1.41	7.55	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ADA	25	3.03	1.78	7.66	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ASO	25	2.65	4.65	7.68	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ALT	16	1.91	1	7.85	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
TBIL	15	1.38	3.84	8.09	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
PA	25	2.8	1.82	8.28	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
TC	14	1.48	0.54	9.09	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
Cys-C	20	2.1	0.7	9.19	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ALP	18	1.71	1.91	9.41	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
CRP	25	2.37	2.57	9.46	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
HBDH	30	3.07	0.94	9.47	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
RF	25	2.25	3.59	9.52	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
UA	12	1.2	0.55	9.54	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
Mg	15	1.41	1.22	9.77	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
LDL	30	2.62	1.89	10.73	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
HDL	30	2.54	1.15	11.36	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
CK	15	1.21	1.01	11.56	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ApoB	30	2.37	1.8	11.9	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
AMY	15	1.18	0.68	12.14	world class	1_{3s} (N = 2, R = 1)	no need for improvement	

Supplementary Table 1. Assessment of performance using Sigma metrics and selection of control rules (continued).

Test	Tea (%)	CV (%)	Bias (%)	Sigma	Performance	QC rule recommendation	QGI	Precision and/or accuracy
Fe	15	1.01	1.14	13.72	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
CHE	20	1.24	1.62	14.82	world class	1_{3s} (N = 2, R = 1)	no need for improvement	
ApoA1	30	1.6	0.93	18.17	world class	1_{3s} (N = 2, R = 1)	no need for improvement	

N - represents the number of QC levels, R - represents the number of daily QC runs, "-" indicates no data available. Ca - calcium, Urea - urea, Cl - chlorine, TP - total protein, TIBC - total iron binding capacity, ALB - albumin, Na - sodium, TBA - total bile acid, K - potassium, GLU - glucose, HCO3 - total carbon dioxide, β2-MG - β2-microglobulin, LDH - lactate dehydrogenase, DBIL - direct bilirubin, HCY - homocysteine, P - phosphorus, Crea - creatinine, AST - aspartate aminotransferase, TG - triglyceride, GGT - L-γ-glutamyl transferase, ADA - adenosine deaminase, ASO - anti-streptolysin O, ALT - alanine aminotransferase, TBIL - total bilirubin, PA - prealbumin, TC - total cholesterol, Cys-C - cystatin C, ALP - alkaline phosphatase, CRP - C-reactive protein, HBDH - α-hydroxybutyrate dehydrogenase, RF - rheumatoid factor, UA - uric acid, Mg - magnesium, LDL - low-density lipoprotein cholesterol, HDL - is high-density lipoprotein cholesterol, CK - creatine kinase, ApoB - apolipoprotein B, AMY - α-amylase, Fe - serum iron, CHE - cholinesterase, ApoA1 - apolipoprotein A1.