

Supplemental Methods

Clinical laboratory system and composition of the laboratory

The clinical laboratories of Seoul National University Bundang Hospital consist of two separate laboratories: a main clinical chemistry laboratory that operates during normal working hours and an emergency laboratory that operates around the clock and analyzes samples from the emergency room as well as from other wards during urgent circumstances. During the study period, the main laboratory was equipped with the AU5800 and Ci16000 instruments, and the emergency laboratory had the Vitros and two Vista instruments.

Concentrations of pooled patient samples

Concentrations of two pooled sera for weekly verification of comparability were generally within the reference range of verified clinical chemistry tests, with the exception of a few tests that showed high or significant clinical decision values, which typically occurred in serial order of each category used to check various clinically important ranges. For example, if liver panel (LP) concentrations were high in the weekly verification pooled sera with values of all other categories being within the reference range, then the following weekly verification concentrations of another category in the other pooled sera would have high concentrations, such as creatinine or cholesterol, with the other test items being normal.

Preparation of commutable reference materials for cholesterol and creatinine

Commutable reference materials produced and stored for nationwide accuracy-based proficiency testing (PT) according to the CLSI C37-A guidelines (CLSI. C37-A. Wayne, PA: Clinical and Laboratory Standards Institute, 1999) with minor modifications were used for the standardization of creatinine and cholesterol results for the initial and simplified comparisons. Briefly, whole blood was collected from 3–10 normal donor controls and 3–5 patients who met the Korean blood donation criteria. Informed consent was obtained from all individuals. The collected whole blood was gathered into an empty plastic bag and placed in an ice bath to delay clot formation. The units of iced

whole blood were centrifuged (2465G, 10 minutes), and the plasma was aseptically transferred from the plastic collection bag to a glass bottle. The plasma was stored at room temperature (20–25°C) for 3–4 hours to permit clot formation and then centrifuged again (2465G, 10 minutes). The sera were transferred to 15 mL conical tube and stored at 4°C. Sera from individual units were pooled to obtain different concentrations. Each pool was incubated overnight at 4°C with constantly mixed to ensure homogeneity of the final pool. Following the cold incubation period, the sera pools were filtered, aliquoted into glass vials, capped, sealed, and frozen at –70°C. A homogeneity test was performed according to the International Organization for Standardization (ISO) Guide 35 (GUIDE, I. S. O. 35, “Reference Materials—Guidance for Characterization and Assessment of Homogeneity and Stability”, 2017. ISO, Geneva, 35). Target values traceable to certified reference materials were measured using RMPs by the US Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA) for cholesterol and Reference Material Institute for Clinical Chemistry Standards (ReCCS; Yokohama Kanagawa, Japan) for creatinine.

Comparability acceptance criteria and statistical analysis

There are no universally accepted criteria for evaluating comparability test results. One candidate approach is to use the acceptance criteria based on allowable limits of performance goals set by the Royal College of Pathologists of Australasia (RCPA) (Jones GR, Sikaris K, Gill J. “Allowable limits of performance” for External Quality Assurance programs—an approach to application of the Stockholm criteria by the RCPA Quality Assurance programs. *Clin Biochem Rev* 2012;33:133-9). This approach is based on a combination of observed performance from PT/external quality assurance data, and advice from industry and professional leaders. Comparability for the initial and simplified comparisons was maintained by forcing agreement of the results among different instruments through mathematical transformation. A generalized linear regression model was used to obtain conversion factors (slope and intercept) for the results from each instrument relative to the AU5800 results for electrolytes and LP, or the RMP results of reference target values for cholesterol and creatinine.

Supplemental Data Table S1. Detailed information of test items and instruments

Analyte	Instrument*	Method	Calibrators	Reagents	Average tests per year N	Imprecision CV (%) during 2015–2019		
						Low	Medium	High
AST	AU5800	LDH without P5P to LDH with P5P	Beckman Coulter System Calibrator	Beckman Coulter AST	121,484	2.54	1.66	1.65
	Ci16000	LDH without P5P to LDH with P5P	Roche C.f.a.s Calibrator	Shinyang Eiken AST	47,070	3.08	1.10	1.35
	Vista1	LDH without P5P to LDH with P5P	Siemens Vista ENZ 2 CAL	Siemens Vista AST	83,990	4.32	2.92	2.72
	Vista2	LDH without P5P to LDH with P5P	Siemens Vista ENZ 2 CAL	Siemens Vista AST	81,496	4.05	2.80	2.58
	Vitros	Vitros Dry chemistry	Ortho Vitros Calibration kit 3	Ortho Vitros-ASTJ	34,901	3.02	2.88	2.41
ALT	AU5800	LDH without P5P to LDH with P5P	Beckman Coulter System Calibrator	Beckman Coulter ALT	121,639	3.25	1.75	1.60
	Ci16000	LDH without P5P to LDH with P5P	Roche C.f.a.s Calibrator	Shinyang Eiken ALT	46,991	7.52	2.08	1.46
	Vista1	LDH without P5P to LDH with P5P	Siemens Vista ENZ 2 CAL	Siemens Vista ALTI	83,811	7.37	3.56	3.15
	Vista2	LDH without P5P to LDH with P5P	Siemens Vista ENZ 2 CAL	Siemens Vista ALTI	81,511	6.47	3.43	3.12
	Vitros	Vitros Dry Chemistry	Ortho Vitros Calibration kit 3	Ortho Vitros-ALTJ	35,070	8.08	3.08	2.40
ALP	AU5800	PNPP, AMP Buffer	Beckman Coulter System Calibrator	Beckman Coulter ALP	119,563	4.77	2.64	2.46
	Ci16000	PNPP, AMP Buffer	Roche C.f.a.s Calibrator	Shinyang Eiken ALP	45,097	6.53	3.93	3.59
	Vista1	PNPP, AMP Buffer	Siemens Vista APLI CAL	Siemens Vista ALPI	83,512	5.90	3.77	3.33
	Vista2	PNPP, AMP Buffer	Siemens Vista APLI CAL	Siemens Vista ALPI	80,971	5.64	3.81	3.40
	Vitros	Vitros Dry Chemistry	Ortho Vitros Calibration kit 3	Ortho Vitros-ALKP	34,180	5.67	4.72	4.69
ALB	AU5800	Dye Binding-BCG	Beckman Coulter System Calibrator	Beckman Coulter ALBUMIN	120,389	2.45	2.16	1.88
	Ci16000	Dye Binding-BCG	Roche C.f.a.s Calibrator	Shinyang Eiken ALB	46,262	2.05	1.92	1.60
	Vista1	Dye Binding-BCG	Siemens Vista APLI CAL	Siemens Vista ALB	83,612	3.04	2.52	2.34
	Vista2	Dye Binding-BCG	Siemens Vista APLI CAL	Siemens Vista ALB	81,098	3.10	2.45	2.25
	Vitros	Dye Binding-BCG	Ortho Vitros Calibration kit 4	Ortho Vitros-ALB	35,116	2.89	2.54	2.40
TP	AU5800	Biuret method	Beckman Coulter System Calibrator	Beckman Coulter TOTAL PROTEIN	123,828	1.39	1.16	1.11
	Ci16000	Biuret method	Roche C.f.a.s Calibrator	Shinyang Eiken TP	47,107	1.19	1.01	0.89
	Vista1	Biuret method	Siemens Vista CHEM 4 CAL	Siemens Vista TP	85,564	1.81	1.61	1.47
	Vista2	Biuret method	Siemens Vista CHEM 4 CAL	Siemens Vista TP	83,985	1.76	1.53	1.40
	Vitros	Biuret method	Ortho Vitros Calibration kit 4	Ortho Vitros TP	37,482	1.81	1.54	1.57
Na	AU5800	ISE diluted	Beckman Coulter ISE Standard	Beckman Coulter ISE reagent	69,541	0.80	0.59	0.63
	Ci16000	ISE diluted	Canon ISE Calibrator	Canon ISE reagent	29,020	0.79	0.60	0.57
	Vista1	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	96,997	0.72	0.67	0.66
	Vista2	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	94,773	0.73	0.67	0.64
	Vitros	ISE undiluted	Ortho Vitros Calibration kit 2	Ortho Vitros-Na ⁺	30,628	0.88	0.79	0.83

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Supplemental Data Table S1. Continued

Analyte	Instrument*	Method	Calibrators	Reagents	Average tests per year N	Imprecision CV (%) during 2015–2019		
						Low	Medium	High
K	AU5800	ISE diluted	Beckman Coulter ISE Standard	Beckman Coulter ISE reagent	69,472	1.14	0.61	1.09
	Ci16000	ISE diluted	Canon ISE Calibrator	Canon ISE reagent	28,997	1.40	0.82	0.66
	Vista1	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	97,752	1.47	0.90	0.92
	Vista2	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	95,611	1.44	0.89	0.85
	Vitros	ISE undiluted	Ortho Vitros Calibration kit 2	Ortho Vitros-K ⁺	31,155	1.26	1.30	1.07
Cl	AU5800	ISE diluted	Beckman Coulter ISE Standard	Beckman Coulter ISE reagent	69,359	0.85	0.68	0.74
	Ci16000	ISE diluted	Canon ISE Calibrator	Canon ISE reagent	28,942	0.90	0.66	0.66
	Vista1	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	96,909	0.99	0.85	1.01
	Vista2	ISE diluted	Siemens Vista V-LYLE Standard A,B	Siemens Vista V-LYTE reagent	94,731	0.96	0.92	0.83
	Vitros	ISE undiluted	Ortho Vitros Calibration kit 2	Ortho Vitros-Cl ⁻	30,694	1.43	1.14	1.11
Ca	AU5800	Arsenazo III	Beckman Coulter System Calibrator	Beckman Coulter CA	121,312	1.57	1.07	1.07
	Ci16000	OCPC	Denka Liquid Calibrator	DENKA Ca-N SEIKEN	46,045	2.00	1.67	1.69
	Vista1	OCPC	Siemens Vista CHEM 1 CAL	Siemens Vista, CA	96,846	2.13	1.68	1.61
	Vista2	OCPC	Siemens Vista CHEM 1 CAL	Siemens Vista, CA	94,011	2.10	1.74	1.89
	Vitros	Arsenazo III	Ortho Vitros Calibration kit 1	Ortho Vitros-Ca	38,241	2.35	1.63	1.34
P	AU5800	Phosphomolybdate	Beckman Coulter System Calibrator	Beckman Coulter Inorganic Phosphorous	120,964	3.23	1.55	1.16
	Ci16000	Phosphomolybdate	Roche C.f.a.s Calibrator	WAKO P-HRII	45,917	3.70	2.38	1.85
	Vista1	Phosphomolybdate	Siemens Vista CHEM 2 CAL	Siemens Vista PHOS	97,109	3.61	2.23	1.78
	Vista2	Phosphomolybdate	Siemens Vista CHEM 2 CAL	Siemens Vista PHOS	94,437	3.92	2.11	1.59
	Vitros	Molybden blue colorimetry	Ortho Vitros Calibration kit 1	Ortho Vitros-PHOS	37,277	1.53	1.39	1.41
Chol	AU5800	Cholesterol esterase	Beckman Coulter System Calibrator	Beckman Coulter CHOLESTEROL	115,380	1.07	0.94	0.91
	Ci16000	Cholesterol esterase	Denka Liquid Calibrator	DENKA T-CHO(S)N SEIKEN	45,603	3.12	2.56	2.46
	Vista1	Cholesterol esterase	Siemens Vista CHEM 1 CAL	Siemens Vista CHOL	65,047	2.84	2.39	2.24
	Vista2	Cholesterol esterase	Siemens Vista CHEM 1 CAL	Siemens Vista CHOL	64,985	2.01	1.74	1.59
	Vitros	Cholesterol esterase	Ortho Vitros Calibration kit 2	Ortho Vitros-CHOL	28,423	3.79	2.90	2.68
Cr	AU5800	kinetic Jaffe with compensation	Beckman Coulter System Calibrator	Beckman Coulter CREATININE	12,570	4.61	1.91	1.20
	Ci16000	kinetic Jaffe with compensation	Roche C.f.a.s Calibrator	ROCHE CREA	47,059	5.58	2.57	2.15
	Vista1	kinetic Jaffe with compensation	Siemens Vista CHEM 1 CAL	Siemens Vista CREA 2	99,469	5.71	2.49	2.14
	Vista2	kinetic Jaffe with compensation	Siemens Vista CHEM 1 CAL	Siemens Vista CREA 2	96,829	3.07	1.85	1.64
	Vitros	Enzymatic method	Ortho Vitros Calibration kit 1	Ortho Vitros-CREA	40,059	3.07	1.85	1.64

*Each instrument was produced by Beckman Coulter (AU5800), Abbott (Architect Ci16000), Siemens (two Vista1500), and Ortho (Vitros5600). Abbreviations: ALP, alkaline phosphatase; TP, total protein; Na, sodium; K, potassium; Cl, chloride; Ca, calcium; P, phosphate; Chol, cholesterol; Cr, creatinine; P5P, pyridoxal-5-phosphate; LDH, lactate dehydrogenase; AMP, 2-amino-2-methyl-1-propanol; PNPP, para-nitrophenylphosphate; ISE, ion-selective electrode; BCG, bromocresol green; OCPC, O-cresolphthalein.

Supplemental Data Table S2. History of conversion actions, respective conversion factors, and possible causal events for conversion action

Analyte	Instrument	Date									
AST		2015-02-03	2016-11-25	2016-12-19	2018-02-01	2018-02-05	2018-03-01	2018-06-11	2018-12-17		
	Ci16000	NA	NA	NA	NA	NA	NA	$y = 1.108x - 13.172$	NC	NC	
	Vista1	$y = 0.915x + 2.721$	NC	NC	NC	$y = 1.080x + 3.119$	NC	NC	NC	NC	
	Vista2	$y = 0.915x + 2.721$	NC	NC	NC	$y = 1.080x + 3.119$	NC	NC	NC	NC	
	Vitros	$y = 1.020x + 2$	$y = x$	$y = 1.050x + 1.4$	NC	NC	$y = 1.060x - 1.0$	NC	$y = 1.100x - 4.0$	Vitros calibrator change	
Possible causal events	Comparability test start	Vitros calibrator change	Reagent change with P5p	Vitros readjustment	Vitros calibrator change	Vista calibrator change	Vitros calibrator change	Ci16000 calibrator change	Vitros calibrator change		
ALT		2015-02-03	2016-11-25	2016-12-09	2016-12-19	2017-03-13	2019-03-01	2019-04-24			
	Ci16000	NA	NA	NA	NA	NA	$y = 1.120x - 20.3$	$y = 1.124x - 9.843$			
	Vista1	$y = 0.946x - 5.441$	NC	$y = 0.958x - 7.141$	NC	NC	$y = 1.060x - 7.6$	NC			
	Vista2	$y = 0.946x - 5.441$	NC	$y = 0.958x - 7.141$	NC	NC	$y = 1.060x - 7.6$	NC			
	Vitros	$y = 1.050x + 3$	$y = x$	NC	$y = 1.030x + 1.1$	$y = 1.040x + 3.0$	$y = 1.066x - 1.5$	NC			
Possible causal events	Comparability test start	Vitros calibrator change	Vitros calibrator change	Vista calibrator change	Vitros calibrator change	Vitros calibrator change	Vista, Vitros calibrator change	Ci16000 calibrator change			
ALP		2015-02-03	2016-01-08	2016-04-18	2016-10-05	2016-12-19	2017-02-03	2017-02-10			
	Ci16000	NA	$y = 1.510x - 1.126$	NC	$y = 1.079x - 1.936$	NC	NC	NC			
	Vista1	$y = 0.954x - 1.676$	$y = 1.099x - 1.667$	NC	$y = 1.061x - 1.557$	NC	NC	NC			
	Vista2	$y = 0.954x - 1.676$	$y = 1.099x - 1.667$	NC	$y = 1.061x - 1.557$	NC	NC	NC			
	Vitros	$y = 1.180x - 1$	$y = 1.320x - 4$	$y = 1.180x - 1$	$y = 1.190x$	$y = 1.260x - 5.0$	$y = 1.170x$	$y = 1.150x - 4$			
Possible causal events	Comparability test start	Vista calibrator change	Vista calibrator change	Vista calibrator change	Vista calibrator change	Vitros calibrator change	Vitros readjustment	Vitros readjustment			
ALB		2015-02-03	2015-12-08	2016-01-29	2016-05-11	2017-03-13	2017-05-29	2017-07-28	2018-07-23		
	Ci16000	NA	NC	$y = x + 0.2$	$y = x - 0.2$	NC	NC	NC	NC		
	Vista1	$y = 0.978x + 0.466$	$y = 0.995x + 0.325$	NC	NC	NC	$y = x$	$y = 1.020x + 0.352$	$y = 0.977x + 0.475$		
	Vista2	$y = 0.978x + 0.466$	$y = 0.995x + 0.325$	NC	NC	NC	$y = x$	$y = 1.020x + 0.352$	$y = 0.977x + 0.475$		
	Vitros	$y = 0.920x + 0.500$	NC	NC	$y = 0.95x + 0.3$	$y = x$	NC	NC	NC		
Possible causal events	Comparability test start	Vista calibrator change	Vista calibrator change	Vista calibrator change	Vista, Vitros calibrator change	Vista, Vitros calibrator change	Vista calibrator change	Vista calibrator change	Vista calibrator change		

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Supplemental Data Table S2. Continued

Analyte	Instrument	Date				
TP		2015-02-03	2015-12-08	2016-01-29	2016-05-30	2016-06-13
	Ci16000	NA	NA	$y = x - 1$	NC	$y = x$
	Vista1	$y = 0.946x + 0.039$	$y = 0.970x - 0.131$	NC	$y = x$	NC
	Vista2	$y = 0.946x + 0.039$	$y = 0.970x - 0.131$	NC	$y = x$	NC
	Vitros	$y = 0.900x + 0.500$	NC	NC	NC	$y = x$
	Possible causal events	Comparability test start	Vista calibrator change		Vista calibrator change	
Na		2015-02-03	2016-01-08	2016-07-12	2016-12-09	2017-05-02
	Ci16000	NA	NA	NA	NA	NA
	Vista1	NA	$y = x - 1.50$	NC	NC	$y = x$
	Vista2	NA	$y = x - 1.50$	NC	NC	$y = x$
	Vitros	NA	NA	$y = x + 3$	$y = x$	NC
	Possible causal events	Comparability test start	Vista calibrator change		Vitros calibrator change	
K		2015-02-03				
	Ci16000	NA				
	Vista1	NA				
	Vista2	NA				
	Vitros	$y = 0.96x + 0.1$				
	Possible causal events	Comparability test start				
Cl		2015-02-03	2015-02-04	2016-01-08	2017-06-30	2017-07-28
	Ci16000	NA	NA	NA	NA	NA
	Vista1	$y = x - 2.500$	NC	$y = x - 4.000$	$y = x$	$y = x - 1.6$
	Vista2	$y = x - 2.500$	NC	$y = x - 4.000$	$y = x$	$y = x - 1.6$
	Vitros	$y = 0.950x + 3$	$y = x$	$y = x$	$y = x + 2$	NC
	Possible causal events	Comparability test start		Vista calibrator change	Vitros calibrator change	Vista calibrator change

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Supplemental Data Table S2. Continued

Analyte	Instrument	Date									
Ca	Ci16000	2015-02-03	2015-04-02	2015-04-29	2015-08-14	2015-08-17	2015-12-08	2016-05-30	2017-05-29		
		$y = 0.980x$	$y = 0.940x + 0.31$	NC	NC	NC	NC	$y = x$	NC	NC	
	Vista1	$y = 1.024x - 0.081$	NC	$y = 0.972x - 0.038$	$y = 1.090x - 0.511$	NC	$y = 1.014x + 0.222$	NC	NC	NC	
	Vista2	$y = 1.024x - 0.081$	NC	$y = 0.972x - 0.038$	$y = 1.090x - 0.511$	NC	$y = 1.014x + 0.222$	NC	NC	NC	
	Vitros	$y = x - 0.2$	NC	NC	NC	$y = 0.870x + 0.65$	NC	NC	NC	$y = x - 0.4$	Vitros calibrator change
Possible causal events	Comparability test start	Ci16000 calibrator change									
P	Ci16000	2015-02-03	2018-06-11								
		NA	NA								
	Vista1	$y = 1.005x - 0.131$	NC								
	Vista2	$y = 1.005x - 0.131$	NC								
	Vitros	$y = 0.990x - 0.5$	$y = x - 0.3$								
Possible causal events	Comparability test start	Vitros calibrator change									
Chol	AU5800	2015-02-03	2016-04-18	2018-01-08	2018-01-08	2018-09-04	2018-11-01	2018-12-17	2019-03-01		
		NA	$y = 0.952x + 5.612$	$y = 0.961x + 4.062$	NC	$y = x$	NC	NC	NC	NC	
	Ci16000	$y = 1.006x - 3.922$	$y = 0.993x - 0.639$	NC	NC	NC	NC	NC	NC	NC	
	Vista1	$y = 1.010x + 7.530$	$y = x$	NC	NC	NC	NC	NC	NC	NC	
	Vista2	$y = 1.010x + 7.530$	$y = x$	NC	NC	NC	NC	NC	NC	NC	
Possible causal events	Comparability test start	NA	NA	NA	$y = 0.950x + 5$	NC	NC	NC	NC	Vitros calibrator change	
Cr	AU5800	2015-02-03	2015-04-02	2015-04-29	2015-07-15	2015-10-22	2016-02-01	2016-02-03	2016-04-18		
		$y = x - 0.2$	NC	NC	$y = 1.054x - 0.220$	NC	NC	$y = 1.034x - 0.282$	$y = 1.038x - 0.227$		
	Ci16000	$y = 0.992x - 0.330$	$y = x - 0.3$	NC	$y = 1.014x - 0.379$	NC	NC	$y = 1.016x - 0.399$	$y = 0.979x - 0.366$		
	Vista1	NA	NA	$y = 0.917x + 0.026$	NC	$y = 1.027x - 0.091$	$y = x$	NC	NC		
	Vista2	NA	NA	$y = 0.917x + 0.026$	NC	$y = 1.027x - 0.091$	$y = x$	NC	NC		
Possible causal events	Comparability test start	NA	NA	NA	NA	NA	NA	NA	NA	Vista reagent change	

Abbreviations: NA, no conversion action; NC, no change in conversion factor; ALP, alkaline phosphatase; ALB, albumin; TP, total protein; Na, sodium; K, potassium; Cl, chloride; Ca, calcium; P, phosphate; Chol, cholesterol; Cr, creatinine.