Short analytical evaluation of the new Beckman Coulter DxC 500i clinical analyzer

H. Baum, A. Sirch, C. Hartmann

Inst. für Laboratoriumsmedizin und Transfusionsmedizin, Standort Bietigheim, RKH Regionale Kliniken Holding und Services GmbH, Ludwigsburg, Germany

RKH Gesundheit

RKH Regionale Kliniken Holding und Services GmbH

INTRODUCTION

The new DxC 500i clinical analyzer from Beckman Coulter combines two analytical units for general chemistry including ISE and for immunochemistry analysis. In this study we tested the analytical performance of this new consolidated system.

METHODS

Imprecision was evaluated using control material for 35 applications representing the majority of the assay menu. All parameters were measured over a period of 20 days twice a day. For selected parameters samples of external quality schemes were measured in duplicate twice a day for three days.

Comparison studies were done using samples from daily routine runs on a Cobas Pro system (Roche).

Statistics were done using Excel

RESULTS

Imprecision of the analytes of the clinical chemistry module as well as the ISE is shown in table and graph 1a and for the immuno module it is shown in table and graph 1b, respectively.

Comparison studies showed a good comparability with the cobas pro (table 2).

Results of the external QC-schemes are shown in table 3.

CONCLUSIONS

The new Beckman Coulter DxC 500i clinical analyzer integrates general chemistry and immunochemistry assays on a single platform for small or mid-size laboratories and shows accurate and precise results including a good method comparability.
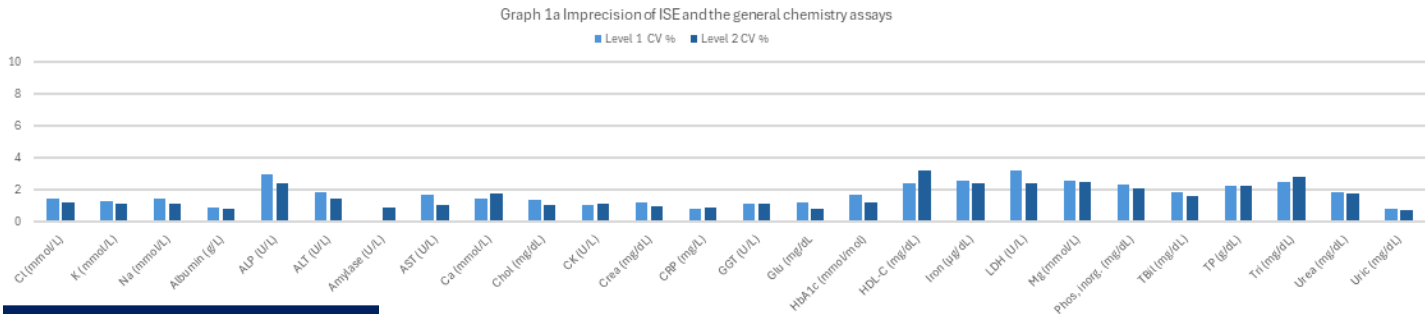
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Graph 1a Imprecision of ISE and the general chemistry assays

Graph 1b Imprecision of the immunological assays

Table 1a Imprecision of ISE and the general chemistry assays

Analyte (unit)	Level 1 Mean value	Level 1 CV %	Level 2 Mean value	Level 2 CV %
Cl (mmol/L)	90.09	1.45	114.72	1.2
K (mmol/L	4.06	1.31	6.81	1.12
Na (mmol/L)	121.93	1.43	153.94	1.11
Albumin (g/L)	24.14	0.9	45.55	0.82
ALP (U/L)	114.12	2.96	473.55	2.42
ALT (U/L)	40.66	1.85	125.65	1.48
Amylase (U/L)	94.96	1,34	253.34	0.91
AST (U/L)	50.52	1.73	141.02	1.08
Ca (mmol/L)	2.39	1.47	3.21	1.78
Chol (mg/dL)	150.31	1.42	296.59	1.08
CK (U/L)	171.43	1.06	395.95	1.16
Crea (mg/dL)	1.26	1.22	5.93	0.98
CRP (mg/L)	12.31	0.84	83.39	0.93
GGT (U/L)	58.07	1.11	163.01	1.15
Glu (mg/dL)	97.42	1.2	237.39	0.79
HbA1c (mmol/mol)	39.37	1.72	69.82	1.25
HDL-C (mg/dL)	36.31	2.46	68.5	3.22
Iron (µg/dL)	69.51	2.62	212.8	2.43
LDH (U/L)	150.48	3.26	566.14	2.44
Mg (mmol/L)	0.99	2.61	1.62	2.49
Phos, inorg. (mg/dL)	7.14	2.34	11.42	2.11
TBil (mg/dL)	1.55	1.87	6.44	1.61
TP (g/dL)	3.82	2.28	7.53	2.26
Tri (mg/dL)	143.03	2.5	339.38	2.81
Urea (mg/dL)	37.34	1.84	169.03	1.8
Uric (mg/dL)	6.09	0.82	9.9	0.77
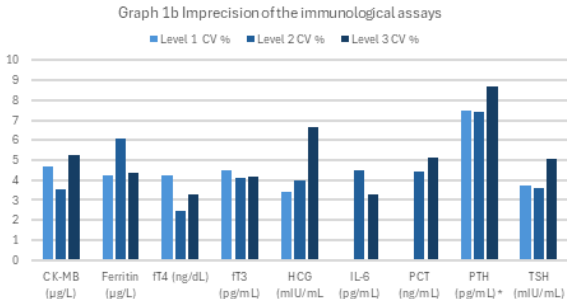
Table 1b Imprecision of the immunological assays

Analyte (unit)	Level 1 Mean value	Level 1 CV %	Level 2 Mean value	Level 2 CV %	Level 3 Mean value	Level 3 CV %
CK-MB (µg/L)	4.38	4.67	55.83	3.56	17.09	5.27
Ferritin (µg/L)	46.94	4.22	399.59	6.09	148.62	4.39
fT4 (ng/dL)	1	4.25	2.03	2.45	3.35	3.28
fT3 (pg/mL)	3.04	4.51	5.97	4.13	10.48	4.15
HCG (mIU/mL)	3.2	3.44	272.11	4	104.14	6.67
IL-6 (pg/mL)	N/A	N/A	48.41	4.49	354.48	3.26
PCT (ng/mL)	N/A	N/A	1.15	4.4	11.13	5.12
PTH (pg/mL)*	18.96	7.49	75.2	7.44	200.18	8.69
TSH (mIU/mL)	3.17	3.72	10.52	3.62	29.8	5.04

Table 2 Results of the comparison with Cobas Pro

Analyte (unit)	N	Range	Mean cobas pro	Mean DxC500i	slope	intercept	r²
Cl (mmol/L)	107	74 - 122	101	103	1.0004	-2.11	0.9574
K (mmol/L)	107	2.74 – 6.25	4.18	4.18	1.0444	-0.18	0.989
Na (mmol/L)	105	118 - 163	138	139	1.0151	-3.23	0.8963
Albumin (g/L)	99	12.4 – 50.4	33.7	32.2	0.9975	1.63	0.9901
ALP (U/L)	89	35 - 2300	200	194	1.0236	1.84	0.9994
ALT (U/L)	103	3 - 514	57	56	0.9425	2.44	0.9978
Amylase (U/L)	101	13 - 1239	86	88	0.9909	1.04	0.9996
AST (U/L)	105	10 - 754	77	78	0.9936	-0.25	0.9938
Ca (mmol/L)	104	1.74 – 3.69	2.26	2.3	0.9916	-0.03	0.9727
Chol mg/dL)	102	45.9 -835	156	168	0.9226	0.63	0.9971
CK (U/L)	101	13 - 2734	182	169	1.1753	-16.67	0.9961
Crea (mg/dL)	107	0.19 – 11.89	1.72	1.79	0.9544	0.02	0.9992
CRP (mg/L)	105	0.13 - 488	89.9	96.8	0.9445	-1.55	0.9975
GGT (U/L)	108	May-52	209	208	1.0219	-3.96	0.9995
Glu (mg/dL)	104	63 - 488	138	142	0.9659	1.24	0.9975
HDL-Chol (mg/dL)	88	5.9 - 133	41.1	40	1.1361	-4.39	0.9379
Iron (µg/dL)	104	4.8 - 215	55.3	50.8	1.0288	3.04	0.9949
LDH (U/L)	103	108 -3144	301	316	0.9907	-13.05	0.9955
Mg (mmol/L)	92	0.47 – 1.47	0.87	0.84	1.0066	0.02	0.9806
Phos, inorg (mg/dL)	110	1.4 – 9.0	3.8	4	0.9645	-0.07	0.9971
TBil (mg/dL)	101	0.15 – 13.63	1.13	1.49	0.8301	-0.11	0.9984
TP (g/dL)	108	3.61 – 8.86	6.05	6.07	0.9853	3.97	0.9904
Tri (mg/dL)	104	39 - 572	145	153	0.9161	3.97	0.9941
Urea (mg/dL)	107	10.6 - 294	77.4	80.1	0.9695	-0.2	0.9991
Uric (mg/dL)	106	1.04 – 15.46	6.25	6.36	0.9759	0.04	0.9985
HbA1c (mmol/mol)	ND¹	ND¹	ND¹	ND¹	ND¹	ND¹	ND¹
CK-MB (ng/mL)	58	0.3 – 75.5	4.5	4.5	1.0154	-0.11	0.991
Ferritin (ng/mL)	52	0.4 - 1181	269	166	1.5294	1'5.59	0.991
fT3 (pg/mL)	23	0.91 – 4.24	2.64	2.89	1.2962	-1.1	0.879
fT4 (ng/dL)	35	0.61 – 1.85	1.34	1.01	0.8412	0.48	0.699
HCG (mIU/mL)	16	0.16 - 519	33.9	34.5	0.9984	-0.55	1
IL-6 (pg/mL)	43	1 - 1216	146	119	1.2812	-6.87	0.983
PCT (ng/mL)	62	0.02 – 97.3	3.31	4.03	0.8607	-0.16	0.997
PTH (pg/mL)*	43	0.9 - 221	57.1	64	0.8023	5.81	0.989
TSH (µIU/mL)	13	0.28 – 14.85	3.39	3.37	0.9139	0.31	0.995

Table 3. Results of the external QC samples

RV CM4/23	sample	median	range	DxC500i mean	D %
CK-MB (ng/dL)	A	44.78	42.5 - 44.78	45.47	1.54
	B	67.1	64.95 - 72.1	70.25	4.69

RV HM4/23	sample	median	range	DxC500i mean	D %
Ferritin (ng/mL)	A	106	86.4 - 385.3	116.65	10.05
	B	140.1	106 - 423.3	148.35	5.89
fT3 (pg/mL)	A	8.36	7.1 - 9.67	8.3	0.4
	B	18.01	15.63 - 20.95	17.14	-4.85
fT4 (ng/dL)	A	3.15	2.76 - 326.01	3.06	-3.02
	B	1.15	0.83 - 126.78	1.14	-0.72
TSH (µIU/mL)	A	24.32	9.43 - 27.5	23.34	-4.01
	B	6.72	6.72 - 34.73	6.71	-0.11

RV KS8/23	sample	median	range	DxC500i mean	D %
Cl (mmol/L)	A	106	102 - 109.3	104.47	-1.45
	B	98	96 - 101	97.3	-0.71
K (mmol/L)	A	3.82	3.71 - 4	3.83	0.26
	B	3.4	3.3 - 3.53	3.4	0.1
Na (mmol/L)	A	123	119 - 127	122.57	-0.35
	B	114	111 - 117	114.38	0.34
Albumin (g/L)	A	3.52	3.26 - 3.7	3.61	2.3
	B	3.09	2.81 - 3.5	3.18	3.02
ALT (U/L)	A	67	61 - 73.8	68.67	2.49
	B	43.2	40.6 - 49	43.67	1.08
ALP (U/L)	A	311.4	273 - 340	274	-12.01
	B	99	86 - 110	87.33	-11.78
Amylase (U/L)	A	79	71 - 84	78	-1.27
	B	49	44 - 52	48.5	-1.02
AST (U/L)	A	209	183 - 228	197.67	-5.42
	B	61	56 - 67	59.33	-2.73
Ca (mmol/L)	A	2.56	2.41 - 2.66	2.6	1.56
	B	1.78	1.7 - 1.84	1.82	2.06
Chol (mg/dL)	A	135	124 - 151	139.88	3.62
	B	116	108 - 133	119.78	3.26
C K (U/L)	A	115	90 - 131	106.9	-7.04
	B	282	179 - 324	250.97	-11
Crea (mg/dL)	A	0.47	0.38 - 0.6	0.48	1.5
	B	2.12	1.89 - 2.38	2.24	5.42
Iron (µg/dL)	A	103	86 - 137	105.52	2.44
	B	94.92	84 - 140	98,53	3.81
GGT (U/L)	A	360.8	335 - 395	357.52	-0.91
	B	47	44 - 52	46.67	-0.71
Glu (mg/dL)	A	125.35	118 - 137	130.82	4.36
	B	68.63	65 - 75	71.88	4.73
LDH (U/L)	A	146	128 - 157	145.17	-0.57
	B	127.5	110 - 137	125.17	-1.83
Mg (mmol/L)	A	0.89	0.82 - 1.01	0.89	0
	B	0.79	0.72 - 1.02	0.81	2.95
Phos, inorg (mg/dL)	A	4.49	4.4 - 4.61	4.59	2.19
	B	2.57	2.51 - 2.69	2.61	1.43
Tbil (mg/dL)	A	0.76	0.71 - 0.8	0.78	2.63
	B	1.06	1.04 - 1.1	1.09	2.73
TP (g/L)	A	5.58	5 - 5.8	5.62	0.66
	B	4.83	4.3 - 5.04	4.89	1.01
Tr i (mg/dL)	A	87.85	Sep-95	88.85	1.14
	B	62	58 - 68	63.58	2.55
Urea (mg/dL)	A	31.95	3.3 - 34.84	32.22	0.83
	B	18.65	17 - 21.62	19.02	1.97
Uric (mg/dL)	A	5.1	5.1 - 5.26	5.24	2.68
	B	4.24	4.2 - 4.34	4.32	2.05