THE ASSESSMENT OF ANALYTICAL CHARACTERISTICS OF A NEW INTEGRATED CLINICAL CHEMISTRY ANALYZER DxC 500i (BECKMAN COULTER, USA)

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BACKGROUND

Tata Medical Center, Kolkata, India, a tertiary cancer care Institute, evaluated the performance of a new platform, the DxC 500i Clinical Analyzer, Beckman Coulter, USA **(Figure 1)**. The investigation of the new instrument focused on thirty-one analytes (metabolic panel, several tumor markers, and procalcitonin), which are of primary importance for the metabolic management of cancer patients.

Figure 1 DxC 500i Clinical Analyzer, Beckman Coulter, USA

METHODS

The total imprecision figures were obtained (as per Clinical and Laboratory Standards Institute (CLSI) EP15-A3 guidelines[1]) using bilevel internal quality controls (IQC) in a design with five runs spread over five nonconsecutive days.

Patient samples for sixteen analytes were compared to an existing dry chemistry platform Vitros XT 7600 Integrated System, QuidelOrtho, USA, according to CLSI EP09-A3 guidelines.[2]

Studies used multiple reagent pack lots, one or more calibrator lots, one DxC 500i analyzer and one Vitros XT 7600 instrument. Quality controls were run in replicates of two on each day to verify the systems were in control. *Analyze-It* software and CLSI working table EP15-ed3-WB[1] were used for statistical assessment.

RESULTS

IMPRECISION

- The total imprecision figures were lower than those recommended by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)[3], incl.
  - lower than optimal specification limits in fourteen analytes: ALT, AST, bilirubin total, cholesterol, CK, GGT, glucose, HDL, iron, LDL, potassium, triglycerides, urea, TSH (56%)
  - lower than desirable specification limits in twenty-one analytes: albumin, alkaline phosphatase, ALT, AST, amylase, bilirubin total, cholesterol, CK, GGT, glucose, HDL, iron, LDH, LDL, magnesium, potassium, total protein, triglycerides, urea, TSH, ferritin (84%)
  - lower than minimal specification limits in twenty-four analytes (i.e., all that have EFLM guidance) except sodium (96%)
- EFLM lacked guidance for six analytes: uric acid, bilirubin direct, lactate, phosphorus, procalcitonin, and total beta HCG (19%)
- Serum sodium did not meet EFLM requirements, but specifications for measured concentrations (125,56 and 157,28 mmol/L) near the medical decision limits (135 and 150 mmol/L)[4] were acceptable according to acceptance limits for proficiency testing of Clinical Laboratory Improvement Amendments (CLIA) (TV<± 4 mmol/L)[5], and the manufacturer's precision claims (0,54%, 0,68% vs 5%)
- All analytes passed manufacturer's claims provided in instructions for use (IFU; within-lab CV%) **(Tables 1,2, Graphs 1,2)**.

Analyte	Units	Study results QC1 Average mean	QC1 Within-lab CV%	QC2 Average mean	QC2 Within-lab CV%	IFU* Within-lab CV%	EFLM Database Optimal	Desirable	Minimal
Clinical chemistry									
Albumin	g/dL	2,49	**1,39**	4,62	**1,14**	**3**	**0,6**	**1,3**	**1,9**
Alkaline Phosph	U/L	123,20	**1,75**	508,44	**1,47**	**5,3**	**1,6**	**3,3**	**4,9**
ALT	U/L	47,64	**1,35**	132,40	**0,87**	**10**	**2,8**	**5,6**	**8,4**
AMY	U/L	95,04	**2,22**	224,60	**1,17**	**5,3**	**1,7**	**3,4**	**5,0**
AST	U/L	61,16	**1,89**	150,60	**0,92**	**10**	**2,1**	**4,2**	**6,3**
Calcium	mg/dL	9,15	**0,99**	12,57	**0,97**	**3**	**0,5**	**0,90**	**1,4**
Bilirubin Direct	mg/dL	1,10	**1,81**	5,12	**1,56**	**7,5**	**N/A**	**N/A**	**N/A**
Bilirubin Total	mg/dL	1,34	**4,09**	6,50	**1,13**	**5**	**5**	**10,1**	**15,1**
Chloride	mmol/L	92,88	**0,72**	112,96	**0,73**	**5**	**0,3**	**0,5**	**0,8**
Cholesterol	mg/dL	149,44	**0,99**	284,32	**0,78**	**3**	**1,4**	**2,7**	**4,1**
CK_NAK	U/L	178,12	**2,48**	415,36	**1,19**	**10**	**3,5**	**7**	**10,6**
GGT	U/L	63,20	**1,15**	168,60	**0,64**	**5,3**	**2**	**4,1**	**6,1**
Glucose	mg/dL	99,83	**1,00**	240,65	**0,64**	**3**	**1,2**	**2,4**	**3,5**
HDL	mg/dL	36,16	**1,04**	68,68	**1,38**	**4**	**1,4**	**2,9**	**4,3**
Iron	µg/dL	71,17	**0,94**	225,43	**0,68**	**5**	**6,9**	**13,8**	**20,7**
Lactate	mg/dL	14,72	**1,11**	44,40	**1,13**	**5**	**N/A**	**N/A**	**N/A**
LDH	U/L	329,96	**1,23**	1178,04	**0,67**	**10**	**1,1**	**2,2**	**3,3**
LDL	mg/dL	85,80	**1,81**	172,84	**1,45**	**4**	**1,9**	**3,9**	**5,8**
Magnesium	mg/dL	2,46	**1,05**	4,11	**0,84**	**5**	**0,7**	**1,4**	**2**
Phosphorus	mg/dL	6,55	**1,72**	11,09	**1,23**	**5**	**N/A**	**N/A**	**N/A**
Potassium	mmol/L	4,20	**0.48**	6,75	**0,78**	**5**	**1**	**1,9**	**2,9**
Sodium	mmol/L	125,56	**0,54**	157,28	**0,68**	**5**	**0,1**	**0,3**	**0,4**
Total Protein	g/dL	4,02	**1,06**	7,63	**0,91**	**4**	**0,7**	**1,3**	**2**
Triglycerides	mg/dL	144,76	**1,09**	326,12	**1.0**	**5**	**5,0**	**9,9**	**14,9**
Urea	mg/dL	36,68	**1,27**	163,57	**1,42**	**10**	**3,3**	**6,5**	**9,8**
Uric Acid	mg/dL	5,75	**1,06**	9,17	**0,68**	**3**	**N/A**	**N/A**	**N/A**

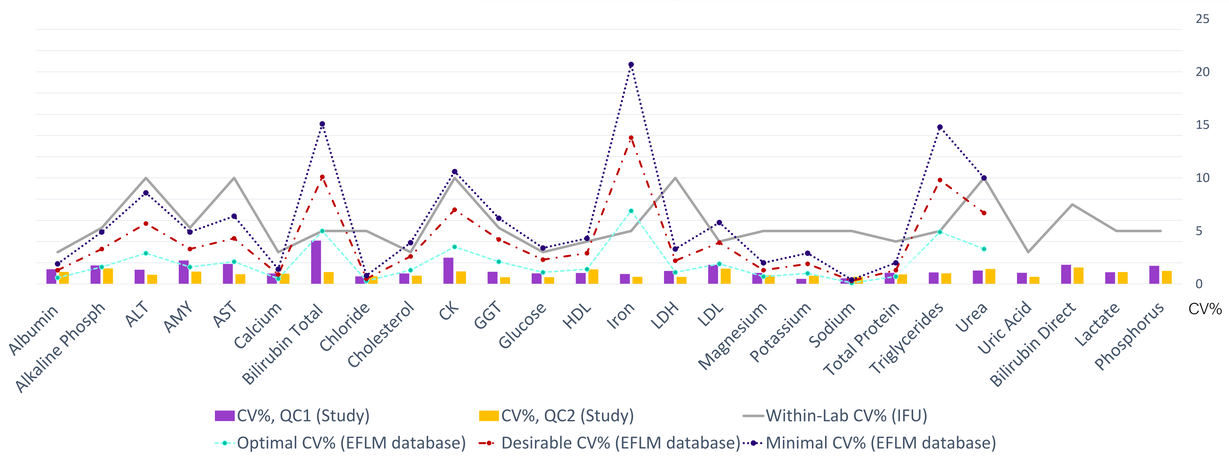


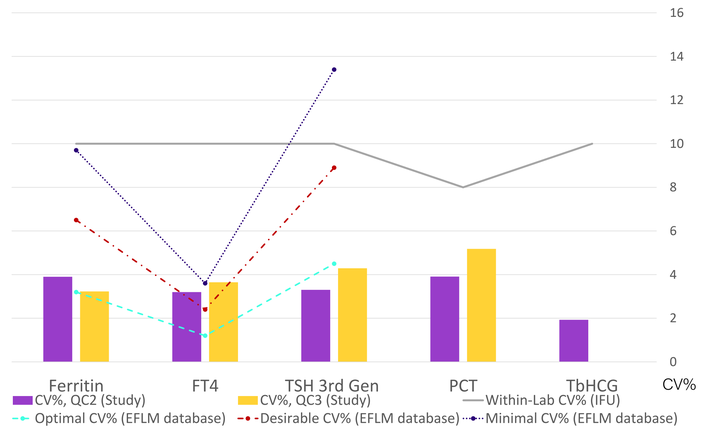
Table 1, Graph 1 Summary table and graph for a representative imprecision study: clinical chemistry analytes.

Comparison of the within-laboratory (total) imprecision (CV%) of the current study with the optimal, desirable, minimal imprecision from the EFLM biological variation database[3] and the total CV% from the manufacturer's instructions for use (IFU*)

Analyte	Units	Study results QC2 Average mean	QC2 Within-lab CV%	QC3 Average mean	QC3 Within-lab CV%	IFU* Within-lab CV%	EFLM Database Optimal	Desirable	Minimal
Immunochemistry									
Ferritin	ng/ml	78,70	**3,90**	203,87	**3,23**	**10**	**3,2**	**6,5**	**9,7**
FT4	ng/dL	1,90	**3,20**	4,27	**3,65**	**10**	**1,2**	**2,4**	**3,6**
TSH 3rd Gen	µIU/mL	2,15	**3,30**	17,85	**4,29**	**10**	**4,50**	**8,90**	**13,40**
TbHCG	mIU/mL	29,59	**1,93**	N/A	**N/A**	**10**	**N/A**	**N/A**	**N/A**
PCT	µg/L	4,15	**3,91**	24,27	**5,18**	**8**	**N/A**	**N/A**	**N/A**

Table 2, Graph 2 Summary table and graph for a representative imprecision study: immunochemistry analytes.

Comparison of the within-laboratory (total) imprecision (CV%) of the current study with the optimal, desirable, minimal imprecision from the EFLM biological variation database[3] and the total CV% from the manufacturer's instructions for use (IFU*)



COMPARISON BETWEEN PLATFORMS

In this study, when comparing sixteen analytes to the dry chemistry platform Vitros XT 7600 Integrated System, twelve analytes showed the Pearson's coefficient (r) to be 0.99 and the remaining four (Bilirubin Total, Chloride, Magnesium, Sodium) above 0.96 **(Table 3)**.

Analyte	Units	N	Concentration range	Slope (95% CI)	Intercept (95% CI)	Correlation coefficient (Pearson, r)
DxC 500i (Beckman Coulter) vs. Vitros XT 7600 (QuidelOrtho)						
Albumin	g/dL	45	2,2-4,8	0,92 (0,86-1)	0,28 (0,1-0,53)	0,99
Alkaline Phosph	U/L	44	49-508	1,01 (0,88-1,1)	-2,45 (-10,12-7,74)	0,99
ALT	U/L	44	12-226	0,95 (0,9-1)	-2 (-3-0,85)	0,998
AST	U/L	42	19-318	1,02 (1-1,06)	-4,9 (-6,4- -4,0)	0,998
Calcium	mg/dL	44	6,8-10,2	1 (0,94-1,08)	-0,1 (-0,74-0,42)	0,987
Bilirubin Total	mg/dL	43	0,1-6,4	1,02 (1-1,17)	0,18 (0,06-0,2)	0,984
Chloride	mmol/L	44	86 -117	1 (1-1,11)	1 (-10,42-1,0)	0,984
GGT	U/L	41	10-500	1,01 (0,95-1,04)	-0,43 (-2,22-1,23)	0,995
Glucose	mg/dL	45	83-282	1,02 (0,98-1,05)	-4,87 (-8,39 - -0,86)	0,998
Magnesium	mg/dL	45	0,5-3,3	0,9 (0,83-1)	0,13 (-0,05-0,29)	0,98
Phosphorus	mg/dL	45	1,5-8,7	1,05 (1-1,13)	-0,17 (-0,44-0,01)	0,989
Potassium	mmol/L	44	2-5,7	1 (0,94-1)	0 (0-0,25)	0,995
Sodium	mmol/L	43	121-149	1 (1-1,1)	2,5 (-11,2-3)	0,968
Total Protein	g/dL	42	4,6-8,4	1 (0,92-1,01)	-0,1 (-0,68-0,42)	0,99
Urea	mg/dL	43	6-228	0,98 (0,94-1)	0,16 (-0,67-1,59)	0,999
Uric Acid	mg/dL	41	0,7-9,5	0,99 (0,96-1)	0,01 (0-0,07)	0,998

Table 3 Comparison of sixteen analytes on the platforms DxC 500i (Beckman Coulter) vs. Vitros XT 7600 (QuidelOrtho)

CONCLUSION

The present document provides data on the performance of thirty-one assays on the DxC 500i analyzer. The assays demonstrate an excellent precision, meeting the specifications of the EFLM' biological variation database and the manufacturer's claims. Agreement with the comparative platform is >96%, which in combination with excellent accuracy will facilitate interpretation of the results. The obtained data allow us to conclude that the DxC 500i clinical analyzer is suitable for regular use in a tertiary oncology clinic in small and medium laboratories.

References
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3. EFLM biological variation database: https://biologicalvariation.eu/
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