THE ASSESSMENT OF ANALYTICAL CHARACTERISTICS OF NEW HIGH-THROUGHPUT DXI 9000 ACCESS IMMUNOASSAY ANALYZER (BECKMAN COULTER INC., USA)

Authors: Pamela Christudoss[1], G.Jayakumar Amirtharaj[1], Murali Kodali[2], Anna Ruzhanskaya[3]

[1]Department of Clinical Biochemistry, Christian Medical College, Tamil Nadu, India; [2]Beckman Coulter Pvt Ltd, Mumbai, India; [3]Beckman Coulter LLC, Moscow, Russia

BACKGROUND

The recently launched DxI 9000 Analyzer is the latest Beckman Coulter offering for high- and ultra-high throughput labs. The DxI 9000 Analyzer addresses the demands of today's laboratories for speed, reliability, reproducibility, quality and menu expansion. The novel Lumi-Phos PRO substrate has shown the capability for increased sensitivity, while ZeroDaily Maintenance will save the laboratory time and PrecisionVision Technology will safeguard against flawed data reports. At CMC Vellore, India, we evaluated the analytical characteristics (Limit of Blank and precision) of the DxI 9000 Access Immunoassay Analyzer for 15 assays, which were then compared against IFU claims and biological variation obtained from the European Federation of Laboratory Medicine (EFLM) database[1]. Method comparison for these 15 assays on the DxI 9000 analyzer was also performed with four other commercial immunoassay platforms analyzers.

METHODS

Limit of blank (LoB) was evaluated for twelve analytes using CLSI EP17-A2 guidelines[2].
Precision was evaluated for 12 analytes using samples with three levels of BioRad Immunoassay Plus quality control (QC); five measurements per each QC sample were done on each of the four pipettors in one day. CV% obtained in the current study were compared to desirable and minimal CVi% (1/2 and 3/4 of CVi% published by the EFLM, respectively)[1,3,4]
DxI 9000 Analyzer results for fifteen analytes were compared to those results obtained on Atellica and Immulite XPi (Siemens Healthcare GmbH), Cobas 8000 (Hoffmann-La Roche Ltd), and BRAHMS Kryptor (Thermo Fisher Scientific Inc.) analyzers, using Passing-Bablok regression analysis in accordance with the CLSI EP 09 guideline[5].
All laboratory measurements were done according to the laboratory's Quality Manual, standard operating procedures (SOPs) and manufacturer's Instructions for Use (IFU). QC was performed through daily measurement of 3 levels of QC specimens.
For statistical calculation, EP Evaluator and Analyze-It software were used.

RESULTS

LoB for twelve analytes fully met manufacturer's claims provided in the respective IFUs (Table 1).
Precision (CV%) for twelve analytes from the current study were compared to desirable and minimal CVi% (1/2 and 3/4 of CVi%) published by the EFLM[1,3] (Figure 1). CV% ranged from 1.5% to 6.4%. All analytes met EFLM specifications for desirable CV, except two levels of Access AFP, and one level of Access Folate, Access Free T4, and Access Vitamin B12, which, however, did fully meet the minimum standard relative to biological variation (3/4 CVi)[1,3]: 2.9 vs 3.45, 6.4 vs. 8.85, 3.1 vs 3.7, and 4.1 vs 5.4 %%, respectively.
All the analytes correlated well, with ranging of coefficient of regression (r) and slope from 0.95 to 0.998, and from 0.85 to 1.28, respectively.

Figure 1. Precision: comparison with desirable CV%

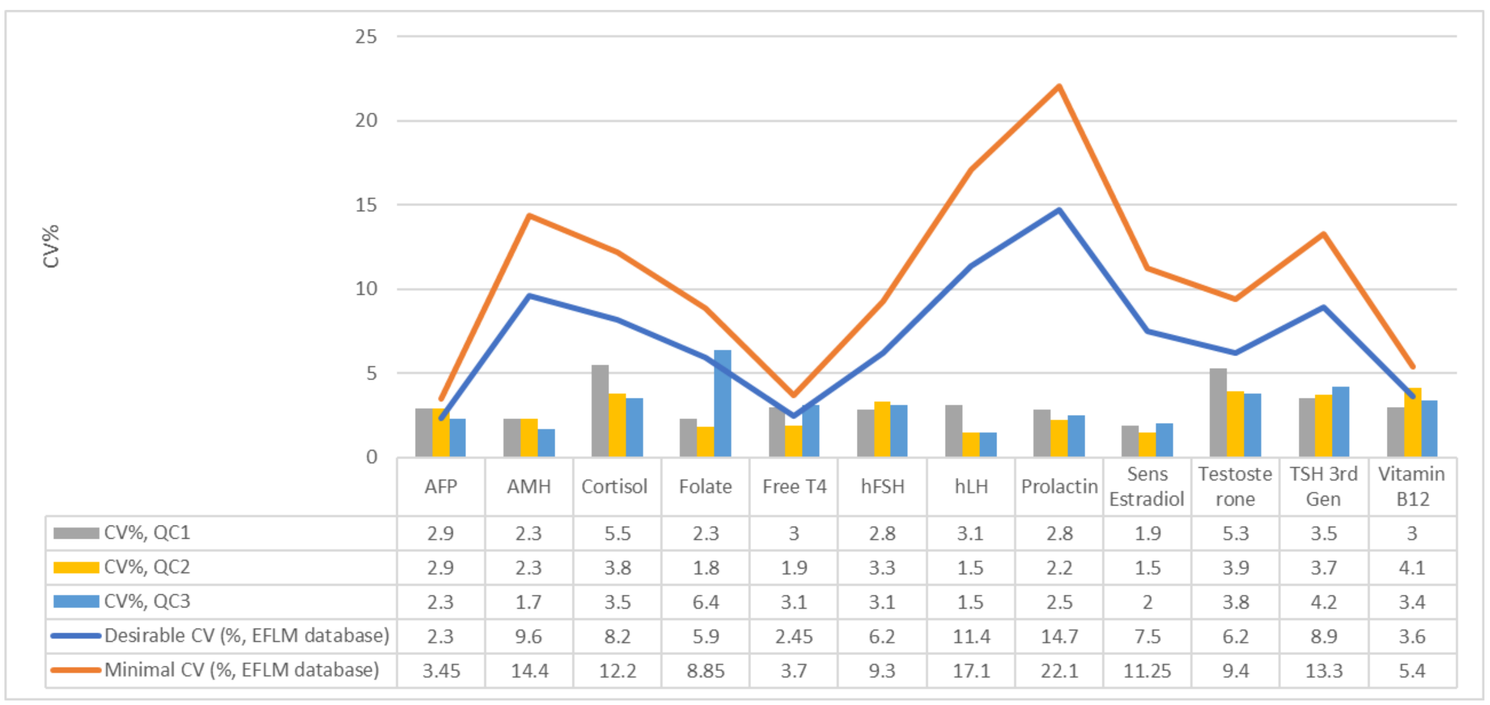

Table 1. LoB comparison with IFU claims

Analyte	Units	LoB	IFU LoB
AFP	ng/ml	0.024	0.5
AMH	ng/ml	0.000	0.02
Cortisol	µg/dL	0.017	0.4
Folate	ng/ml	0.000	0.8
Free T4	ng/dL	0.018	0.22
TbHCG	mIU/mL	0.036	0.2
hFSH	mIU/mL	0.005	0.2
hLH	mIU/mL	0.019	0.040
Prolactin	ng/ml	0.047	0.25
Estradiol	pg/ml	0.000	15
TSH	mIU/mL	0.0000	0.005
Vitamin B12	pg/ml	34.2	50

Table 2. Regression analysis: DxI 9000 vs 4 analyzers

Analyte	Units	N	Concentration range (DxI 9000)	Slope (95% CI)	Intercept (95% CI)	Correlation coefficient (r)
DxI 9000 vs. Atellica (Siemens Healthcare GmbH)						
TSH 3rd Gen	µIU/mL	112	0.002 - 45.227	1.01 (0.99 - 1.02)	0.02 (-0.00 - 0.06)	0.998
FT4	ng/dL	105	0.35 - 7.70	1.022 (0.96 - 1.1)	-0.23 (-0.31- -0.16)	0.97
Testosterone	ng/dL	103	25.80 - 834.00	1.02 (0.96 - 1.1)	23.51 (13.42 - 37.24)	0.97
Vit D	ng/ml	100	4.17 - 75.2	0.98 (0.93 - 1.04)	2.3 (1.16 - 3.6)	0.97
Cortisol	µg/dL	110	0.70 - 67.90	0.85 (0.81 - 0.88)	0.248 (-0.09 - 0.54)	0.99
DxI 9000 vs. Cobas 8000 (Hoffmann-La Roche Ltd)						
AFP	ng/ml	108	0.00 - 461.00	1.19 (1.13 - 1.24)	0.00 (-0.16 - 0.2)	0.99
AMH	ng/ml	100	0.048 - 12.400	1.2 (1.16 - 1.27)	0.02 (-0.04 - 0.1)	0.98
Folate	ng/ml	103	1.60 - 19.60	0.94 (0.9 - 1.0)	0.76 (0.33 - 1.05)	0.96
TbHCG	mIU/mL	80	0.150 - 990.600	1.28 (1.25 - 1.30)	0.96 (0.19 - 1.55)	0.99
Vitamin B12	pg/ml	118	100 - 1748	0.76 (0.74 - 0.78)	-22.0 (-29.5- -14.6)	0.99
Vitamin D	ng/ml	100	3.10 - 80.10	0.98 (0.93 - 1.04)	2.35 (1.1 - 3.6)	0.97
DxI 9000 vs. Immuite 2000 Xpi (Siemens Healthcare GmbH)						
hFSH	mIU/mL	122	0.59 - 161.00	1.07 (0.99 - 1.12)	0.4 (0.1 - 0.78)	0.98
hLH	mIU/mL	105	0.12 - 78.60	1.12 (1.08 - 1.19)	-0.08 (-0.23 - 0.0)	0.98
Prolactin	ng/ml	93	0.95 - 101.80	1.070 (1.00 - 1.14)	0.03 (-0.52 - 0.52)	0.95
DxI 9000 vs. Brahms Kryptor (Thermo Fisher Scientific Inc.)						
PCT	ng/ml	114	0.030 - 64.400	1.018 (0.99 -1.06)	-0.05 (-0.06- -0.04)	0.997

CONCLUSION

The DxI 9000 analyzer was assessed using main recommendations from CLSI and showed excellent performance, met manufacturer claims, and met specifications from EFLM. There was overall good correlation between the DxI 9000 analyzer and the 4 commercial immunoassay platforms used in this study when investigating the respective tests.

Literature:
1. EFLM database; https://biologicalvariation.eu
2. CLSI EP17-A2 Verification of detection capability for clinical laboratory measurement procedures; 2nd edition
3. CLSI C24-ED4:2016 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th edition
4. www. Westgard. com
5. CLSI EP09C-ED3:2018 Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd edition