AN INDEPENDENT ANALYTICAL EVALUATION OF BECKMAN COULTER'S NEW HIGH THROUGHPUT IMMUNOASSAY ANALYSER

Niamh O Mahony, Sarah Ni NiShuilleabhain, Ray Divilley - Mayo University Hospital (MUH), Ireland

Background Beckman Coulter has recently developed the DxI 9000 Access Immunoassay Analyser, a high throughput system designed for busy laboratories. With a newly formulated chemiluminescent substrate, innovative engineering and novel features it promises to be precise, reliable and productive. As a pioneer in embracing new technology, Mayo University Hospital (MUH) installed the first DxI 9000 in Ireland, with the aim to verify the claims made by Beckman Coulter in an independent laboratory setting. 8 assays currently in use in the biochemistry laboratory of MUH were verified between August and December 2022.

METHODS

The manufacturers claims for precision, detection capabilities and linearity for Access Total β-HCG (5th IS), Access Free T4, Access Ferritin, Access Folate, Access Vitamin B12, Access PCT, Access hsTnI and Access TSH 3rd IS were evaluated on the DxI 9000, in accordance with CLSI guidelines. Within run and within laboratory precision studies were performed for all tests in accordance with CLSI EP15 using 3 levels of pooled patient samples for PCT and 3 levels of Technopath Multichem IA Plus for other analytes. Claims for Limit of Blank (LOB), Limit of Detection (LOD) and Limit of Quantitation (LOQ) were assessed using pooled serum and diluent following CLSI EP17 and EP15. Linearity was evaluated as per CLSI EP06 using Technopath Immunoassay L3 QC material and fT4 was evaluated using Beckman Coulter Access fT4 calibrator set. Patient and EQA results generated by DxI 9000 were compared to those produced by DxI 800 analysers for four analytes, using Passing-Bablok regression analysis and in accordance with EP09c.

Carryover studies were also performed on β-HCG and hs-Troponin I using an internal laboratory protocol involving running three replicates of a high concentration sample, followed by three replicates of a very low concentration sample.

Three levels of Technopath Multichem QC was run each day and a maintenance schedule was followed for the duration of the study.

RESULTS

Precision

Within run percent coefficient of variation (% CV) and within laboratory % CV met manufacturers published claims for all analytes. Within run % CV ranged from 1.1% to 5.1%. Within laboratory % CV ranged from 1.8% to 7.3%. 88% of within laboratory CVs were below 4% (*Table 1*). Precision specifications published by the European Federation of Laboratory Medicine were met.

Detection Capabilities: LOB & LOD

The manufacturers claims for LOB and LOD (*Table 2*) were met for all analytes.

Detection Capabilities: LOQ

The manufacturers claims for LOQ were met for all analytes. The %CV observed in samples with concentrations at the manufacturer's quoted 20% LOQ ranged from 3.5% to 14.6% (*Figure 1*).

Linearity

The linearity claims passed for all assays.

Carryover

No clinically significant carryover was detected.

Comparison v DxI 800

Results obtained on the DxI 9000 compared well with those generated on the DxI 800. Slopes ranged from 0.93 to 1.08 (Table 3).

System Maintenance

No daily maintenance is required.

Average system time required for weekly maintenance procedures was under 12 minutes.

Average monthly maintenance procedures was under 15 minutes.

Table 1 Precision

	Mean	% CV Within Run	%CV Within Lab
Folate	3.63 ng/ml	1.7	2.4
	5.82 ng/ml	1.4	2.2
	12.85 ng/ml	1.1	1.8
hCG	4.59 IU/l	2.0	2.4
	25.05 IU/l	2.5	2.6
	503.5 IU/l	1.8	2.6
PCT	0.418 ng/ml	3.9	5.4
	1.855 ng/ml	2.8	3.3
	15.96 ng/ml	2.5	3.0
hsTnI	15.54 ng/ml	1.5	2.1
	148.48 ng/ml	2.1	2.4
	1063.44 ng/ml	2.0	2.3
TSH	0.067 mIU/l	2.8	3.5
	3.557 mIU/l	5.1	5.6
	19.961 mIU/l	3.2	3.5
FT4	8.13 pmol/l	2.4	3.8
	21.73 pmol/l	2.1	3.2
	42.61 pmol/l	1.7	2.8
B12	218.11 pg/ml	2.4	3.2
	534.62 pg/ml	2.9	3.8
	1130.65 pg/ml	3.0	7.3
Ferritin	14.56 µg/l	2.5	2.5
	157.86 µg/l	2.5	3.0
	293.75 µg/l	3.2	3.7

Table 2 Detection Capability - IFU Claims

Assay	IFU LOB claim	IFU LOD claim	IFU LOQ (20%CV) claim
Ferritin (ng/ml)	≤0.2	≤0.4	≤0.6
Folate (ng/ml)	<0.8	<1.0	<2.0
hCG (IU/L)	≤ 0.5	≤ 0.5	0.6
PCT (ng/ml)	≤ 0.005	≤ 0.01	≤ 0.02
hsTnI (ng/l)	0.5	0.9 (ser)	1.0 (ser)
TSH (mIU/l)	≤ 0.005	≤ 0.005	≤ 0.01
B12 (pg/ml)	≤ 50	<68	<68

Figure 1 Within lab precision at claimed LOQ (20% CV)

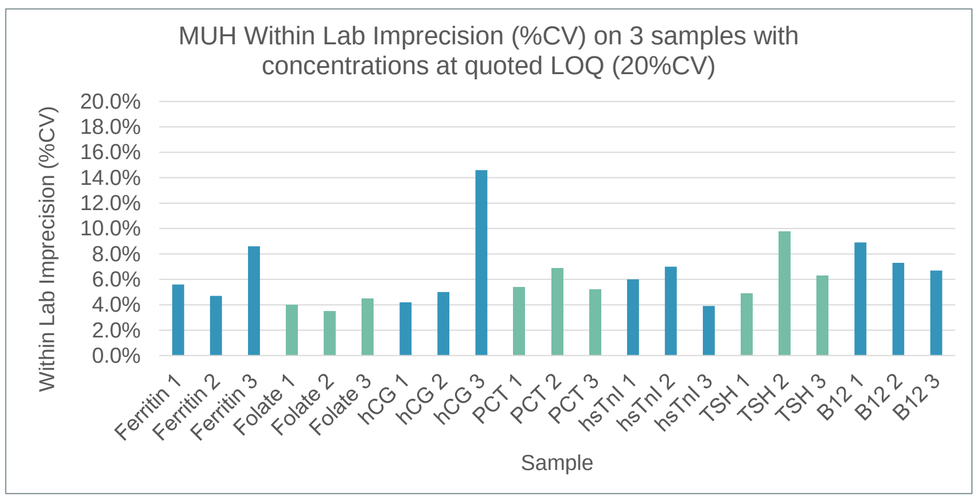

Table 3 Regression analysis DxI 9000 v DxI 800

Access Assay	N	Concentration Range (DxI800)	Slope [95% CI]	Intercept [95% CI]	Correlation Coefficient (R)
FT4	106	8.21 - 21.25 pmol/l	0.93 [0.83 - 1.03]	0.16 [-0.97 - 1.24]	0.91
hsTnI	103	2.3 – 37625 ng/l	0.94 [0.86 - 1.0]	-0.94 [-1.38 - -0.34]	1.00
TSH 3rd IS	108	0.026 - 13.995 mIU/l	1.01 [0.98 - 1.04]	0.033 [-0.005 - 0.068]	1.00
B12	89	58.4 - 182.9 pg/ml	1.082 [0.98-1.19]	14.01 [0.73 - 25.63]	0.93

CONCLUSION

When evaluated in accordance with CLSI guidelines, the DxI 9000 Access Immunoassay Analyser achieved, and in some cases, surpassed, the manufacturer's claims for all analytes, demonstrating excellent analytical performance.