AN EVALUATION OF THE ANALYTICAL PERFORMANCE OF THE NEW BECKMAN COULTER DxC 500 AU CLINICAL CHEMISTRY SYSTEM

Keith Lynch[1], Michael Meade[1], Laura Frost'[1], Terry Rice[1], Marco Cavalleri[1], Stephen Frost[1]
Beckman Coulter, Co Clare, Ireland

BACKGROUND

The Beckman Coulter DxC 500 AU clinical chemistry analyzer* is the latest system from Beckman Coulter. It is a fully automated, random-access analyzer, designed for medium to high throughput laboratories, with a throughput of 800 tests/hour including ion selective electrodes. The purpose of this study was to evaluate the analytical performance of the new DxC 500 AU analyser and to compare the performance against the DxC 700 AU analyzers.

**Product In development. Pending clearance by the United States Food and Drug Administration and achievement of CE compliance. Not currently available for in vitro diagnostic use.*

METHODS

General: To assess the performance of the DxC 500 AU, Beckman Coulter assays were selected for evaluation that covered a range of sample types and assay methodologies. Table 1 shows the Beckman Coulter AU products chosen for the evaluation.

Table 1: Reagent tested on the Beckman Coulter DxC 500 AU analyser

Product Name	Product Code	Type	Application
CRP Latex	OSR6x99	Specific Protein	High Sensitive Serum
Glucose	OSR6x21	Metabolite	Serum
Glucose	OSR6x21	Metabolite	Urine
Glucose	OSR6x21	Metabolite	CSF
IgG	OSR6x172	Specific Protein	Serum
IgG	OSR6x172	Specific Protein	CSF
Sodium	AUH1011/66320	Electrolyte	Serum
Sodium	AUH1011/66320	Electrolyte	Urine
Potassium	AUH1011/66320	Electrolyte	Serum
Potassium	AUH1011/66320	Electrolyte	Urine
Chloride	AUH1011/66320	Electrolyte	Serum
Chloride	AUH1011/66320	Electrolyte	Urine

Assays were calibrated using the appropriate calibration method as specified in the IFU's. All assays were controlled using at least 2 levels of control material with values assigned for the method.

Precision: Studies were carried out on the DxC 500 AU using 1 lot of reagent and 1 lot of calibrator for each of the assays. Within run (repeatability) and total imprecision (within laboratory) studies followed CLSI guideline EP05-A3. The experimental design utilized duplicate sample analysis, twice daily, over the course of 20 working days (n=80) for multiple samples that covered the range of the assay. For brevity the data from 2 concentrations of analyte are shown, low and high.

Method Comparison: The DxC 500 AU was compared to the AU480 and DxC 700 AU analyzers following the method in CLSI guideline EP09-A3. Greater than 100 relevant samples were analysed in duplicate over a minimum of 3 days on all systems using one lot of each reagent. To ensure complete coverage of the assay range some samples were either spiked or diluted but accounted for less than 20% of the samples. Any samples that were outside of the measuring range were excluded. The means of the results were compared between analyzers using Deming regression.

Linearity: The linearity of the assay response throughout the measuring range was assessed on the DxC 500 AU following the method detailed in CLSI EP-06A. For each assay two pools were prepared with analyte concentrations less than and greater than the assay measuring range and a panel was prepared by inter-dilution of these pools. Each pool was run n=4 using one lot of reagent. Both a first order and higher order line was fitted and the bias at each point compared.

RESULTS

Precision: Estimates of repeatability and within laboratory precision were assessed at multiple analyte concentrations. The data from 2 concentrations summarized in Tables 2 demonstrates that the new DXC 500 AU produces reliable results.

Table 2: Summary of Precision for a representative selection of analytes on the Beckman Coulter DXC 500 AU Clinical Chemistry System.

Analyte/	Units	Level 1 (low)			Level 2 (high)		
		Mean	Within Run %CV	Total %CV	Mean	Within Run %CV	Total %CV
CRP Serum	mg/L	1.00	1.4	3.8	70.00	0.8	1.0
Glucose Serum	mg/dL	51.1	0.4	0.9	288.9	0.3	1.0
Glucose Urine	mg/dL	56.8	0.5	0.7	341.8	0.4	0.9
Glucose CSF	mg/dL	36.9	0.5	1.2	317.2	0.4	1.0
IgG Serum	mg/dL	504.0	1.2	1.2	2576.2	3.4	3.7
IgG CSF	mg/dL	4.1	4.7	5.6	36.3	1.6	2.6
Sodium Serum	mEq/L	60.5	0.4	0.8	172.3	0.2	0.3
Sodium Urine	mEq/L	21.4	1.1	1.7	351.9	0.4	0.6
Potassium Serum	mEq/L	2.5	0.2	0.3	8.5	0.2	0.5
Potassium Urine	mEq/L	9.9	0.3	0.5	178.0	0.4	1.0
Chloride Serum	mEq/L	51.5	0.4	0.5	150.1	0.5	0.5
Chloride Urine	mEq/L	25.7	0.8	1.1	374.7	0.4	0.6

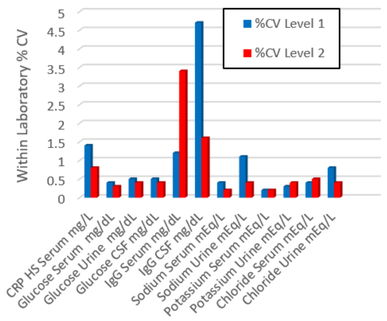

Figure 1: Summary of the Within Laboratory Precision for all representative assays on the Beckman Coulter DXC 500 AU Clinical Chemistry System.

Method Comparison: The DxC 500 AU was compared to the current DxC700 AU analyzers by running patient samples using the representative panel of assays.

The slopes and offsets were analyzed using Deming Regression and all assays showed excellent correlation with all slopes between 0.95 to1.05 .

A summary of these regressions for DxC 500 AU (Y) vs DxC 700 is shown in Table 3 and The method comparison plots for IgG, Glucose Serum, Glucose Urine, CRP Serum, ISE Sodium Serum, ISE Chloride Serum, ISE Potassium Serum and ISE Potassium Urine are shown in Figures 2a-h.

Table 3: Summary the regressions for DxC 500 AU (Y) vs DxC 700 AU (X) and for the representative selection of analytes.

Analyte	Units	Analyzer	Slope	Intercept	R
CRP Serum	mg/L	DxC 700 AU	0.990	0.0421	0.9997
Glucose Serum	mg/dL	DxC 700 AU	0.986	0.227	0.9999
Glucose Urine	mg/dL	DxC 700 AU	1.007	-0.953	1.0000
Glucose CSF	mg/dL	DxC 700 AU	1.009	0.891	0.9998
IgG Serum	mg/dL	DxC 700 AU	1.015	-25.422	0.9981
IgG CSF	mg/dL	DxC 700 AU	0.998	0.1141	0.9995
Sodium Serum	mEq/L	DxC 700 AU	1.018	-2.077	0.9995
Sodium Urine	mEq/L	DxC 700 AU	1.008	-0.150	0.9999
Potassium Serum	mEq/L	DxC 700 AU	1.015	-0.048	0.9998
Potassium Urine	mEq/L	DxC 700 AU	1.000	0.194	0.9998
Chloride Serum	mEq/L	DxC 700 AU	1.007	-0.379	0.9997
Chloride Urine	mEq/L	DxC 700 AU	1.002	-0.291	0.9999

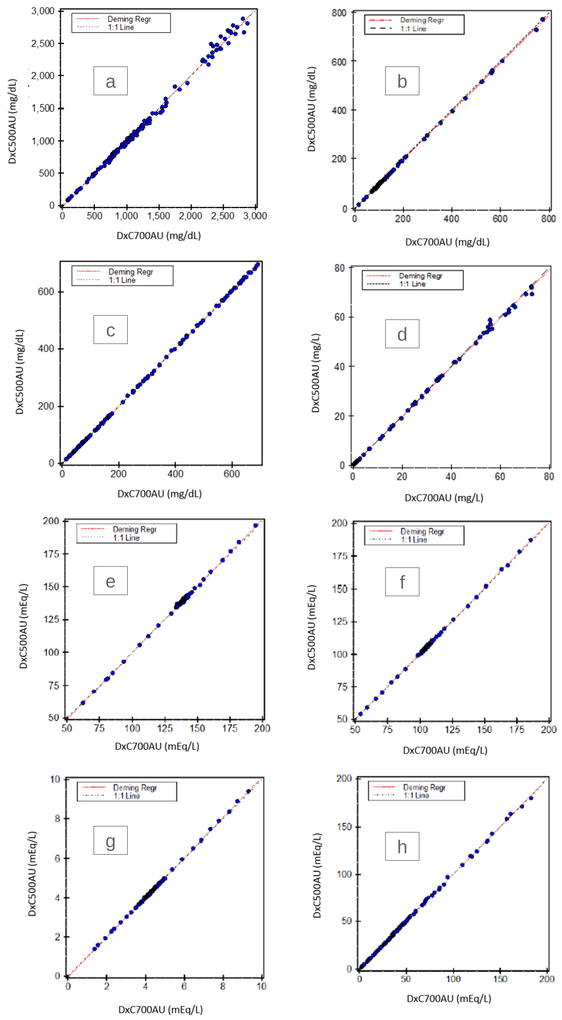

Figure 2: Method Comparison Plots comparing IgG (a), Glucose Serum (b), Glucose Urine (c), CRP Serum (d), ISE Sodium Serum (e), ISE Chloride Serum (f), ISE Potassium Serum (g) and ISE Potassium Urine (h).

Linearity: The linearity of the assay response throughout the measuring range was assessed on the DxC 700 AU. All assays were shown to be linear over the respective assay's analytical range as shown in table 4.

The linearity plot for CRP Serum, Glucose Serum, Glucose Urine, Sodium Serum, Sodium Urine, Chloride Serum, Potassium Serum and Potassium Urine are shown in Figures 3a to h.

Table 4: Summary of assay range for a representative selection of analytes on the Beckman Coulter DXC 500 AU Clinical Chemistry System.

Analyte	Linear Range	Analyte	Linear Range
CRP Serum	0.2 – 80 mg/L	Sodium Serum	50 – 200 mEq/L
Glucose Serum	10 – 800 mg/dL	Sodium Urine	10 – 400 mEq/L
Glucose Urine	10 – 700 mg/dL	Potassium Serum	1.0 – 10.0 mEq/L
Glucose CSF	10 – 800 mg/dL	Potassium Urine	2.0 – 200.0 mEq/L
IgG Serum	75 – 3000 mg/dL	Chloride Serum	50 – 200 mEq/L
IgG CSF	2 – 50 mg/dL	Chloride Urine	15 – 400 mEq/L

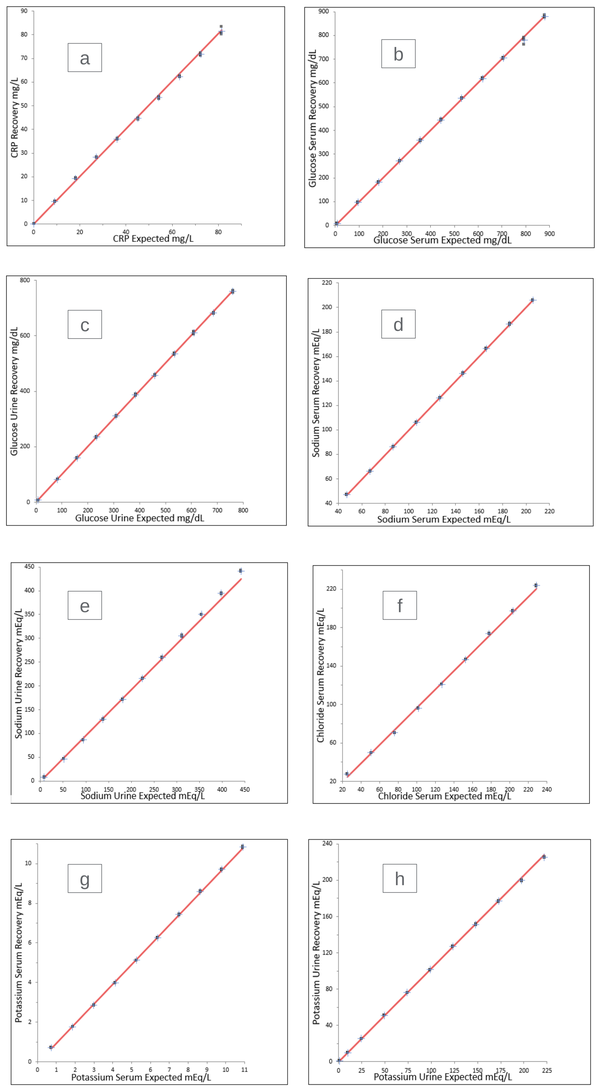

Figure 3: Linearity Plot for CRP Serum (a), Glucose Serum (b), Glucose Urine (c), ISE Sodium Serum (d), ISE Sodium Urine (e), ISE Chloride Serum (f), ISE Potassium Serum (g) and ISE Potassium Urine (h) on the DxC 500 AU.

CONCLUSION

The results of the study demonstrated excellent analytical performance of the new Beckman Coulter DxC 500 AU analyzer and confirms comparable performance to the DxC 700 AU analyzers.