EVALUATION OF THE ANALYTICAL PERFORMANCE OF THE NEW BECKMAN COULTER DxC 700 AU CLINICAL CHEMISTRY SYSTEM

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BACKGROUND

The Beckman Coulter DxC 700 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 1200 tests/hour including ion selective electrodes. The purpose of this study was to evaluate the analytical performance of the new DxC 700 AU analyzer and to compare the performance against the current AU680 and AU5800 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 700 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: Reagents tested on the Beckman Coulter DxC 700 AU analyser

Product Name	Product Code	Type	Application
CRP Latex	OSR6x99	Specific Protein	High Sensitive Serum
Glucose	OSR6x21	Metabolite	Serum
IgG	OSR6x172	Specific Protein	Serum & CSF
IgG	OSR6x172	Specific Protein	CSF
α-Amylase	OSR6x06	Enzyme	Serum
ALP	OSR6x04	Enzyme	Serum
Albumin	OSR6x02	Metabolite	Serum
Total Bilirubin	OSR6x12	Metabolite	Serum
GGT	OSR6x19	Enzyme	Serum
Total Protein	OSR6x32	Metabolite	Serum
Urea	OSR6x34	Metabolite	Serum
AST	OSR6x09	Enzyme	Serum
Calcium (Arsenazo)	OSR6x117	Metabolite	Serum
Creatinine	OSR6x78	Metabolite	Serum
Sodium/Potassium/ Chloride	AUH1011	Electrolyte	Serum & 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 700 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 most clinically relevant concentrations of analyte are shown.

Method Comparison: The DxC 700 AU was compared to the AU680 and AU5800 analyzers following the method in CLSI guideline EP09-A3. Greater than 100 relevant samples were analyzed in duplicate over 5 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 this 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 700 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 & 3 demonstrates that the new DXC 700 AU produces reliable results.

Table 2: Summary of Precision for a representative selection of analytes on the Beckman Coulter DXC 700 AU Clinical Chemistry System.

Analyte	Units	Level 1			Level 2		
		Mean	Within Run %CV	Total %CV	Mean	Within Run %CV	Total %CV
Albumin	g/dL	3.5	0.55	1.10	5.5	0.93	1.73
ALP	U/L	29	0.97	2.63	330	0.58	1.36
Urine Amylase	U/L	42	1.4	1.8	1315	0.8	1.0
AST	U/L	17.3	2.82	3.56	311.0	0.54	1.16
GGT	U/L	21.6	0.84	1.47	246.2	0.56	0.81
Calcium	mg/dL	9.3	0.47	0.68	15.9	0.71	1.51
Creatinine	mg/dL	0.54	1.34	3.66	1.02	1.20	2.23
Glucose	mg/dL	26	1.3	2.4	281	0.9	0.9
CRP HS	mg/L	0.5	3.84	3.48	50.1	0.63	0.78
IgG	mg/dL	486	0.7	1.4	1831	1.5	1.6
IgG CSF	mg/dL	4.4	2.8	4.2	34.8	0.9	1.8
Total Bilirubin	mg/dl	1.1	0.57	2.57	18.1	0.25	1.23
Total Protein	g/dL	3.7	0.41	1.01	10.4	0.44	0.98
Urea	mg/dL	15.9	1.02	2.53	102.8	0.93	2.29

Table 3: Summary of Precision for Ion Selective Electrodes on the Beckman Coulter DXC 700 AU Clinical Chemistry System.

Analyte	Units	Level 1			Level 2		
		Mean	Within Run %CV	Total %CV	Mean	Within Run %CV	Total %CV
Chloride Serum	mEq/L	105.25	0.26	0.42	151.82	0.26	0.68
Chloride Urine	mEq/L	25.50	0.68	2.19	148.47	0.26	0.51
Potassium Serum	mEq/L	4.56	0.25	0.48	6.46	0.33	0.60
Potassium Urine	mEq/L	10.50	0.45	1.21	101.11	0.59	1.29
Sodium Serum	mEq/L	139.51	0.15	0.40	167.78	0.18	0.50
Sodium Urine	mEq/L	21.98	1.19	1.89	245.49	0.39	1.30

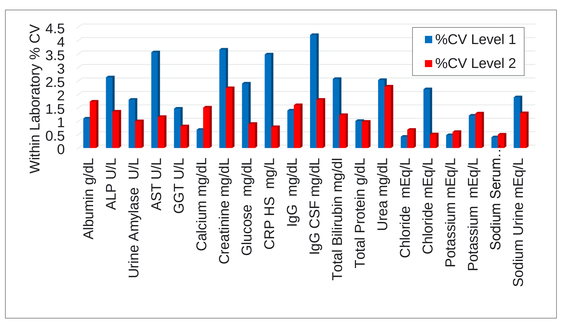

Figure 1: Summary of the Within Laboratory Precision for all representative assays on the Beckman Coulter DXC 700 AU Clinical Chemistry System.

Method Comparison: The DxC 700 AU was compared to the current AU680 and AU5800 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 700 AU (Y) vs AU5800 (X) and DxC 700 AU (Y) vs AU680 (X) is shown in Tables 4 & 5 and the method comparison plots for Urea and Glucose are shown in Figures 2a-d, Bias plots shown in Figures 2e-f.

Table 4: Summary the regressions for DxC 700 AU (Y) vs AU5800 (X) and DxC 700 AU (Y) vs AU680 (X) for a representative selection of analytes.

Analyte	Units	Analyzer	Slope	Intercept	R
Albumin	g/dL	AU5800	0.989	0.055	0.997
		AU680	1.012	0.057	0.997
ALP	U/L	AU5800	1.000	0.167	1.000
		AU680	0.987	0.802	1.000
Urine Amylase	U/L	AU5800	0.984	0.658	1.000
		AU680	1.030	-3.182	1.000
AST	U/L	AU5800	0.988	-0.038	1.000
		AU680	0.992	0.354	1.000
Calcium	mg/dL	AU5800	1.017	-0.213	0.999
		AU680	0.997	-0.099	0.999
Creatinine	mg/dL	AU5800	1.003	-0.017	1.000
		AU680	1.008	-0.025	1.000
CRP HS	mg/L	AU5800	1.013	-0.050	1.000
		AU680	1.004	-0.008	1.000
GGT	U/L	AU5800	1.036	-0.165	1.000
		AU680	1.027	-0.332	1.000
Glucose	mg/dL	AU5800	1.014	0.040	1.000
		AU680	0.997	-2.012	1.000
IgG	mg/dL	AU5800	0.984	23.134	0.997
		AU680	0.971	-3.487	0.997
IgG CSF	mg/dL	AU5800	1.002	-0.055	0.999
		AU680	1.001	0.071	0.999
Total Bilirubin	mg/dL	AU5800	0.981	0.016	1.000
		AU680	0.995	0.011	1.000
Total Protein	g/dL	AU5800	0.992	0.028	0.999
		AU680	1.007	-0.106	0.999
Urea	mg/dL	AU5800	1.004	0.182	1.000
		AU680	1.022	-0.147	1.000

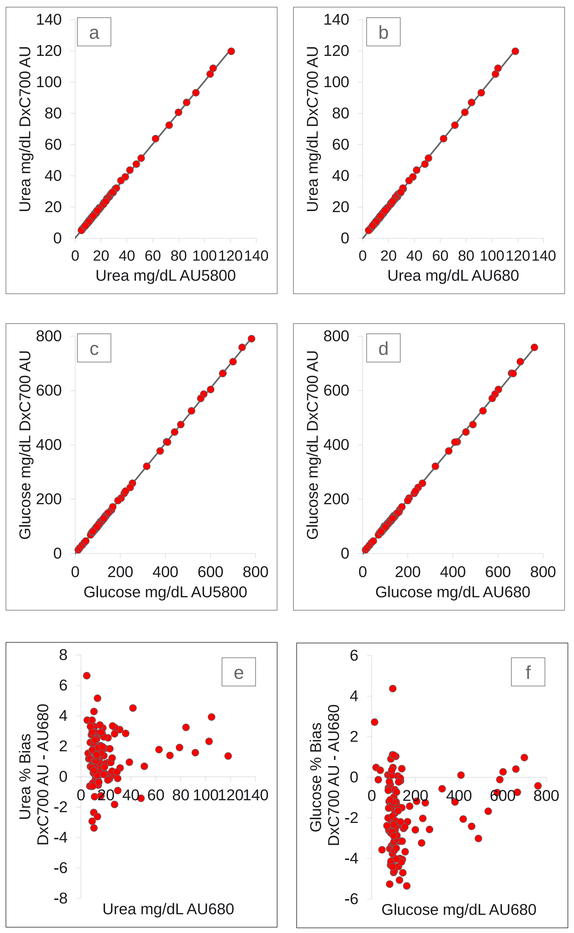

Figure 2: Method Comparison Plots comparing Urea (a & b) and Glucose (c & d). Bias plots for Urea and Glucose comparing the DxC 700 AU and the AU680 are shown (e & f).

Table 5: Summary the regressions for DxC 700 AU (Y) vs AU5800 (X) and DxC 700 AU (Y) vs AU680 (X) for Ion Selective Electrodes.

Analyte	Units	Analyzer	Slope	Intercept	R
Chloride Serum	mEq/L	AU5800	0.999	0.224	0.999
		AU680	0.993	0.723	0.999
Chloride Urine	mEq/L	AU5800	1.036	-3.679	1.000
		AU680	1.017	-1.840	1.000
Potassium Serum	mEq/L	AU5800	0.990	0.042	1.000
		AU680	0.983	0.075	0.999
Potassium Urine	mEq/L	AU5800	1.011	-0.149	1.000
		AU680	0.991	0.381	1.000
Sodium Serum	mEq/L	AU5800	1.007	-0.779	0.999
		AU680	0.980	3.037	0.999
Sodium Urine	mEq/L	AU5800	1.014	-1.392	1.000
		AU680	1.001	0.256	1.000

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 6.

The linearity plot for Glucose, Urea, Urine Amylase and Potassium are shown in Figures 3a to d.

Table 6: Summary of assay range for a representative selection of analytes on the Beckman Coulter DXC 700 AU Clinical Chemistry System.

Analyte	Linear Range	Analyte	Linear Range
Albumin	1.5 – 6.0 g/dL	Glucose	10 – 800 mg/dL
ALP	5 – 1500 U/L	CRP HS	0.2 – 80 mg/L
Urine Amylase	10 – 1500 U/L	IgG	75 – 3000 mg/dL
AST	3 – 1000 U/L	IgG CSF	2 – 50 mg/dL
GGT	3 – 1200 U/L	Total Bilirubin	0 – 30 mg/dL
Calcium	4.0 – 18.0 mg/dL	Total Protein	3 – 12 g/dL
Creatinine	0.2 – 25.0 mg/dL	Urea	2 – 130 mg/dL
Chloride Serum	50 – 200 mEq/L	Chloride Urine	15 - 400 mEq/L
Potassium Serum	1.0 – 10.0 mEq/L	Potassium Urine	2.0 – 200.0 mEq/L
Sodium Serum	50 – 200 mEq/L	Sodium Urine	10 - 400 mEq/L

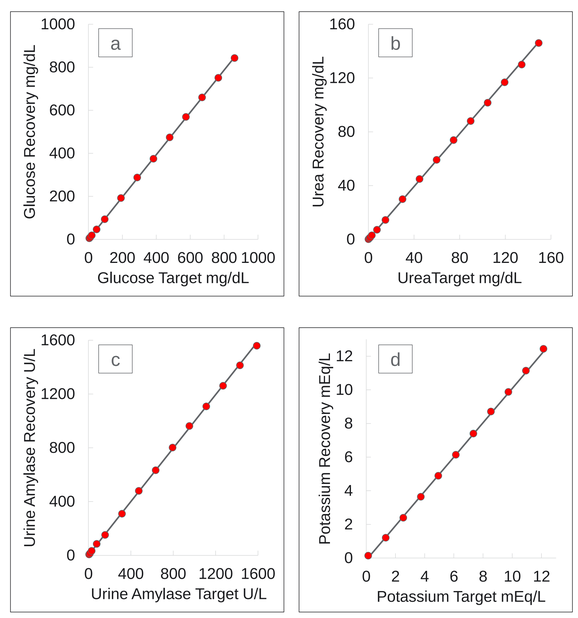

Figure 3: Linearity Plot for Glucose (a), Urea (b), Urine Amylase (c) and Potassium (d) on the DxC 700 AU.

CONCLUSION

The results of the study demonstrated excellent analytical performance of the new Beckman Coulter DxC 700 AU analyzer and confirms comparable performance to the AU680 and AU5800 analyzers.