The New respons 920®System - Adaptation of a Panel of Kidney Disease Markers

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Introduction

The DiaSys respons®920 system is a fully automated, random access analyser designed for small to medium size workloads. The system has a throughput of about 240 tests/h with ISE and 200 tests/h without. Key features are the one-grip loading of a complete reagent set (twin-container). Up to 30 slots for refrigerated and barcoded reagent containers are on board. The system features an optional 4 channel ISE. A panel of more than 60 clinical chemistry and immunoturbidimetric methods is available.

Figure 1: *DiaSys respons®920*

Because of the growing relevance and the steadily increasing number of cases of metabolic syndrome and diabetes in many countries, the adaptation of a panel of kidney disease markers has been chosen to demonstrate the performance of the system.

This kidney disease package includes the following assays:

Creatinine
Cystatin C
Total Protein
Urea
Urinary Albumin

Results

Assay	Unit	Range		
Creatinine	mg/dL	0.10	-	15
Urea	mg/dL	3.00	-	300
Albumin U/CSF	mg/L	2.00	-	350
Total Protein	g/dL	0.05	-	15
Cystatin C	mg/L	0.06	-	8.0

Table 1: *Summary Measuring Ranges*

Assay	Unit	Slope	Intercept	r	n
Creatinine	mg/dL	1.038	-0.052	0.999	110
Urea	mg/dL	1.010	1.120	0.999	110
Albumin U/CSF	mg/L	0.935	1.400	0.999	92
Total Protein	g/dL	1.020	0.017	0.955	110
Cystatin C	mg/L	0.959	-0.043	0.998	100

Table 2: *Summary Method Comparison*

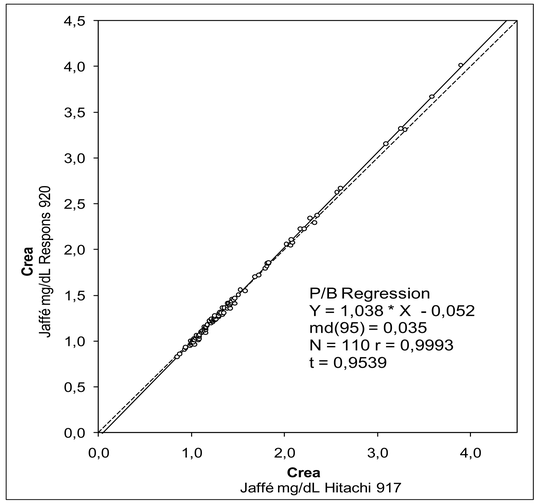

Figure 2: *Creatinine Method Comparison*
Sample specimen: human serum

Assay	Unit	Sample 1 Mean	Sample 1 CV %	Sample 2 Mean	Sample 2 CV %	Sample 3 Mean	Sample 3 CV %
Creatinine	mg/dL	1.02	2.68	1.21	3.01	7.57	0.88
Urea	mg/dL	39.2	2.54	77.8	2.90	152	2.34
Albumin U/CSF	mg/L	20.3	3.01	34.1	1.55	106	0.56
Total Protein	g/dL	5.09	1.02	6.20	0.93	10.9	0.90
Cystatin C	mg/L	0.70	2.33	0.95	2.26	3.08	1.88

Table 3: *Summary Precision in Series (n=20)*

Assay	Unit	Sample 1 Mean	Sample 1 CV %	Sample 2 Mean	Sample 2 CV %	Sample 3 Mean	Sample 3 CV %
Creatinine	mg/dL	1.00	3.21	1.11	2.59	7.53	2.63
Urea	mg/dL	39.8	2.22	66.9	3.68	150	2.24
Albumin U/CSF	mg/L	20.8	3.46	35.0	2.91	110	1.94
Total Protein	g/dL	4.91	2.11	5.96	1.62	11.0	2.25
Cystatin C	mg/L	0.91	3.71	1.12	3.08	3.44	3.53

Table 4: *Summary Precision from Day-to-Day (n=20)*

Interferent		Creatinine	Urea	Albumin U/CSF Serum	Albumin U/CSF Urine	Total Protein	Cystatin C
Lipid	mg/dL	1800	2000	2000	-	2000	1000
Bilirubin	mg/dL	3	60	60	25	60	60
Hemoglobin	mg/dL	500	1000	1000	240	500	1000
Ascorbate	mg/dL	30	30	-	-	30	-
Urea	g/L	-	-	-	40	-	-
Dextran	mg/dL	-	-	-	-	2000	-
Rheumatoid factor	IU/mL	-	-	-	-	-	600

Table 5: *Summary Interferences (Table indicates the maximum tolerable interferences within ± 10% limits)*

Materials & Methods

The assay adaptation and performance verification was carried out on 3 DiaSys respons®920 systems in parallel. All reagents, calibrators and controls were provided by DiaSys Diagnostic Systems GmbH. Method comparisons were performed on DiaSys respons®920 and Hitachi 917 as a reference system. The data was evaluated by using regression analysis according to Passing and Bablok [1-3]. Inter- and intra-assay imprecision data were recorded according to a DiaSys internal protocol in serial 20-fold repetition and a 4-fold day-to-day repetition over 5 days, respectively [4-5]. The analytical sensitivity was determined by adding 3 SD to the mean signal of a 20-fold repeated blank measurement. The assay interferences were assessed according to a DiaSys internal protocol based on CLSI guidelines [6].

Conclusion

The DiaSys respons®920 benchtop analyser demonstrated a good precision and accuracy and the ease of workflow fulfills the needs of mid-sized laboratories. The analytical performance compares very well to the established Hitachi 917 floor model analyser and is fully compliant with the quality assurance demands of a state of the art clinical laboratory.

References

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