Evaluation of Colorimetric and B-026 Electrolyte Test Assays on the Fuji Dri-Chem NX700i Clinical Chemistry Analyzer

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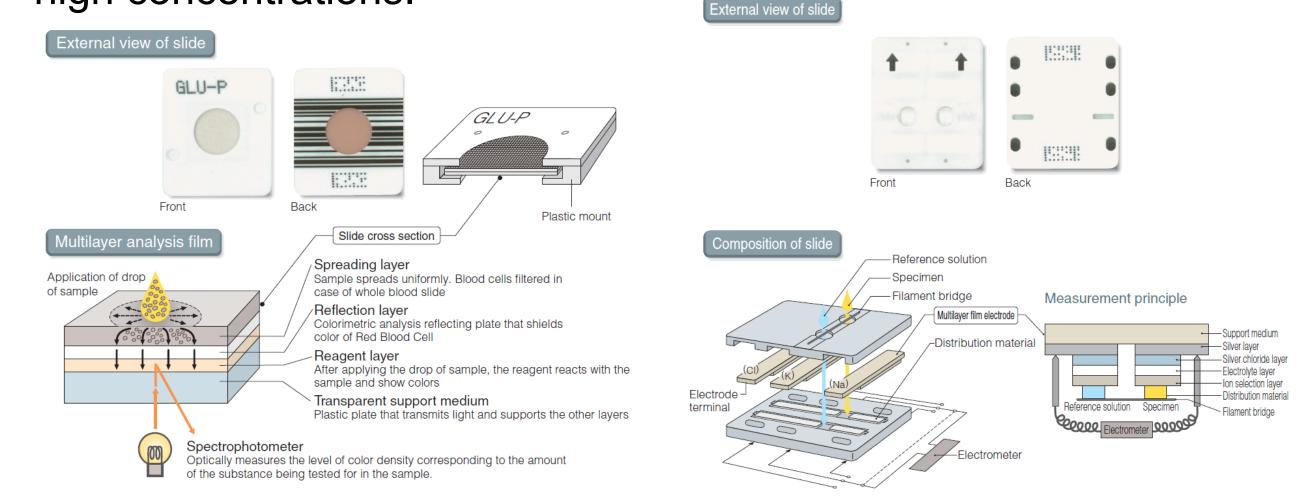
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BACKGROUND

The Fuji Dri-Chem NX700i holds 28 colorimetric and 3 electrolyte test assays and analyzes up to five different samples simultaneously with 190 tests/hour (colorimetry + electrolytes). A STAT testing position is available. The colorimetric method slide is a multilayered slide composed of dry chemical ingredients needed for the reaction quantifying enzymes and substrates by colorimetric methods. The potentiometric method slide contains ion selective film electrodes for Na, K, and Cl. Calibration is done with QC cards except for CRP working with a calibrator. Each test needs only 10µL of sample except for CRP (5µL) and ISE (50µL for all 3 tests). Whereas the NX700i can only be used for serum or plasma samples the NX700 uses plasma filters for whole blood separation and can therefore be used in POCT settings.

METHODS

In this study the Fuji Dri-Chem NX700i was evaluated using serum samples. The parameters investigated were albumin (ALB), blood urea nitrogen (BUN), creatinine (CRE), total bilirubin (TBIL), aspartate aminotrans-ferase (AST/GOT), Alanine Aminotransferase (ALT/GPT), y-glutamyltransferase (GGT), Creactive protein (CRP), lipase (LIP), triglycerides (TG), ammonia (NH3) and the three electrolytes sodium, potassium and chloride. Interferences from hemolytic, lipemic, icteric or highly elevated total protein samples were excluded according manufacturers method specific declarations and studied separately. Method comparison was done by measuring 50 samples for each analyte at the same time on the NX700i and the Siemens Atellica CH analyzer. For each parameter inter-(controls, n=10) and intra-assay (patient samples, n=10) coefficients of variation (CV) were calculated for low, medium and high concentrations.



Colorimetric method slides
(FUJI DRI-CHEM BOOK, FUJIFILM Corporation, 08-10 · GA · 1-1)

Potentiometric method slide

RESULTS

For the colorimetric assays inter-assay CVs (n=10) were 1.4 to 7.7% (Low), 1.1 to 5.5% (Medium) and 1.1 to 3.9% (High). Intra-assay CVs (n=10) were 1.2 to 4.1% (Low), 1.1 to 3.7% (Medium) and 0.8 to 3.3% (High). Method comparison (Passing-Bablok Regression) of routine samples from hospital patients showed good agreement of the two methods with correlation coefficients of r = 0.98 and higher except for LIP (0.83), NH3 (0.87) and Alb (0.93).

For the potentiometric assays inter-assay CVs (n=10) were 1.1 to 1.6% (Low), 0.7 to 1.2% (Medium) and 0.8 to 1.0% (High). Intra-assay CVs (n=10) were 0.1 to 0.5% (Low), 0.3 to 1.3% (Medium) and 0.7 to 0.9% (High). Method comparison (Passing-Bablok Regression) of routine samples from hospital patients showed good agreement of the two methods with correlation coefficients of r = 0.98 except for Chloride (0.83).

		Albumin			Ammonia	
	Low	Medium	High	Low	Medium	High
CV inter assay	2.8%	2.6%	2.3%	5.2%		2.4%
CV intra assay	2.5%	2.2%	1.6%	1.9%	3.7%	1.8%
PB Regression	y=1.141x-8.377			y=0.828x+14.422		
R ²	0.92 0.865					

	Bilirubin Total			Blood Urea Nitrogen		
	Low	Medium	High	Low	Middle	High
CV inter assay	7.7%	2.1%	1.1%	1.4%	1.7%	2.2%
CV intra assay	9.5%	1.5%	0.8%	4.1%	1.2%	1.1%
PB Regression	y=1.031x-0.155			y=1.160x+1.150		
R ²	0.994			0.986		

	Creatinine			CRP		
	Low	Middle	High	Low	Medium	High
CV inter assay	2.6%	2.3%	1.7%	5.7%		5.5%
CV intra assay	2.3%	2.6%	2.1%	11.1%	2.5%	3.3%
PB Regression	y=1.101x-0.041			y=1.142x-0.128		
R ²	0.996			0.996		

	GGT			GOT		
	Low	Medium	High	Low	Medium	High
CV inter assay	4.8%	1.7%	2.4%	2.5%	2.4%	1.7%
CV intra assay	1.5%	1.3%	1.4%	1.6%	0.0%	1.1%
PB Regression	y=1.043x-1.769			y=0.739x+1.875		
R ²	0.997			0.988		

		GPT			Lipase	
	Low	Medium	High	Low	Medium	High
CV inter assay	4.4%	3.9%	2.6%	1.9%	2.9%	3.9%
CV intra assay	1.9%	2.1%	1.4%	3.1%	3.1%	2.6%
PB Regression	y=0.860x+1.200			y=0.881x+1.859		
R ²	0.969			0.834		

	Triglyceride				Sodium		
	Low	Medium	High	Low	Medium	High	
CV inter assay	1.5%	1.1%	1.4%	1.1%	0.7%	0.8%	
CV intra assay	1.2%	1.1%	1.3%	0.5%	0.3%	0.8%	
PB Regression	y=1.058x-15.724			y=1.1385x+1.5922			
R ²	0.988			0.985			

	Potassium			Chloride		
	Low	Medium	High	Low	Medium	High
CV inter assay	1.6%	1.2%	0.8%	1.5%	0.8%	1.0%
CV intra assay	0,0%	1.3%	0.9%	0.5%	0.6%	0.7%
PB Regression	y=1.0876x-0.0775			y=0.8627x+3.6568		
R ²	0.9786			0.8335		

	Potassium			Chloride		
	Low	Medium	High	Low	Medium	High
CV inter assay	1.6%	1.2%	0.8%	1.5%	0.8%	1.0%
CV intra assay	0,0%	1.3%	0.9%	0.5%	0.6%	0.7%
PB Regression	y=1.0876x-0.0775			y=0.8627x+3.6568		
R ²	0.9786			0.8335		

CV: coefficients of variation PB: Passing Bablok Regression

Interferences:

When looking at the principle of measurement of CRP, Glucose takes part in the process leading to the final color change which is then measured as correlation to the CRP quantity in the sample. Glucose is listed as interfering substance for the CRP measurement when above the concentration of 400 mg/dl (22.2 mmol/L). In this study there were false low CRP values above Glucose values of 417 mg/dl.

CONCLUSIONS

The Fuji Dri-Chem NX700i shows good intra- and inter-assay precision with low CVs and excellent correlation with the Siemens Atellica CH analyzer.

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