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Performance Evaluation of Atellica CH 930 Analyzer Assays at a Medical laboratory

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Background

The Atellica® CH 930 Analyzer is a new automated, high through-put clinical chemistry (CH) analyzer from Siemens Healthcare Diagnostics that has a bidirectional magnetic sample-transport technology. The goal of this study was to verify the manufacturer's stated specifications for several clinical chemistry and special protein assays under routine laboratory testing at Laboratoire de Biologie Medicale Bioesterel. Studies included precision, linearity, and method comparison between the Atellica CH 930 Analyzer and the current method established in the laboratory (ADVIA® 1800 Chemistry System).

Methods

Precision (repeatability and within-lab) Protocol: CLSI EP05-A3[1]

Precision was performed using one reagent lot and one Atellica CH 930 Analyzer; five test days, five replicates, one run/day; total n = 25 samples/assay. Quality Control /precision samples included: Bio-Rad Multiqual Liquid Assayed Control Level 1 (PCHEL1), Level 2 (PCHEL2), and Level 3 (PCHEL3), lot #45770; Bio-Rad Liquichek Immunology Control Level 1 (PCHIML1), Level 2 (PCHIML2), and Level 3 (PCHIML3), lot #40940; Liquichek™ Qualitative Urine Toxicology Quality samples for cannabinoid (THC50) assay; Quality control was performed daily. For each run, one freshly thawed aliquot of Quality Control material was centrifuged prior to testing. Results were analyzed using the ANOVA method.

Comparison to the ADVIA 1800 Chemistry System assays Protocol: CLSI EP09-A3[2]

Method comparison was performed with one reagent lot; and, one Atellica CH 930 Analyzer and one ADVIA 1800 Chemistry System. At least forty samples per assay that covered each assay measuring range were tested in singlicate. Deming, Weighted Deming, and Passing-Bablok regression analyses were performed as in the IFU and CSLI document guidance. Serum samples were selected from the site's routine testing and were stored as frozen aliquots at -20°C. Prior to testing an aliquot was thawed and centrifuged.

Linearity Protocol: CLSI EP06-A3[3]

For linearity testing one reagent lot, one Atellica CH 930 Analyzer, five levels of linearity materials, and three replicates for each level were used for each assay. Samples were processed in a randomized order. Sample types were VALIDATE® general chemistry products (LGC Maine Standards).

Statistics

Precision analysis for the CH assays was performed using a Siemens internally developed software program based on analysis suggested in the CLSI guidelines.[1,3] Method Comparison analysis was performed using the Analyze-It add in, version 3.80 for Microsoft Excel®. Linearity for CH assays was performed using the Maine Standards MSDRx® software package, version 6.7.31.

Results

Precision

The standard deviation (SD) and coefficient of variance (CV) observed for all samples, demonstrated acceptable results (Tables 1 and 2).

Note: Precision results in the IFUs were generated using a 20-day ANOVA study design of two runs per day, two replicates per run for twenty days, as described in CLSI EP05-A3.[1] Precision results performed in this study used one run per day, five replicates per run in a five-day design, per the procedure described in CLSI EP15-A3.[4]

Table 1. Summary of precision results for clinical chemistry assays on the Atellica CH 930 Analyzer. n=25 per assay.

Assay	IFU Assay Range	Sample	Mean, n=25	Repeatability		Within-Lab	
			SD	SD	CV, %	SD	CV, %
Albumin (Alb)	1.0–6.0 g/dL	PCHEL1	2.61	0.04	1.5	0.04	1.6
		PCHEL2	3.45	0.05	1.6	0.05	1.6
		PCHEL3	4.47	0.06	1.2	0.07	1.6
Alanine Aminotransferase (ALT)	7–1100 U/L	PCHEL1	31.57	1.69	5.3	1.69	5.3
		PCHEL2	103.13	3.30	3.2	3.56	3.5
		PCHEL3	213.43	3.42	1.6	6.12	2.9
Aspartate Aminotransferase (AST)	8–1000 U/L	PCHEL1	46.37	1.27	2.7	1.45	3.1
		PCHEL2	117.20	3.03	2.6	3.18	2.7
		PCHEL3	291.63	3.85	1.3	5.14	1.8
Calcium (Ca)	10–150 mg/L	PCHEL1	55.03	0.60	1.1	0.87	1.6
		PCHEL2	101.14	0.73	0.7	0.77	0.8
		PCHEL3	133.36	0.65	0.5	0.86	0.6
Chloride (Cl)	50–200 mmol/L	PCHEL1	77.58	0.21	0.3	0.67	0.9
		PCHEL2	101.76	0.20	0.2	1.06	1.0
		PCHEL3	120.80	0.28	0.2	1.64	1.4
Creatinine (Crea_2)	1.5–300 mg/L	PCHEL1	10.15	0.14	1.4	0.19	1.8
		PCHEL2	20.66	0.14	0.7	0.23	1.1
		PCHEL3	66.43	0.40	0.6	0.64	1.0
Enzymatic Creatinine (ECre_2)	1.0–3000 mg/L	PCHEL1	8.13	0.19	2.3	0.27	3.3
		PCHEL2	19.15	0.34	1.8	0.35	1.8
		PCHEL3	68.32	0.80	1.2	0.80	1.2
Glucose Oxidase (GluO)	0.06–7.5 g/L	PCHEL1	0.58	0.01	0.9	0.01	2.0
		PCHEL2	1.15	0.01	0.6	0.01	1.2
		PCHEL3	3.44	0.02	0.5	0.04	1.3
Potassium (K)	1–10 mmol/L	PCHEL1	2.47	0.01	0.4	0.03	1.4
		PCHEL2	4.00	0.01	0.2	0.06	1.5
		PCHEL3	7.33	0.01	0.2	0.11	1.6
Sodium (Na)	50–200 mmol/L	PCHEL1	115.07	0.50	0.4	1.45	1.3
		PCHEL2	140.24	0.25	0.2	2.07	1.5
		PCHEL3	157.43	0.25	0.2	2.54	1.6
Total Bilirubin (TBil_2)	1.0–350 mg/L	PCHEL1	6.18	0.07	1.1	0.28	4.6
		PCHEL2	32.82	0.10	0.3	0.87	2.6
		PCHEL3	73.81	0.23	0.3	2.52	3.4
Total Protein (TP)	20–120 g/L	PCHEL1	39.86	1.78	4.5	1.85	4.6
		PCHEL2	53.45	0.31	0.6	0.31	0.6
		PCHEL3	70.36	0.21	0.3	0.31	0.4
Triglycerides (Trig)	0.1–5.5 g/L	PCHEL1	0.89	0.01	0.7	0.02	2.3
		PCHEL2	1.40	0.01	1.0	0.02	1.6
		PCHEL3	2.13	0.01	0.7	0.02	1.1
Uric Acid (UA)	5.0–200 mg/L	PCHEL1	34.52	0.18	0.5	0.31	0.9
		PCHEL2	59.44	0.27	0.5	0.46	0.8
		PCHEL3	96.68	0.35	0.4	0.68	0.7
Urea Nitrogen (UN_c)	5–150 mg/dL	PCHEL1	15.18	0.38	2.5	0.50	3.3
		PCHEL2	39.72	0.36	0.9	0.64	1.6
		PCHEL3	71.88	0.36	0.5	0.93	1.3

Table 2. Summary of precision results for specific protein assays on the Atellica CH 930 Analyzer. n=25 per assay.

Assay	IFU Assay Range	Sample	Mean, n=25	Repeatability		Within-Lab	
			SD	SD	CV, %	SD	CV, %
β2-Microglobulin (B2M)	0.25–18.00 mg/L	PCHIML1	681.76	21.98	3.2	24.0	3.5
		PCHIML2	1757.80	101.53	5.8	101.53	5.8
		PCHIML3	3086.40	26.0	0.8	27.71	0.9
C-Reactive Protein (CRP_2)	4–304 mg/L	PCHIML1	6.70	0.09	1.4	0.19	2.8
		PCHIML2	30.12	1.75	5.8	2.07	6.9
		PCHIML3	51.24	0.42	0.8	0.59	1.2
Prealbumin (PreAlb)	0.05–0.7 g/L	PCHIML1	0.14	0.00	1.4	0.00	2.5
		PCHIML2	0.25	0.00	1.4	0.01	2.9
		PCHIML3	0.34	0.01	1.6	0.01	3.2
Rheumatoid Factor (RF)	3.5–90.0 IU/mL	PCHIML1	23.96	0.53	2.2	0.85	3.5
		PCHIML2	32.86	0.33	1.0	1.17	3.5
		PCHIML3	43.49	0.36	0.8	1.68	3.9

Method Comparison

Correlation results indicated acceptable agreement with the established method in the laboratory (ADVIA 1800 System) (Table 3).

Table 3. Summary of method comparison results between the Atellica CH 930 Analyzer and ADVIA 1800 Chemistry System (comparative device) for clinical chemistry and specific protein assays using serum samples. n=40 per assay except for ALT (n=41).

Assay (units)	Regression Analysis[a]	Measuring interval: ADVIA 1800 System, Atellica CH 930 Analyzer	Slope	95% CI	Intercept	95%CI	r
Alb (g/dL)	Deming	Ad: 22.6 to 52.3 At: 22.8 to 53.6	0.997	0.978 to 1.016	0.729	0.077 to 1.380	0.999
ALT (U/L)	Deming	Ad: 11.0 to 377.3 At: 7.2 to 383.8	1.032	0.992 to 1.072	-2.810	-4.449 to -1.171	0.999
AST (U/L)	Deming	Ad: 20.8 to 1642.4 At: 21.3 to 1648.9	0.988	0.960 to 1.016	6.401	-1.914 to 14.72	0.999
Cl (mmol/L)	Passing-Bablok	Ad: 99.9 to 129.6 At: 101.0 to 131.0	1.000	0.941 to 1.071	1.500	-6.125 to 7.765	0.983
ECre_2 (mg/L)	Weighted Deming	Ad: 6.5 to 111.9 At: 6.3 to 105.9	0.955	0.949 to 0.961	-0.029	-0.182 to 0.124	1.000
GluO (g/L)	Weighted Deming	Ad: 0.67 to 3.60 At: 0.67 to 3.52	0.988	0.978 to 0.997	0.007	-0.004 to 0.018	1.000
K (mmol/L)	Passing-Bablok	Ad: 2.01 to 6.12 At: 1.98 to 6.21	1.041	1.030 to 1.054	-0.155	-0.214 to -0.105	1.000
Na (mmol/L)	Passing-Bablok	Ad: 119.1 to 157.1 At: 120.5 to 159.2	1.041	1.020 to 1.072	-3.628	-7.777 to -0.577	0.998
TBil_2 (mg/L)	Deming	Ad: 2.2 to 170.4 At: 2.1 to 175.5	1.037	1.031 to 1.043	-0.239	-0.402 to -0.075	1.000
UN_c (mg/dL)	Deming	Ad: 13.6 to 139.7 At: 14.8 to 141.0	1.009	1.001 to 1.018	1.222	0.683 to 1.760	1.000
TP (g/L)	Deming	Ad: 38.4 to 108.5 At: 37.2 to 103.5	0.934	0.919 to 0.949	2.018	1.079 to 2.956	0.999
Trig (g/L)	Deming	Ad: 0.67 to 5.25 At: 0.62 to 4.89	0.943	0.928 to 0957	-0.017	-0.037 to 0.004	0.999
UA (mg/L)	Deming	Ad: 27.6 to 1.64.6 At: 27.3 to 165.5	1.006	1.002 to 1.011	-0.426	-0.730 to -0.122	1.000
CRP_2 (mg/L)	Weighted Deming	Ad: 10.2 to 265.3 At: 9.4 to 291.4	1.027	0.994 to 1.060	-1.226	-1.633 to -0.818	0.995
PreAlb (g/L)	Deming	Ad: 0.053 to 0.425 At: 0.060 to 0.430	0.993	0.977 to 1.009	0.016	0.012 to 0.019	0.999
RF (IU/mL)	Deming	Ad: 9.1 to 742.4 At: 8.5 to 725.4	0.981	0.603 to 1.359	2.001	-14.62 to 18.62	0.998

[a] Type of regression analysis performed matches that used in IFU and CLSI EP09-A3 guidance; Ad: ADVIA 1800 System; At: Atellica CH 930 Analyzer

Table 4. Summary of results for clinical concordance of cannabinoids (THC50) on the Atellica CH 930 Analyzer and ADVIA 1800 System. The Atellica CH Thc Assay detects the major metabolite of Δ9-THC, 11-nor-Δ9-THC-9-carboxylic acid, in human urine. It also detects other Δ9-THC metabolites. The cutoff level for distinguishing positive from negative specimens is 20 ng/mL, 50 ng/mL, or 100 ng/mL.

		ADVIA 1800 THC assay (>50 ng/mL)	
		Positive	Negative
Atellica CH THC Assay (>50 ng/mL)	Negative	0	20
	Positive	20	0
		100% Concordance	

Linearity

Overall, each assay was linear across each assay range and met acceptance limit criteria (Table 5).

Table 5. Summary of linearity results for clinical chemistry assays on the Atellica CH 930 Analyzer.

Assay	Linearity Product Levels=5	Assay Range Tested	Regression Equation	Acceptance Limits[a]
Alb	Maine GC1	1.13–5.89 mg/dL	y=0.950x+0.13	0.2 g/dL or 10%
ALT	Maine GC3	5.39–1,135.3 U/L	y=1.011x+5.550[b]	5 U/L or 20%
AST	Maine GC3	8.85–527.2 U/L	y=1.018x+2.005[b]	5 U/L or 20%
Ca	Maine GC1	17.37–144.7 mg/L	y=1.006x-0.15	10 mg/L or 8.3%
Cl	Maine GC1	50.2–198 mmol/L	y=1.010-0.028	2 mmol/L or 5%
ECre_2	Maine GC1	3.6–278 mg/L	y=0.982x-0.99	3.0mg/L or 15%
GluO	Maine GC1	9–648 mg/dL	y=0.976x+3.291	6 mg/dL or 10%
Na	Maine GC1	65.7–221.5 mmol/L	y=1.014x-1.219	4 mmol/L or 3.1%
K	Maine GC1	1.143–9.52 mmol/L	y=1.041x-0.155	±0.5 mmol/L
TBil_2	Maine GC4	0.97–338.3 mg/L	y=1.011x-0.59	0.4 mg/dL or 20%
TP	Maine GC1	22.53–117.83 g/L	y=0.952x+2.061	2 g/L or 10%
Trig	Maine GC1	11.5–470.5 g/L	y=0.943x-0.015	0.133 g/L or 25%
UA	Maine GC2	63.9–2039 mg/L	y=1.000x+0.61	0.5 mg/dL or 17%
UN_c	Maine GC1	10.53–134.5 mg/dL	y=0. 954x+1.660	2 mg/dL or 9%

[a]Whichever is greater; [b]Level 4 slightly off target acceptance.

Conclusions

Overall, precision, method comparison, and linearity results for clinical chemistry and specific protein assay testing on the Atellica CH 930 Analyzer were excellent and met manufacturer's specifications. The Atellica CH 930 Analyzer and assays are fit for routine use in a clinical laboratory.

References:

1. CLSI. Document EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods.
2. CLSI. Document EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples.
3. CLSI. Document EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures.
4. CLSI. Document EP15-A3: User Verification of Performance for Precision and Trueness.

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