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Performance evaluation of five Sentinel Diagnostics' assays on Beckman Coulter DxC 500 AU Clinical Chemistry Analyzer

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Background

The aim of this study is to evaluate the analytical performances of the following Sentinel Diagnostics' assays: ACE Liquid, Lp(a) Ultra, Pancreatic Amylase, Lipase NG, Albumin BCP on the Beckman Coulter DxC 500 AU Clinical Chemistry Analyzer. Angiotensin converting enzyme (ACE) is a glycoprotein that converts angiotensin I, a relatively inactive decapeptide, into the potent vasoconstrictor, angiotensin II. Elevated levels of ACE activity occur in patients with active sarcoidosis, and occasionally in premature infants with respiratory distress syndrome, in adults with tuberculosis, Gaucher's disease, leprosy, and in many other pathologic conditions involving lung and liver diseases. Lipoprotein (a) has been found in artery walls and can have atherogenic effects. Because of its structural similarity to plasminogen, it can also inhibit fibrinolysis and hence acts thrombogenically. High Lp(a) concentrations in serum correlate with premature manifestation of atherosclerosis and strokes. In combination with elevated LDL Cholesterol concentrations, the coronary risk increases approximately six-fold. Alpha-amylases are hydrolytic enzymes which break down starch into maltose. Pancreatic alpha-amylase, produced almost exclusively by the pancreas and released into the intestinal tract, is measured for monitoring acute pancreatitis and acute attacks during chronic pancreatitis. Lipase enzymes are produced in the pancreas and also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Determination of lipase is used for diagnosis and treatment of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Albumin is one of the most important carrier and binding proteins for various substances in serum and plasma and is also responsible for maintaining the osmotic pressure. Albumin measurements are used in the diagnosis and treatment of numerous diseases, primarily involving the liver or kidneys.

Methods

Performance evaluation included Limit of Blank (LoB), Limit of Detection (LoD), Limit of Quantitation (LoQ), linearity, intra assay precision, inter assay precision, on board reagent stability and instrument correlation, following the current CLSI (Clinical and Laboratory Standards Institute) guidelines protocols[1]. Data were evaluated using Microsoft Excel statistical tool Analyse-it. Analytical Measuring Range (AMR) was defined through linearity and sensitivity.

Results

A summary of the main analytical performances for all the tested assays is reported in the table below.

Test/Assay	ACE Liquid	Lp(a) Ultra	Pancreatic Amylase	Lipase NG	Albumin BCP
Limit of Blank (LoB)	Lot A 2.8 U/L Lot B 2.5 U/L	Lot A 0.7 mg/dL Lot B 1.0 mg/dL	Lot A 1 U/L Lot B 1 U/L	Lot A 0.3 U/L Lot B 0.3 U/L	Lot A 0.3 g/L Lot B 0.4 g/L
Limit of Detection (LoD)	Lot A 4.6 U/L Lot B 5.8 U/L	Lot A 1.4 mg/dL Lot B 1.5 mg/dL	Lot A 2 U/L Lot B 1 U/L	Lot A 1.1 U/L Lot B 1.1 U/L	Lot A 0.4 g/L Lot B 0.7 g/L
Limit of Quantitation (LoQ)	Lot A 7.4 U/L Lot B 6.8 U/L	Lot A 3.0 mg/dL Lot B 2.6 mg/dL	Lot A 3 U/L Lot B 2 U/L	Lot A 2.7 U/L Lot B 2.9 U/L	Lot A 0.9 g/L Lot B 0.9 g/L
Linearity	Lot A Linear up to 121.4 U/L Lot B Linear up to 121.8 U/L	Lot A Linear up to 115.5 mg/dL Lot B Linear up to 113.3 mg/dL	Lot A Linear up to 2125 U/L Lot B Linear up to 2098 U/L	Lot A Linear up to 341.3 U/L Lot B Linear up to 343.7 U/L	Lot A Linear up to 82.2 g/L Lot B Linear up to 82.9 g/L
Intra Assay Imprecision	Sample 1 (16.6 U/L): %CV: 6.3% Sample 2 (33.2 U/L): %CV: 4.2% Sample 3 (48.6 U/L): %CV: 3.5% Sample 4 (75.1 U/L): %CV: 2.0% Sample 5 (103.9 U/L): %CV: 1.6%	S1 (15.4 mg/dL): %CV: 3.1% S2 (21.5 mg/dL): %CV: 1.9% S3 (32.9 mg/dL): %CV: 1.2% S4 (53.0 mg/dL): %CV: 0.9% S5 (88.4 mg/dL): %CV: 0.6%	Sample 1 (9 U/L): %CV: 2.5% Sample 2 (68 U/L): %CV: 1.0% Sample 3 (188 U/L): %CV: 0.8% Sample 4 (248 U/L): %CV: 1.0% Sample 5 (1629 U/L): %CV: 0.7%	Sample 1 (16 U/L): %CV: 3.2% Sample 2 (36 U/L): %CV: 1.4% Sample 3 (60 U/L): %CV: 0.9% Sample 4 (83 U/L): %CV: 0.8% Sample 5 (249 U/L): %CV: 0.5%	Sample 1 (8.7 g/L): SD: 0.19 g/L Sample 2 (16.2 g/L): %CV: 1.4% Sample 3 (33.4 g/L): %CV: 1.0% Sample 4 (50.1 g/L): %CV: 1.1% Sample 5 (56.8 g/L): %CV: 1.0%
Total Imprecision (During 20 testing days up to reagent age of 32 days)	Sample 1 (17.2 U/L): %CV: 7.0% Sample 2 (35.6 U/L): %CV: 5.7% Sample 3 (53.1 U/L): %CV: 4.5% Sample 4 (80.9 U/L): %CV: 3.3% Sample 5 (108.7 U/L): %CV: 3.4%	S1 (14.0 mg/dL): %CV: 4.9% S2 (20.9 mg/dL): %CV: 3.8% S3 (32.3 mg/dL): %CV: 2.7% S4 (50.9 mg/dL): %CV: 2.3% S5 (88.2 mg/dL): %CV: 2.6%	Sample 1 (9 U/L): %CV: 4.3% Sample 2 (67 U/L): %CV: 2.1% Sample 3 (184 U/L): %CV: 2.0% Sample 4 (285 U/L): %CV: 2.0% Sample 5 (1596 U/L): %CV: 1.9%	Sample 1 (15 U/L): %CV: 3.2% Sample 2 (36 U/L): %CV: 1.6% Sample 3 (59 U/L): %CV: 1.8% Sample 4 (79 U/L): %CV: 1.8% Sample 5 (239 U/L): %CV: 1.5%	Sample 1 (9.0 g/L): SD: 0.23 g/L Sample 2 (17.0 g/L): %CV: 2.2% Sample 3 (33.9 g/L): %CV: 1.9% Sample 4 (50.5 g/L): %CV: 1.6% Sample 5 (57.2 g/L): %CV: 1.6%
On board reagent stability up to 32 days	S1 (18.0 U/L): min %bias -7.9% max %bias: 7.5% S2 (35.7 U/L): min %bias: -7.4% max %bias: 9.2% S3 (53.5 U/L): min %bias: 0.0% max %bias: 9.3% S4 (81.5 U/L): min %bias: -0.3% max %bias: 5.0% S5 (108.9 U/L): min %bias: -3.3% max %bias: 9.9%	S1 (14.0 mg/dL): min %bias: -5.7% max % bias: 9.2% S2 (20.6 mg/dL): min %bias: -1.7% max % bias: 7.5% S3 (32.3 mg/dL): min %bias: -2.5% max % bias: 6.0% S4 (50.8 mg/dL): min %bias: -1.3% max % bias: 5.4% S5 (87.8 mg/dL): min %bias: -1.5% max % bias: 5.3%	S1 (9 U/L): min %bias: -5.6% max % bias: 7.4% S2 (67 U/L): min % bias: -3.3% max % bias: 3.4% S3 (184 U/L): min % bias: -3.6% max % bias: 3.0% S4 (287 U/L): min % bias: -3.6% max % bias: 3.3% S5 (1605 U/L): min % bias: -1.3% max % bias: 3.1%	S1 (15.0 U/L): min %bias: -6.7% max %bias: 6.7% S2 (36.7 U/L): min %bias: -2.1% max %bias: 2.4% S3 (61.0 U/L): min %bias: -6.1% max %bias: 5.8% S4 (82.0 U/L): min %bias: -5.6% max %bias: 7.2% S5 (250.0 U/L): min %bias: -8.9% max %bias: 8.5%	S1 (9.1 g/L): min % bias: 0.2% max % bias: 8.2% S2 (17.1 g/L): min % bias: -3.0% max % bias: 8.7% S3 (34.4 g/L): min % bias: -1.4% max % bias: 9.4% S4 (51.1 g/L): min % bias: -0.4% max % bias: 9.5% S5 (57.7 g/L): min % bias: -1.9% max % bias: 7.5%
Instrument correlation (vs. Beckman Coulter AU480)	Passing-Bablok fit: y = 1.10x + 1.98 r = 0.982 N= 103	Passing-Bablok fit: y = 1.01x – 0.21 r = 0.999 N= 65	Passing-Bablok fit: y = 1.00x + 0.00 r = 1.000 N= 120	Passing-Bablok fit: y = 1.00x + 0.00 r = 1.000 N= 120	Passing-Bablok fit: y = 1.04x – 1.50 r = 0.997 N= 120

Conclusions

All assays showed good results for the parameters tested on the Beckman Coulter DxC 500 AU Clinical Chemistry Analyzer making these kits very suitable for a routine measurement of these analytes.

References

1) CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures (EP17-A2); Evaluation of Linearity of Quantitative Measurement Procedures (EP06); Evaluation of Precision of Quantitative Measurement Procedures (EP05-A3); Verification of Precision and Estimation of Bias (EP15-A3); Evaluation of Stability of In Vitro Diagnostic Reagents (EP25-A); Measurement Procedure Comparison and Bias Estimation Using Patient Samples (EP09-A3)