

Precision Performance of the Chengdu Seamaty SMT-100, Point of Care Test (POCT) Device for General Chemistry and Liver Function Panels – A Manufacturer and Customer Laboratory Experience

Bolodeoku J^{1*}, Pinkney S¹, Anyaeche C², Xia A³ and Bin R³

¹JB Consulting (MDP) Limited, Cherwell Innovation Centre, 77 Heyford Park, Upper Heyford, Oxfordshire, UK

²Pathway Services Limited, Headlands House, 1 Kings Court, Kettering, UK

³Chengdu Seamaty Technology Company Limited, No 333 Hezuo Road, High Tech West Zone, Chengdu, P.R. China

*Corresponding author: Bolodeoku J, JB Consulting (MDP) Limited, Cherwell Innovation Centre, 77 Heyford Park, Upper Heyford, Oxfordshire, OX25 5HD, UK, Tel: +447765401135; E-mail: john.bolodeoku@jbconsultingmdp.com

Received Date: July 26, 2019; Accepted Date: August 7, 2019; Published Date: August 13, 2019

Citation: Bolodeoku J, Pinkney S, Anyaeche C, Xia A, Bin R (2019) Precision Performance of the Chengdu Seamaty SMT-100, Point of Care Test (POCT) Device for General Chemistry and Liver Function Panels – A Manufacturer and Customer Laboratory Experience. *Biochem Mol Biol J* Vol.5: No.1:03.

Abstract

The SMT-100 is a general chemistry point of care testing device similar to the Piccolo Xpress device, an example of a microfluidic based platforms. In this study, we performed a precision evaluation of the SMT-100's Healthy Check and Electrolyte Panel consisting of 14 and 7 analytes and compared with the evaluation carried out in the manufacturer's laboratory using commercial quality control samples and whole blood samples in our laboratory. From the manufacturer's laboratory using commercial quality control samples, there was good precision <10% for all analytes in the healthy check panel (total protein, total cholesterol, total bilirubin, albumin, amylase, alkaline phosphatase, triglyceride, creatinine, gamma glutamyl transferase, glucose, urate, urea, aspartate transaminase, alanine transaminase) and the electrolyte panel (bicarbonate, calcium, phosphate, magnesium, potassium, sodium and chloride). From our laboratory using whole blood samples, the precision was not as tight as that seen using commercial material but there was a good precision <10% for all analytes in the Healthy Check panel, albumin, total protein, total bilirubin, aspartate transaminase, alanine transaminase, amylase, creatinine, urea, creatinine kinase, triglyceride, glucose, calcium apart from globulin with a CV % of 11. The precision of the electrolyte panel analytes, bicarbonate, calcium, phosphate, magnesium, potassium, sodium and chloride was also good with a precision of < 10% apart from potassium with a CV% of 12.1%, after the exclusion of an outlier result, the precision of all the analytes was good (<10%). In addition, these preliminary results on the Chengdu Seamaty SMT-100 showed very reasonable precision results obtained for the general chemistry and liver function analytes comparable to those seen achieved by the Piccolo Xpress.

Keywords: General chemistry; Albumin; Amylase

Introduction

Point of Care Testing (POCT) is performed near the site of patient care avoiding the test being sent off to the laboratory [1]. POCT devices have become increasingly popular and the market is growing recently [2]. Lateral Flow Immunoassay (LFIA) technology is the simple and successful rapid diagnostic platform used for POCT, it has well been applied and developed in situations where timely intervention is required such as cardiac disease or diagnosis of infection and cancers. One such device is the i-CHROMA manufactured by Boditech Med Inc, which we have extensively evaluated for Prostate Specific antigen (PSA) [3-5], Vitamin D6, Human Chorionic Gonadotrophin (HCG)7, Luteinizing Hormone (LH) [6], Follicle Stimulating Hormone (FSH) [7], C-reactive protein (CRP) [8] and Microalbumin [8].

Recently, microfluidics platform technologies have developed in the area of diagnosis and been successful in blood chemistry (Piccolo), blood gases, coagulation and cardiac markers (i-STAT Analyzer) immunoassays, nucleic acid amplification tests and flow cytometry [9]. There are examples of microfluidic based platforms such as the lab-on-a-disc diagnostic device, the Piccolo Xpress produced by Abaxis and now distributed by Abbott Point of Care, US. This device measures the reagent reactions simultaneously using nine wavelengths, calculates the results from the absorbance data and reports the results in 12 minutes. A newly CE certified POCT device for clinical chemistry, the Seamaty SMT-100 – is portable, easy to use and performs a flexible panel of tests from a single platform - enabling you to perform more quickly and effectively monitor and manage your patients using the same microfluidics technology as the Abaxis Piccolo Xpress. In this study, we performed a precision evaluation of the Healthy Check and Electrolyte Panel consisting of 14 and 7 analytes and compared with the evaluation carried out in the manufacturer's laboratory using commercial quality control samples and whole blood samples in our laboratory.

Materials and Methods

The analytical performance of the Healthy Check and Electrolyte panels was evaluated for precision using commercially available quality material and whole blood from a healthy volunteer. The SMT-100 uses microfluidic technology using the principles of absorption spectroscopy and transmission turbidimetry. The principle for the methods used is seen in **Table 1**.

Table 1 Principles of methods of SMT-100.

No	Assay	Methodology
1	TC	Dehydrogenase Method
2	ALT	Rate Method
3	AMY	EPS Act
4	ALB	Bromocresol Green Method
5	ALP	Rate Method
6	GLU	Hexokinase Method
7	GGT	Rate Method
8	UA	Oxidase Method
9	AST	Rate Method
10	TB	Oxidase Method
11	UREA	Glutamate Dehydrogenase Method
12	CREA	Oxidase Method
13	TG	Dehydrogenase Method
14	TP	Biuret Method
15	TBA	Enzymatic cycling methods
17	PHOS	Enzymatic methods
18	tCO ₂	PEP-C Enzymic Methods
19	CA	Arsenazo III Method
20	K	Enzymatic methods
21	Na	Enzymatic methods
22	CL	Enzymatic methods
23	Mg	Enzymatic methods

Precision (intra-assay) studies using 10 replicates were performed in the Seamaty Chengdu's Laboratory using the Randox QC 2 and QC 3 verification samples using the SMT-100 Healthy Check Panel with the following analytes: Total Protein, Total Cholesterol, Total Bilirubin, Albumin, Amylase, Alkaline Phosphatase, Triglyceride, Creatinine, Gamma Glutamyl Transferase, Glucose, Urate, Urea, Aspartate Transaminase, Alanine Transaminase and Electrolyte Panels with the following analytes: Bicarbonate (tCO₂), Calcium (Ca), Phosphate (Phos), Magnesium (Mg), Potassium (K), Sodium (Na) and Chloride (Cl).

Precision (intra-assay) studies using 10 replicates were performed in JB Consulting's Laboratory using whole blood from a healthy volunteer using the SMT-100 Healthy Check with the

following analytes: Albumin, Total Protein, Total Bilirubin, Aspartate Transaminase, Alanine Transaminase, Amylase, Creatinine, Urea, Creatinine Kinase, Triglyceride, Glucose, Calcium and Electrolyte Panels with the following analytes.

Results

Precision of healthy check panel using commercial QA verification samples QC2 and QC3

Randox QC2: Precision was estimated as coefficient of variation percent (CV%), the intra-assay precision results are shown in **Table 2**. The intra-assay precision (CV <5%) was very good for the following analytes: total protein, total cholesterol, total bilirubin, albumin, amylase, alkaline phosphatase, triglyceride, creatinine, gamma glutamyl transferase, glucose, urates and urea. The precision was >5% but <10% for alanine transaminase and aspartate transaminase as shown in **Table 2**.

Randox QC3: Precision was estimated as coefficient of variation percent (CV%), the intra-assay precision results are shown in **Table 2**. The intra-assay precision (CV <5%) was very good for the following analytes: total protein, total cholesterol, total bilirubin, albumin, amylase, alkaline phosphatase, triglyceride, creatinine, gamma glutamyl transferase, glucose, urate, urea, aspartate transaminase, alanine transaminase as shown in **Table 2**.

Table 2 Showing precision values obtained for health check panel analytes using Randox quality controls 2 and 3.

Assay	QC2	QC3
TP	2.60%	2.90%
TC	1.40%	1.00%
TB	2.70%	3.70%
ALB	1.10%	1.10%
AMY	2.30%	2.60%
ALP	1.60%	1.70%
TG	2.30%	2.50%
Crea	3.80%	1.90%
GGT	2.00%	2.20%
GLU	1.30%	1.80%
UA	2.50%	2.20%
Urea	2.90%	2.20%
AST	6.30%	3.80%
ALT	5.40%	3.00%

Precision of healthy check panel analytes using whole blood sample

Precision was estimated as coefficient of variation percent (CV %), the intra-assay precision results are shown in **Table 3**. The intra-assay precisions (CV <5%) were very good for the following

analytes: Albumin, total protein, total bilirubin, aspartate transaminase, alanine transaminase, amylase, creatinine, urea, creatinine kinase, triglyceride, glucose, calcium. The CV% of phosphate was 6.1% which was greater than 5% but less than 10%, whilst that of globulin was greater than 10%.

Table 3 Showing precision values obtained for healthy check panel analytes using whole blood.

Analytes	1	2	3	4	5	6	7	8	9	10	AV	CV%
ALB	39.4	39.4	40.1	40.1	40.6	40.2	40.2	40	40.2	39.7	39.63333	0.9
TP	62.1	56.6	60.3	65	62.4	63.6	61.1	61.6	64.5	62.4	59.66667	3.8
GLOB	22.7	17.2	20.2	24.9	21.8	23.4	20.9	21.6	24.3	22.7	20.03333	11
TB	46.2	45.5	47.5	46.5	47.4	46.7	46.6	47.1	47.5	44.6	46.4	2
AST	83	73	79	73	71	78	79	76	73	77	78.33333	4.5
ALT	83	76	77	74	72	73	77	77	76	73	78.66667	3.8
AMY	220	223	219	233	221	228	222	232	219	219	220.6667	2.3
Crea	162.1	155.4	172.7	157.5	171.3	157.4	168.5	155.7	161.2	169.6	163.4	4
Urea	5.46	5.78	5.43	5.77	5.72	5.78	5.64	5.73	5.71	5.7	5.556667	2.2
CK	329	336	337	339	338	345	345	338	330	320	334	2.2
TG	1.25	1.37	1.3	1.33	1.42	1.38	1.45	1.46	1.33	1.42	1.306667	5
Glu	4.06	4.03	4.18	4.17	4.22	4.04	4.04	4.04	4.04	4.14	4.09	1.7
Ca	4.12	4.04	3.98	4.16	4.2	4.06	4.2	4.08	4.28	4.13	4.046667	2.1
Phos	1.47	1.63	1.64	1.66	1.84	1.72	1.6	1.59	1.68	1.77	1.58	6.1

Table 4 Showing precision values obtained on electrolyte panel analytes using Randox quality controls 2 and 3.

Electrolyte Panel Analytes	QC 2	QC3
tCO ₂	2.5%	3.0%
Ca	2.4%	3.5%
Phos	2.5%	3.6%
Mg	4.4%	4.8%
K	5.3%	3.6%
Na	1.8%	3.8%
Cl	2.4%	2.6%

Precision of electrolyte panel using commercial QA verification samples QC2 and QC3

QC2 - The CV (%) for the following analytes: Bicarbonate, calcium, phosphate, magnesium, potassium, sodium and chloride were less than 5% apart from potassium in QC2 which was less than 10% (**Table 4**).

Precision of electrolyte panel using whole blood

The CV% of the analytes in the electrolyte panel was less than 10% apart from potassium with a CV% of 12.1%. However, when the analysis done on day 8 was removed as this value appeared to be an outlier most of the analytes fell within the intra-assay precision of less than 5% apart from potassium with a CV of 6.5%, see values in brackets (**Table 5**).

Table 5 Showing precision values obtained for electrolyte panel analytes using whole blood.

Analytes	1	2	3	4	5	6	7	8	9	10	AV	CV%
tCO ₂	13.9	14.4	15.4	14	12.7	13.3	13.7	11.4	13.3	12.9	13.5	7 (5.3)
Ca	4.01	3.99	3.99	4.06	4.08	3.79	4.11	2.95	3.98	4.04	3.9	8.1 (2.1)
Phos	1.52	1.46	1.46	1.63	1.59	1.57	1.57	1.33	1.53	1.56	1.522	6 (3.6)
Mg	1.7	1.64	1.76	1.68	1.74	1.79	1.75	1.25	1.72	1.69	1.672	8.6 (2.5)
K	4.87	5.44	5.45	5.89	4.86	5.5	5.02	3.4	4.95	4.94	5.032	12.1 (6.5)
Na	164	168.7	157.2	172.9	170.7	162.9	151.5	136.9	162.9	178.1	162.58	6.9 (4.7)

CI	99.4	97.7	92.6	97.7	100.5	94.3	95.8	78.3	95.7	95.5	94.75	6.1 (2.4)
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Discussion

In this study, we have evaluated the precision of the SMT-100 which is based on similar technology as the Abaxis Piccolo Xpress. Using the commercial material in the manufacturer's laboratory, there was good precision <10% for all analytes in the healthy check panel (total protein, total cholesterol, total bilirubin, albumin, amylase, alkaline phosphatase, triglyceride, creatinine, gamma glutamyl transferase, glucose, urate, urea, aspartate transaminase, alanine transaminase) and the electrolyte panel (bicarbonate, calcium, phosphate, magnesium, potassium, sodium and chloride). When the precision range was tightened less than 5%, there was very good precision for all the analytes obtained by the manufacturer's laboratory, except for alanine transaminase and aspartate transaminase in the middle control sample. In this study, using whole blood samples in the customers laboratory, the precision was not as tight as that seen using commercial material but there was a good precision <10% for all analytes in the Healthy Check panel, albumin, total protein, total bilirubin, aspartate transaminase, alanine transaminase, amylase, creatinine, urea, creatinine kinase, triglyceride, glucose, calcium, phosphate apart from globulin. The electrolyte panel (bicarbonate, calcium, phosphate, magnesium, potassium, sodium and chloride) the precision of all analytes was good with a precision of less than 10% apart from potassium with a CV% of 12.1%. This slight difference observed in the precision observed between the manufacturer and our laboratory could have arisen as a result of the difference of samples used, which was commercial quality material in the case of the manufacturer's laboratory and whole blood in our laboratory. Interestingly, similar patterns of precision have been reported in the literature of a similar device the Abaxis Piccolo Xpress Chemistry Analyzer which uses the same technology. In one study using 2 levels of commercial quality control assessing the liver function panel analytes, all the analytes achieved a precision of <5% apart from the total bilirubin which had a precision >5% [10], in another study all the analytes achieved a precision of <5% apart from total carbon dioxide, alanine transaminase, alkaline phosphatase, total bilirubin and creatinine in the low control level and creatinine in the middle control level [11]. In the study which serum, plasma and whole blood samples were used from 23 healthy volunteers to evaluate the precision performance of 14 comprehensive metabolic panel analytes a higher precision value was observed >5% but overall was still quite good as they were all <10% [12]. This corroborates the observations in our study, that the precision appears to be much tighter with the use of commercial quality material compared to serum or whole blood samples from patients or human volunteers.

Conclusion

Overall, one can conclude from this precision evaluation of the Chengdu Seamaty SMT-100, that the precision results obtained in the manufacturer's and our laboratory were very

reasonable (<10%) and comparable for analytes of the healthy check and electrolyte panels of the Chengdu Seamaty SMT-100. In addition, comparing the observations of the precision results obtained with the Chengdu Seamaty SMT-100 in this study and the precision results from the literature of the Abaxis Piccolo Xpress, they are comparable.

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