COMPARISON OF THE NOVA STAT PROFILE PRIME PLUS POINT OF CARE ANALYSER TO THE RADIOMETER ABL 800 AND ABBOTT i-STAT

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DECLARATION

I, Ali Azher Jawa, hereby declare that this research report is my own work and has not been submitted or presented for any other degree or professional qualification at this or any other Institute. This research was undertaken in the Division of Emergency Medicine, University of the Witwatersrand, Johannesburg.

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Comparative Assessment of the Nova Stat Profile Prime Plus®

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CONFLICTS OF INTEREST

The authors hereby certify that this submission is not under publication consideration elsewhere, and there is no conflict of interest to declare.

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SUBMISSION LETTER TO THE EDITOR

Dear Editor – "Cureus"

Thank you for considering our article entitled: *" A Comparative Assessment of the Nova Stat Profile Prime Plus® Critical Care Analyzer"*. Point of Care Testing (POCT) plays an integral role in the management of acutely ill patients presenting to the Emergency Department (ED). Due to its rapid turnaround time, POCT has been shown to improve ED workflow, reduce unnecessary admissions and lessen the burden on ED staff.

The Nova Stat Profile Prime Plus Critical Care Analyzer® was introduced in 2018. Since it is capable of analyzing an extended panel of 21 analytes within 90 seconds, it confers a potential advantage over similar established devices. In this manuscript we compare the Nova Stat Profile Prime Plus Critical Care Analyzer® to the Radiometer ABL800 FLEX® and the Abbott i-STAT Chem8+® analyzers. We are confident that this article will appeal to the readership of the ***Cureus***. Furthermore, it carries a high citation potential as it is not only applicable to laboratory based personal, but also to acute care clinicians working in the fields of Emergency Medicine, Critical Care and Anesthesia.

ABSTRACT

Background: Point of Care Testing (POCT) plays an integral role in the management of acutely ill patients presenting to the Emergency Department (ED). Due to its rapid turnaround time, POCT has been shown to improve ED workflow, reduce unnecessary admissions and lessen the burden on ED staff. The aim of the study was to compare the accuracy, precision and linearity of the Nova Stat Profile Prime Plus® to the Radiometer ABL800 FLEX® and the Abbott i-stat Chem8+® POCT analyzers.

Methods: A convenience sample of 150 discarded whole blood specimens were obtained and analyzed. Paired test measurements were conducted for method comparison. Accuracy was measured by pairing individual results from the Nova Stat Profile Prime Plus® with either the Radiometer ABL 800 FLEX® or the Abbot i-stat Chem8+® analyzers by calculating the differences.

Results: The with-in run percentage coefficient of variation (%CV) was below 2.4% for pH, carboxyhemoglobin (COHb), deoxyhemoglobin (HHb), total hemoglobin (tHb), total bilirubin (tBil), sodium (Na), potassium (K), chloride (Cl), ionized calcium (iCa), urea, glucose and lactate, and was below 5.1% for all other analytes. The day-to-day %CV was below 1.6% for pH, COHb, HHb, tHb, tBil, Na, K, Cl, iCa, urea, glucose and lactate, and below 6.10% for all other analytes. The correlation coefficient (r) was 0.351 and ranged from 0.897 to 0.998 for all analytes. The mean bias was minimal for all analytes.

Conclusion: There was a good correlation between the Nova Stat Profile Prime Plus® and the Radiometer ABL800 FLEX® / Abbott i-STAT Chem8+® POCT analyzers. The Stat Profile Prime Plus® exhibited good precision both within-run and day-to-day.

KEY WORDS

point of care testing; POCT; emergency department; analyzers; chemistry; Nova Stat Profile Prime Plus®; Radiometer ABL 800 FLEX®; Abbot i-stat Chem8+®

INTRODUCTION

Technological advances in point-of-care testing (POCT) has revolutionized the practice of emergency medicine over recent years [1, 2]. By facilitating rapid clinical decision making and earlier targeted management of patients in the Emergency Department (ED), POCT has been shown to improve patient flow, reduce length of ED stay, decrease overall staff workload, improve patient satisfaction and reduce costs [3–5].

There has been a significant increase in the production and manufacture of POCT diagnostic devices over the last decade [6]. Prior to the implementation of new devices in the clinical environment, due consideration must be given to several factors including device validity, reliability, performance, durability, practicality, portability, ease of use, sample processing time and cost [7]. Clinical Laboratory Improvement Amendments (CLIA) regulations requires a new clinical instrument to undergo rigorous analytical method validation with respect to various performance characteristics that include accuracy, precision, linearity, range, robustness, analytical sensitivity and specificity, detection limits, quantification limits and reference intervals [8].

The Nova Stat Profile Prime Plus® is marketed as a compact maintenance free POCT biochemical analyzer that is capable of measuring a comprehensive range of biochemical analytes including blood gas parameters, electrolytes, metabolites and Co-oximetry from a single sample of blood in less than two minutes [9, 10]. In Africa and other resource-limited settings, the implementation of this or similar POCT devices may positively influence patient outcomes by facilitating early appropriate risk stratification and management decisions. In this study, the objective was to evaluate the accuracy of this device by performing a method comparison with specific analytes measured by either the Radiometer ABL 800 FLEX® or the Abbott i-STAT Chem8+® analyzer. We also evaluated the precision of the Nova Stat Profile

Prime Plus® device by investigating the within-run and day-to-day precision for various analytes.

MATERIALS AND METHODS

This was a prospective, observational, cross-sectional, comparative validation study conducted at the ED of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). CMJAH is a teaching hospital affiliated with the University of the Witwatersrand. Permission to conduct the study was obtained from the hospital manager and the clinical head of the ED. Ethics approval was granted by the Human Research Ethic Committee (Medical) of University of the Witwatersrand (certificate no. M180643). Data was collected on consecutive days between 9am and 5pm over a 2-week period (12-25 May 2019).

Table 1 describes the characteristics of the Nova Stat Profile Prime Plus®, Radiometer ABL 800 FLEX® and Abbott i-STAT Chem8+® analyzers [9–12]. Sixteen of the 21 analytes measured (pH, PCO_2 (partial pressure of carbon dioxide), PO_2 (partial pressure of oxygen), SO_2% (percentage of oxygen saturation), Lactate, O_2Hb (oxyhemoglobin), COHb (carboxyhemoglobin), MetHb (methemoglobin), HHb (deoxyhemoglobin), tHb (total hemoglobin), Hct (Hematocrit), Na (sodium), K (potassium), Cl (chloride), iCa (ionized calcium) and Glucose) were compared with those measured by the Radiometer ABL800 FLEX® analyzer, while urea and creatinine were compared with those measured by the Abbott i-STAT Chem8+® analyzer.

Table 1: Description of analyzers compared in the study [9–12]

Analyzer	FDA approval	Measured analytes	Sample type	Time to sample analysis	Minimum volume of sample required
Nova Stat Profile Prime Plus®	2018	21 measured analytes: pH, PCO_2, PO_2, SO_2, Lactate, O_2Hb, COHb, MetHb, HHb, HbF, Hct, tHb, Na, K, Cl, iCa, iMg, Urea, Cr, Glu, tBil,	Heparinized whole blood	90 seconds	135µl
Radiometer ABL 800 FLEX®	2004	18 measured analytes: pH, PCO_2, PO_2, SO_2, Lactate, O_2Hb, COHb, MetHb, HHb, HbF, tHb, Na, K, Cl, iCa^{2+}, Glu, Cr, tBil	Heparinized whole blood	80 seconds	195µl
Abbott i-STAT Chem8+®	2007	9 measured analytes: Na, K, Cl, TCO_2, iCa, Urea, Cr, Glu, Hct	Whole blood	2 minutes	95µl

PCO_2- partial pressure of carbon dioxide, PO_2- partial pressure of oxygen, SO_2- oxygen saturation, O_2Hb- oxyhemoglobin, COHb- carboxyhemoglobin, MetHb- methemoglobin, HHb- deoxyhemoglobin, HbF- fetal hemoglobin, tHb- total hemoglobin, Hct- hematocrit, Na- sodium, K- potassium, Cl- chloride, iCa- ionized calcium, iMg- ionised magnesium, Cr- creatinine, Glu- glucose, tBil- total bilirubin, TCO_2- total carbon dioxide

Prior to the initiation of data collection, staff members employed at the CMJAH ED were informed of the study aims, objectives and methodology. Consent was obtained from patients or their next of kin if the patient was unable to give consent. Daily device performance checks of all three analyzers were conducted as per manufacturer recommendations. In addition, Quality Control (QC) checks were also conducted twice daily on each of the study devices. All QC measurements were within the ±2 SD range.

A convenience sample of 150 discarded heparinized blood samples of adult patients (>18 years) who had undergone phlebotomy for routine POCT as part of their clinical management in the ED were analyzed. Samples were thoroughly mixed, and any air bubbles were removed prior to and between instrument comparisons. Paired test measurements of samples were conducted for method comparison. Accuracy was measured by pairing the individual results from the Stat Profile Prime Plus® with either the Radiometer ABL 800 FLEX® or the Abbot i-

stat Chem8+® and calculating the differences. All the results were recorded on the study data collection sheet.

Precision, which evaluates the ability of the device to produce consistent results over a period of time, can be evaluated by conducting within-run and between-run (day-to-day) measurements on quality control (QC) material. As per the Clinical Laboratory Standards Institute (CLSI) recommendations, imprecision testing should be conducted at a minimum of two levels of QC material by running at-least three replicates over five days [13, 14]. For this study, within-run imprecision (expressed as coefficient of variation [%CV]) was determined by assaying 5 replicates of commercial QC material at different levels. Whereas day-to-day imprecision (expressed as coefficient of variation [%CV]) was determined by assaying commercial QC material at different levels over 5 consecutive days. The percentage coefficient of variation (%CV) was calculated by dividing the mean from the standard deviation of replicate measurements and expressing it as a percentage. Correlation (r) between the Nova Stat Profile Prime Plus® and the corresponding reference analyzer measurements were determined and tabulated.

RESULTS

A total of 150 discarded blood samples were analysed. Within-run precision results for all analytes measured with the Nova Stat Profile Prime Plus® analyzer are summarized in table 2. Within-run %CV's were below 2.4% for pH, COHb, HHB, tHb, tBil, Na, K, Cl, iCa, Urea, Glucose and Lactate and was below 5.1% for all other analytes.

Table 2: Within-run imprecision data of the Nova Stat Profile Prime Plus® analyzer

Analytes	Level	N	Mean	SD	%CV
pH	1	10	7.22	0.00	0.03
	2	10	7.41	0.00	0.02
	3	10	7.61	0.00	0.03
pCO_2 (mmHg)	1	10	61.6	2.10	3.41
	2	10	47.0	1.61	3.54
	3	10	22.4	0.40	1.72
pO_2 (%)	1	10	59.5	1.95	3.29
	2	10	99.6	2.14	2.15
	3	10	139.5	6.68	4.79
SO_2 (%)	1	10	60.0	0.00	0.00
	2	10	86.8	2.90	3.34
	3	10	95.0	0.00	0.00
O_2Hb (%)	1	10	28.2	1.44	5.10
	2	10	57.7	0.08	0.15
	3	10	86.7	0.05	0.06
COHb (%)	1	10	24.1	0.07	0.28
	2	10	15.5	0.09	0.61
	3	10	3.7	0.03	0.85
HHb (%)	1	10	18.8	0.07	0.36
	2	10	9.7	0.06	0.59
	3	10	4.8	0.00	0.00
tHb (g/dL)	1	10	20.1	0.07	0.33
	2	10	14.7	0.15	1.06
	3	10	8.6	0.15	0.78
tBil (mg/dL)	1	10	18.7	0.05	0.25
	2	10	8.9	0.03	0.35
	3	10	3.8	0.04	1.12
Na (mmol/L)	4	10	142.4	0.42	0.32
	5	10	120.2	1.54	1.42
K (mmol/L)	4	10	3.9	0.01	0.23
	5	10	6.1	0.09	1.41
Cl (mmol/L)	4	10	126.6	0.70	0.53
	5	10	100.1	0.83	0.84
iCa (mmol/L)	4	10	1.1	0.00	0.39
	5	10	1.5	0.03	2.32
iMg (mmol/L)	4	10	0.6	0.00	3.92
	5	10	1.2	0.10	5.01
Urea (mmol/L)	4	10	6.1	0.00	0.72
	5	10	19.3	0.32	1.53
Creatinine (mmol/L)	4	10	82.6	3.91	4.82
	5	10	583.0	7.73	1.35
Glucose (mmol/L)	4	10	5.4	0.00	0.96
	5	10	16.3	0.03	1.87
Lactate (mmol/L)	4	10	2.0	0.00	0.00
	5	10	6.9	0.12	0.81

SD- standard deviation, %CV- coefficient of variation percentage, PCO_2- partial pressure of carbon dioxide, PO_2- partial pressure of oxygen, SO_2- oxygen saturation, O_2Hb-

oxyhemoglobin, COHb- carboxyhemoglobin, MetHb- methemoglobin, HHb- deoxyhemoglobin, tHb- total hemoglobin, tBil- total bilirubin, Na- sodium, K- potassium, Cl- chloride, iCa- ionized calcium, iMg- ionised magnesium

Day-to-day precision results for all analytes measured with the Nova Stat Profile Prime Plus® analyzer are summarized in table 3. The %CV was below 1.6% for pH, COHb, HHB, tHb, tBil, Na, K, Cl, iCa, urea, Glucose and Lactate and below 6.10% for all other analytes.

Table 3: Day-to-day imprecision data of the Nova Stat Profile Prime Plus® analyzer

Analytes	Level	N	Mean	SD	%CV
pH	1	10	7.20	0.002	0.01
	2	10	7.39	0.002	0.02
	3	10	7.62	0.002	0.00
pCO_2 (mmHg)	1	10	57.8	3.35	5.83
	2	10	40.9	2.25	5.43
	3	10	19.7	0.80	4.12
pO_2 (%)	1	10	54.9	1.73	2.96
	2	10	91.2	2.59	2.77
	3	10	128.0	4.82	3.61
SO_2 (%)	1	10	62.1	0.01	0.03
	2	10	84.6	3.80	3.56
	3	10	97.2	0.03	0.05
O_2Hb (%)	1	10	26.3	1.80	4.09
	2	10	61.7	0.12	0.25
	3	10	83.9	0.03	0.09
COHb (%)	1	10	26.4	0.06	0.32
	2	10	14.4	0.09	0.67
	3	10	3.9	0.04	0.82
HHb (%)	1	10	20.1	0.07	0.38
	2	10	9.4	0.08	0.61
	3	10	4.0	0.01	0.01
tHb (g/dL)	1	10	19.7	0.09	0.48
	2	10	24.3	0.18	0.90
	3	10	8.9	0.06	0.81
tBil (mg/dL)	1	10	19.9	0.06	0.28
	2	10	8.5	0.03	0.39
	3	10	4.2	0.05	1.18
Na (mmol/L)	4	10	141.2	0.16	0.11
	5	10	116.3	0.19	0.21
K (mmol/L)	4	10	3.9	0.004	0.13
	5	10	6.2	0.008	0.17
Cl (mmol/L)	4	10	128.2	1.47	1.18
	5	10	99.0	0.63	0.65
iCa (mmol/L)	4	10	1.1	0.004	0.42

	5	10	1.5	0.005	0.04
iMg (mmol/L)	4	10	0.6	0.009	1.42
	5	10	1.2	0.02	2.03
Urea (mmol/L)		10	7.3	0.13	0.92
	5	10	23.1	0.14	1.84
Creatinine (mmol/L)		10	84.3	3.34	3.97
	5	10	583.6	13.81	2.43
Glucose (mmol/L)	4	10	4.5	0.06	0.05
	5	10	15.8	0.34	1.62
Lactate (mmol/L)		10	2.0	0.00	0.06
	5	10	6.9	0.12	1.62

SD- standard deviation, %CV- coefficient of variation percentage, PCO_2- partial pressure of carbon dioxide, PO_2- partial pressure of oxygen, SO_2- oxygen saturation, O_2Hb- oxyhemoglobin, COHb- carboxyhemoglobin, MetHb- methemoglobin, HHb- deoxyhemoglobin, tHb- total hemoglobin, tBil- total bilirubin, Na- sodium, K- potassium, Cl- chloride, iCa- ionized calcium, iMg- ionised magnesium

Table 4 describes the correlation between the Nova Stat Profile Prime Plus® analyzer and the Radiometer ABL800 FLEX® / Abbott i-STAT Chem8+® analyzers. The correlation coefficient ranged between 0.898 to 0.998 for all analytes.

Table 4: Correlation data for the Nova Stat Profile Prime Plus® analyzer

Analyte	Analyzer	Minimum	Maximum	Correlation (r)
pH	Radiometer ABL800 FLEX®	6.74	7.60	0.992
	Nova Stat Profile Prime Plus®	6.71	7.59	
pCO_2	Radiometer ABL800 FLEX®	17.00	71.90	0.945
	Nova Stat Profile Prime Plus®	14.80	83.70	
pO_2	Radiometer ABL800 FLEX®	13.60	178.00	0.994
	Nova Stat Profile Prime Plus®	18.30	180.20	
SO_2	Radiometer ABL800 FLEX®	34.20	99.70	0.994
	Nova Stat Profile Prime Plus®	30.00	99.00	
Lactate	Radiometer ABL800 FLEX®	0.40	17.00	0.998
	Nova Stat Profile Prime Plus®	0.40	18.30	
O_2Hb	Radiometer ABL800 FLEX®	12.70	98.80	0.998
	Nova Stat Profile Prime Plus®	7.20	97.70	
COHb	Radiometer ABL800 FLEX®	0.20	11.30	0.909
	Nova Stat Profile Prime Plus®	0.30	10.00	
HHb	Radiometer ABL800 FLEX®	0.30	33.90	0.994
	Nova Stat Profile Prime Plus®	1.00	39.70	
tHb	Radiometer ABL800 FLEX®	4.70	19.70	0.990
	Nova Stat Profile Prime Plus®	5.30	19.90	
Hematocrit	Radiometer ABL800 FLEX®	15.00	60.20	0.935
	Nova Stat Profile Prime Plus®	16.00	58.00	
Na	Radiometer ABL800 FLEX®	111.00	165.00	0.898

	Nova Stat Profile Prime Plus®	115.50	164.00	
K	Radiometer ABL800 FLEX®	2.20	6.30	0.987
	Nova Stat Profile Prime Plus®	2.40	6.48	
Cl	Radiometer ABL800 FLEX®	80.00	124.00	0.953
	Nova Stat Profile Prime Plus®	87.40	120.90	
iCa	Radiometer ABL800 FLEX®	0.57	1.99	0.969
	Nova Stat Profile Prime Plus®	0.71	2.00	
Glucose	Radiometer ABL800 FLEX®	3.10	21.00	0.992
	Nova Stat Profile Prime Plus®	3.50	22.40	
Urea	Abbott i-STAT Chem8+®	1.00	29.80	0.982
	Nova Stat Profile Prime Plus®	1.70	30.70	
Creatinine	Abbott i-STAT Chem8+®	19.0	1030.00	0.972
	Nova Stat Profile Prime Plus®	51.0	758.00	

PCO_2- partial pressure of carbon dioxide, PO_2- partial pressure of oxygen, SO_2- oxygen saturation, O_2Hb- oxyhemoglobin, COHb- carboxyhemoglobin, MetHb- methemoglobin, HHb- deoxyhemoglobin, tHb- total hemoglobin, tBil- total bilirubin, Na- sodium, K- potassium, Cl- chloride, iCa- ionized calcium

DISCUSSION

Everyday many patients present to the ED in a critical state requiring quick decision making [5], with POCT playing a crucial role in the management of these patients. POCT testing is laboratory diagnostic testing performed at or near the site where clinical care is delivered. The key objective of POCT is to acquire rapid and accurate results thereby facilitating timeous and appropriate management [15].

Specimens sent to the central laboratory are generally subjected to prolonged delays in acquiring results. Additionally, potential alteration may occur to samples due to the instability of analyte during transport, environmental exposure, cellular metabolism and temperature variation [16]. Since POCT is initiated and performed rapidly once the sample is collected, the potential of sample deterioration is reduced.

POCT is a rapidly evolving field with an annual growth rate of 7-8%. In Africa, less than 500 laboratories fulfil the criteria for international standard requirements, while less than one laboratory professional is available for every 10 000 people [17]. A single, reliable and cost-

effective analyzer providing timely and reliable results of an expanded panel of analytes will be of value not only in low- and middle-income countries, but in any ED setting.

Recent advances in medical technology have greatly expanded the capacity of POCT systems. Modern POCT analyzers are capable of measuring an extended panel of biochemical analytes in a short period of time and wirelessly transmitting results to synchronize with electronic patient medical records [12].

The Nova Stat Profile Prime® is a POCT analyser that has been in use since 2014 and is capable of measuring and calculating 10 biochemical parameters in 60 seconds. In comparison, the Nova Stat Profile Prime Plus® was introduced in 2017, offering an expanded profile of 22 parameters with a shorter duration to complete analysis of the sample. The Nova Stat Profile Prime Plus® has individual cartridges in comparison to other POCT devices, offering a significant advantage in analyser uptime compared to combined sensor / calibrator systems [9].

In this study, the Nova Stat Profile Prime Plus® POCT analyzer was compared with other established validated analyzers in current use at the study site. We compared various blood gas parameters, electrolytes, metabolites and co-oximetry variables, most of which are essential for the management of critically ill patients in an ED setting.

Our study showed that agreement targets for all analytes were met when compared to the method of comparison. The correlation coefficient of all analytes measured ranged from 0.898 to 0.998. As per the Westgard classification, a correlation coefficient ranging between 0.90 – 1.00 can be regarded as very high, while a correlation coefficient ranging between 0.70 – 0.89 can be regarded as high [18]. Additionally, the analyte concentration directly impacts on the correlation coefficient (*r*), with a wider analyte range having a greater r value [19]. Therefore,

in this study values of *r* for all analytes were suggestive of a good correlation. Furthermore, the %CV for all the analytes tested were acceptable, indicating that the imprecision of the Nova Stat Profile Prime Plus® was minimal and in accordance with the manufacturer's specifications.

This study had few limitations. Firstly, it was not possible to obtain extremely high and low ranges for all the analytes. Secondly, although every attempt was made to process samples with minimal time delays, there is a possibility that air exposure due to slight time delays could have altered blood gas levels [20].

CONCLUSION

The Nova Stat Profile Prime Plus® correlated well with the Radiometer ABL 800 FLEX® and the Abbott i-STAT Chem8+® in both high and low ranges of the analyte. The Stat Profile Prime Plus® exhibited good precision both within-run as well as day-to-day. Hence, it can be concluded that the Nova Stat Profile Prime Plus® is a reliable device that is capable of analyzing a comprehensive panel of analytes in the ED setting.

DISCLOSURES

Human subjects: Consent was obtained by all participants in this study. University of the Witwatersrand Human Research Ethics Committee issued approval M180643. The research study has been approved unconditionally.

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue.

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following:

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REFERENCES

1. Yarmohammadian M, Rezaei F, Haghshenas, Tavakoli N: Overcrowding in emergency departments: A review of strategies to decrease future challenges. J Res Med Sci. 2017, 22:23. 10.4103/1735-1995.200277
2. Nayak S, Blumenfeld NR, Laksanasopin T, Sia SK: Point-of-care diagnostics: recent developments in a connected age. Anal Chem. 2017, 89:102-123. 10.1021/acs.analchem.6b04630
3. Murray RP, Leroux M, Sabga E, Palatnik W, Ludwig L: Effect of point of care testing on length of stay in an adult emergency department. J Emerg Med. 1999, 17:811-814. 10.1016/S0736-4679(99)00107-9
4. Bailey TM, Topham TM, Wantz S, et al.: Laboratory process improvement through point-of care testing. Jt Comm J Qual Improv. 1997, 23:362-380. 10.1016/S1070-

3241(16)30325-X

5. Fermann GJ, Suyama J: Point of care testing in the emergency department. J Emerg Med. 2002, 22:393-404. 10.1016/S0736-4679(02)00429-8
6. Point of care diagnostics market. (2019). Accessed: December 17, 2019: http://www.marketsandmarkets.com/Market-Reports/point-of-care-diagnostic-market 106829185.html.
7. 7. Vashist S: Point-of-care diagnostics: recent advances and trends. Biosensors. 2017, 7:62. 10.3390/bios7040062
8. 8. Interpretive guidelines for laboratories. (2019). Accessed: January 9, 2020: http://www.cms.gov/Regulations-and-
9. Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories. Stat Profile Prime Plus® Critical Care Analyzer. (2019). Accessed: November 20, 2019: https://www.novabio.us/uk/prime-plus/index.php.
10. K180428 - Stat Profile Prime Plus® Analyzer System. (2018). Accessed: November 21, 2019: http://www.accessdata.fda.gov/cdrh_docs/pdf18/K180428.pdf.
11. ABL800 FLEX blood gas analyser. (2020). Accessed: January 17, 2020: https://www.radiometer.co.za/en-za/products/blood-gas-testing/abl800-flex-blood-gasanalyzer.
12. CHEM8+ Test Cartridge. (2019). Accessed: January 21, 2020: http://www.pointofcare.abbott/int/en/offerings/istat/istat-test-cartridges/Chem8+.
13. Precision indicates how closely a test result is reproduced. (2020). Accessed: January 19, 2020: http://www.clinlabnavigator.com/precision.html.
14. Chesher D: Evaluating assay precision. Clin Biochem Rev. 2008, 29:S23-S26.
15. Nichols J: Point of care testing. Clin Lab Med. 2007, 27:893-908. 10.1016/j.cll.2007.07.003
16. Advantages of POCT. (2020). Accessed: March 17, 2020:

https://www.labce.com/spg1033982_advantages_of_poct.aspx.

17. Point of care testing in Africa: embrace rather than resist. (2015). Accessed: January 18, 2020: http://www.samed.org.za/DynamicData/LibraryDownloads/186.pdf.
18. Z-12: Correlation and simple least squares regression. (2000). Accessed: January 23, 2020: https://www.westgard.com/lesson42.htm.
19. Bland JM, Altman DG: Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986, 1:307-310.
20. Boonlert W, Lolekha PH, Kost GJ, Lolekha S: Comparison of the performance of point-of-care and device analyzers to hospital laboratory instruments. Point Care. 2003, 2:172-178. 10.1097/00134384-200309000-00004

RESEARCH PROTOCOL

Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-stat

Research protocol in partial fulfilment of the degree for Master of Science in Medicine (Emergency Medicine)

Dr Ali Azher Jawa

Student number: 1271287

Supervisors: Prof Abdullah Laher

Dr Muhammed Moolla

INTRODUCTION

Everyday many patients present to the emergency department (ED) in a critical state, requiring quick decision making [1]. Point of care testing (POCT) plays a crucial role in the management of these patients. POCT testing is laboratory diagnostic testing performed at or near the site where clinical care is delivered [2]. The key objective of POCT is to acquire rapid and accurate results so that appropriate management can be timeously implemented. POCT has proven to reduce hospital stay, improve adherence to treatment, improve patient flow and reduce overall morbidity [3].

Specimens sent to the central laboratory are generally subject to prolonged delays in acquiring results. Additionally, potential alteration may occur to samples due to the instability of analyte during transport, environmental exposure, cellular metabolism and temperature variations [4].

Since POCT is initiated and performed rapidly once the sample is collected, the potential of sample deterioration is reduced.

There is huge competition between companies to introduce new devices and technology into the health system. Recent advances have greatly expanded the capabilities of POCT systems, offering a growing menu of tests and results that can be wirelessly transmitted in real-time to patient's electronic medical record for physician review [2]. Advances in medical technology has made a significant contribution to the progress of modern medicine.

The Nova Stat Profile Prime® is a POCT analyser that has been in use since 2014. It is capable of measuring and calculating 10 biochemical parameters (pH, PCO2, PO2, Na, K, Cl, iCa, Glu, Lac, Hct) in 60 seconds. The Nova Stat Profile Prime Plus ® was introduced in 2017. In comparison to its predecessor, it offers an expanded profile of 22 parameters (Ph, PCO_2, PO_2, Hct, SO_2, NA, K, iCa, iMg, GLU, Lac, TCO_2, O_2Hb, COHb, MetHb, HHb, tBil, HbF, Urea, Creatinine, eGFR) and a shorter duration to complete analysis of the sample (less than 60 seconds). The Nova Stat Profile Prime Plus® has individual cartridges in comparison to other POCT devices, offering a significant advantage in analyser uptime compared to combined sensor / calibrator systems. It is capable of analysing blood gases, electrolytes, metabolites, Co-Oximetry and various calculated results from small whole blood samples [5].

Currently POCT devices such as the Radiometer ABL 800 FLEX® and the Abbott i-STAT Chem8+®, have previously been compared and validated against standard central laboratory auto-analysers. Both devices have been evaluated for precision, accuracy and utility in both the ED and laboratory settings [6].

The Radiometer ABL 800 FLEX® has been in clinical use since 2014 and is capable of measuring 18 parameters (pH, PCO_2, PO_2, SO_2, ctHb, O_2Hb, COHb, MetHb, HHb, HbF, K, Na, Ca, Cl, Glu, Lac, Creatinine, tBil) on the same blood sample. It is the only available device that is able to analyse most of the parameters that can be measured by the Nova Stat Profile Prime Plus®. The Abbott i-STAT Chem8+® is one of the pioneer POCT devices available in the market and is been currently used at the medical ED of CMJAH. Compared to its competitors, the Stat Nova Profile Prime Plus® is marketed as easier to maintain and more cost effective [5].

Accuracy and precision are key markers in evaluating a laboratory device as these devices are used for the management of critically ill patients. Accuracy can be defined as, the closeness of a measured value to a standard value. A device may be evaluated for accuracy by performing a method comparison. Method comparisons are studies comparing a new method with an already established method, to determine whether the new measurements are comparable with the current accepted standard. Paired results from the standard and comparator may be evaluated for analytical errors [7].

Precision can be defined as the closeness of agreement between independent results of measurements obtained under stipulated conditions. It is solely related to the random error of measurements and has no relation to accuracy [8]. Precision also assesses the ability of the device to repeatedly produce consistent results over a period of time. Total precision can be evaluated by obtaining within-run and between-run (day-to-day) precision. Within-run precision is defined as the closeness of agreement between the results of successive measurements obtained under identical conditions, whereas between-run precision measures result variations between different calibration runs between days. According to the Clinical and Laboratory Standard Institute (CLSI) document EP1-A2, precision claims by a

manufacturer should be tested at at-least two levels, by running three replicates over five days [9].

No significant study has been conducted thus far to compare the Nova Stat Profile Prime Plus® POCT device.

STUDY AIM AND OBJECTIVES

Study aim

The aim of this study is to compare the new Nova Stat Profile Prime Plus® POC analyser to the Radiometer ABL 800 FLEX® and the Abbott i-STAT Chem8+®.

Study objectives

- To evaluate the accuracy of the Nova Stat Profile Prime Plus® by performing a method comparison to the Radiometer ABL 800 FLEX® for the following analytes: pH, pCO2, pO2, O_2Hb, COHb, MetHb, HHb, tHb, Haematocrit, Na, K, Cl, iCa, Glucose, Lactate and to the Abbott i-STAT Chem8+® for the following analytes: Urea and Creatinine.
- To evaluate the precision of the Nova Stat Prime Plus® by investigating the within-run and between-run laboratory precision of the above test measurements.

METHODOLOGY

Study design

Prospective, observational, cross-sectional and comparative validation study.

Study site

The study will be conducted at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) ED.

Study population

The study will be conducted on consecutive patients requiring POCT laboratory analysis at the CMJAH ED, from 7 am until 5pm on consecutive days until the required number of specimens are obtained.

Inclusion criteria

All adult patients older than 18 years will be included.

Exclusion criteria

Insufficient blood sample available after routine tests are performed.

Sample size

This convenience sample will aim to include 150 discarded blood samples.

Data collection

- Data collection will commence once ethical clearance and permission has been granted from the relevant authorities to commence the study.
- All results will be recorded on the data sheets.
- Data collection sheets will be anonymous and patient identifying information will not be included on the data collection sheet.
- All data will be treated confidentially and stored in a password protected personal computer. Hard copies of the data collection sheets will be kept under lock and key.
- Discarded blood specimens will be used for this study.
- These samples will be obtained after routine POCT samples are analysed by the emergency department doctors examining the patients.
- Sample analyses will be simultaneously conducted on the Nova Stat Profile Prime Plus®, Radiometer ABL 800 FLEX® and Abbott i-STAT Chem8+® analyzers.
- All three analyzers with consumables will be sponsored/loaned by the relevant manufacturers.
- The Nova Stat Profile Prime Plus® will be configured prior to sample analyses using the set-up menu to reflect the set-up of the reference analyser.
- All blood specimen will be mixed on a rocker prior to blood analysis.
- At random intervals the consumables used on both analysers will be changed to ensure quality control and to assure appropriate maintenance.
- To ensure within-run precision, ten whole blood samples will be obtained and reanalysed at different levels.
- To ensure between-day precision, ten whole blood samples will be obtained daily and reanalysed four times a day on five consecutive days.
- The study will also check performance using the Nova Stat Profile Prime Plus® Quality Control (QC) material.

DATA ANALYSIS

Precision of the Nova Stat Profile Prime Plus® will be assessed by calculating the coefficient of variation (%CV) from the mean and standard deviation from replicate measurements. Analysis of accuracy will be based on pairing individual results from the Nova Stat Profile Prime Plus®

with the corresponding reference analyser measurement and calculating the difference. Correlation (r) between the Nova Stat Profile Prime Plus® and comparator devices will be determined for each of the variables.

ETHICS

Permission for this study will be sought from CEO of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) and head of the ED. The University of Witwatersrand Human Research Ethics Committee will be approached for ethical approval. All information gathered will be saved in a password protected computer, and only the researcher will have access to this computer.

TIMING

- Protocol preparation — April 2018
- Protocol assessment — July 2018
- Ethics application — September 2018
- Data collection — January 2019
- Data analysis — March 2019
- Writing up thesis — August 2019

FUNDING

Medhold Ltd (Kempton Park, Johannesburg, South Africa) have agreed to loan the Radiometer ABL 800 FLEX® device and sponsor the consumables. *The Scientific Group Ltd* (Randburg, Johannesburg, South Africa) have agreed to loan the Abbott i-Stat® and the Nova Stat Profile Prime Plus® devices and sponsor the consumables.

Item	Cost (Rands)
Radiometer ABL 800 FLEX® consumables	38 000

Nova Stat Profile Prime Plus® consumables	27 000
Abott i-Stat Chem8+® consumables	13 000
Total value to be sponsored	86 000

Stationery and travel costs will be borne by the researcher:

- Car Fuel R6000
- Stationery R1500

LIMITATIONS

Normal and abnormal (high & low) values will be required. However, it may be difficult to get sufficient samples at the extremities of the range.

REFERENCES

1 Fermann GJ, Suyama J. Point of care testing in the emergency department. *J Emerg Med* 2002;**22**:393–404. doi:10.1016/S0736-4679(02)00429-8

2 Point of care testing. https://www.pointofcare.abbott/int/en/about-us/benefits-of-point-of-care-testing (accessed 14 Mar 2020).

3 Murray RP, Leroux M, Sabga E, *et al.* Effect of point of care testing on length of stay in an adult emergency department. *J Emerg Med* 1999;**17**:811–4. doi:10.1016/S0736-4679(99)00107-9

4 Advantages of POCT. 2020.https://www.labce.com/spg1033982_advantages_of_poct.aspx (accessed 17 Mar 2020).

5 Stat Profile Prime Plus® Critical Care Analyzer. https://www.novabio.us/uk/prime-plus/index.php (accessed 20 Nov 2019).

6 Erickson KA, Wilding P. Evaluation of a novel point-of-care system, the i-STAT portable clinical analyzer. *Clin Chem* 1993;**39**:283–7.

7 Jensen AL, Kjelgaard-Hansen M. Method comparison in the clinical laboratory. *Vet Clin Pathol* 2006;**35**:276–86. doi:10.1111/j.1939-165X.2006.tb00131.x

8 Betz JM, Brown PN, Roman MC. Accuracy, precision, and reliability of chemical measurements in natural products research. *Fitoterapia* 2011;**82**:44–52. doi:10.1016/j.fitote.2010.09.011

9 EP15 User Verification of Precision and Estimation of Bias, 3rd Edition. https://clsi.org/standards/products/method-evaluation/documents/ep15/ (accessed 2 Apr 2020).

APPENDIX A: DATA COLLECTION SHEET

Stat Profile Prime Plus Serial no.: _____ Radiometer ABL800 Serial no.: _____ Abott i-Stat Serial No.: _____

Microsensor Card Co-oximetry Lot no.: _____ Microsensor Card BUN/Creatinine Lot no.: _____

	pH		PCO2 (mmHg)		PO2 (mmHg)		SO2 (%)		Na (mmol/L)		K (mmol/L)		Cl (mmol/L)		iCa (mmol/L)		tCO2 (mmol/L		Glu (mmol/L)		Lac (mmol/L)	
	Pr+	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**
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	Hct (%)		tHb (g/dL)		O2Hb (%)		COHb (%)		MetHb (%)		HHb (%)		HbF (%)		**tBil mmol/L**		**Urea mmol/L**		**Cr (µmol/L)**		**iMg (mmol/L)**	
	Pr+	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**ABL**	**Pr+**	**i-Stat**	**Pr+**	**i-Stat**	**ABL**	
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APPENDIX B: PATIENT INFORMATION SHEET

Good day, my name is Doctor Ali Jawa. I am a medical doctor conducting a research project for my master's degree. Thank you for taking the time to read this information sheet.

Study Title: *Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT*
Invitation to participate: I am inviting you to voluntarily take part in this research project.
Introduction: You presented to the hospital and are receiving treatment as per standard treatment guidelines. This is a study involving research and not routine care. Research is just the way we learn the answer to a question. My research project relates to Point of Care Testing (POCT) devices. In this study we want to compare a new POCT device with already validated POCT devices. POCT devices are used to obtain diagnostic results while with the patient or close to the patient. POCT devices reduce the delay in treatment as we can perform necessary tests and get results same time. They are very useful in Emergency Department (ED). The new device being compared in this study has been claimed to do more tests, consumes less time and much affordable.
What is involved in the study: Information for the study will be collected from the left-over blood of the patient. When the patient presents at ED, the blood tests are performed by the attending doctor and for that purpose the blood sample is taken. After all the tests been done only the discarded blood will be used for the study.
Benefits: The information obtained may be useful for future patients as we may then be able to perform more necessary blood tests and get the results in less time. This may also help the hospital as tests would be done on much affordable price.
Risks: It is completely safe; there is no pain, no cost on your part and no side effects or risk of any harm. Only left-over blood will be used for this study, no extra blood will be required for this study.
Confidentiality: All your information is anonymous and cannot be later linked to you. Every effort will be made to keep your information confidential.
Participation is voluntary: You may choose to withdraw from the study at any time. Your treatment will not be affected if you take part, do not take part or at any time decide you no longer want to take part in the study.
Reimbursements: There will be no money paid to you for participating in the study. The results of the study will be available to you once the study has been completed.
Ethics: This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair; Professor on 011 717-1234. The results of the study will be submitted for publication once the study has been completed.
I really appreciate your time and help if you choose to volunteer for my research project.

Please feel free to contact me if you have any questions on 0847680419 or email me: allijawa17@gmail.com

Sincerely yours
Doctor Ali Jawa

APPENDIX C: DEFERRED PATIENT INFORMATION SHEET (UNABLE TO GET NEXT OF KIN / LEGAL GUARDIAN CONSENT)

Good day, my name is. Doctor Ali Jawa. I am a medical doctor conducting a research project for my master's degree. Thank you for taking the time to read this information sheet.
Study Title: *Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT.*
Invitation to participate: I am inviting you to voluntarily take part in this research project.
Introduction: You were brought to the Charlotte Maxeke Johannesburg Academic Hospital Emergency Department on _____. At that time, you were not in a condition to volunteer to take part in this study. Now that your condition has been getting better, I would like to ask you to volunteer your information. This is a study involving research and not routine care. Research is just the way we learn the answer to a question. My research project relates to Point of Care Testing (POCT) devices. In this study we want to compare a new POCT device with already validated POCT devices. POCT devices are used to obtain diagnostic results while with the patient or close to the patient. POCT devices reduce the delay in treatment as we can perform necessary tests and get results same time. They are very useful in Emergency Department (ED). The new device being compared in this study has been claimed to do more tests, consumes less time and much affordable.
What is involved in the study: Information for the study will be collected from the left-over blood of the patient. When the patient presents at ED, the blood tests are performed by the attending doctor and for that purpose the blood sample is taken. After all the tests were done, then only the discarded blood will be used for the study.
Benefits: The information obtained may be useful for future patients as we may then be able to perform more necessary blood tests and get the results in less time. This may also help the hospital as tests would be done on much affordable price.
Risks: This study is completely safe; no cost on your part and no side effects or risk of any harm. Only discarded blood specimen will be used for required, no extra blood is required.
Confidentiality: All your information is anonymous and cannot be later linked to you. Every effort will be made to keep your information confidential.
Participation is voluntary: You may choose to withdraw from the study at any time. Your treatment was not and will not be affected if you take part, do not take part or at any time decide you no longer want to take part in the study. If you decide not to take part, your information will not be used for this study.
Reimbursements: There will be no money paid to you for participating in the study. The results of the study will be available to you once the study has been completed.
Ethics: This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234. The results of the study will be submitted for publication once the study has been completed.
I really appreciate your time and help if you choose to volunteer for my research project.

Please feel free to contact me if you have any questions on 0847680419 or email me: allijawa17@gmail.com

Sincerely yours
Doctor Ali Jawa

APPENDIX D: DEFERRED PATIENT INFORMATION SHEET (WITH NEXT OF KIN / LEGAL GUARDIAN CONSENT)

Good day, my name is Doctor Ali Jawa. I am a medical doctor conducting a research project for my master's degree. Thank you for taking the time to read this information sheet.

Study Title: *Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT.*
Invitation to participate: I am inviting you to voluntarily take part in this research project.
Introduction: You were brought to the Charlotte Maxeke Johannesburg Academic Hospital Emergency Department on _____. At that time, you were not in a condition to volunteer to take part in this study. Now that your condition has been getting better, I would like to ask you to volunteer your information. In this study we want to compare a new POCT device with already validated POCT devices. POCT devices are used to obtain diagnostic results while with the patient or close to the patient. POCT devices reduce the delay in treatment as we can perform necessary tests and get results same time. They are very useful in Emergency Department (ED). The new device being compared in this study has been claimed to do more tests, consumes less time and much affordable.
What is involved in the study: Information for the study will be collected from the left-over blood of the patient. When the patient presents at ED, the blood tests are performed by the attending doctor and for that purpose the blood sample is taken. After all the tests been done only the discarded blood will be used for the study.
Benefits: The information obtained may be useful for future patients as we may then be able to perform more necessary blood tests and get the results in less time. This may also help the hospital as tests would be done on much affordable price.
Risks: This study is completely safe; no cost on your part and no side effects or risk of any harm.
Confidentiality: All your information is anonymous and cannot be later linked to you. Every effort will be made to keep your information confidential.
Participation is voluntary: You may choose to withdraw from the study at any time. Your treatment was not and will not be affected if you take part, do not take part or at any time decide you no longer want to take part in the study. If you decide not to take part, your information will not be used for this study.
Reimbursements: There will be no money paid to you for participating in the study. The results of the study will be available to you once the study has been completed.
Ethics: This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234. The results of the study will be submitted for publication once the study has been completed.
I really appreciate your time and help if you choose to volunteer for my research project.

Please feel free to contact me if you have any questions on 0847680419 or email me: allijawa17@gmail.com

Sincerely yours
Doctor Ali Jawa

APPENDIX E: NEXT OF KIN / LEGAL GUARDIAN INFORMATION SHEET

Good day, my name is Doctor Ali Jawa. I am a medical doctor conducting a research project for my master's degree. Thank you for taking the time to read this information sheet.

Invitation to participate: Since you are the next of kin / relative of _____, I am inviting you to voluntarily take part in this research project on behalf of him / her.

Introduction: _____ (name of patient) presented to the hospital and is receiving treatment as per standard treatment guidelines. This is a study involving research and not routine care. Research is just the way we learn the answer to a question. In this study we want to learn more about the blood testing devices been used in the Emergency Department.

What is involved in the study: Information for the study will be collected from the left-over blood specimen of _____ (name of patient), who is your husband / wife / father / mother / son / daughter / other (specify): _____. When the patient presents at ED, the blood tests are performed by the attending doctor and for that purpose the blood sample is taken. After all the tests been done only the discarded blood will be used for the study

Benefits: The information obtained may be useful for future patients as we may then be able to perform more necessary blood tests and get the results in less time. This may also help the hospital as tests would be done on much affordable price.

Risks: It is completely safe; there is no pain, no cost and no side effects or risk of any harm to you or the patient. Only discarded blood will be used for the study.

Confidentiality: All information is anonymous and cannot be later linked to you or the patients. Every effort will be made to keep all information confidential.

Participation is voluntary: You may choose to withdraw him / her from the study at any time. His / her treatment will not be affected by taking part, not take part or at any time deciding to no longer want to take part in the study.

Reimbursements: There will be no money paid to you or the patients for participating in the study. The results of the study will be available to the patient once the study has been completed.

Ethics: This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234.The results of the study will be submitted for publication once the study has been completed.

I really appreciate your time and help if you choose to volunteer for my research project on behalf of _____.

Please feel free to contact me if you have any questions on 084 840 2508 or e-mail me allijawa17@gmail.com

Sincerely yours
Doctor Ali Jawa

APPENDIX F: DOCTOR / MEDICAL STAFF INFORMATION SHEET

Good day, my name is Doctor Ali Jawa. I am a medical doctor conducting a research project for my Master of Science (M.Sc.) degree. Thank you for taking the time to read this information sheet.

My research topic is entitled: *Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT.*
The aims of this study are: The aim of this study is to compare the new Nova Stat Profile Prime Plus POC analyser to the Radiometer ABL 800 and Abbott i-STAT.
Study design, population and site: This is a prospective, observational, cross-sectional and comparative validation study. The study will be conducted at the Medical Emergency Department of Charlotte Maxeke Johannesburg Academic Hospital on all adult patients older than 18 years, who present from 7am till 5pm on consecutive days until the required number of specimens are obtained.
What is required from you and your colleagues: Kindly provide me with the discarded blood specimen. No extra blood is required. Once you and your colleague have performed the tests then the discarded specimen will be analysed at relevant POCT devices.
Benefits: The information obtained may be useful for future patients as we may then be able to perform more necessary blood tests and get the results in less time. This may also help the hospital as tests would be done on much affordable price. There will be no direct benefit to you or the patient.
Risks: This study is completely safe; there is no pain, no cost and no side effects or risk of any harm to you or the patient.
Confidentiality: All information is anonymous and cannot be later linked to you or the patients. Every effort will be made to keep all information confidential.
Participation is voluntary: If you choose not to get involved in the study, kindly inform me so that I can make other plans to identify potential study subjects. Your job and our working relationship will not be affected in any way if you choose to get involved, not to get involved, or at any time decide to withdraw involvement in the study.
Reimbursements: There will be no money paid to you or the patients for participating in the study.
Ethics: This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234.The results of the study will be submitted for publication once the study has been completed.

I really appreciate your time and assistance. Please feel free to contact me if you have any questions on 0847680419 or e-mail me allijawa17@gmail.com

Sincerely yours
Dr Ali Jawa

APPENDIX G: CONSENT FORM (PATIENT)

Consent to act as a participant in research

I, _____, who is 18 years or older, consent / do not consent to participate in the research project entitled:

Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT

The procedures have been explained to me and I understand and appreciate their purpose, and the extent of my involvement.

I have read and understand the attached patient information leaflet.

I understand that the research forms part of a research project, and may not provide any direct benefit to me.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234

I am aware that my participation is voluntary, and that I am free to withdraw from the project at any time without any consequences.

_____	_____
Date	Date
_____	_____
Participant Name	Researcher
_____	_____
Participant Signature	Researcher Signature

Researcher contact details:
Cell: 0847680419
Email: allijawa17@gmail.com

APPENDIX H: CONSENT FORM (PATIENT - DEFERRED)

Consent to act as a participant in research

I, _____, who is 18 years or older, consent / do not consent for the information collected from my records thus to be used and I also consent / do not consent to continue to participate in this research project entitled:

Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT

The procedures have been explained to me and I understand and appreciate their purpose, and the extent of my involvement.

I have read and understand the attached patient information leaflet.

I understand that the research forms part of a research project and may not provide any direct benefit to me.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234

I am aware that my participation is voluntary, and that I am free to withdraw from the project at any time without any consequences.
P

_____	_____
Date	Date
_____	_____
Participant Name	Researcher
_____	_____
Participant Signature	Researcher Signature

Researcher contact details:
Cell: 0847680419
Email: allijawa17@gmail.com

APPENDIX I: CONSENT FORM (NEXT OF KIN / LEGAL GUARDIAN)

Consent from next of kin / legal representative for participant in research

I, _____, who is 18 years or older, consent / do not consent to participate in the research project on behalf of:
_____

The procedures have been explained to me and I understand and appreciate their purpose, and the extent of my involvement.

I have read and understand the attached study information leaflet.

I understand that the research forms part of a research project, and may not provide any direct benefit to me or the patient.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the chair on 011 717-1234

I am aware that participation is voluntary, and that I am free to withdraw from the project at any time without any consequences.

_____	_____
Date	Date
_____	_____
Next of kin / patient representative Name	Researcher
_____	_____
Next of kin / patient representative Signature	Researcher Signature

Researcher contact details:
Cell: 0847680419
Email: allijawa17@gmail.com

APPENDIX 1: ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Ali Azher Jawa

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180643

NAME: (Principal Investigator)	Dr Ali Azher Jawa
DEPARTMENT:	Emergency Medicine Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Comparison of the Nova Stat Profile Prime Plus point of care analyser to the Radiometer ABL 800 and Abbott i-STAT
DATE CONSIDERED:	29/06/2018
DECISION:	Approved Unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Abdullah Laher and Dr Muhammed Moolla
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	22/08/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 2: TURN-IT-IN REPORT

1271287:Comparison_Of_Nova_Stat_Profile_Prime_Plus_point_.Stat.pdf

ORIGINALITY REPORT

9%	5%	5%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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