

Implementation of Point of Care Testing in the Emergency Department of a Teaching Hospital in U.A.E

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Abstract

Background/objectives: Rapid and reliable diagnostic testing is important for clinical decision making and treatment initiation in emergency departments (ED). Point of care (POC) testing offers a unique alternative with fast, accurate and easy to use systems. The purpose of this study was to evaluate the performance and describe the implementation experience of using Abbott i-STAT Alinity point of care testing system in the emergency department of a tertiary care hospital in UAE.

Methods: Two i-STAT cartridges CG4+ (pCO₂, pH, pO₂, lactate and TCO₂) and CHEM8+ (Na, K, Cl, iCa, glucose, urea nitrogen, creatinine, hematocrit) were evaluated for precision, linearity and accuracy using aqueous solutions and blood samples (n=50). A post-training operator survey was conducted among the ED nurses to assess the level of confidence and satisfaction with the instrument and impact on patient care.

Results: Precision was high (<2% CV) for Na, K, Cl, pH, pO₂, pCO₂, ionized calcium (iCa) and satisfactory (2.1%-4.3% CV) for lactate, urea nitrogen, glucose, hematocrit and TCO₂ at all three concentrations. Linearity studies showed good linearity for the five different levels tested. Analytical ranges for all the tested analytes were within the reportable range except creatinine which was slightly higher. Findings from method comparison studies demonstrated close correlation of i-STAT Alinity results with laboratory methods. 75% of the survey participants reported high confidence with the use of i-STAT Alinity with easy connectivity to printer, extended battery life and on-screen error assistance ranking as the most satisfactory features. 100% of the responders indicated that the rapid availability and accuracy of the test results had a positive impact on the patient treatment decision and disposition, improving patient experience.

Conclusion: The study results suggest that i-STAT Alinity provides adequate precision, linearity and comparable accuracy to existing laboratory methods for blood gases and electrolytes testing. The user- friendly features, portability of the instrument and rapid results led to operator confidence and an overall positive implementation.

Keywords: i-STAT alinity; Point of care; Electrolytes; Blood gases; Operator satisfaction survey

Introduction

The last decade has witnessed significant technological advancements in diagnostic modalities enabling improved outcome of patients visiting emergency departments. To aid in clinical decision making and timely initiation of appropriate treatment, rapid and reliable investigations play a vital role. Patients seeking care at Emergency Departments (ED) are subjected to multiple investigations and evaluations often aided by central laboratories. However, the turnaround time (TAT) of these investigations varies considerably causing delay in clinical decision making and subsequent treatment initiation [1,2]. This may further contribute to the already existing challenge with overcrowding at ED. Therefore, alternatives which are rapid and easy to perform in the ED setting may help to overcome these challenges.

Point of care testing has been developed to provide rapid and accurate results in a convenient way at multiple health care settings [3,4]. This mode of evaluation is relevant in ED facilities, since it aids swift decision making by providing results with minimal turnaround

time. Point of care testing is suggested to reduce Thematic Apperception Test (TAT), patient disposition time and expedite time to treatment initiation with a possibility to improve outcomes [5-8]. Additionally, being fast helps optimal utilization of ED facilities, therefore improving quality and access to care.

ED facilities across the world are often faced with overcrowding and sub-optimal utilization. United Arab Emirates (UAE) is one of the key countries in the Gulf region of Middle East and healthcare system of UAE consists of numerous tertiary care hospitals spread across different cities with most hospitals possessing ED facilities. In UAE, the Ministry of Health and prevention (MOHAP) is the health governing body, responsible for evaluation and implementation of quality systems and standards for health care services. Currently, MOHAP ED lab services face some challenges with chemistry STAT lab testing where in spite of the labs giving the highest priority for processing, analysing and reporting STAT tests, they manage to achieve only an average of 74% of the desired target (to achieve 100% TAT in 1 hour). This could be due to pre- and post-analytic stage workflow challenges or sheer volume of STAT tests. Implementation of point of care testing may help overcome these challenges by optimizing the workflow and sharing a significant volume of STAT tests.

This study was commissioned by UAE MOHAP-Hospitals sector with the objective to evaluate performance and potential value of i-STAT Alinity point of care testing system in comparison to laboratory methods in a tertiary care hospital ED facility. This paper describes the implementation experience of using i-STAT Alinity system. Analytical validation (precision, linearity, method comparison) of two different i-STAT Alinity cartridges (CG4+ and CHEM8+) was performed and evaluated in comparison to clinical laboratory methods. A survey was conducted post operator training to assess the level of satisfaction and confidence with i-STAT usage by non-laboratory personnel.

Materials and Methods

Study setting

The study was conducted at Al Qassimi hospital, Sharjah, United Arab Emirates for a period of 5 months (August 2017-December 2017) and the study protocol was approved by MOHAP ethics committee. Al-Qassimi is the main tertiary hospital with a 230-bed capacity. It provides a wide range of medical, surgical, critical care and dental services. The Emergency Department at Al Qassimi Hospital is the main trauma centre in the region with total capacity of 33 beds, serves an average of 7000 patient/month and a total of 90,000-100,000 patient per year. ED is provided with Emergency Medicine Consultants, Specialists and general practitioners 24/7.

Methods

Two cartridges CG4+ and CHEM8+ were evaluated on i-STAT Alinity system (Abbott Point of Care, Princeton NJ, USA) for precision (reproducibility), linearity (analytical range), and method comparison (accuracy): a) CG4+ for partial pressure of CO₂ (pCO₂), pH, partial pressure of O₂ (pO₂) Lactate and Total bicarbonate (TCO₂). b) CHEM8+ for Sodium (Na), Potassium (K), Cholesterol (CL), Ionized Calcium (iCa), Glucose, Blood Urea Nitrogen (BUN), Creatinine, Hematocrit (HCT).

Comparative laboratory testing was performed on the ABL 80 Flex blood gas analyser (Radiometer, Copenhagen, Denmark) for blood gases. The Dimension RXL Max analyser was used to analyse clinical chemistry (Siemens, USA) and the Cobas 121 (Roche, Basel, Switzerland) was used for electrolytes. Sysmex XT4000i (Sysmex, Kobe, Japan) was used to determine the hematocrit concentration.

Precision and linearity studies were performed in Biochemistry department. For method comparison, blood samples were obtained from adult patients admitted to ED. Patient samples were tested on the i-STAT Alinity prior to the same sample being sent to the Biochemistry and Haematology laboratories. Samples for blood gases analysis (pH, pO₂, pCO₂, Lactate and ionized Calcium (iCa) were collected in prefilled balanced heparin blood gas syringes. For all other analytes measurements, samples were collected in standard testing vials.

Precision study

Precision analysis indicates the degree of reproducibility or repeatability of the analytical procedure. It is usually expressed as the standard deviation or relative standard deviation (coefficient of variation). In the current study, precision testing was determined using 3 concentrations of one lot of i-STAT aqueous controls for 2 days. Duplicate values for each analytes were obtained and the average values were used for analysis.

Linearity study

Linearity refers to the verification of analytical range over which the values of samples can be estimated without subjecting them to dilutions. Linearity performance of the i-STAT Alinity cartridges was determined using 5 levels of i-STAT tri controls calibration verification material on two i-STAT Alinity instruments. These calibration materials were aqueous solutions and each calibration level was run one time on each instrument. Duplicate values for each level were generated and average values are reported.

Method comparison (accuracy) study

Accuracy studies were conducted to determine the strength of correlation between the i-STAT Alinity and comparative instrument values. Patient samples (n=50) were assayed for the tested cartridge analytes on both i-STAT and comparative instruments. Duplicate values were obtained from two i-STAT Alinity instruments (one from each) and average value was used for analysis whereas single values were used from comparative instrument. Results were assessed using Deming's regression to calculate the slope, intercept and r values.

Validation reports for evaluation studies were generated using EP evaluator software version 11.3.0.23.

Training and Operator Survey: i-STAT Alinity user training was provided to all ED nurses by the Abbott team. Training sessions covered the i-STAT system, cartridge components, operation theory, QC procedures, sample handling, test performance procedures and instrument care.

A post-training operator survey was conducted to assess the level of satisfaction and confidence with i-STAT Alinity usage. The survey questionnaire was focused on operator confidence in using the instrument, familiarity with its features, the expected impact on patient care and overall satisfaction. (Appendix 1).

The respondents were asked to rate their experience on a 5-point Likert scale with 1 being the lowest level of experience and 5 being the highest. Patient management and experience was measured on 0-3 scale: 0 (did not have contact with patient), 1 (patients were inconvenienced), 2 (no difference in patient experience), 3 (patients were more engaged).

Statistical analysis

Descriptive analysis was performed using SPSS version 23. Deming regression analysis was conducted using the EP Evaluator software for the linearity and method comparison data.

Results

Results of precision, linearity and method comparison studies are summarized in Tables 1-3 Measurement of precision is expressed numerically as imprecision Standard deviation (SD) or Coefficient of Variation (CV). To verify the precision results, the observed SD value should be less than target SD value, which is calculated based on Allowable Total Error (TEa). TEa values were provided by manufacturer and were considered for calculations. Random Error budget was considered as 25% of TEa.

For example, if TEa value for chloride (Cl) is $\pm 5\%$ and observed Mean is 70.4 mmol/L, random Error is kept at 25% of TEa which is 1.25% or 1.3%. Target SD for Cl is 0.9 which is 1.3% of 70.4. All the

analytes showed good precision as observed SD values were much below than target SD (Tables 1a and 1b).

HCT and TCO₂, the % CVs were also within target % CV and ranged from 2.1-4.3 (Tables 1a and 1b).

The % CVs for all levels of Na, K, Cl, pH, PO₂, PCO₂, and ionized Ca were highly precise (<2%). For lactate, BUN, creatinine, glucose,

CG4+						
N=20	Levels (L)=x (Mean)	Obs	Target SD	Obs SD	Target CV (%)	Obs CV (%)
pH	7.058 (L1)	7.0707	0.01	0.0024	0.1	0
	7.448 (L2)	7.4533	0.01	0.0027	0.1	0
	7.692 (L3)	7.699	0.01	0.0038	0.1	0
pCO ₂ (mmHg)	59.6 (L1)	57.21	1.25	1.17	-	2
	35.6 (L2)	34.57	1.25	0.64	3.6	1.8
	21.9 (L3)	21.63	1.25	0.299	5.8	1.4
pO ₂ (mmHg)	83 (L1)	83.55	2.09	0.94	2.5	1.1
	114 (L2)	111.4	2.8	1.6	2.5	1.4
	139 (L3)	134.6	3.4	1.4	2.5	1.4
TCO ₂ (mmol/L)	20 (L1)	19.3	1	0.6	5.2	3
	28 (L2)	27.9	1	0.7	3.6	2.7
	31 (L3)	29.6	1	1	3.4	3.4
Lactate (mmol/L)	7.2 (L1)	7.133	0.214	0.036	3	0.5
	1.77 (L2)	1.765	0.152	0.025	8.6	1.4
	0.71 (L3)	0.715	0.152	0.015	21.2	2.1

CV: Coefficient of Variation; SD: Standard Deviation; Obs: Observed

Table 1a: Precision studies using Quality Control (QC) aqueous standards on the i-STAT alinity CG4 cartridge.

CHEM8+						
N=20	Levels (L)=x (Mean)	Obs Mean	Target SD	Obs SD	Target CV (%)	Obs CV (%)
BUN (mmol/L)	19.6 (L1)	19.56	0.44	0.193	2.2	1
	4.3 (L2)	4.055	0.177	0.06	4.4	1.5
	2.1 (L3)	2.185	0.177	0.049	8.1	2.2
Chloride (mmol/L)	71 (L1)	70.4	0.9	0.6	1.3	0.8
	92 (L2)	90.8	1.1	0.5	1.2	0.5
	115 (L3)	115.1	1.4	0.6	1.2	0.6
Creatinine (umol/L)	327 (L1)	331.1	12.416	5.937	3.7	1.8
	88 (L2)	89.9	6.625	1.997	7.4	2.2

	35 (L3)	39.8	6.63	1.7	16.7	4.3
Glucose (mmol/L)	14.7 (L1)	14.64	0.366	0.119	2.5	0.8
	6.5 (L2)	6.48	0.162	0.07	2.5	1.1
	2 (L3)	1.94	0.083	0.082	4.3	4.2
	17 (L1)	16.3	0.4	0.4	2.5	2.7
HCT (%)	34 (L2)	33.4	0.8	0.5	2.4	1.5
	54 (L3)	53.9	1.3	0.9	2.4	1.6
	0.86 (L1)	0.86	0.018	0.006	2.1	0.7
ICa (mmol/L)	1.25 (L2)	1.258	0.024	0.005	1.9	0.4
	1.58 (L3)	1.575	0.03	0.014	1.9	0.9
Potassium (K) (mmol/L)	2.9 (L1)	2.9	0.13	0	4.5	0
	3.8 (L2)	3.8	0.13	0	3.4	0
	6.1 (L3)	6.165	0.125	0.049	2	0.8
Sodium (Na) (mmol/L)	122 (L1)	122.2	1	0.5	0.8	0.4
	132 (L2)	131.7	1	0.6	0.8	0.4
	159 (L3)	157.6	1	0.6	0.6	0.4

CV: Coefficient of Variation; SD: Standard Deviation; Obs: Observed

Table 1b: Precision studies using Quality Control (QC) aqueous standards on the i-STAT alinity CHEM8 cartridge.

CG4+					
N=5	Observed Range (Reportable Range)	Slope	y-Intercept	Obs Error	Allowable Total Error
pCO ₂ mmHg	16.95-86.15 (15-95)	1.006	-1.683	0.556	8.0% or 5.0 mmHg
pH mmHg	6.5-7.96 (6.5-8.2)	0.996	0.037	0.003	0.04 mmHg
pO ₂ mmHg	57-392.5 (50-450)	0.94	4.631	0.731	10.0% or 5 mmHg
TCO ₂ mmol/L	11-44.5 (10-46)	1.054	-1.69	0.593	10.0% or 4.0 mmol/L
Lactate mmol/L	0.51-16 (0.5-17)	0.993	-0.011	0.007	12.0% or 0.61 mmHg

CV: Coefficient of Variation; SD: Standard Deviation; Obs: Observed

Table 2a: Linearity results for analytes measured with i-STAT Alinity CG4+ cartridges.

CHEM8+					
N=5	Observed Range (Reportable Range)	Slope	y-Intercept	Obs Error	Allowable Total Error

HCT %	10-63.5 (10-65)	1.002	-0.275	--	6.00%
BUN mmol/L	1.65-39.25 (1.4-42)	0.986	0.02	0.051	9.0% or 0.71 mmol/L
Chloride mmol/L	60-125 (60-130)	1.028	-2.872	--	5.00%
Creatinine umol/L	18-1337.5 (18-1300)	1.019	-0.252	1.716	15.0% or 26.5 umol/L
Glucose mmol/L	1.3-32.85 (1.1-35)	1.007	-0.01	0.057	10.0% or 0.33 mmol/L
iCa mmol/L	0.35-2.30 (0.25-2.5)	0.992	0.011	0.004	7.5% or 0.07 mmol/L
Potassium mmol/L	2.3-7.9 (2-8)	1.02	-0.062	0.013	0.5 mmol/L
Sodium mmol/L	100.5-172.5 (100-180)	0.978	-0.062	0.359	4.0 mmol/L

CV: Coefficient of Variation; SD: Standard Deviation; Obs: Observed

Table 2b: Linearity results for analytes measured with i-STAT Alinity CHEM8+ cartridges.

CG4+								
N=50	Study Device	Comparator Device	Result Ranges		Corr. Coeff (r)	Slope	SE* (Slope)	y-Intercept
			Comparison	i-STAT				
pCO2 mmHg			29.0-336.8	25.50-329.5	0.9823	0.998	2.05	-1.434
pH		Cobas b121	7.02-7.53	7.05-7.54	0.974	0.952	0.021	0.353
pO2 mmHg	i-STAT Alinity		31.40-90.0	28.25-89.7	0.9976	1.013	4.627	-3.698
TCO2 mmol/L		Dimension	11.00-32.0	12.0- 31.0	0.9266	1.01	1.7135	0.2482

*Standard Error: SE

Table 3a: Method comparison summaries for analytes measured with i-STAT Alinity CG4+ Cartridges.

CHEM8+								
N=50	Study Device	Comparator Device	Result Ranges		Corr. Coeff	Slope	SE* Slope	y-Intercept
			Comparison	i-STAT				
HCT %		Sysmex XT 4000i	25.0-55.0	25.5-53.0	0.9843	0.985	1.3308	-0.1894
BUN mmol/L			1.46-23.21	1.0-23.5	0.9934	1.103	0.7282	-0.4015
Chloride mmol/L			90.0-109.0	91.0-110.5	0.9261	0.998	1.4353	0.5006
Creatinine umol/L			30.0- 642.82	28.0-611.0	0.9948	1.019	11.0784	-0.0125
Glucose mmol/L			4.70-25.20	4.450-24.450	0.9967	0.978	0.3566	-0.1107
Potassium mmol/L			3.00-5.41	3.100-5.500	0.9881	0.996	0.0798	0.1102
Sodium mmol/L	i-STAT Alinity	Dimension	124.0-143.0	124.0-142.0	0.9779	0.973	0.7356	3.3645

*Standard Error: SE

Table 3b: Method comparison summaries for analytes measured with i-STAT alinity CHEM8+ cartridges.

Operator Survey

Twenty Emergency Department (ED) nurses who received training on the i-STAT Alinity system completed the operator survey. 75% of the trained ED nurses rated that they were very confident in operating the instrument and 70% rated that they were very familiar with i-STAT Alinity features. Specifically, connectivity to printer (75%), extended battery life (75%) and on-error assistance were the highest rated

features of i-STAT Alinity (Figure 1). With regard to the impact on patient care, all of the survey participant nurses (100%) reported that rapid availability and accuracy of the results from i-STAT Alinity had positive impact on patient treatment decision and disposition, improving overall patient satisfaction. Overall, 55% of the trained ED nurses were very satisfied with i-STAT Alinity rating mean overall satisfaction score 4.45 of highest possible 5.

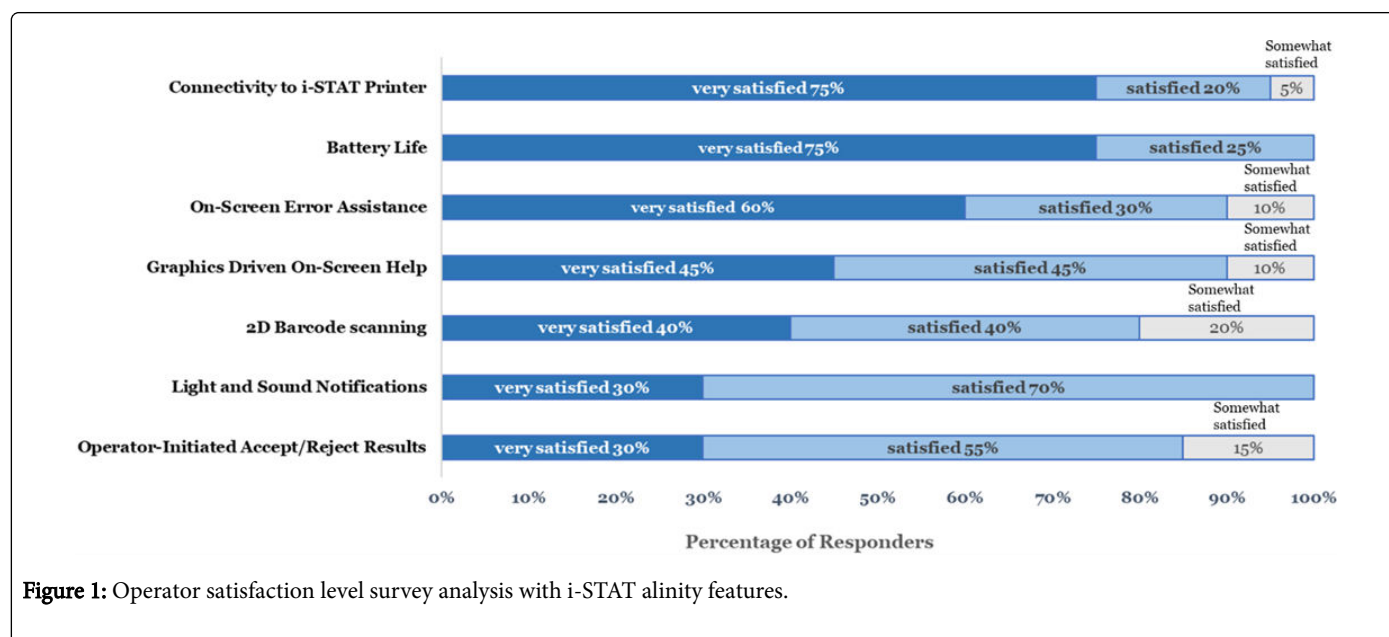


Figure 1: Operator satisfaction level survey analysis with i-STAT alinity features.

Discussion

EDs cater to a varied patient population with different disease conditions. In order to treat these patients, physicians rely on fast and accurate diagnostic test results, often provided by central laboratories. The laboratory results from the cornerstone to a successful clinical diagnosis and treatment initiation. However, the turnaround time for these laboratory results is variable and for specific investigations longer than others. Additionally, establishing such advanced technical infrastructure requires resources upfront and subsequent maintenance. As a result of these factors among others, EDs are often overcrowded or faced with situation where there is delay in clinical decision making and treatment initiation. Therefore, any effort in reducing the TAT of diagnostic tests can aid in rapid diagnosis and clinical management of patients in the ED with the potential to improve patient satisfaction, patient outcomes and optimal utilization of ED facilities. This paper describes the point of care testing implementation experience, using the i-STAT Alinity system at the Al Qassimi hospital ED.

Performance evaluation results from the current study demonstrated that i-STAT Alinity has high precision, linearity and equivalent accuracy when compared with existing laboratory methods. Our study results are in close agreement with results of other studies performed for evaluation of i-STAT [9,10]. Though, previous i-STAT studies differ in experimental design, type of cartridges and patient

population, results obtained from the present study are in concordance with earlier reports [10,11].

Precision results (%CV) displayed by i-STAT Alinity for Na, K, Cl, pH, iCa was <2 in this study which was similar to the earlier reports [10,12]. Linearity studies confirmed the analytical ranges claimed by manufacturer for all the analytes except creatinine for which observed range results were slightly higher. Results were consistent with the method comparison report by Papadea et al. Who also observed high creatinine levels in patient sample measurements using i-STAT.

Analysis of accuracy results demonstrated that i-STAT Alinity has good correlation when compared with laboratory methods. A prospective cohort study by Thomas et al. using i-STAT CG4 cartridge conducted in intubated adult intensive care unit patients has shown that i-STAT pO₂, pH and pCO₂ measurement were equivalent to laboratory methods [13]. The study observed a measure of agreement between i-STAT and laboratory blood gas values of 97% for pO₂, 88% for pH and 97% for pCO₂. In the present study, we observed a correlation of 99% for pO₂, 97% for pH and 98% for pCO₂. Observed difference in degree of correlation among studies might be attributed to different patient group and larger sample size.

One of the major obstacles to the implementation of POC testing, in addition to concerns about precision and analytical accuracy, are handling of these systems by non-laboratory health care professionals

and the potential challenges with quality control [14]. The post-operator training survey addressed this obstacle to understand user confidence and satisfaction with POC testing implementation. The survey results revealed that all the trained users were satisfied and confident with

i-STAT usage: Easy connectivity to printer to print the test results and attach to patient charts, extended battery life (easy to recharge or replace battery) and on-screen assistance which might help in reducing user errors were the most satisfactory features of i-STAT demonstrated in survey results. Survey users also reported, subjectively, that i-STAT Alinity helped in reducing treatment decision and disposition time.

The extended battery life is particularly important in developing nations, where scarcity of reliable electrical services and frequent power outages pose additional challenges to diagnostics testing. Additionally, owing to the handheld, portable nature of i-STAT Alinity, the instrument could be used in multiple triage areas within the ED, maximizing its utilization.

POC testing is easy, accurate, rapid and portable-thus making it suitable for varied healthcare settings at primary, secondary and tertiary levels. Despite this, POC testing encounters widespread implementation challenges because of changing workflow, training requirements and confidence in results leading to inertia by healthcare providers. Current study demonstrated that i-STAT Alinity system is reliable with adequate precision, linearity and accuracy when compared with laboratory methods. Further, survey results revealed that rapid results availability helped in reducing patient treatment and disposition time and easy to use features helped in achieving operator confidence and satisfaction.

The performance verification data obtained from this study was reviewed by the MOHAP regulatory team and i-STAT Alinity is now approved for clinical use in Al Qassimi hospital and rest of MOHAP facilities. Future prospective research studies directed towards evaluating the operational values of POC testing such as reducing LOS, TAT (Length of stay, turnaround time) need to be performed.

Conclusion

Results of this study have shown that i-STAT Alinity has adequate precision, linearity and comparable accuracy to existing laboratory methods.

Operator survey results have demonstrated that ED nurses were confident of using i-STAT Alinity System after a standard operator training course and believed its implementation improved patient experience and led to faster patient disposition and treatment initiation. Connectivity to the i-STAT printer to immediately print test results and attach to patient charts, integrated rechargeable battery allows it to be portable and especially useful during unreliable electrical services and on-screen help, especially for new users, were the most beneficial features of i-STAT Alinity as demonstrated through the survey results.

After reviewing the results of this study, the Ministry of Health and prevention (MOHAP), has approved i-STAT Alinity for clinical use at Al Qassimi hospital and rest of MOHAP facilities.

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