POCT-for-Scot

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Device evaluation report

i-STAT Alinity

i-STAT Chem8+ and i-STAT CG4+

by

Abbott

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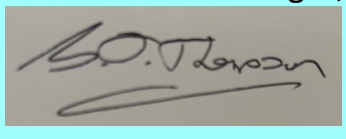
Signature: 
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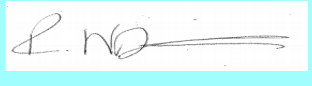
Signature: 
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1. Abstract

We evaluated the i-STAT Alinity manufactured by Abbott using the i-STAT Chem8+ and i-STAT CG4+ assays, for its ease of use within point of care settings. Testing was quick and intuitive, with a user-friendly interface. Minimal training would be required for a user to accurately perform a test and to interpret the results. The device was fully portable, and its small size would allow the device to be set-up in a clinic or a designated testing area, as well as allowing for movement between patients (bedside testing) and/or clinical areas. Testing was initially impaired by the need for the device to be at 16 °C for a test to be performed; this became a non-issue when the device was stored in a warmer environment. However, this does have implications for community use where the device may be transported in cooler environments (particularly the winter months in Scotland). POCT-for-Scot Ltd concludes that the device and the kit is fit for use as a POCT application, as advertised by Abbott.

2. Introduction

POCT-for-Scot completed a service evaluation of the i-STAT Alinity using the single use i-STAT Chem8+ and the i-STAT CG4+ cartridges (see section 3 for further cartridge details). The purpose of the evaluation was to determine the feasibility of the device for a Point of Care setting.

The i-STAT Alinity is marketed as:

'….an easy-to-use, portable blood analyzer that delivers real-time, lab-quality diagnostic test results. The i-STAT Alinity's award-winning design features a more intuitive interface that simplifies the testing process even further, allowing for minimal operator training. i-STAT Alinity is the i-STAT family's most advanced testing solution.' (https://www.globalpointofcare.abbott/us/en/product-details/apoc/istat-alinity.html accessed 19th July 2024)

The i-STAT Chem8+ cartridge is marketed as:

'With i-STAT CHEM8+, healthcare professionals can obtain chemistries, electrolytes, hematocrit and hemoglobin levels in approximately two minutes without leaving the patient's side. Incorporating i-STAT CHEM8+ early in the patient experience may help transform the delivery of care by empowering you to accelerate clinical decision-making and increase operational efficiency. The i-STAT Alinity has the capability to test a diverse range of test panels included electrolytes, hemotology, coagulation, blood gases, cardiac markers and endocrinology.'
https://www.globalpointofcare.abbott/us/en/product-details/apoc/istat-chem8.html accessed 19th July 2024)

The i-STAT CG4+ cartridge is marketed as:

'With i-STAT CG4+, clinicians may quickly assess the respiratory status of the patient or determine the presence of hyperlactatemia to inform the risk stratification of patients diagnosed with sepsis, all without leaving the patient's bedside.'
(https://www.globalpointofcare.abbott/us/en/product-details/apoc/istat-cg4plus.html accessed 19th July 2024)

There are several considerations to take into account when marketing a Point of Care device and so our evaluation served to look at those considerations on an individual basis. This would allow POCT-for-Scot to provide feedback on the services that would benefit from using the device as well as marketing recommendations based on the discovered strengths during our evaluation.

Clinical indication overview

The iSTAT Alinity measures blood gases and electrolytes and can be used in a variety of settings such as patient homes, outpatient clinics, hospitals or GP surgeries. It can be utilised to indicate metabolic or respiratory acid-base disorders, anaemia and blood loss, sepsis and renal function. Although this device is not used to provide specific diagnoses, it would be a useful tool to aid clinical decision making and would allow for appropriate placement on to a clinical pathway in a much quicker time than traditional laboratory testing.

3. Materials and Method

Materials

All materials were supplied by Abbott to POCT-for-scot as follows:

i-STAT Alinity device and kit

i-STAT Alinity device (SN 810464), electronic simulator test (SN 501191), base station (charging dock) (SN BT000259) results printer (SN PR1600531) Systems Operating Manual (version 22, revision A) and Quick Reference Guide (revision C). When not in use, the i-STAT Alinity device and kit were securely stored in the travel bag provided. The travel bag was stored at room temperature.

Note: we were originally provided with another i-STAT Alinity device which was found to be faulty. For more information, please refer to section 5 'Other considerations.'

i-STAT Chem8 + cartridges

x2 25 i-STAT Chem8 + cartridges: LOT H24156, expiry 01.12.2024, refrigerated storage (2-8 °C)
LOT H24027A, expiry 25.07.2024, refrigerated storage (2-8 °C)

The i-STAT Chem8+ cartridges tested for the following analytes:
Biochemistry/electrolytes- Sodium (Na), Potassium (K), Chloride (Cl), TCO2, Ionised Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), Creatinine (Crea)
Haematology- Hematocrit (Hct)

*Anion Gap and haemoglobin can be calculated using patient metrics.

i-STAT CG4+ cartridges

x2 25 i-STAT CG4 + cartridges: LOT M24144, expiry 20.01.2025, refrigerated storage (2-8 °C)
LOT M24023, expiry 21.09.2024, refrigerated storage (2-8 °C)

The i-STAT CG4+ cartridges tested for the following analytes:
Biochemistry- Lactate
Blood gases- pH, PCO2, PO2,
*TCO2, HCO3, Base Excess and sO2 can be calculated using patient metrics.

Test samples

i-STAT Tri Controls (QC samples)

Aqueous based sample level 1, x10 1.7 ml vials, LOT 321168, expiry 31.12.2024, refrigerated storage (2-8 °C)
Aqueous based sample level 3, x10 1.7 ml vials, LOT 321168, expiry 31.12.2024, refrigerated storage (2-8 °C)

Method

Abbott provided comprehensive hands-on training prior to the undertaking of the precision study.

A precision study was performed using 2 liquid QC samples (level 1 and level 3). The QC samples were tested using the i-STAT Chem8 + and i-STAT CG4+ cartridges conducted over 5 testing days, 5 replicate runs per day, using 1 device and 1 user. Samples were dispensed using 4-5 drops (95 uL) from a pipette. The QC samples and required number of cartridges were removed from refrigeration and allowed to come to room temperature before processing as per user instructions. Similarly, the device was used at room temperature.

The samples were processed following the written guidance provided within the user manuals and following the on-screen instructions.

Alcohol based cleaning products were used on the preparation surfaces between each sample and at the start and end of the day. The device was cleaned with a wet wipe as per instructions within the Quick Reference Guide.

4. Results

Table 1: iSTAT Chem8+ cartridge				
Analyte	**Sample**	**Mean**	**SD**	**CV%**
Na mmol/L	Level 1	123.5	0.51	0.41
	Level 3	159.6	1	0.63
K mmol/L	Level 1	3	0.05	1.6
	Level 3	6.1	0.03	0.45
Cl mmol/L	Level 1	75.8	0.97	1.28
	Level 3	112.8	0.75	0.66
iCa mmol/L	Level 1	0.85	0.01	1.09
	Level 3	1.55	0.02	1.26
Glu mmol/L	Level 1	14.5	0.1	0.66
	Level 3	2	0.06	3.23
Urea mmol/L	Level 1	20.7	0.34	1.63
	Level 3	2.5	0.16	6.3
TCo2 mmol/L	Level 1	19.24	0.72	3.76
	Level 3	28.12	0.93	3.3
Crea umol/L	Level 1	315.28	8.08	2.56
	Level 3	41.6	1.96	4.71
Hct %PCV	Level 1	20	0.61	3.06
	Level 3	54.8	0.75	1.36

CV%, coefficient of variation expressed as a percentage; SD, standard deviation.

Table 1: The results have shown that the device displayed very good precision with overall very low CV levels across most of the analytes. These are within or very close to Abbott's allowable levels of imprecision.

Table 2: iSTAT CG4+ cartridge				
Analyte	**Sample**	**Mean**	**SD**	**CV%**
PH	Level 1	7.09	0.03	0.38
	Level 3	7.67	0.01	0.14
PCO2 kPa	Level 1	6.95	0.65	9.32
	Level 3	2.69	0.08	3.13
PO2 kPa	Level 1	15.06	1.79	11.90
	Level 3	18.94	0.48	2.55
Lactate mmol/L	Level 1	6.61	0.06	0.90
	Level 3	0.76	0.03	4.37

Table 2: The results have shown that the device displayed very good precision with an overall very low CV levels across most of the analytes.

Results discussion

The levels of imprecision observed for the Chem8+ cartridges were as expected. Similar findings were seen for the CG4+ cartridge results, however the CV for PCO2 and PO2 sample level 1 were approximately 7% higher than that observed by Abbott. A potential consideration is the samples over exposure to oxygen as we used 1 QC vial per 5 repetitions. Abbott recommends that in clinical practice, a fresh QC vial should be used per test.

5. Device overview

Design

The i-STAT Alinity is a fully automated portable system, capable of laboratory standard measurements including a range of biochemistry, electrolyte, haematology, coagulation and endocrinology tests.

The T-shaped device is small (25.6cm length x 14.3cm width x 8.1cm depth) and takes up minimal space on a workbench or table. Should the full kit be used, the space required would remain minimal as the base station is marginally larger (30cm length x 15cm width) and the printer is compact (14cm length x 13cm width). The device is relatively light at 840g (out of base station) and easily held with one hand, however, the device is top heavy due to the location of the rechargeable battery, and users should hold the handle centrally to avoid tipping. Areas of contact are non-slip to mitigate the risk of dropping the device. The power button is the small, not labelled with the universal 'power-on' sign, and isn't defined by a differentiating colour, so it could be missed at first glance, however, as there are only 2 buttons on the device, finding the power button isn't difficult after it is initially identified (labelled within diagram in the user manual). The device is equipped with a 1D/2D barcode scanner, located at the top. There are no sharp edges or protrusions that could easily break, this is an important consideration for Point of Care devices as travelling may be part of the role and the device is required to be very robust.

The device can be used with a power cable via the base station or a rechargeable battery. The advantages of using the device whilst docked within the base station include hands-free results processing as well as stability (a flat and stable surface is a processing criteria). The printer can also be used with a power cable or batteries.

The device is supplied with hard copies of the user manuals and online versions can also be accessed via an Abbott i-STAT user account; registration is required.

The full kit could be stored within the travel bag and the kit remained secure when travelling due to internal secure straps. The travel bag has both a shoulder strap and a carry handle for ease of transporting. The travel bag doesn't have capacity to store a box of cartridges, however there is a zipped pocket where loose cartridges could be stored if necessary.

Useability

The i-STAT Alinity is very user-friendly and is quick to set-up and to put away. There is an additional step at set-up where an electronic simulator test is recommended to be run before each use, or if the device is dropped. The device can be programmed to 'lock' until the electronic simulator test is run each time it is switched on. The simulator test is quick and simple to perform following the on-screen instructions, we found the test to take approximately 1 minute. The simulator test provides an independent check on the device's ability to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. This would provide a user an extra level of confidence in the accuracy of the results. The electronic record simulator is stored at room temperature and the contact pads are protected from contamination via a plastic cap and a protective case. The electronic simulator is labelled with a barcode which is scanned using the device, prior to use. The barcode scanner does not require precise orientation alignment of the device and the barcode and is therefore very easy to use.

The device has a high-resolution touch screen as well as audio, colour and light cues to signal completion of tests results and when errors in processing have occurred. The font is bold, and the on-screen layout allows easy selection of the correct function. The touch is appropriately sensitive and there is no delay from touch to action. When an error does occur (e.g. insufficient sample in the sample well), on-screen resolution assistance is provided. To perform a test, on-screen instructions provide adequate pictorial and written guidance, which are easy to understand. The on-screen instructions automatically move through each step and the speed may be a little quick for a first-time user, however, the instructions can be paused whilst the user familiarises themselves with each step. The sample well on the cartridges aren't immediately obvious, however the pictorial guide ensures they are easily identifiable. The required sample size is small (95ul. approximately 4-5 drops) and a fill mark on the cartridge reduces sample size error (over or under filling). Cartridge processing time is advertised as 2 mins, however we found them to be nearer 3 mins which is still very quick.

The results display is easily interpreted, colours indicate out of range results (white if within range, yellow if out of range but below the action range, red if in the action range) and arrows signify they are above or below the lower/upper reference. Reference ranges and units are included within the on-screen presentation.

The device has a good battery life and after 3 hours of use, the battery symbol displayed half-full. When the battery life is less than 10%, a warning appears advising the user to change the battery or place the device in the docking station. The device will no longer run samples until the charge has reached a minimum of 15%. We found the battery to take 12 minutes to charge to the minimum operating battery level (from 9% charge). The device can be interfaced with a printer or data can be stored for retrieval later. Connecting to the printer was straightforward, however changing the printer paper was a challenge, due to the paper texture.

The device needs to be stored and operated at room temperature as the minimum operating temperature is 16 °C. Abbott advises that community users that travel with the device should not keep the kit in a car boot for this reason. The device does display its current temperature, so it is easy to identify how far it is from the target operating temperature. We found it took approximately 10 minutes for the device to reach 16°C from 12°C. The device gives an audible alert once it is within acceptable operating range (16 °- 30 °C). A thermal sleeve may mitigate this issue for community users who may need to travel with the device. The minimum operating temperature is unlikely to be an issue in hospital environments as wards and clinical areas are kept above 16°C.

Beyond sample collection (which would require phlebotomy certification), we feel minimal training would be required for a user to accurately perform a test. Aside from the electronic simulator test, there is no other maintenance involved with running the device, apart from keeping it clean and performing internal quality control checks, as is standard practice with all point of care devices.

Consumables: Storage and stock management

The cartridges come in small boxes and are sealed in individual portion packs. Each individual pack is labelled with a bar code which is scanned before use. The main supply of cartridges must be stored at a refrigerated temperature between 2°C to 8°C until expiration date (up to 11 months from manufacture, although this is cartridge specific and can vary). The cartridges may be also stored at room temperature (18°C to 30°C) for 14 days (Chem8+) or 60 days (CG4+), allowing for community use where access to a fridge or a constant cool temperature may be limited. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C. The individual portion packs have a space for recording the expiry date should the cartridge require storing at room temperature. Although the sample is contained within the cartridge, cartridges should be disposed of as biohazardous waste.

Sample collection: To avoid the sample clotting, Abbott recommends using heparinised blood gas sampler, capillary tubes or vacutainer tubes.

Other considerations

Troubleshooting: The first device we were supplied with was unable to process samples. We followed all the recommended steps provided on-screen and within the manuals, and we eventually emailed Abbott support services. The issue with our device was escalated very quickly, and we were assigned a designated customer assistant and again we worked through basic troubleshooting and explained potential remedial actions. As this did not solve the issue, our problem was escalated within Abbott and this is when it was determined the device was faulty. A replacement was immediately dispatched. Abbott's support services were thorough and would give confidence to potential users that they would be well supported should help be required.

Training: Abbott tailor training to the clinical and testing needs of the organisation purchasing the device. Most commonly included, is how to use the device, how the cartridges work, correct sampling techniques and troubleshooting. Training is free of charge for new users.

6. Conclusions

The i-STAT Alinity is fully portable, requires minimal hands-on interaction and has an intuitive user interface. Both the device and the cartridges have been thoughtfully designed and provide the user with practical support. We found the i-STAT Alinity to display high levels of precision, and the device has therefore demonstrated its usability in the Point of Care setting and should be considered by anyone who wishes to add a diverse range testing to their point of care repertoire.