**Ward based SOP for Abbott i-Stat**

All staff using the i-Stat must have read and understood this SOP. A copy must always be available for reference. Only staff who have received **DOCUMENTED TRAINING** (this must also be registered on ESR) are authorised to use the i-Stat. It is the responsibility of all staff that the correct procedures are followed.

**Daily procedures**

A) **Run electronic simulator test**
   1. Turn the analyser on
   2. Press the menu key to access the Administrative Menu
   3. Press the 3 key for Quality Tests
   4. Press the 4 key for Simulator
   5. Scan/enter Operator ID
   6. Scan/enter the Simulator ID (serial No)
   7. Insert the simulator in the cartridge port
   8. View results on the screen
   9. If **PASS** is displayed, continue to use the analyser
   10. If **FAIL** is displayed, re-insert the simulator and run the check again
   11. If **FAIL** is displayed a second time **DO NOT** use the analyser and contact the **POINT OF CARE TEAM**.

B) **Run patient sample**

Remove cartridge from the fridge at least 5 minutes prior to testing. Check the expiry date. Once the cartridge is removed from the fridge it is stable at room temperature for 14 days. If the cartridge is removed from the fridge but not used it is advisable to write a 14 day expiry on the pack. **Never put a cartridge back in the fridge if not used.**

**Ear lobe sample method:**

Adapted from: Wythenshawe lung function department guidelines
The paper “Arterialised ear lobe samples for blood gas Tensions” SG Spir and IR Dowdeswell.

Wearing gloves, liberally rub earlobe with thurfyl nicotinate cream (Transvasin) to dilate blood vessels and leave for 10 minutes to allow an increased blood flow to the puncture site. (This should help to produce a more arterialised sample).

1. Take the i-STAT analyser and cartridge to the patient.
2. Turn the i-STAT on using the bottom right hand button.
3. Press 2 to select i-STAT cartridge.
4. Enter operator ID by scanning the barcode present on your Trust ID badge, by pressing and holding the scan button. Analyser will bleep when barcode has been read.

5. Enter the patient's ID by scanning the patient's barcode or manually entering the case note number or patient name. If manually entering (depending on how the i-Stat is set up) you may need to do this twice.

6. Enter the cartridge lot number (located at the bottom of the individual packet).

7. The insert cartridge screen should be visible. This will remain present for 15 minutes.

8. Place the analyser on a flat surface, ready for testing.

9. Carefully remove the cartridge from the packaging, holding it at the sides only, ensuring that no pressure is exerted over the centre of the cartridge and that nothing comes into contact with the electrodes.

10. Place the cartridge next to the analyser in a convenient location.

11. Wash hands and wear apron and gloves in line with infection control procedure.

12. Clean the area from which the sample is to be taken from using an alcohol wipe, removing all of the Transvasin cream (Thurfyl nicotinate).

13. Cover the patient's shoulder with inco pad to protect clothing.

14. Support the back of the ear lobe using a bung, press the auto lancet (Unistix 3 neonatal and laboratory-Owen Mumford) firmly against the earlobe as near to the lower tip as possible and press to activate the lancet.

15. Ask the patient to tip their head to the side of the ear used. Hold a heparinised capillary tube horizontally against the forming droplets of blood. These should be taken up immediately and the blood flow should be adequate to fill the tube without squeezing the ear lobe. Blood should not be allowed to run down the earlobe before collection and bubbles of air should not be allowed to form within the capillary tube as contact with atmospheric air will affect the partial pressure of oxygen and carbon dioxide in the sample.

16. Once sampling is complete the site should be covered by gauze held in place by an ear clip.

17. Immediately transfer the sample into the cartridge well, slowly filling until the fill mark is reached. NB it is possible to under and overfill the cartridge so ensure volume is correct before entering the cartridge (sample volume 95µl).

18. Carefully fold the snap closure over the sample using the far edge, ensuring pressure isn't exerted directly over the well.

19. Holding the cartridge by its edges, introduce it in to the bottom of the analyser until it clicks into place.

20. **Do not attempt to remove the cartridge while the cartridge locked message is displayed at the bottom of the screen, this will result in expensive damage.**

21. If required, use the left and right arrow keys to scroll through results and enter extra information. The amount of oxygen the patient is using should be entered as a percentage (e.g. 21 - room air, 28 - 28%) for those on a venturi enter as litres (eg 2, 4, etc) for those on nasal cannulae, etc.
22. Results will be displayed in approx 2 minutes.
23. Once results have been displayed and cartridge locked message disappears, remove cartridge and dispose of safely.
24. Use the left and right arrow keys to scroll through results and enter extra information.
25. Make a note of the results in the blood gas record table (located in i-STAT folder) ensuring to complete all fields. Results must also be entered in the patient’s notes.
27. Remove apron and gloves and wash hands.
28. To print the results, switch the printer on, align the infra red windows on the printer and the analyser and press and hold the print button until complete.

**Arterial/ Venous / heel prick sample method:**

1. Take the i-STAT analyser and cartridge to the patient.
2. Turn the i-STAT on using the bottom right hand button.
3. Press 2 to select i-STAT cartridge.
4. Enter operator ID by scanning the barcode present on your Trust ID badge, by pressing and holding the scan button. Analyser will bleep when barcode has been read.
5. Enter the patients ID by scanning the patient’s barcode or manually entering the case note number. If manually entering (depending on how the i-Stat is set up) you may need to do this twice.
6. Enter the cartridge lot number (located at the bottom of the individual packet).
7. The insert cartridge screen should be visible. This will remain present for 15 minutes.
8. Place the analyser on a flat surface, ready for testing.
9. Carefully remove the cartridge from the packaging, holding it at the sides only, ensuring that no pressure is exerted over the centre of the cartridge and that nothing comes into contact with the electrodes.
10. Place the cartridge next to the analyser in a convenient location.
11. Clean the area from which the sample is to be taken from using an alcohol wipe.
12. Adhere to usual precautions for blood taking procedures; apron, gloves, hand washing pre/post procedure.
13. Use a Trust approved heparinised blood gas syringe to take the arterial/venous sample, or heparinised capillary for the heel prick. The sample must be mixed thoroughly to ensure the heparin is fully dispersed, ensuring the sample does not clot (Samples are stable for 10 minutes at room temperature, and must be measured within this time frame).
14. Immediately after mixing the sample, transfer into the cartridge well, slowly filling until the fill mark is reached. NB it is possible to under and overfill the cartridge so ensure volume is correct before entering the cartridge (sample volume 95µl).
15. Carefully fold the snap closure over the sample using the far edge, ensuring pressure isn’t exerted directly over the well.
16. Holding the cartridge by its edges, introduce it in to the bottom of the analyser until it clicks into place.
17. **Do not attempt to remove the cartridge while the cartridge locked message is displayed at the bottom of the screen, this will result in expensive damage.**
18. If required, use the left and right arrow keys to scroll through results and enter extra information. The amount of oxygen the patient is using should be entered as percentage (e.g. 21 - room air, 28 - 28%) for those on a venturi enter as litres (eg 2, 4, etc) for those on nasal cannulae, etc.
19. Results will be displayed in approx 2 minutes.
20. Once results have bee displayed and cartridge locked message disappears, remove cartridge and dispose of safely.
21. Make a note of the results in the blood gas record table (located in i-STAT folder) ensuring all fields are completed. Results must also be entered in the patient’s notes.
22. Dispose of any sharps and clinical waste safely.
23. Remove apron and gloves and wash hands.
24. To print the results, switch the printer on, align the infra red windows on the printer and the analyser and press and hold the print button until complete.

**Finger prick sample method:**

Please note. This finger prick method is only recommended for INR testing. The i-STAT analysers has only been assessed for the confirmation of warfarin reversal prior to theatre, and therefore **MUST NOT** be used to monitor warfarin.

It has been agreed by the Haematology Department that INR testing on the i-Stat, for confirmation of warfarin reversal prior to theatre, can be performed at **Chapel Allerton only.**

1. Take the i-STAT analyser and cartridge to the patient.
2. Turn the i-STAT on using the bottom right hand button.
3. Press 2 to select i-STAT cartridge.
4. Enter operator ID by scanning the barcode present on your Trust ID badge, by pressing and holding the scan button. Analyser will bleep when barcode has been read.
5. Enter the patients ID by scanning the patient’s barcode or manually entering the case note number. If manually entering (depending on how the i-Stat is set up) you may need to do this twice.
6. Enter the cartridge lot number (located at the bottom of the individual packet).
7. The insert cartridge screen should be visible. This will remain present for 15 minutes.
8. Place the analyser on a flat surface, ready for testing.
9. Carefully remove the cartridge from the packaging, holding it at the sides only, ensuring that no pressure is exerted over the centre of the cartridge and that nothing comes into contact with the electrodes.

10. Place the cartridge next to the analyser in a convenient location.

11. Clean the finger from which the sample is to be taken, using an alcohol wipe. Allow finger to dry thoroughly before sampling.

12. Adhere to usual precautions for blood taking procedures; apron, gloves, hand washing pre/post procedure.

Prick the finger with Trust approved lancing device. The PT/INR cartridge should be filled directly from the puncture site- no transfer device should be used. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood.

13. Touch the drop of blood against the bottom of the sample well, slowly filling until the fill mark is reached. NB it is possible to under and overfill the cartridge so ensure volume is correct.

14. Carefully fold the snap closure over the sample using the far edge, ensuring pressure isn’t exerted directly over the well.

15. Holding the cartridge by its edges, introduce it in to the bottom of the analyser until it clicks into place.

16. Do not attempt to remove the cartridge while the cartridge locked message is displayed at the bottom of the screen, this will result in expensive damage.

17. Results will be displayed in approx 2 minutes.

18. Once results have been displayed and cartridge locked message disappears, remove cartridge and dispose of safely.

19. Make a note of the results in the INR record table (located in i-STAT folder) ensuring all fields are completed. Results must also be entered in the patient’s notes.

20. Dispose of any sharps and clinical waste safely.

21. Remove apron and gloves and wash hands.

22. To print the results, switch the printer on, align the infra red windows on the printer and the analyser and press and hold the print button until complete.

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**Monthly procedures**

External Quality Control (WEQAS)

Run WEQAS samples. There are 3 ampoules to be measured each month. They must be analysed as if they were a patient, results recorded and returned to Biochemistry/WEQAS. Results are compared against results from other i-Stats across the country.
1. Ampoules must be left to reach room temperature for a minimum of 4 hours.
2. Run as a patient sample using the number on each vial as the patient ID.
3. Shake the ampoule for 15 seconds until there is visible foam.
4. Swirl the ampoule gently to return liquid to the bottom. Stand for 15 seconds to allow bubbles to rise to the top of the solution.
5. Break ampoule at neck. Immediately transfer the solution from ampoule to a capillary tube or plain syringe and then immediately transfer solution to the sample chamber of cartridge.
6. Seal the cartridge and insert into cartridge port.
7. Record results and return to WEQAS / Biochemistry Department, LGI.

**Periodic procedures**

Validate each new batch of cartridges using quality control solutions.

On receipt of a new delivery of cartridges the following checks must be done:-

1. It is essential to check that the cartridges have been delivered at the correct temperature. This can be done by viewing the blue temperature strip on the delivery note immediately after unpacking the delivery. There should be no pink colour in boxes 3 and 4. If the temperature strip is pink in these areas do not use the cartridges. Contact Abbott Customer Services to order replacement cartridges. If the cartridges have been transported at the correct temperature store immediately in a temperature monitored fridge between 2-8°C.

2. Level 1 and 3 quality control (codes 6F12-01,6F14-01) must be run on receipt of a new batch of cartridges.( For the INR testing at Chapel Allerton use PT Level 1 and 2 controls- codes 4J50-21, 4J50-22) Results must be recorded and compared against target values. All results must be within these target values.

**How to run Quality Control Solution**

Blood gas:

1. Remove QC ampoules, Level 1 and 3, and leave to reach room temperature for a minimum of 4 hours.
2. Turn on the i-STAT
3. Press the Menu key to access the Administrative Menu
4. Press 3 key for Quality tests
5. Press 1 key for Control
6. Scan/enter Operator ID
7. Scan/enter control lot number- on side of vial.
8. Scan/enter cartridge lot number-on side of packet.
9. Shake the ampoule for 5-10 seconds until there is visible foam. Break ampoule at neck. Immediately transfer the solution from ampoule to a capillary tube or plain syringe and then immediately transfer solution to the sample chamber of cartridge. Seal the cartridge.

10. Insert the cartridge into the cartridge port

11. View the results on the analyser display. Compare the results obtained with the target values and ranges on the assignment sheet. **Ensure the lot number on the sheet corresponds with the lot number of the QC used.** Record results on QC log Sheet.

12. Remove and discard the cartridge when the cartridge **locked message disappears**

13. Press the 1 key for test options on the results page and press 1 for testing another level of QC control. Repeat steps 9-13.

**PT/INR:**

Remove the vials for PT Level 1 and 2 from the fridge.

1. Allow to equilibrate at room temperature for 45 minutes.

2. Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial.

3. Replace the stopper firmly on the reconstituted control vial.

4. Allow to sit for 1 minute at room temperature.

5. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. Avoid vigorous mixing/foaming. Visually inspect to ensure the vial is fully reconstituted.

6. The sample is then ready to use.

**Limitations**

All POCT devices have limitations and this should be remembered at all times. All results need to be interpreted in the light of the patient's condition.

**Health and Safety**

Particular care should be taken to ensure that lancets, syringes and cartridges are disposed of in a sharps container.

**Troubleshooting**

Never use the i-Stat if there are concerns that it is not functioning correctly. Samples must be analysed on another gas machine or sent to the laboratory. The laboratory does possess a spare i-Stat which can be loaned. Please use contacts below for assistance.

**Clew updates**

These are sent out every 6 months to update information on the i-Stat. The Point of Care team will carry out this update and at the same time will complete a 6 monthly audit, to ensure correct procedures are being followed.
### 6 Monthly AUDIT CHECKLIST FOR i-STAT

<table>
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| Named individuals responsible for analyser and consumables  
Key trainer(s) |
| SOPs/instructions for:  
sampling  
analysis  
simulator  
QC  
ordering |
| Cartridges correctly stored  
Fridge temperature log (QC & cartridge storage) |
| Results recorded in patient record in permanent form |
| Central record of results kept |
| Membership of EQA scheme  
EQA conducted and records retained |
| **Liquid QC & simulator test** conducted according to manufacturer’s recommendation.  
QC recorded  
QC action log |
| Records kept of:  
service contract  
repairs  
software updates  
(CD) |
| Records kept of cartridge:  
orders  
storage  
usage |
| Record of trained operators with date/trainer  
Annual update training |
Contacts for Abbott i-STAT

**Point of Care Team**

LGI ext 22338

SJUH ext 64791

Wharfedale Alistair Hamilton ext 21618

**Bleeps POCT Team**

Rob Coleman - 2320
Andrew Sheppard - 2310
Rupert Smith-Moorhouse - 2311
Lindsey Riley - 1804
Rotational BMS - 1801

**Abbott**

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This SOP was prepared largely from information/SOPS provided by Tracey Hughes (Senior Physiotherapist Cystic Fibrosis, Leeds Adult CF Unit), and Yvonne Walker, Sister, Elective Orthopaedic Centre, Chapel Allerton, and Rupert Smith-Moorhouse (Biochemistry Dept).

Robert Coleman
POCT Manager
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