

28/05/2025

BY EMAIL: <u>cpuresponses@courts.vic.gov.au</u>

Coroners Court of Victoria 65 Kavanagh Street SOUTHBANK VIC 3006

Dear Ms Lancuba

Investigation into the death of Adelaide Wilson Your ref: COR 2022 000978

We refer to His Honour's Findings dated 8 April 2024.

We note the Coroner's recommendation that:

ii I recommend that CAH [**Colac Area Health**] and Australian Clinical Labs reconsider a point-ofcare testing machine whose print-out/interface contains reference ranges and other cognitive aids.

In response to the above recommendation, CAH notes as follows:

- to date, CAH has been unable to source an appropriate i-Stat machine which provides reference ranges that flag abnormal results on the machine and print out;
- on 9 March 2023, CAH introduced the enclosed MR10 Special Investigations Form. This was done to ensure clear referencing of the i-Stat report, following the successful trial of a version in 2022. All i-Stat results are now placed on this form, which provides reference ranges to aid in interpreting the report, as outlined in the i-Stat Analyser Guideline, a copy of which is enclosed; and
- further, in 2023, an escalation process was refined and included in the House Medical Officer (HMO) Handbook to obtain support from the on-call general practitioner and/or relevant specialists at Barwon Health. Additional services such as My Emergency Doctor telehealth program and the Barwon health Virtual ED are also utilised.

CAH acknowledges the responses provided by both Australian Clinical Labs (**ACL**) and Abbott Point of Care Diagnostics (**Abbott**), dated 30 April 2024 and 25 June 2024 respectively. ACL states that no point of care device is available in Australia that imbeds and produces reference ranges in reports, or provides cognitive aids to assist with result interpretation. Abbott, however, states that the i-Stat 1 analyser has the functionality to display reference ranges and flag abnormal results, and the capability to print reference ranges.

Given the differing responses from ACL and Abbott, CAH will engage in discussions with both to determine whether a point of care testing machine that complies with the Coroner's recommendation noted above can be implemented at CAH. CAH will advise the Coroner of the outcome of these discussions. If a suitable point of care testing machine is available for implementation at CAH which complies with the Coroner's above recommendation, CAH would, of course, be open to considering the implementation of same.

Alice Bennett is the relevant contact person responsible for the consideration of the recommendation.

CAH extends its sincere condolences to Mrs Wilson's family.

Yours faithfully

Alice Bennett Director of Quality and Safety Colac Area Health

Enclosures: MR10 Special Investigations Form i-Stat Analyser Clinical Guidelines dated 26 April 2023

MR 10

Special Investigations

Please place Identification Label here

PTO for i-STAT reference ranges

SPECIAL INVESTIGATIONS

BLOOD GAS REFERENCE RANGES

Clinicalabs

ANALYTE	SEX	AGE	ARTERIAL	UNITS	VENOUS	UNITES
BLOOD GASES	-	-	-	-	-	-
pН	All	All	7.35 - 7.45		7.30 - 7.40	
pCO2	All	All	35 - 46	mmHg	40 - 60	mmHg
рО2	All	All	80 - 100	mmHg	No Range	
s02	All	All	>95	%	No Range	
Base Excess	All	All	-2 - +3	mmol/L	-2 - +3	mmol/L
FO₂Hb	All	All	> 95	%	No Range	
FCOHb	All	All	< 2	%	No Range	
FMetHb	All	All	< 3	%	No Range	
FHHb	All	All	< 5	%	No Range	
CHEMISTRIES						
Sodium			135 - 145	mmol/L	135 - 145	mmol/L
Potassium			3.4 - 4.8	mmol/L	3.4 - 4.8	mmol/L
Chloride			95 - 110	mmol/L	95 - 110	mmol/L
Bicarbonate			21 - 28	mmol/L	22 - 32	mmol/L
Urea	All	5 - 15 y/o	2.5 - 7.5	mmol/L	2.5 - 7.5	mmol/L
Urea	All	15 - 50 y/o	2.5 - 8.0	mmol/L	2.5 - 8.0	mmol/L
Urea	All	50 - 60 y/o	2.5 - 8.5	mmol/L	2.5 - 8.5	mmol/L
Urea	All	60 - 70 y/o	3.0 - 9.0	mmol/L	3.0 - 9.0	mmol/L
Urea	All	70 - 80 y/o	3.0 - 10.0	mmol/L	3.0 - 10.0	mmol/L
Urea	All	80 - 90 y/o	3.5 - 11.0	mmol/L	3.5 - 11.0	mmol/L
Urea	All	> 90 y/o	3.5 - 13.0	mmol/L	3.5 - 13.0	mmol/L
Creatinine	All	< 1 y/o	10 - 30	mmol/L	10 - 30	mmol/L
Creatinine	All	1 - 5 y/o	20 - 60	mmol/L	20 - 60	mmol/L
Creatinine	All	5 - 15 y/o	30 - 90	mmol/L	30 - 90	mmol/L
Creatinine	F	> 15 y/o	45 - 90	mmol/L	45 - 90	mmol/L
Creatinine	М	> 15 y/o	60 - 110	mmol/L	60 - 110	mmol/L
Glucose	All	All	3.0 - 6.9	mmol/L	3.0 - 6.9	mmol/L
Lactate			< 1.5	mmol/L	< 2.0	mmol/L
Ionised Calcium	All	All	1.15 - 1.35	mmol/L	1.15 - 1.35	mmol/L
CARDIAC MARKERS						
Troponin	All	All	< 0.05	Ug/L	< 0.05	Ug/L
HAEMATOLOGY						
Haemoglobin	All	All	120 - 180	g/L	120 - 180	g/L
Haematocrit	All	All	35 - 51	L/L	35 - 51	L/L

Issue Date: Effective Date: Authorised by:



Document Type:	Clinical Guideline	Approved by:	Clinical Governance Committee
Department:	Nursing & Clinical Care	Section:	Urgent Care

OBJECTIVE/EXPECTED OUTCOME:

This document provides guidelines for the testing procedure using the I-Stat 300 machine.

SCOPE:

Only persons trained and have been deemed competent by Australian Clinical Labs Colac are authorised to use the I-Stat 1.

PRINCIPLES:

- The analyser is used in conjunction with single use disposable I-Stat cartridges which contain a microfabricated biosensor array, a calibration system, fluidics system and waste chamber. The system provides a range of analytes using whole blood only.
- The I-Stat system consists of the analyser, the printer, electronic simulator and the test cartridges.
- At Colac Area Health the EG7, Chem8+, PT/INR and cTnl are available.
- EG7+ cartridges test for Na, K, iCa, Haematocrit, pH, pCO2, pO2, HCO2, Urea, sO2.
- cTnl cartridge tests for Troponin I.
- Chem 8+ includes Na, K, Cl, iCa, Glu, Bun/Urea, TCo3, Crea and HcT, with AnGap and Hb as calculated values.
- The PT/INR cartridge is for PT/INR only.
- The I-Stat results should be printed and glued onto the MR 10 form which includes all reference ranges on the back.
- All I-Stat results should be shown to the Medical Officer once completed.

PROCESS:

Electronic Simulator: To be performed by Nursing Staff

The I-Stat analyser has the in-built capacity to determine electronically whether or not the analyser is working properly. It should be tested daily or if error is displayed.

- Turn the analyser on.
- Press the **M**enu key to access the Administration Menu.
- Press the **3** key for Quality Tests.
- Press the **4** key for Simulator.
- Enter Operator ID
- Scan the Simulator barcode located on the box of the simulator.
- Insert the electronic simulator into the cartridge port.
- Do not touch the contact pads on the simulator.
- Wait 2 minutes then view results on the analysers screen and complete I-Stat log (NB: Please use the Bio-Abbott I-Stat Maintenance Log provided with the Abbott I-Stat manual).
- If PASS is displayed, continue to use the analyser.
- If FAIL is displayed for the external simulator, repeat the electronic check.
- If FAIL is displayed for a second time, the I-Stat CANNOT be used until it passes the daily maintenance.
- Contact a scientist at Australian Clinical Labs Geelong. 5225 1180

New Cartridges:

Quality Controls for each new lot are performed by Pathology Scientist prior to use.

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SPECIMEN COLLECTION:

TITLE: I-STAT ANALYSER

- Lithium heparin (Green top)tubes or syringes should be used for blood gas analysis.
- For troponin analysis the tube must be filled at least half-filled and thoroughly mixed by gently inverting the tube.
- Plain syringe or finger prick must be used to test PT/INR. (*INR need to be tested within* 30 seconds of obtaining the sample)

PROCEDURES

Cartridges at room temperature must be used within 14 days for troponins and Chem-8 and 2 months for EG7+

- Turn on I-Stat
- Select 2 from menu for new cartridge
- Enter operator ID
- Scan specimen barcode.
- Scan cartridge barcode (entering the number manually is no longer working)
- Remove cartridge from packet, handle by sides, do not touch centre of cartridge. (Troponin cartridge must not be opened before it is scanned.)
- Mix syringe of blood thoroughly by rolling in the palms of hands. Expel first two drops of blood into waste.
- Run blood into well of cartridge until the fill mark is reached. Ensure I-STAT is on a flat service.
- Fold snap cover over using clear side of cover, without pressing the middle. Mop up any excess blood with a tissue.
- Insert cartridge into analyser. DO NOT try to remove cartridge until the result is displayed. Analyser must not be moved while running a test. The cartridge is locked until end of test. Please check display for instruction to remove cartridge.
- Align sensor on I-stat with sensor on printer. Print 2 copies of results. When printing copies, press paper feed before tearing off allowing space for patients BRADMA label. If machine has gone into sleep mode turn on, press 1 for last result and print as above.
- Apply one specimen barcode to top left hand corner of pathology request slip. Handwrite patient's name and DOB, and name of staff member completing the test. *When performing ABG's, make note of 02L/min the patient is currently on.*
- Place BRADMA label below test results. Attach one copy to MR 10, Special Observation Sheet for medical record, and attach second copy to Pathology request form and leave in box provided. These are then sent to ACL.
- Compete details in I-Stat book in UC

CARTRIDGE FAILURE

If an error message appears on screen -

- Record cartridge lot number and name of staff member completing the test.
- Dispose of failed cartridge
- Complete the I-Stat record of use form indicating 'failed test'.
- Repeat the test using the same specimen barcode.

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I-STAT Quick Reference for nursing staff;

- 1. Ensure you have request form from MO
- 2. 4 patient ID Labels (Bradma)
- 3. Green topped tube or blood gas syringe (plain syringe for INR)
- 4. Cartridge
- 5. Ensure I-Stat is on a flat service
- 6. Staff login ID Number
- 7. Scan pathology barcode (single stickers available in UC and placed on path form)
- 8. Scan cartridge barcode
- 9. Discard first few drops of blood
- 10.Immediately fill cartridge, careful not to overfill and put any blood into I-Stat machine
- 11.Insert cartridge into I-Stat machine
- 12.Pathology barcode to be placed on top left corner of path request form
- 13.Complete I-Stat book/record details
- 14. Print result strip, advance the printing to enable attachment of patient bradma (2 copies)
- 15.Complete other details on result strip ie; name of operator, date, time
- 16.Glue test strip to MR10
- 17.Staple result strip to request slip; send to pathology
- 18.Whilst cartridge is calculating result, keep I-Stat machine still
- 19.New Cartridge = New pathology bar code

RESULTS

Reference Ranges

TEST	UNITS	REPORTABLE RANGE (I-Stat)	REFERENCE RANGE	
			(Arterial)	Venous
Na	mmol/L	100 - 180	135 - 145	135 -145
К	mmol/L	2.0 - 9.0	3.4 - 4.8	3.4 - 4.8
рН		6.5-8.2	7.35 - 7.45	7.30-7.40
pCO2	mmHg	5 - 130	35 - 46	40-60
PO2	mmHg	5 - 800	80 - 100	No Range
iCa	mmol/L	0.25 – 2.5	1.15 - 1.35	1.15 - 1.35
Glu	mmol/L	1.1 - 38.9	3.0-6.9	3.0 - 6.9
HCO3*	mmol/L	1 - 85	21 - 28	22-32
Beecf*	mmol/L	(-30) - (+30)	(-2) - (+3)	(-2) - (+3)
s02*	%	0 - 100	>95%	No Range
Troponin	Ng/ml		<0.05	

REFERENCES:

- 1. Abbott: i-STAT 1 Userguide, 2006
- 2. NSQHS Standards 5.2.2, 5.3.1, 5.4.1, 5.5.1, 5.5.3, 6.2.1
- 3. Bio STA Abbott I-STAT Manual (BIO-STA-004), Australian Clinical Labs

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DOCUMENT DEVELOPMENT/REVIEW PROCESS

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