SALINE INFUSION TEST (SIT) IN THE INVESTIGATION OF PRIMARY ALDOSTERONISM (PAL) IN AMBULATORY CARE UNIT (ACU) - ST GEORGE HOSPITAL

1. Purpose	A guide to assist staff in performing saline infusion test for the investigation of Primary Aldosteronism (PAL) in the Ambulatory Care Unit
2. Risk Rating	Medium
3. National Standards	1 – Clinical Governance 3 – Infection Prevention and Control 4 – Medication Safety 5 – Comprehensive Care
4. Employees it Applies to	Registered Nurses who have read this document and have a clear understanding of procedure requirements. Medical Officers

5. PROCESS

BACKGROUND INFORMATION

- SIT is used to determine whether patients with elevated aldosterone to renin ratio (greater than 70) have autonomous aldosterone production, as part of the investigations for suspected primary aldosteronism (PAL).
- Aldosterone is produced by the adrenal glands, normally under the regulation of angiotensin 2 and the serum potassium concentration. Angiotensin 2 and potassium both stimulate aldosterone production (hypokalaemia suppresses aldosterone).
- In the condition known as primary aldosteronism, the adrenal gland produces aldosterone independently (autonomously), with little regulation by angiotensin 2 or potassium. Excess aldosterone circulating in the blood leads to hypertension by the reabsorption of sodium and water from the kidney.
- The SIT is one of the ways of determining whether the adrenal glands are indeed autonomous (ie abnormal) or normal. The intravenous infusion of 2 litres of saline would normally switch off renin secretion from the kidneys, and a lack of renin leads to reduction in angiotensin 2 and therefore reduction in aldosterone. This would be a normal response and hence the aldosterone level should fall after 2 litres of saline.

5.1 INDICATIONS

- The saline infusion test (SIT) is indicated as a diagnostic tool for primary aldosteronism in the presence of:
    - Hypertension with unexplained hypokalaemia / metabolic alkalosis
    - Resistant hypertension (with or without unexplained hypokalaemia).
    - As part of secondary hypertension screen.
- The initial screening includes two elevated resting plasma aldosterone/ renin ratios.

5.2 REFERRAL FOR TREATMENT

- Patients requiring the SIT test as screening for PAL in the ACU must be referred to the unit in accordance with SGH CLIN166 *Ambulatory Care Unit - Referrals and Process For Administration Of Medications And Treatments*
- All referrals are to be made on the approved ACU referral form (SES010.413) or via eMR.

5.3 PRIOR TO THE SIT INVESTIGATION

- Patients must withdraw (or reduce if not possible to withdraw) from beta blockers (where there is no coexistent ischaemic heart disease), diuretics, ACE inhibitors and vasodilators, as ordered by the treating medical officer. A minimum of 4 weeks off interfering medications is recommended. Suitable replacement drugs include Prazosin, Calcium channel blockers, and Hydralazine. The nephrology service can be consulted to assist with blood pressure management during withdrawal of usual antihypertensives (the decision to consult is at the discretion of the treating medical officer and is not required for all patients).
- Serum potassium should be checked within two months of the test and should be at least 3.6mmol/L prior to the test being undertaken. Potassium supplements may be required for patients with serum potassium of 3.5mmol/L or lower.
- If a family history of primary hyperaldosteronism is found, patients should be screened for the disorder 'FH-1' (familial aldosteronism type – 1 OR glucocorticoid remediable aldosteronism) by collecting blood (in 2 x 4mL EDTA tube) to test for the presence of the hybrid FHI gene. At present this is sent to a laboratory in Queensland (Prof M Stowasser).

5.4 SIT INVESTIGATION PROCEDURE

5.4.1 Pre-infusion

- Confirm that the patient has an understanding of the procedure as per NSW Health IB2020_010 *Consent to Medical and Healthcare Treatment Manual* and SGH CLIN677 *Capacity - Decision making capacity in adults (≥ 16 years of age) - assessing* and has been out of bed for at least 2 hours.
- Position the patient on a chair WITHOUT elevation of their feet.
- A complete set of baseline observations are to be documented pre-procedure in patient record.
- Establish intravenous access as per NSW Health PD2019_040 *Intravenous Access Devices (IVAD) – Infection Prevention and Control*. Difficult intravenous access management must be in accordance with SGH CLIN691 *Peripheral Intravenous Cannulation (sterile insertion) – clinically indicated dwell time for DIVA*.
- Collect blood after the patient has been seated for 10 minutes, without the use of a tourniquet on the arm if possible to avoid falsely high plasma potassium levels. Alternatively, wait for 5 seconds after tourniquet release to insert the needle.
- Blood is tested for plasma renin and aldosterone concentration, as well as plasma sodium, potassium, cortisol, and creatinine levels. You will need 1x EDTA purple tube and 1x yellow top tube.
- If a family history of primary hyperaldosteronism is found, patients should be screened for the disorder 'FH-1', by collecting blood samples (in 2 x 4mL EDTA purple tube). At present this screening blood test is sent to a laboratory in QLD for attention of Prof M Stowasser (See **Appendix 1**).
- The patient should empty their bladder just prior to the procedure.

5.4.2 During the infusion

- Administer TWO litres 0.9% sodium chloride intravenously over four hours, as ordered by a Medical officer via the Adult Fluid order form (SMR120.003) or eFluids as per approved departmental processes.
- Inform the patient that they can eat, drink and use the bathroom if required during the procedure. Minimal standing is requested.
- A complete set of baseline observations are to be completed and documented two hours following infusion commencement.

5.4.3 Post infusion

- Blood is collected and tested for renin, aldosterone and cortisol at the completion of the infusion from a **separate peripheral venous site.** You will need 1x EDTA purple tube and 1x yellow top tube.
- Blood needs to be kept at room temperature (no ice) and transferred to the laboratory. In the laboratory, blood is spun at room temperature, then snap frozen in ethanol/ dry ice prior to assay. (**See Appendix 2**)
- A complete set of baseline observations are to be documented post-procedure in patient record

5.5 INTERPRETATION OF TEST RESULTS

- A normal result is where the aldosterone concentration suppresses below 170 pmol/L.
- A positive result is where aldosterone does not suppress below the above cut off, confirming autonomous production of aldosterone and a diagnosis of PAL.

5.6 PREPARATION, ADMINISTRATION AND DOCUMENTATION

- All medications must be prepared and administered in accordance with the five rights as per NSW Health PD2013_043 *Medication Handling in NSW Public Health Facilities* *and* SGH-TSH CLIN115 *Medications – Intravenous Medications, Therapy and Additives*
- Labelling to occur as per NSW Health PD2016_058 *User-applied Labelling of Injectable Medicines, Fluids and Lines*
- Document on the National Inpatient Medication Chart (NIMC) as per Australian Commission on Safety and Quality in Healthcare *National Inpatient Medication Chart (NIMC) – Local Management Guidelines*
- Adverse drug reaction (ADR) history and new ADRs during an episode of care must be documented as specified in SESLHDPR/267 *Medicine: Continuity of Management and Documentation*

6. Cross References	NSW Health PD2013_043 *Medication Handling in NSW Public Health Facilities* NSW Health IB2020_010 *Consent to Medical and Healthcare Treatment Manual* NSW Health PD2019_040 *Intravenous Access Devices (IVAD) – Infection Prevention and Control* SGH CLIN691 *Peripheral Intravenous Cannulation (sterile insertion) – clinically indicated dwell time for DIVA*. SGH CLIN166 *Ambulatory Care Unit - Referrals and Process For Administration Of Medications And Treatments* SGH CLIN677 *Capacity - Decision making capacity in adults (≥ 16 years of age) - assessing*
7. Keywords	Saline Loading, Saline Infusion Test, Primary Aldosteronism, Hypertension
8. Document Location	Ambulatory Care Unit
9. External References	1. Saline Loading in the Investigation of Primary Aldosteronism (PAL) policy. Location: St George Hospital Intranet Site. Accessed 11th March 2022.

	2. Monash Health Protocol for Seated Saline Suppression Test (SSST) – extracted from the full Monash Health Primary Aldosteronism Diagnostic Protocol. Modified for seated SST on 6th May 2019. 3. Funder JW, Carey RM, Fardella C, Gomez-Sanchez CE, Mantero F, Stowasser M, Young WF, Jr., and Montori VM. Case Detection, Diagnosis, and Treatment of Patients with Primary Aldosteronism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2008;93(9):3266-81.
10. Consumer Advisory Group (CAG) Approval	Not Applicable
11. Aboriginal Health Impact Statement	The Aboriginal Health Impact Statement does not require completion because there is no direct or indirect impact on Aboriginal people as the process is the same for all adults. Approval: T22/xxxx
12. Implementation and Evaluation Plan	**Implementation:** The document will be published on the SGH-TSH business rule webpage and distributed via the monthly SGH-TSH CGD report. ACU staff will be advised of updated CBR at ward meetings and inservices as appropriate. **Evaluation:** Compliance will be monitored by individual case review.
13. Knowledge Evaluation	**Q1:** When are bloods to be taken on the patient? *A1:* Prior to saline infusion when patient has been seated for 10 minutes and at the completion of the infusion. **Q2:** What is the quantity of saline infused and the time frame that it is to be administered over? *A2:* Two litres of saline administered intravenously over 4 hours. **Q3:** What drugs does a patient need to withdraw from before the saline infusion test is commenced? *A3:* Beta blockers (where there is no coexistent ischaemic heart disease), diuretics, ACE inhibitors and vasodilators, as ordered by the treating medical officer.
14. Who is Responsible	Divisional Director Aged & Integrated Care

Approval for: **SALINE INFUSION TEST (SIT) IN THE INVESTIGATION OF PRIMARY ALDOSTERONISM (PAL) IN ACU – SGH**	
Nurse Manager (SGH)	Helen Logounov, Divisional Director Aged and Integrated Care Date: 01.04.2022
Medical Head of Department (SGH)	Prof George Mangos, Head of Department of Renal Medicine Date: 21.03.2022
Safe Use of Medicines Committee (SGH)	Chairperson: A/Prof Winston Liauw Date: 09.05.2022
Executive Sponsor	Prof George Mangos, Head of Department of Renal Medicine Date: 21.03.2022
Contributors to ClBR	**Contribution**: Meera Kannan, CNE ACU, OPD, HiTH, SGH Prof Mangos, Staff Specialist Nephrology, SGH Dr Brendan Smyth, Staff Specialist Nephrology, SGH
	Consultation: Charlotte Bryant, NUM ACU, OPD, HiTH & CTAC, SGH Dr Parthasarathy Shanmugasundaram, Staff Specialist Nephrology, SGH

Revision and Approval History

Revision Date	Revision number	Reason	Coordinator/Author (Position)	Revision Due
Oct 2012	0		J. Burgess, CNC Ambulatory Care Unit - SGH	Oct 2015
Dec 2015	1		Kerrie Thomas, Clinical Nurse Consultant, Ambulatory Care Unit & Outpatients Department	Dec 2018
Jan 2019	2		Kerrie Thomas, Clinical Nurse Consultant, Ambulatory Care Unit & Outpatients Department	Jan 2022
Apr 2022	3	Review. Test name changed and positioning requirements updated.	Julia Earnshaw, A/CNC Ambulatory Care Unit, Outpatients Department & Hospital in the Home	Apr 2025

General Manager's Ratification	
Angela Karooz (GM SGH)	Date: 27.04.2022

APPENDIX 1: Example of pre-screening pathology form

SOUTH EASTERN AREA LABORATORY SERVICES
Excellence in diagnosis, research, teaching
www.seals.health.nsw.gov.au
Phone 1800 073 257

NSW GOVERNMENT Health Pathology
NSW Health Pathology; APA 1142
SEALS Executive
Level 4 Campus Centre
Barker Street
Randwick NSW 2031

SAMPLE ONLY

PATIENT DETAILS
Med. Rec. No: .... Ward: ....
Hospital: ....
SURNAME: ....
FIRST NAME: ....
DOB: ....../....../...... Sex: ....
Address: .... Phone: ....
.... Postcode: ....

TESTS REQUESTED
ROUTINE: **Prior to saline infusion**

Hybrid FHI gene test - to test for familial aldosteronism type – 1 /glucocorticoid remediable aldosteronism

Renin
Aldosterone
EUC
Cortisol

(2x 4mL EDTA tubes to be sent to Prof M Stowasser in Queensland)

3x EDTA (purple), 1x serum gel (yellow)

URGENT:

"LIFE THREATENING" MUST CALL LAB Tick ☐

CONSULTANT: ....
REQUESTING PRACTITIONER:
Surname: .... Initials: ....
Phone: .... Fax: .... Pager No: ....
Address: ....
Postcode: ....
Signature .... Date ....

COPY OF REPORT TO:
Name: ....
Address: ....
Postcode: .... Phone/Fax: ....
COPY OF REPORT TO:
Name: ....
Address: ....
Postcode: .... Phone/Fax: ....

DO NOT USE THIS FORM FOR BLOOD BANK or TRANSFUSION REQUESTS

CLINICAL NOTES Pregnant: Yes ☐ No ☐ SD ☐

Medication: Date/Time of last dose: Dosage:

GYNAECOLOGICAL CYTOLOGY
Post Menopausal ☐ Pregnant ☐ Post Natal ☐
IUCD ☐ Abnormal Bleeding ☐ Radiotherapy ☐
Chemotherapy ☐ Hormones ☐
L.M.P. ....../....../......
NSW PAP TEST Register YES ☐ NO ☐ (If no, attach official sticker)

Your doctor has recommended that you use SEALS Pathology. You are free to choose your own pathology provider. However, if your doctor has specified a particular pathologist on clinical grounds, a Medicare rebate will only be payable if that pathologist performs the service. You should discuss this with your doctor.

Name of APP: ....

HOSPITAL STATUS Was or will the patient be, at the time of the service or when the specimen is obtained (please tick):
(a) a private patient in a private hospital or approved day hospital facility Yes ☐ No ☐
(b) a private patient in a recognised hospital Yes ☐ No ☐
(c) a public patient in a recognised hospital Yes ☐ No ☐
(d) an outpatient of a recognised hospital Yes ☐ No ☐

MEDICARE ASSIGNMENT: Medicare ☐ Vet Affairs ☐ REF

SAMPLE ONLY

Medica... (S...on ...the ...rance ...973). I offer to assign my right to be... the approved pathology ... who ...nder the requested pathology service(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.

Patient Signature: .... Date: ....../....../......

Practitioner's use only (Reason why patient cannot sign)

CONFIRMATION OF PATIENT DETAILS
I confirm that patient details on this request and on all specimens collected are correct.

Patient/Carer's Signature: ....

COLLECTOR DECLARATION
I certify that I collected the accompanying specimens from the above patient, whose identity was confirmed by enquiry and/or examination of their name band and that I labelled the specimens immediately following collection.

Collector's Name: .... Signature: ....

Collection Date: ....../....../...... Collection Time: .... Sample Type/Site: .... Fasting: Yes / No CSR Initial: ....

S-Gel	Serum	LiHep	Grey	EDTA	Coag	ESR	Blood Gas	Blood Culture	Urine	Fluid	Swab	Viral	CSF	Histo	Cyto	Pap	Stool	Sput	pLiHep	pSerum	pEDTA	pGrey	pCoag	Other

APPENDIX 2: Example of post-screening pathology form

SOUTH EASTERN AREA LABORATORY SERVICES
Excellence in diagnosis, research, teaching
www.seals.health.nsw.gov.au
Phone 1800 073 257

NSW Health Pathology
NSW Health Pathology; APA 1142
SEALS Executive
Level 4 Campus Centre
Barker Street
Randwick NSW 2031

SAMPLE ONLY

PATIENT DETAILS
Med. Rec. No: .... Ward: ....
Hospital: ....
SURNAME: ....
FIRST NAME: ....
DOB: ...... / ...... / ...... Sex: ....
Address: .... Phone: ....
.... Postcode: ....

DO NOT USE THIS FORM FOR BLOOD BANK or TRANSFUSION REQUESTS

CLINICAL NOTES Pregnant: Yes ☐ No ☐ SD ☐

Medication: Date/Time of last dose: Dosage:

TESTS REQUESTED
ROUTINE:

After saline infusion

Renin
Aldosterone
Cortisol

1x EDTA (purple), 1x serum gel (yellow)

URGENT:

"LIFE THREATENING" MUST CALL LAB Tick ☐

GYNAECOLOGICAL CYTOLOGY
Post Menopausal ☐ Pregnant ☐ Post Natal ☐
IUCD ☐ Abnormal Bleeding ☐ Radiotherapy ☐
Chemotherapy ☐ Hormones ☐
L.M.P. ...... / ...... / ......
NSW PAP TEST Register YES ☐ NO ☐ (If no, attach official sticker)

Your doctor has recommended that you use SEALS Pathology. You are free to choose your own pathology provider. However, if your doctor has specified a particular pathologist on clinical grounds, a Medicare rebate will only be payable if that pathologist performs the service. You should discuss this with your doctor.

Name of APP: ....

HOSPITAL STATUS Was or will the patient be, at the time of the service or when the specimen is obtained (please tick):
(a) a private patient in a private hospital or approved day hospital facility Yes ☐ No ☐
(b) a private patient in a recognised hospital Yes ☐ No ☐
(c) a public patient in a recognised hospital Yes ☐ No ☐
(d) an outpatient of a recognised hospital Yes ☐ No ☐

CONSULTANT: ....
REQUESTING PRACTITIONER:
Surname: .... Initials: ....
Phone: .... Fax: .... Pager No: ....
Address: ....
Postcode: ....
Signature .... Date ....

SAMPLE ONLY

MEDICARE ASSIGNMENT: Medicare ☐ Vet Affairs ☐ REF

Medicare ... (1973). I offer to assign my right to benefits to the approved pathology practitioner who will render the requested pathology service(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.
Patient Signature: .... Date: ...... / ...... / ......

Practitioner's use only (Reason why patient cannot sign)

COPY OF REPORT TO:
Name: ....
Address: ....
Postcode: .... Phone/Fax: ....
COPY OF REPORT TO:
Name: ....
Address: ....
Postcode: .... Phone/Fax: ....

CONFIRMATION OF PATIENT DETAILS
I confirm that patient details on this request and on all specimens collected are correct.
Patient/Carer's Signature: ....

COLLECTOR DECLARATION
I certify that I collected the accompanying specimens from the above patient, whose identity was confirmed by enquiry and/or examination of their name band and that I labelled the specimens immediately following collection.

Collector's Name: .... Signature: ....

Collection Date: ...... / ...... / ...... Collection Time: .... Sample Type/Site: .... Fasting: Yes / No CSR Initial: ....

S-Gel	Serum	LiHep	Grey	EDTA	Coag	ESR	Blood Gas	Blood Culture	Urine	Fluids	Swab	Viral	CSF	Histo	Cyto	Pap	Stool	Sput	pLiHep	pSerum	pEDTA	pGrey	pCoag	Other