

# CLINICAL BIOCHEMISTRY SERVICES IN GG&C

## HANDBOOK FOR PRIMARY CARE USERS

PUBLICATION DATE OCTOBER 2008 (REVISED MARCH 2018)

REV.7

---

### REQUESTING TESTS

If you require urgent analysis of any sample, please contact the Reporting Biochemist prior to sending the sample to the lab. Please limit requests to those which are truly urgent since these create a significant amount of extra work for the laboratory. We are unable to guarantee rapid turnaround of samples where “urgent” is merely written on the request form.

Electronic request intervention processes are in use to prevent clinically unnecessary repeat analyses (see below for relevant time intervals). If you feel that repeat testing within the specified time interval is justified in a specific patient, please ensure that you include the clinical indication for the repeat request in the clinical details. If a test is not performed, you will receive a report by the following working day detailing the most recent result, and still have the option of contacting the laboratory to arrange analysis of the sample.

Test	Period	Test	Period
Cholesterol / Triglycerides	28 days	B12	28 days
Lipid profile	28 days	Serum folate	28 days
Serum Electrophoresis	90 days	Ferritin	28 days
PSA	21 days		
TFTs	30 days		
Total T3	30 days		
Vitamin D	340 days		

## **RESULTS REPORTING**

In general, samples received in the laboratory before 2 pm will be analysed on the same day. Some low volume tests are handled in batches that are processed less frequently. Paper reports for commonly requested tests will usually be delivered to practices within one working day of the date of specimen receipt.

SCI Store should be used wherever possible for accessing patient results more promptly. Results should be available on SCI Store within 5 minutes of laboratory authorization. Please do not phone the laboratory for a result without checking SCI Store first. Results are now being directly downloaded electronically to GP practices across Glasgow four times daily.

The Biochemistry Service will phone abnormal results where clinical intervention may be warranted urgently (i.e. within a matter of hours) or may be warranted before the anticipated delivery of the paper report.

SCI Store can be accessed at

<https://www.scigw.scot.nhs.uk/web/login.aspx?instance=Live&qpassAction=login>

If you experience difficulties using SCI Store, contact your IT support team. The IT helpdesk can be contacted on 0845 612 5000

## **INFORMATION AND ADVICE**

Detailed information on sample requirements and reference ranges may be accessed via the pages of the Biochemistry website <http://www.nhs.uk/clinical-portal/about-us/professional-support-sites/biochemistry/>

Information and advice are also available by telephone. Our reporting rooms are staffed by a combination of clinical scientists and medical biochemists – some are trainees, some are consultant level. If the Reporting Biochemist is unable to help, then they

should usually be able to pass your query to a medical consultant or a relevant specialist.

### North Glasgow Contact Numbers

**0141 211 4003/4**

- option 2 (secretaries) for results / general enquiries
- option 3 (reporting room) for clinical advice / emergency tests

Senior staff contact details:

<b>Name</b>	<b>Job Title</b>	<b>Contact</b>
<b><i>Consultants</i></b>		
Prof Marek Dominiczak	Consultant Medical Biochemist	Tel: 0141 211 2788 <a href="mailto:marek.dominiczek@ggc.scot.nhs.uk">marek.dominiczek@ggc.scot.nhs.uk</a>
Dr Janet Horner	Consultant Medical Biochemist Lead Clinician	Tel: 0141 211 4631 <a href="mailto:janet.horner@ggc.scot.nhs.uk">janet.horner@ggc.scot.nhs.uk</a>
Dr Maurizio Panarelli	Consultant Medical Biochemist, GGC Head of Service	Tel: 0141 211 0830 <a href="mailto:Maurizio.panarelli@ggc.scot.nhs.uk">Maurizio.panarelli@ggc.scot.nhs.uk</a>
Ms Karen Smith	Consultant Clinical Scientist	Tel: 0141 211 4424 <a href="mailto:karen.smith2@ggc.scot.nhs.uk">karen.smith2@ggc.scot.nhs.uk</a>
Dr Dinesh Talwar	Consultant Clinical Scientist	Tel: 0141 211 5178 <a href="mailto:Dinesh.talwar@ggc.scot.nhs.uk">Dinesh.talwar@ggc.scot.nhs.uk</a>
<b><i>Managers</i></b>		
Mrs Christine Brownlie	Technical Services Manager	Tel: 0141 211 5534 <a href="mailto:Christine.brownlie@ggc.scot.nhs.uk">Christine.brownlie@ggc.scot.nhs.uk</a>
Mrs Linda McKinnon	Quality Manager	Tel: 0141 211 4339 <a href="mailto:Linda.mackinnon@ggc.scot.nhs.uk">Linda.mackinnon@ggc.scot.nhs.uk</a>

**South Glasgow Contact Number****0141 354 9060**

- option 2 (secretaries) for results/ general enquiries
- option 4 (reporting room) for clinical advice/ emergency tests

Senior staff contact details:

<b>Name</b>	<b>Job Title</b>	<b>Contact</b>
<b><i>Consultants</i></b>		
Dr Anne Cruickshank	Consultant Medical Biochemist,	Tel: 0141 354 9035 <a href="mailto:Anne.Cruickshank@ggc.scot.nhs.uk">Anne.Cruickshank@ggc.scot.nhs.uk</a>
Mr Frank Finlay	Consultant Clinical Scientist	Tel: 0141 354 9032 <a href="mailto:Frank.Finlay@ggc.scot.nhs.uk">Frank.Finlay@ggc.scot.nhs.uk</a>
Dr Peter Galloway	Consultant Medical Biochemist	Tel: 0141 354 9034 <a href="mailto:Peter.Galloway@ggc.scot.nhs.uk">Peter.Galloway@ggc.scot.nhs.uk</a>
Dr Jane McNeilly	Consultant Clinical Scientist	Tel: 0141 354 9047 <a href="mailto:J.McNeilly@nhs.net">J.McNeilly@nhs.net</a>
Dr Rajeev Srivastava	Consultant Medical Biochemist	Tel: 0141 354 9030 <a href="mailto:Rajeev.Srivastava@nhs.net">Rajeev.Srivastava@nhs.net</a>
Dr Shona Twaddle	Consultant Medical Biochemist Lead Clinician	Tel: 0141 354 9036 <a href="mailto:Shona.Twaddle@ggc.scot.nhs.uk">Shona.Twaddle@ggc.scot.nhs.uk</a>
<b><i>Managers</i></b>		
Mr Colin Smith	Technical Services Manager	Tel: 0141 354 9031 <a href="mailto:Colin.Smith@ggc.scot.nhs.uk">Colin.Smith@ggc.scot.nhs.uk</a>
Mrs Laura Scott	Quality Manager	Tel: 0141 354 9053 <a href="mailto:LauraJane.scott@ggc.scot.nhs.uk">LauraJane.scott@ggc.scot.nhs.uk</a>

## Clyde Contact Numbers

Inverclyde Royal Hospital:	01475 504285 Emergency requests	ext 04827 ext 04213
Royal Alexandra Hospital:	0141 314 6157	ext 06157
Vale of Leven Hospital:	01389 817568	ext 87568

### Senior staff contact details:

Name	Job Title	Contact
<b>Consultants</b>		
Dr Iain Jones	Consultant Medical Biochemist Lead Clinician	Tel: 0141 532 7209 <a href="mailto:iain.jones@nhs.net">iain.jones@nhs.net</a>
Mr Andrew Kerry	Consultant Clinical Scientist	Tel: 0141 314 6657 <a href="mailto:Andrew.Kerry@ggc.scot.nhs.uk">Andrew.Kerry@ggc.scot.nhs.uk</a>
Dr Caroline Millar	Consultant Medical Biochemist	Tel: 0141 532 7585 <a href="mailto:carolinemillar@nhs.net">carolinemillar@nhs.net</a>
Dr Colleen Ross	Consultant Medical Biochemist,	Tel: 0141 314 6056 <a href="mailto:Colleen.ross@ggc.scot.nhs.uk">Colleen.ross@ggc.scot.nhs.uk</a>
<b>Managers</b>		
Ms Karen Brazier	Technical Services Manager	Tel: 0141 314 6098 <a href="mailto:karenbrazier1@nhs.net">karenbrazier1@nhs.net</a>
Ms Pamela Craig	Quality Manager	Tel: 0141 314 6160 <a href="mailto:Pamela.craig@nhs.net">Pamela.craig@nhs.net</a>

## **PRACTICAL ASPECTS OF TEST REQUESTING**

### **Preparation of patient:**

The patient should be resting for at least 5 minutes before withdrawal of blood.

Venous blood samples should be taken with minimal stasis.

Many analyses require that the specimen be collected under specified conditions, e.g. fasting for glucose and full lipid profile. Please ensure that the appropriate requirements are met. If in doubt, please consult the relevant Biochemistry webpage or contact the Reporting Biochemist.

### **Confirm the identity of the patient prior to sampling**

#### **Sample containers:**

For venous blood use appropriate vacuum blood collection tubes for each test

Where more than one tube is required, the potassium EDTA tube (purple top) should be filled last to avoid errors in potassium and calcium measurement.

Anticoagulant tubes should be inverted several times to ensure adequate mixing.

Note that a specimen bag can contain specimens from one patient only.

Where there is any doubt about sample preparation, storage or transport, please contact the Reporting Biochemist.

#### **Sample Labeling:**

The minimum data for adequate identification are the patient's forename and surname, Date of Birth and CHI number. A pre-printed sample label is preferred. Use of CHI number is mandatory for accurate patient identification.

The name and full address to which the report should be sent must be included on any written request form if the request is not electronic.

Sample containers of any type should be obtained through normal supply routes for consumables. The Biochemistry Department does not supply containers or packing materials except by special arrangement.

Clinical information included with the request permits laboratory staff to assess the validity of results and may prevent unnecessary repeat analyses. Supporting information may be required for correct interpretation. For example, therapeutic drug monitoring requests require information about dosage, time since last dose, and a complete list of prescribed drugs.

### REFERENCE RANGES FOR COMMON TESTS

Where available an appropriate reference range will be supplied with your result. If further information is required please consult the relevant Biochemistry webpage or contact the Reporting Biochemist for more detailed information on reference range.

Reference ranges quoted are for general guidance only. Results falling outside the reference range do not necessarily indicate an underlying pathology.

Analyte	Adult serum reference range
<b>Urea and Electrolytes:</b>	
Sodium	133 – 146 mmol/L
Potassium	3.5 – 5.3 mmol/L*
Chloride	95 – 108 mmol/L
Bicarbonate	22 – 29 mmol/L
Urea	2.5 – 7.8 mmol/L
Creatinine	40 – 130 µmol/L
EGFR	>60 mL/min/1.73m <sup>2</sup>
<b>Liver function tests:</b>	
Bilirubin	<20 µmol/L
AST	<40 U/L
ALT	<50 U/L
GGT	Male <70 U/L Female <40 U/L
Alkaline phosphatase	30 – 130 U/L <sup>a</sup>
Protein	60 – 80 g/L
Albumin	35 – 50 g/L
Globulins	23 – 38 g/L

Analyte	Adult serum reference range
<b>Bone profile:</b>	
Alkaline phosphatase	30 – 130 U/L <sup>a</sup>
Protein	60 – 80 g/L
Albumin	35 – 50 g/L
Globulins	23 – 38 g/L
Adjusted calcium	2.20 – 2.60 mmol/L
Phosphate	0.80 – 1.50 mmol/L
Glucose (fasting)	3.5 – 6.0 mmol/L
<b>Lipids:</b>	
Total cholesterol	refer to GGC cholesterol guidelines
Triglycerides	0.2 - 2.3 mmol/L (fasting sample required)
HDL	>1.0 mmol/L
LDL	refer to GGC cholesterol guidelines
<b>Endocrinology:</b>	
TSH	0.35 – 5.00 mU/L
Free T4	9.0 – 21.0 pmol/L
LH	See page 15-18
FSH	See page 15-18
Prolactin	Male <400 mU/L Female <630 mU/L
PSA	See page 19

\* Invalid in old/ haemolysed samples

<sup>a</sup> Increased in childhood, pregnancy and the elderly. Age and sex-adjusted ranges available

Urine analyte	Reference range
Microalbumin	<20 mg/L
Albumin: creatinine ratio	Male <2.5 mg/mmol creatinine Female <3.5 mg/mmol creatinine
Albumin excretion rate	<20 µg/min (24 hour collection required)
Protein: creatinine ratio	<30 mg/mmol creatinine
Protein excretion rate	<0.1 g/24h (24 hour collection required)



## USE OF ESTIMATED GLOMERULAR FILTRATION RATE (EGFR)

CKD may be suspected on clinical grounds (e.g. patients with hypertension, diabetes or recurrent UTIs are known to be at increased risk). Detection of early chronic kidney disease (CKD) is important as early identification and intervention can slow the progression of disease and reduce associated cardiovascular risk

### **Suspected CKD**

Detection of CKD can be improved using eGFR, as it unmasks minor degrees of renal impairment that may be unnoticed by measurement of creatinine alone, due to the influences of age and sex on the reference ranges for serum creatinine, eGFR is not valid in children (<18 years) and acutely ill patients. Its role is in the detection and monitoring of 'stable' patients with suspected or established CKD. eGFR should be multiplied by 1.2 for African-Caribbean patients.

eGFR greater than 60mL/min/1.73m<sup>2</sup> does not exclude stages 1 and 2 CKD. Where suspected, urinalysis and other investigations may be appropriate.

Patients with eGFR between 30 and 59 mL/min/1.73m<sup>2</sup> on **two** separate samples **about 90 days apart** are classified as CKD stage 3.

Persistent proteinuria (protein: creatinine ratio (PCR) greater than 100mg protein/mmol creatinine) is the best indicator of risk of progression to end stage renal disease in patients with early CKD (stages 1- 3).

All patients with suspected early CKD should have a urine dipstick test for protein; PCR should be quantified where results are positive.

Urinary albumin estimations should be used in diabetic patients.

Further information may be found at <https://renal.org/information-resources/the-uk-eCKD-guide/about-egfr/>

## **LIPID ABNORMALITIES/ CARDIOVASCULAR RISK**

### **Cholesterol Measurement in Assessment of Cardiovascular Risk**

All adults aged 40 or above should have an assessment of cardiovascular risk at least once every 5 years. Individuals with a first-degree relative who has premature atherosclerotic CVD or familial dyslipidaemia should also have a risk assessment every 5 years.

In high-risk primary prevention patients, patients below the treatment threshold should be tested annually. In lower risk patients measurement every 5 years should be adequate.

### **Secondary Hyperlipidaemia**

Secondary hyperlipidaemia should be excluded in all patients being considered for lipid-lowering therapy. The following investigations are recommended:

- Dietary, alcohol and drug history

- Urine dipstick for protein

- Urea and electrolytes (eGFR) and liver function tests

- Blood glucose measurement to exclude diabetes

- Thyroid function tests (if total cholesterol is >8mmol/L or thyroid disease is suspected clinically)

### **Patients on Lipid Lowering Therapy**

The decision to start lipid-lowering therapy should be based on at least 2 cholesterol measurements.

Lipids should be checked about 1-2 months after starting drug treatment; measurements every 8 weeks should be continued until the patient reaches their target value. After reaching target concentration, lipids should be checked annually, unless there is a clinical indication to do so sooner.

### **Liver Function Tests for Patients on Lipid Lowering Therapy**

LFTs should be measured prior to commencing statin therapy and 1-2 months after starting therapy or any dose increase. If LFTs are stable, annual measurement should be adequate unless there is a clinical indication to measure sooner.

If AST and ALT rise in a patient taking a statin:

If less than 3 times the upper limit of normal, continue therapy but repeat LFTs in 4-6 weeks to exclude further rises. No further monitoring is required if LFTs are stable.

If more than 3 times the upper limit of normal, consider reducing the dose or stopping statin therapy.

Scottish Intercollegiate Guidelines, 2017: Risk estimation and the prevention of cardiovascular disease. Available at <http://www.sign.ac.uk/sign-149-risk-estimation-and-the-prevention-of-cardiovascular-disease.html>

If Lipid Profile is requested, total cholesterol and triglycerides and HDL will be measured, and LDL calculated if appropriate.

## DIAGNOSIS OF DIABETES

The full NHSGGC guidance on diagnosis of diabetes is available electronically:

<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Diabetes%20Mellitus,%20Diagnosis.pdf>

Salient points of the guidance are highlighted below:

The following glucose results are diagnostic of diabetes in a symptomatic patient if type 2 Diabetes is suspected. If the patient is asymptomatic, the test should be repeated on a subsequent occasion for confirmation. New Type 1 diabetes presentations can be a clinical emergency and diagnosis is made on symptoms and random glucose – fasting glucose, HbA1c and OGTT are all inappropriate tests for diagnosis of T1DM.

Random venous plasma glucose  $\geq 11.1$ mmol/L

Fasting plasma glucose  $\geq 7.0$ mmol/L

In an asymptomatic patient, when the fasting plasma glucose concentration is between 6.0 and 6.9 mmol/L, measure HbA1c. In the vast majority of cases an oral glucose tolerance test (OGTT) is not necessary for the diagnosis of diabetes.

### **Biochemical follow-up of patients with diabetes**

Monitoring of patients with diabetes should include measurement of HbA1c, U&E, lipid profile and urine microalbumin

HbA1c	Should be measured annually in patients who are meeting treatment goals, with stable glycaemic control. More frequent measurement may be indicated in patients who are difficult to control, up to a maximum of 4 measurements per year.
Microalbumin	Should be measured every 12-15 months in adult diabetic patients.

## **Other Disorders of Glucose Homeostasis**

### Impaired fasting glycaemia (IFG)

Fasting plasma glucose between 6.0 and 7.0mmol/L

Check HbA1c

### Impaired glucose tolerance (IGT)

OGTT 2hr value between 7.8 and 11.0mmol/L. IGT is a state of impaired glucose homeostasis, diagnosed on the basis of a glucose tolerance test (OGTT) (please see below for detailed guidance on OGTT).

IGF and IGT are not clinical diagnoses – these results suggest that there is a degree of impairment in processing glucose in the body.

Poor diet, being overweight and a sedentary lifestyle are risk factors. May be an early indication of insulin resistance and there may be an increased risk of CVD with IGT and both IGT and IFG may confer an increased risk of developing DM.

## **75g Oral Glucose tolerance test**

Under current NHSGGC guidelines the use of OGTT is only recommended for early pregnancy when the diagnosis of gestational diabetes is in doubt or if at high risk in late pregnancy – OGTT will seldom be necessary outside of gestational diabetes.

Due to reformulation in April 2017 Lucozade Energy Original is no longer recommended for use in OGTT.

The patient should be fasted overnight, prior to commencement of the test.

A baseline sample should be taken for fasting blood glucose (grey top tube)

The patient should drink 75g of glucose (preferably anhydrous glucose) dissolved in 250-350 ml water then a further glucose sample should be taken at 2hours post glucose load. Smoking is not permitted during the test and the patient should preferably remain seated.

Commercial preparations such as RapiLOSE oral glucose tolerance test solution 75g/300ml are available.

## **APPROPRIATE USE OF THYROID FUNCTION TESTS**

### **When to measure**

Indications for thyroid function testing include patients presenting with:

- signs/ symptoms associated with thyroid dysfunction
- a suspected goitre
- atrial fibrillation, dyslipidaemia, osteoporosis or sub-fertility.

Patients who are acutely unwell should not have thyroid function tests carried out unless there are specific indications to do so. Thyroid function tests often show abnormal patterns in illness, which resolve with an improvement in clinical condition. Thyroid function tests should therefore not be carried out during or immediately following an acute illness unless thyroid involvement is strongly suspected.

TFTs should not be measured within 6 weeks of a change in dose of anti-thyroid drugs or thyroxine replacement, as misleading results may be obtained

### **What to measure**

When TFTs are requested both TSH and free T4 will be measured. Other tests of thyroid function may be added on at the discretion of the Reporting Biochemist, once the results of these first line tests are known. Serum T3 may be added in patients with results suggestive of hyperthyroidism and serum anti-TPO antibodies may be added in patients with a pattern of sub-clinical hypothyroidism who are not on thyroxine.

### **Interpretation and follow up**

Interpretative advice will be provided by the Reporting Biochemist for abnormal results. To assist the biochemists in this role, please provide relevant clinical information and drug history, in particular details of anti-thyroid drugs or thyroid hormone replacement.

There is no merit in repeated testing of individuals with completely normal TFT results. Causes other than thyroid dysfunction should be sought to explain the symptoms.

Autoimmune thyroid disease may take many years to develop. The frequency of follow up in patients with a pattern of subclinical hypothyroidism should be annual if the anti-TPO antibodies are positive, or 2-3years if negative.

### INVESTIGATION OF THE MENOPAUSE

The menopausal transition can most often be determined on clinical grounds alone and **measurement of hormones in all patients is not appropriate.** Hormone concentrations fluctuate widely during the menopausal transition, and measurement is not appropriate unless there are **specific indications** to do so.

Gonadotrophins should not be measured in patients receiving oral hormone replacement therapy (HRT).

#### When are Hormone Measurements Appropriate?

Patients	Clinical Picture	Biochemical assessment
>40 years old	Clinical evidence of menopause (menstrual disturbance and vasomotor symptoms)	Hormone measurements not indicated
>40 years old	Equivocal menopausal symptoms	Gonadotrophins (LH & FSH) may be of value
<40 years old	Suspected menopausal symptoms	Measure gonadotrophins
Post-hysterectomy		Annual gonadotrophin measurement or when symptoms develop

#### When to Collect Samples

When possible collect samples during the follicular phase (days 1-7 of cycle / during menstruation). Avoid sampling during the mid-cycle gonadotrophin surge (days 13-17 of cycle).

#### Additional Investigations

In women with equivocal menopausal symptoms consider other causes (e.g. thyroid disease, depression, alcohol excess and, rarely, phaeochromocytoma).

### **Interpretation**

**To assist in interpretation of results, please include details of: LMP, symptoms, suspected diagnosis and any hormone treatment.**

Elevated FSH (>25 U/L) with a 1-year history of amenorrhoea indicates ovarian failure. Premenopausal concentrations do not exclude the perimenopause.

Hormone measurements are of little assistance in determining whether a patient is at risk of becoming pregnant and it should be assumed that pregnancy is a possibility for up to 2 years after the last menstrual period.

For further advice please contact the Reporting Biochemist (see page 3-5 for contact details)



**LABORATORY INVESTIGATION OF MENSTRUAL IRREGULARITY/ AMENORRHOEA IN FEMALES  
UNDER 40 YEARS**

Secondary amenorrhoea is defined as more than 6 months without menses, after prior establishment of regular periods.

When investigating amenorrhoea, pregnancy should be ruled out first.

Non-endocrine causes such as general illness, anorexia and excessive weight loss should also be excluded.

When requesting laboratory tests for investigation of menstrual irregularity (or infertility) please include the following details on the request form:

reason for request (amenorrhoea, oligomenorrhoea, infertility etc)

date of last menstrual period

drug history

relevant clinical details (e.g. hirsutism, obesity etc)

Appropriate first line investigations include:

LH, FSH and prolactin

Androgen profile (testosterone, 17 hydroxyprogesterone and androstenedione)

Thyroid function tests

**Reference Intervals**

Analyte	Phase of cycle	Reference interval
FSH	Follicular	3-8 U/L
	Mid-cycle	2-16 U/L
	Luteal	1-5 U/L
LH	Follicular	2-13 U/L
	Mid-cycle	34-115 U/L
	Luteal	1-16 U/L
Prolactin		<630 mU/L

Progesterone should only be measured to determine if ovulation has occurred. Samples for progesterone measurement should be collected on day 21 of a 28 day cycle (or 7

days before next period is due, if cycle length is different). A progesterone concentration of  $>20\text{nmol/L}$  is consistent with ovulation

Please contact the Reporting Biochemist (see page 3-5 for contact details) for assistance with interpreting abnormal or borderline results.

## USE OF TUMOUR MARKERS IN GENERAL PRACTICE

The use of most tumour markers is not recommended in a Primary Care Setting due to their lack of specificity for malignancy and reference ranges that are generally not well defined. For most serum tumour markers a concentration within the reference range does not exclude malignancy and an elevated concentration does not confirm it. Markers such as CEA and CA125 should generally only be requested where recommended by an oncologist for monitoring purposes. Recent NICE guidelines on Ovarian Cancer (April 2011) suggest measurement of Ca125 in women over 50 years of age with persistent symptoms (see <https://www.nice.org.uk/guidance/cg122>)

Prostate specific antigen (PSA) is often used in Primary Care to aid the assessment of patients with suspected prostate pathology

### **Prostate Specific Antigen**

The following guidance is based on the NICE Guideline 'Referral Guidelines for Suspected Cancer' June 2015 (see <https://www.nice.org.uk/guidance/ng12>)

Screening for prostatic cancer using PSA is not recommended routinely in asymptomatic men. However, the test should be available to patients requesting it.

Patients should be counseled prior to consenting to the test, including details of the limitations of the test, natural history of the disease and treatment options.

An isolated increase in an asymptomatic patient should be confirmed before further tests are considered.

Patients with borderline PSA concentrations should have the measurement repeated in 6-12 weeks; if the concentration is rising, the patient should be referred urgently.

The urology team should provide guidance on PSA monitoring following treatment for prostatic cancer.

Age-related reference ranges are used in the interpretation of PSA results:

50 – 59 years	<3µg/L
60 – 69 years	<4µg/L

70+ years

<5µg/L

A PSA concentration within the reference range does not exclude malignancy; a raised concentration may be due to a benign cause, such as benign prostatic hyperplasia.

PSA concentration should not be measured in patients with a urinary tract infection (wait at least 1 month following a UTI to perform the test).

PSA concentration should not be measured within 6 weeks of a prostatic biopsy or colonoscopy. Ejaculation should be avoided in the 48 hours prior to the test.

## THERAPEUTIC DRUG MONITORING

For all assays 4mL blood in a gel tube (yellow/ ochre top) is appropriate. Clinical details and accurate dosage information are required for interpretation of results.

Samples should generally be taken at steady-state (see table on next page) but earlier analysis may be indicated in the following circumstances:

- Suspected overdose or toxicity
- Poor clinical response despite high dose
- Unstable clinical condition (particularly changing renal function)
- Potential/ suspected drug interactions

Drug analysis is **not** recommended in the following circumstances:

- Routine analysis of anticonvulsants and digoxin, especially when clinical control is satisfactory
- Valproic acid therapy (poor correlation between serum concentration and clinical effect)
- Digoxin within 6 hours of oral dose

### Lithium

For patients on lithium therapy, lithium concentrations should be checked every 3 months, and thyroid function tests, calcium and renal function should be assessed annually.

### Phenytoin

There is a non-linear rise in serum concentration with increasing dose. Toxicity may develop with small dose adjustments or the introduction of interacting drugs.

Free (active) phenytoin concentrations can increase from normal when serum albumin concentration falls and when phenytoin is displaced from albumin with co-administered drugs. **Care should be taken in interpreting results when albumin concentration is less than 32g/L.** Contact the Reporting Biochemist for interpretative advice, if required.

Care in interpretation should also be taken when renal failure is present. Contact the Reporting Biochemist for interpretative advice, if required.

## Digoxin

Results from samples taken within 6 hours of an oral dose are unreliable.

Hypokalaemia, hypomagnesaemia and hypercalcaemia potentiate digoxin toxicity; contact the Reporting Biochemist for interpretative advice, if required.

Unexpected results in hepatic and renal failure should be interpreted with caution; contact Reporting Biochemist for interpretation.

## Target Ranges for Therapeutic Drugs

Drug	Time to steady state	Ideal sample time	Target range
Carbamazepine	2-3 weeks (new therapy) 2-4 days (dose change)	Predose (not critical)	4.0 – 12.0 mg/L
Phenytoin	2-3 weeks	Predose (not critical)	Adults: 5.0 – 20.0 mg/L
Theophylline	2-3 days	Predose (not critical)	Adults: 10.0 – 20.0 mg/L (5.0 – 10.0 mg/L adequate in some circumstances)
Digoxin	7-10 days	6-24 hours after dose	0.5 – 2.0 µg/L
Lithium	5 days	12 hours after dose	0.6 – 1.0 mmol/L (0.4 – 0.8 mmol/L for prophylaxis and older patients)

## INVESTIGATION OF SUSPECTED MYELOMA

The initial screening test for detecting paraproteins is serum protein electrophoresis (yellow/ ochre top gel tube). In addition, immunoglobulin quantification is useful to identify immunoparesis or polyclonal increases in immunoglobulin subclasses.

Urine electrophoresis (early morning urine in white topped universal for BJP) is useful if a serum paraprotein is detected or if no paraprotein is detected in serum but there remains a high index of suspicion of myeloma or other B-cell dyscrasia e.g. in otherwise unexplained renal failure, anaemia, back pain, fever or hypercalcaemia.

A myeloma screen order set is available in the Anglia ICE system (blood for immunoglobulins & electrophoresis PLUS urine for BJP)

Asymptomatic paraproteinaemia i.e. MGUS, is a relatively common incidental finding in the elderly or those with any chronic inflammatory condition. A very small proportion of patients with MGUS may progress to a clinically significant myeloma, therefore follow up should be considered. Typically this should consist of 3-4 monthly repeat serum protein electrophoresis for 2 years, then annually if serum paraprotein concentration is stable or the patient is asymptomatic. Where serum free light chain levels have been assessed and indicate lower risk of progression, less frequent monitoring may be appropriate. However, if the patient develops symptoms or signs of myeloma or lymphoma at any point, re-assessment is advised.

For further information please see <http://www.b-s-h.org.uk/guidelines/guidelines/investigation-of-newly-detected-m-proteins-and-the-management-of-mgus/>

Turnaround time for serum and urine electrophoresis may be up to two or three weeks, respectively if a paraprotein is detected. Please do not send repeat specimens without checking with laboratory as previous specimens may still be in process.

## **SAFETY AND DANGEROUS SPECIMENS**

The laboratory will not process a leaking specimen or one that arrives with a needle attached.

Clinical staff need no longer use “DANGER OF INFECTION” stickers to highlight samples containing (or suspected of containing) blood borne viruses (BBV) such as HIV and hepatitis B or C.

### **Note**

No body fluid samples should be taken if a patient is suffering an illness associated with, or suspected of being caused by, a Category 4 pathogen such as viral haemorrhagic fever. The patient should be referred according to existing clinical protocols.



## **DATA PROTECTION**

### **The Data Protection Act**

The Data Protection Act 1998 is based upon eight enforceable principles of good practice:

1. Personal data shall be obtained and processed fairly and lawfully
2. Personal data shall be held only for specified and lawful purposes and shall not be further processed in any manner incompatible with those purposes
3. Personal data shall be adequate, relevant, and not excessive in the relation to the required purposes
4. Personal data shall be accurate and, where necessary, kept up-to-date
5. Personal data shall not be retained longer than is necessary
6. An individual shall be entitled to have access to his or her data and where appropriate, have it corrected or erased
7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of the data
8. Personal data shall not be transferred outside EU countries unless an adequate level of data protection exists

Organisations are obliged to comply with these principles. Failure to comply can result in an enforcement notice being issued by the Registrar

### **GREATER GLASGOW GUIDELINES FOR COMPUTER TERMINAL USAGE**

Do not allow unauthorised persons to see the data on screens

Log off the system when finished

Do not by any action or inaction allow disclosure of information, either directly or indirectly, from the system to any unauthorised person

<b>INDEX</b>	<b>PAGE</b>
Requesting Tests	1
Results Reporting	2
Information & Advice	2 - 5
Practical aspects of test requesting	6
Common reference ranges	7 - 8
Use of estimated glomerular filtration rate	9
Lipid abnormalities/ cardiovascular risk	10
Diagnosis of diabetes	12
Appropriate use of thyroid function tests	14
Investigation of the menopause	15
Laboratory Investigation of Menstrual Irregularity/Amenorrhoea in Females under 40 years	17
Use of tumour markers in general practice	19
Therapeutic drug monitoring	21
Investigation of suspected myeloma	23
Safety and dangerous specimens	24
Data protection	25