



GUIDELINES AND AUDIT
IMPLEMENTATION NETWORK

GUIDELINES & AUDIT IMPLEMENTATION NETWORK

GUIDELINES ON THE USE OF THE LABORATORY

MARCH 2008



**promoting
quality
through
audit
and
guidelines**



PREFACE

Guidelines on the Use of the Laboratory

These guidelines have been published by the Guidelines and Audit Implementation Network (GAIN), which is a team of health care professionals established under the auspices of the Department of Health, Social Services and Public Safety in 2008. The aim of GAIN is to promote quality in the Health Service in Northern Ireland, through audit and guidelines, while ensuring the highest possible standard of clinical practice is maintained.



This guideline has been produced by a sub-group of health care professionals from varied backgrounds including medical (primary and secondary care), nursing, management and public health, co-chaired by Dr Kieran Fitzpatrick and myself.

GAIN wishes to thank all those who contributed in any way to the development of these guidelines.

A handwritten signature in black ink that reads "Tom Trinick". The signature is written in a cursive, flowing style.

DR. T. TRINICK
Chairman of GAIN



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FOREWORD

Laboratory testing is expensive and can vary from 3-5% of the total Hospital budget. In addition the waste through too frequent re-testing and the difficulties in test interpretation have led to a desire to have a simple easy to read guide to laboratory services. It is hoped that this publication will attempt to address this need, and through better use of tests there will be significant benefits to our patients.



The tests selected for inclusion in this guideline are the common or difficult to interpret tests that are readily available from the laboratories in Northern Ireland.

I hope this publication will help in reducing waste and improving the value of laboratory tests.

A handwritten signature in black ink that reads "David Stewart".

DAVID GT STEWART
Vice-Chairman of GAIN



INTRODUCTION

This GAIN publication contains advice on how to improve the appropriateness of laboratory test requesting. There is a desire to re-focus on the diagnostic process, emphasising the clinical history, since 75% of diagnoses come from a good history. Clinical examination confirms the history and laboratory tests are used to confirm findings, aid prognosis, assist disease classification or, in some cases, make a diagnosis which cannot be determined other than by laboratory testing.

To this end we have set out some of the commoner tests giving their indications, common non-indications of the test, frequency for re-testing accompanied by some estimate of reasonable testing frequency, the samples required, value in disease monitoring, reference interval and other considerations mainly of a physiological nature. It is important to contact your laboratory if there is any doubt as to the sample required, or for advice on the appropriateness of test requesting and for interpretation of results.

All laboratories in the Province use an evacuated blood collection system with colour coded tubes. Many tests use the gel tube (serum separator tube -SST), which contains material to separate the serum from the red cells in order to preserve the sample prior to analysis. The laboratory handbook should be used to determine which tube is required. Samples must always be submitted in properly labelled tubes accompanied by a fully completed request form including clinical information, the test requested, date and time of sampling together with the return details for the requesting doctor, otherwise the laboratory may have to request a repeat sample together with a properly completed form.

A subsidiary aim for these guidelines is to reduce unnecessary testing. Laboratory sample numbers rise at 5-15% per annum in many laboratories, driven in part by protocols and by the increasing number of laboratory users. It is thought that as many as 40% of test ordering in the acute hospital setting are inappropriate or non-contributory to clinical decision making, the equivalent percentage in General Practice is not known. In order to help this situation we have included advice where appropriate on frequency of re-testing and this comes from a number of areas. These

include guidelines from authoritative bodies and from experienced clinicians. We have introduced the concept of the Minimum-Retesting Interval (MRI). The MRI of a particular test is the time required to allow a significant change to occur in the test. MRI's reflect the test's biological variability and biological half-life and are a useful guide to determine when the test should be repeated.

Additional information may be found at the following site:

<http://www.labtestsonline.org.uk/>

HAEMATOLOGY

Coagulation Screen Requests

Overview:

The coagulation screen is useful in the assessment of patients with suspected congenital or acquired bleeding diatheses. In the acute hospital setting the coagulation screen is most valuable in the assessment and monitoring of patients with haemorrhagic problems or with the potential to develop bleeding, for example:

- (a) Acute bleeding associated with a **clinically suspected** coagulopathy.
- (b) Monitoring blood product therapy in patients with liver disease, DIC, or massive transfusion, and/or
- (c) Haemostasis assessment before invasive procedures in (b).
- (d) Prognostic evaluation and management of patients with paracetamol over-dose.
- (e) Acute bleeding in patients receiving anticoagulants.

The use of routine coagulation screening prior to invasive procedures/surgery has poor predictive value for post-procedure bleeding. Similarly, routine coagulation screening of acute medical admission patients has no useful predictive value for bleeding or thrombosis. In both situations the most important aspect of determining the bleeding risk is to take a detailed history: those with a personal or family history suggestive of a bleeding diathesis, patients with chronic liver or renal disease, and patients on anticoagulant therapy are candidates for further coagulation investigation. Patients with a strong personal or family history of bleeding and a normal routine coagulation screen result should be discussed with a haematologist.

When patients who are on long term oral anticoagulant treatment are admitted it is reasonable to request an INR, but there is no need to request a full coagulation screen unless the patients has acute bleeding.

Indications for a Coagulation Screen*:

- Personal history suggestive of a bleeding disorder
 - Recurrent, spontaneous epistaxis lasting at least ten minutes despite external compression
 - Recurrent spontaneous bruising
 - Unexplained menorrhagia

- Unexplained prolonged bleeding after dental extraction, invasive procedures, surgery, or childbirth
- Family history of a bleeding disorder
- Acute bleeding and clinically suspected coagulopathy
- Warfarin – INR only (see notes above)
- Liver disease/chronic renal impairment
 - Acute/chronic bleeding
 - Requiring an invasive procedure/surgery
- Patients with obstructive jaundice
- Severe sepsis – at risk of DIC
- Paracetamol overdose

**A full blood count should be done at the same time to estimate the platelet count.*

Not Indicated: See overview above.

Minimum frequency to repeat: Daily when monitoring of replacement therapy, e.g. fresh frozen plasma, etc.

Sample to Send: 4 ml citrated blood.

Other Considerations: The sample bottle must be filled accurately; otherwise an unreliable result will be obtained. (Most labs will reject the sample if it is over- or under- filled.)

References:

Chee et al. Guideline on the Assessment of Bleeding Risk Prior to Surgery or Invasive Procedures. www.bcshguidelines

Mainwaring et al. Best Practice in Audit: Audit of Coagulation Screen Requests from Patients admitted to the Medical Assessment Unit 2007. www.rcpath.org

D-dimer Requests

Overview:

Thrombus formation is followed by an immediate fibrinolytic response. This generates fibrin degradation products, containing D-dimers. It follows that absence of a rise in D-dimers implies that thrombosis is not occurring. A low D-dimer value may help to exclude DVT/PE if used with a clinical risk prediction model. A high value is non-specific and cannot be used to make a diagnosis of DVT/PE - a specific radiological investigation is required.

Because D-dimer levels are high in a number of clinical circumstances the assay should not be used in DVT/PE assessment in the following circumstances:

- Within 4 weeks of surgery
- In trauma cases
- During active infection
- Pregnancy

Disseminated Intravascular Coagulation (DIC) is associated with uncontrolled fibrin generation and secondary fibrinolysis. Usually there is prolongation of the PT and APPT with depletion of fibrinogen. In most clinical circumstances a coagulation screen alone is enough to identify DIC. However, D-dimers are generated at a rapid rate in DIC, and in the correct clinical context an elevated D-dimer result can contribute to confirmation of the presence of DIC.

Indications for D-dimers:

- Suspected DIC
- Assessment of thrombolytic therapy
- Suspected DVT or PE when used with a clinical risk prediction model

Not Indicated: See overview above.

Minimum frequency to repeat: No recommendation.

Other considerations: See overview above

References:

Keeling DM et al. Guideline: The diagnosis of deep vein thrombosis in symptomatic outpatients and the potential for clinical assessment and D-dimer assays to reduce the need for diagnostic imaging. *Br J Haematol*, 2004;124:15-25

Erythrocyte Sedimentation Rate (ESR)

Indications: The ESR may be used to evaluate patients with unexplained symptoms or deteriorating health when:

- (a) an inflammatory neoplastic or infectious disease is suspected
- (b) a specific diagnosis is not made by other means

The ESR is often employed clinically to monitor activity of giant cell arthritis, polymyalgia rheumatica, inflammatory arthritis and some infections.

Not indicated: No evidence to support the use of ESR in asymptomatic individuals and the test should not be appended to routine investigations.

Minimum frequency to repeat: 7 days. As levels take a week to rise in inflammatory states there is little value in estimating the ESR at more than weekly intervals.

Samples to send: 4 ml EDTA sample.

Reference interval: 2-15 mm/h

Other considerations (physiological variables): Relatively non specific test that can be affected by a variety of factors that may be unrelated to the disease process including red cell count, fluid status, age, sex, smoking and drugs.

References:

1. Brigden M. The Erythrocyte Sedimentation Rate. Still a helpful test when used judiciously. *Postgrad Med* 1998; 103: 257-274.
2. Saadeh C. The Erythrocyte Sedimentation Rate: Old and New Clinical Applications. *South Med J* 1998; 3: 220-225.
3. Sox HC Jr, Liang MH. The Erythrocyte Sedimentation Rate: Guidelines for Rational Use. *Ann Intern Med* 1986; 104: 515-523.

Heparin-induced Thrombocytopenic Thrombosis (HITT)

Indications: Patients receiving any heparin preparation including heparin/saline flushes who develop:

- New acute thrombotic problems
- Thrombocytopenia

Use the pre-test probability scoring system to guide clinical action/testing (see Table below)

Not indicated: Routine monitoring

Minimum frequency to repeat: No recommendation

Pre-test probability of HITT: the 'four Ts'

Category	Score		
	2	1	0
Thrombocytopenia	> 50% fall or nadir 20–100	30–50% fall or 10–19	<30% fall nadir <10
Timing of platelet count fall	5-10 days or <1 day if recent heparin exposure	>10 days	<5 days if no recent heparin exposure
Thrombosis	New thrombosis; skin necrosis; post heparin acute systemic reaction	Progressive or recurrent thrombosis; erythematous skin lesions; suspected thrombosis	None
Other causes of thrombocytopenia	No other cause for platelet count fall	Possible other cause	Definite other cause

Action based on pre-test probability score:

High (6-8): Send test and treat without result

Intermediate (4-5): Wait for test result

Low (0-3): No need to test

Contact haematology if further advice is required

Samples to send: Clotted venous blood

References:

BCSH Guideline: The Management of Heparin-induced Thrombocytopenia. Br J Haematol, 2006; 133: 259-269

Warkentin & Heddle. Laboratory Diagnosis of Immune Heparin-induced Thrombocytopenia. Curr Hematol Rep, 2003; 2: 148-157

Thrombophilia Screening

Indications: Recurrent venous thromboembolism (VTE) in individuals aged < 40 years. Apparently spontaneous VTE in individuals < 40 years, and strong family history of VTE.

Not indicated: DVT after known provoking factor such as trauma, surgery, immobility, cancer, pregnancy, oral contraceptive pill, HRT, etc.

Routine testing in individuals > 40 years with VTE

Arterial thrombosis (except lupus anticoagulant - may be useful in selected cases)

Samples to send: See lab handbook.

Other considerations (physiological variables): Timing of Investigation:

Most of the tests can be adversely affected by acute thrombosis, pregnancy, OCP, HRT, and anticoagulant treatment. Early diagnosis of a thrombophilia defect does not influence acute management.

Therefore, avoid testing during:

- Acute thrombotic event
- Other acute intercurrent illness
- Pregnancy
- Whilst the patient is receiving OCP, HRT, or anticoagulants

CLINICAL CHEMISTRY

Numerical results quoted should be regarded as typical target values rather than absolute cut offs. Values may change slightly between different laboratories.

Alpha-fetoprotein (AFP)

Indications: Used to diagnose and monitor hepatocellular carcinoma and hepatoblastoma and monitor non-seminomatous germ cell tumours of testis.

Not indicated: Screening

Minimum frequency to repeat: Outpatient 20 days, GP 28 days.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* non-seminiferous germ cell tumours of testis, ovary and other sites. Hepatocellular carcinoma. Hepatoblastoma.

Reference interval: <10 kU/L

Other considerations (physiological variables): Elevated in certain non-neoplastic conditions such as liver cirrhosis and alcoholic liver disease.

References:

Guidelines on the use of Tumour Markers
ACBI 2005. <http://www.acbi.ie>

Brain Natriuretic Peptide (BNP)

BNP and N terminal pro-BNP are elevated in patients with heart failure and with left ventricular systolic impairment. A normal level makes these diagnoses highly unlikely.

Indications: For the diagnosis of left ventricular systolic impairment in symptomatic patients i.e. symptoms compatible with heart failure and normal or mildly abnormal 12 lead ECG.

Can help in the assessment of drug therapy or the prognosis in certain patients with known heart failure or left ventricular systolic impairment.

Not indicated: If the ECG has major abnormality e.g. LBBB, LAHB, atrial fibrillation, Q waves, left ventricular failure. In patients with dyspnoea where a non-cardiac diagnosis seems likely.

Minimum frequency to repeat: Single estimation sufficient for diagnosis.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* levels increase with severity of cardiac impairment.

Reference interval: Your laboratory will give guidance and should be contacted for interpretation.

NT pro-BNP is considered elevated if above 300pg/ml. A recent expert panel of the European Society of Cardiology (ESC Vienna Sept 2007) recommended an age related cut off for the diagnosis of heart failure.

Age <50 years > 450 pg/ml

Age 50-75 years > 900 pg/ml

Age >75 years > 1800 pg/ml

This approach adjusts for changes in renal function.

Other considerations (physiological variables): There is variability in BNP values so small changes should be viewed with caution. Levels change with age (particularly NT pro-BNP), hypertension and renal impairment. Diseases such as pulmonary embolism and atrial fibrillation cause elevated levels (particularly NT pro-BNP). The result must be interpreted in the light of the clinical presentation.

References:

Guidelines on the management of chronic heart failure in Northern Ireland. CREST, DHSSPS, 2005. www.crestni.org.uk

Meuller C, Scholer A, Laule-Killian K et al. Use of B-type natriuretic peptide in the evaluation and management of acute dyspnoea. *N Eng J Med* 2004; 350: 647-654.

Latini R, Masson S, Anand I et al. The comparative prognostic value of plasma neurohormones at baseline in patients with heart failure enrolled in Val-HeFT. *Eur Heart J* 2004; 25: 292-219.

Clerico A, Amdin M. Diagnostic accuracy and prognostic relevance of the measurement of cardiac natriuretic peptides: A review. *Clin Chem* 2004; 50: 33-50.

Bone Profile

Indications: To identify any suspected problems with bone metabolism.

Not indicated: For screening.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Calcium is commonly elevated by primary hyperparathyroidism, osteolytic bone secondaries, sarcoidosis, excess vitamin D. Clearly alkaline phosphatase rises with obstructive liver disease, rises with bone secondaries, and because it is produced by the placenta, will rise in pregnancy.

Pathological decrease: Calcium is often reduced in vitamin D deficiency, renal failure and where albumin is reduced as part of the acute phase response to inflammation, when corrected calcium may be normal.

Reference interval:

Alkaline phosphatase

40 – 129 U/L Adult males

35 – 104 U/L Adult females

Age related reference interval

Calcium

2.15 – 2.55 mmol/L

Phosphate

0.87 – 1.45 mmol/L

Age related reference interval

Other considerations (physiological variables): Corrected calcium is useful and the sample should be taken uncuffed to give a correct value. Parathyroid hormone measurement may sometimes be indicated (EDTA sample on ice).

CA 125

Indications: Used in the differential diagnosis of pelvic masses and monitoring of ovarian cancers.

Not indicated: Screening

Minimum frequency to repeat: Outpatient: 20 days. GP: 28 days.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Epithelial ovarian cancer, any adenocarcinoma with advanced disease.

Reference interval: <35 kU/L

Other considerations (physiological variables): Certain benign conditions lead to elevated levels. Conditions such as cirrhosis, endometriosis and pancreatitis.

References:

Guidelines on the use of Tumour Markers. ACBI 2005. <http://www.acbi.ie>

Cardiac Troponins

Indications: In the diagnosis and treatment of acute myocardial infarction (AMI) and in risk stratification of patients with acute coronary syndromes.

Not indicated: Cardiovascular disturbance for which there is another evident cause e.g. hypovolaemic shock. Not used as 'baseline' or 'screening' tests in patients without acute symptoms.

Minimum frequency to repeat: 12 hours post event. Can be elevated up to two weeks after an event.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* As a result of myocardial necrosis, levels rise from approximately 4 hours post event to reach measurable levels at 6h and continuing to rise for approximately 24h before falling over a number of days.

Reference interval: This varies with the particular Troponin assay used by the laboratory. If in doubt contact your laboratory for help with interpretation.

Other considerations (physiological variables): Troponin measurements are a sensitive marker of myocardial damage and may be released in any situation when the myocardium is stressed i.e. prolonged tachycardia or hypotension. Can be raised in renal failure and it is not clear whether the rise indicates myocardial damage under these circumstances. It is essential to consider the full clinical picture when diagnosing myocardial ischaemia or infarction.

References:

1. Alpert et al. Myocardial Infarction Redefined – A Consensus Document of the Joint European Society of Cardiology / American College of Cardiology Committee for the redefinition of myocardial infarction. J Am Coll Cardiol 2000; 36: 959-969.
2. Goodacre et al. A Prospective, Observational Unit of a Chest Pain Unit in a British Hospital. Emerg Med J 2002; 19: 117-121.
3. Burness CE, Beacock D, Channer KS. Pitfalls and Problems of relying on Serum Troponins. Q J Med 2005; 98: 365-371.

CEA

Indications: Monitoring patients with diagnosed colorectal cancers. Elevated in many advanced adenocarcinomas.

Not indicated: Screening

Minimum frequency to repeat: Outpatient: 20 days. GP: 28 days.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Almost any advanced adenocarcinoma.

Reference interval: <5 µg/L

Other considerations (physiological variables): Can be elevated in a number of non-cancer diseases such as cirrhosis, ulcerative colitis, Crohn's disease.

References:

Guidelines on the use of Tumour Markers
ACBI 2005. <http://www.acbi.ie>

C-Reactive Protein (CRP)

CRP is an acute-phase protein synthesised by hepatocytes that increases in plasma in response to inflammation and infection.

Indications: Serial measurements of CRP can be used as a diagnostic tool for infection or inflammation, monitoring the effect of treatment, or early detection of relapse.

Advantages over ESR:

- (a) monitoring risk of infection following a surgical procedure – if levels high after 3rd post surgical day an infection may be present.
- (b) monitoring cancer treatment and treatment in children.

Not indicated: No evidence for evaluation in asymptomatic individuals and the test should not be appended to routine investigations.

Minimum frequency to repeat: As levels can increase within 4 hours and double every 8 hours (half-life <24 hours) serial measurements at 24 - 48 hour intervals may be indicated to monitor effects of treatment.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Different forms of tissue injury such as infection, immuno/allergic reaction, thermal injury, hypoxic injury, trauma, surgery and malignancy.

Reference interval: <6 mg/L

Other considerations (physiological variables): Changes in CRP levels must be evaluated in the clinical context and NOT employed as the sole arbiter for guiding treatment.

References:

1. Castell JV, Gomez-Lechon MJ, David M, Fabra R, Trullen R, Heinrich PC. Acute-Phase Response of Human Hepatocytes: Regulation of Acute-phase Protein Synthesis by Interleukin-6. *Hepatology* 1990; 12: 1179-1186.
2. Clyne B, Olshaker JS. The C-Reactive Protein. *J Emerg Med* 1999; 17: 1019-1025.
3. van der Meer V, Neven AK, van der Broek PJ, Assendelft WJ. Diagnostic Value of C-Reactive Protein in Infections of the Lower Respiratory Tract: Systematic Review. *BMJ* 2005; 331: 26-32.

Estimated Glomerular Filtration Rate (eGFR)

Indicated: eGFR provides a mathematically derived indication of renal function based on serum creatinine. It is closely correlated to isotopic GFR and is normally > 100ml/min/1.73m² in healthy young adults. However reduced GFR occurs with aging, so often a stable eGFR of 60-90 may not be of consequence. Its role is to highlight degrees of acute and chronic kidney disease (CKD) and to track its progression similarly to serum creatinine measurement.

Causes of reduced eGFR/elevated creatinine include pre-renal (dehydration), renal (especially associated with diabetes, hypertension, atherosclerotic and proteinuric diseases) and post-renal (obstruction with bladder, prostate and renal stone disease) causes. Please refer to the reference Northern Ireland CKD guidelines 'CREST Guidelines for Chronic Kidney Disease in Northern Ireland' and similar information at the sites below:

www.crestni.org.uk

www.renal.org/guidelines

Minimum frequency to repeat: All patients with newly detected abnormal kidney function should be assumed to have ARF until proven otherwise. eGFR/serum creatinine should be repeated urgently (in days) if ARF suspected and at least annually/often 3 or 6 monthly if CKD confirmed (see NI guidelines). A decline of 25% in eGFR or a 15% rise in creatinine requires urgent assessment as do patients with systemic symptoms or urine dipstick abnormalities.

Value in disease monitoring: *Pathological rise:* Useful regular marker for high-risk patients (diabetes, hypertension, CCF, IHD, urinary symptoms) or if on potentially nephrotoxic drugs (ACEI/ARBs/Diuretics/NSAIDs/Lithium).

Sample to send: Clotted Blood (Gel Tube) will allow for both U+E and eGFR. If non-caucasian please mention race on the form.

Other Considerations: eGFR uses the serum creatinine measurement along with 3 other variables (age, sex and race) to estimate the glomerular filtration rate. Use of eGFR allows earlier identification of patients with chronic kidney disease than use of serum creatinine alone. This is especially the case for the elderly and females where reduced muscle mass results in a lower creatinine reference range. There is an influence of BMI and body surface area on eGFR.

References:

1. Current Laboratory Practise, Ontario Society for Clinical Chemists (OSCC). OSCC website www.clinicalchemistry.on.ca
2. Chronic Kidney Disease in Adults: UK Guidelines for Identification, Management and Referral. <http://www.renal.org/CKDguide/ckd.html>
3. NI Guidelines - 'CREST Guidelines for Chronic Kidney Disease in Northern Ireland.'

HbA1c

Indications: Indication of blood glucose control in past 2-4 weeks.

Not indicated: Diagnosis of diabetes mellitus.

Minimum frequency to repeat: 40 days.

Samples to send: EDTA sample

Value in disease monitoring: *Pathological rise:* High glucose values result in more binding to haemoglobin giving an increase % value. Good indicator of diabetic control.

Reference interval: <7% good control.

Other considerations (physiological variables): HGA1c is now standardised in Northern Ireland to the DCCT (Diabetes Complications and Control Trial) Standard. Anything that alters the life span of the red cell will affect the percentage of glucose bound to haemoglobin. Some patients have haemoglobin variants present which will affect the result. If you have any doubts contact your laboratory.

Iron Assessment Profile

Indications: To assist with determining body iron stores – either iron deficiency or iron excess. Iron and transferrin, the major plasma transport protein for iron, and percentage saturation are helpful. Serum ferritin is a measure of iron stores but rises in acute inflammation. Soluble transferrin receptor (sTfR) may be a more accurate reflection of absolute iron availability and is less affected by acute inflammation.

Minimum frequency to repeat: 60 days. When treating iron deficiency with oral iron it is useful to repeat the test at monthly intervals.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: Low iron and reduced percentage saturation is in keeping with iron deficiency. A low ferritin, low transferrin and increased sTfR are in keeping with iron deficiency. High serum iron and increased percentage saturation are in keeping with iron storage conditions such as haemochromatosis, which will require genetic testing if suspected. Raised ferritin is due to acute inflammation or iron storage disease such as haemochromatosis.

Reference interval:

<i>Iron</i>	Male 6-26 µmol/L Female 5-28 µmol/L
<i>Transferrin</i>	Male 1.74- 3.64 g/L Female 1.8-3.82 g/L
<i>% Saturation</i>	Male 20-55% Female 15-50%
<i>Ferritin</i>	Male 20-275 µg/L Female 5-204 µg/L
<i>Soluble Transferrin Receptor</i>	> 1.90 mg/L indicates iron deficient anaemia

Other considerations (physiological variables): The oral contraceptive pill can raise transferrin results. With chronic (long term) illness, a low iron occurs with a low transferrin. Eating has an effect on percentage saturation so a fasting sample will give a more definitive estimate.

Lipid Measurement

Indications: To assess risk factors for vascular disease and to determine the need for, and the effectiveness of lipid lowering therapy. A fasting sample for measurement of total cholesterol, total triglyceride and HDL cholesterol is required. The laboratory should give a calculated LDL cholesterol value and a total cholesterol to HDL ratio. The recently published 'European guidelines on cardiovascular disease prevention in clinical practice' gives excellent information on lipid and cardiovascular risk factor evaluation.

The European guidelines suggest that priorities for CVD prevention in clinical practice include:

1. Patients with established atherosclerotic CVD.
2. Asymptomatic individuals who are at increased risk of CVD because of:
 - a. Multiple risk factors resulting in raised total CVD risk (>5% 10-year risk of CVD death).
 - b. Diabetes type 2 and type 1 with microalbuminuria.
 - c. Markedly raised single risk factors especially if associated with end-organ damage.
3. Close relatives of subjects with premature atherosclerotic CVD or of those at particularly high-risk.

Not indicated: Unless carried out within 24 hours of a Myocardial Infarction (MI), the measurement should not be carried out for a month after an MI. Measurement in the ill patient will give abnormally low results.

Minimum frequency to repeat: Every five years in the clinically normal adult and annually in patients stable on therapy. The MRI is 28 days if the situation is changing.

Reference interval:

Total cholesterol <5.0 mmol/L desirable, <4.0 mmol/L in secondary prevention.

HDL > 1.0 mmol/L.

LDL < 3.0 mmol/L desirable in primary prevention, < 2.0 mmol/L in secondary prevention.

The NI 'Service Framework for Cardiovascular Health and Wellbeing' is out for consultation at present and contains much useful information.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: Usually life style measures should be considered for a short period before lipid-lowering drugs are used. Life style measures take six weeks to achieve change. Lipid lowering therapy should be considered for primary prevention when the 10 year risk of a major coronary event is >20% using the Joint British Societies Risk Prediction Chart (back of the BNF). The treatment target for primary prevention should be a total cholesterol <5 mmol/l, with a fall of at least 1 mmol/l (SIGN Guidelines). The precise value to treat to is a clinical decision.

The European guidelines suggest that in general, a middle-aged person with a 10-year risk of CVD death of 5% or more is regarded as at increased risk. The aim of therapy would be to achieve a total cholesterol of < 5 mmol/L (or < 4 mmol/L in high-risk), and an LDL cholesterol of < 3 mmol/L (<2 mmol/L in high-risk individuals).

Other considerations (physiological variables): Cholesterol levels will fall in any illness, so the sample should be taken when the patient is apparently healthy.

References:

<http://www.bmj.com/cgi/content/full/320/7236/705>

SIGN guidelines on 'Lipids and the Primary Prevention of Coronary Heart Disease'.

SIGN guidelines on 'Management of Diabetes'.

CREST 'Guidelines on the use of Lipid Lowering Drugs' 2000. www.crestni.org.uk

European Guidelines on Cardiovascular Disease Prevention in Clinical Practice. Atherosclerosis 2007; 194: 1-45.

Interim Guide to the use of Dyslipidaemic Drugs, March 2007. Published by the DHSSPS.

Liver Biochemistry in Adults

Abnormal liver tests indicate liver pathology and provide clues as to the nature of the problem.

Indicated:

Evaluation and monitoring liver pathology:

Two broad categories of liver enzyme abnormalities indicate -

(a) damage to liver cells (hepatocellular injury) reflected by elevation in Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT)

(b) obstruction/damage to intra- or extra-hepatic bile ducts (cholestasis) reflected by elevation in alkaline phosphatase (ALP) and Gamma Glutamyl Transpeptidase (GGT). Bilirubin may be elevated in hepatocellular injury and cholestasis.

Evaluation and monitoring liver function:

Synthetic function may be estimated by measuring serum albumin and the International Normalised Ratio (INR).

Monitoring liver chemistry with specific medication use.

Not Indicated: Routine assessment without specific indication or suspicion of liver pathology.

Minimum frequency to repeat: The MRI for these tests is 3 days. In most cases twice-weekly measurement is adequate for assessment and monitoring purposes.

Sample to send: Clotted Blood (Gel Tube).

Reference interval:

<i>Bilirubin</i>	<17 mmol/L adults
<i>Aspartate Aminotransferase (AST)</i>	< 37 U/L males < 31 U/L females
<i>Alanine Aminotransferase (ALT)</i>	< 41 U/L males < 31 U/L females
<i>Alkaline Phosphatase (ALP)</i>	40 – 129 U/L adult males 35 – 104 U/L adult females
<i>Albumin</i>	34 – 48 g/L adults

Other Considerations: Serum enzyme levels can correlate poorly with the severity of underlying pathology and metabolic activities of the liver.

Isolated minor abnormalities in serum enzyme levels in an asymptomatic patient should prompt retesting in 1-3 months, after addressing potential causes.

Disease specific tests (auto-antibodies, copper and iron studies, alpha-feto protein, viral markers) should be obtained in appropriate circumstances.

References:

1. American Gastroenterological Association. American Gastroenterological Association Medical Position Statement: Evaluation of Liver Chemistry Test. *Gastroenterology* 2002; 123:1364-1366.
2. Green RM, Flamm S. AGA Technical Review on the Evaluation of Liver Chemistry Tests. *Gastroenterology* 2002; 123:1367-84.
3. Lee WM. Drug-Induced Hepatotoxicity. *N Engl J Med* 2003;349:474-85.
4. Minuk GY. Canadian Association of Gastroenterology Practice Guidelines: Evaluation of Abnormal Liver Enzyme Tests. *Can J Gastroenterol* 1998; 19:203-15.

Prostate-Specific Antigen (PSA)

Indications: Men > 50, + ve family history, Afro-American, high fat diet.

Not indicated: Screening.

Minimum frequency to repeat: Outpatient 20 days, GP 28 days. If normal repeat annually.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Useful in detecting prostate cancer early. Rapid rise correlates with tumour aggression.

Reference interval: <2.5 µg/l. Age related.

Other considerations (physiological variables): Raised in benign prostatic hypertrophy, prostatitis, urinary tract infection.

References:

Guidelines on the use of Tumour Markers. ACBI 2005. <http://www.acbi.ie>

Thyroid Function Tests

Indications: To determine thyroid status or to monitor therapy.

Primary hypothyroidism:

Subjects with a TSH of >10 mU/L and FT_4 below the reference range have overt primary hypothyroidism and should be treated with thyroid hormone replacement. Monitor with measurements every 2 months

Subclinical hypothyroidism:

TSH concentration above the upper limit of reference range but <10 mU/L measure thyroid peroxidase antibodies.

If high: serum TSH should be measured annually or earlier if symptoms develop; thyroxine therapy started if serum TSH concentration rises above 10 mU/L.

If normal: measure TSH every three years.

Secondary hypothyroidism:

Low FT_4 and TSH of secondary hypothyroidism distinguished from non-thyroidal illness by clinical history, FT_3 and concentrations of other pituitary hormones.

Hyperthyroidism:

Patients with elevated FT_4 and TSH <0.1 mU/L - refer to specialist to confirm diagnosis and optimal treatment plan. TSH receptor antibodies and thyroid peroxide antibodies may sometimes be indicated.

Subnormal TSH, FT_4 not elevated - FT_3 should be measured to identify cases of T_3 thyrotoxicosis.

Serum TSH concentration below the lower limit of reference range but >0.1 mU/L repeat measurements one or two months later including a serum FT_4 and FT_3 , after excluding non-thyroidal illness and drug interferences.

If treatment is not undertaken, serum TSH should be measured every 6-12 months, with follow-up measurements of serum FT_4 and FT_3 if the serum TSH result is low.

- Particular care is required in the diagnosis of hyperthyroidism in patients taking amiodarone. The measurement of TSH, FT_4 and FT_3 is required.

- Thyroid function testing during pregnancy should comprise both TSH and FT₄. TPO-Ab should also be considered as this has predictive value for both post-partum thyroiditis and foetal impairment.

Sick-euthyroid syndrome: Patients with a wide range of acute or chronic illness may show changes in thyroid function tests even though they are clinically euthyroid. In most of these patients TSH will be normal and this gives a good guide to thyroid status. In some patients TSH may be suppressed acutely and on recovery TSH can rise into the hypothyroid range briefly. T3 (total and free) usually fall. If in doubt consult a thyroid physician or the laboratory.

Minimum frequency to repeat: 14 days or annually if stable.

Samples to send: Clotted Blood (Gel Tube).

Reference interval:

These may vary between laboratories and the figures below are indicative only:

<i>TSH</i>	0.3 - 4.5 mU/L
<i>Free T4</i>	11 - 21 pmol/L
<i>Free T3</i>	3.5 - 7.9 pmol/L

Other considerations (physiological variables): Thyroid function tests should not be carried out in an ill patient unless there is overriding clinical necessity, as illness itself can alter values. Used to determine neonatal hypothyroidism, in the treatment of hyper and hypothyroidism, after neck irradiation, after pituitary surgery or irradiation, in patients on amiodarone or lithium and in type 1 diabetes post partum.

References:

www.british-thyroid-association.org
www.acb.org.uk

Urea and Electrolytes

Indications: Blood urea and creatinine are indicators of renal function and rise due to pre-renal (dehydration), renal (intrinsic renal disease) and post renal (obstruction) causes. As part of routine blood testing, or if there is a suspicion of electrolyte imbalance (usually sodium or potassium), or if an acid-base imbalance is suspected. Electrolytes may also be checked if the patient is prescribed certain drugs, particularly diuretics or ACE inhibitors.

Minimum frequency to repeat: 24 hours. Often daily in acute illness that can affect renal function and more often in certain conditions such as hyponatraemia and hyperkalaemia. Useful if ACEI or other potentially nephrotoxic drugs are used (alternate days or weekly). In a stable patient in the community, as part of a health check.

Samples to send: Clotted Blood (Gel Tube).

Value in disease monitoring: *Pathological rise:* Serum creatinine of 150-300 mmol/l indicates mild renal impairment, 300-500 mmol/l indicates moderate renal impairment and over 500 mmol/l indicates severe renal impairment. The aim of assessment is to identify those patients with mild to moderate renal impairment as they have the most to gain from treatment to prevent their situation deteriorating. The eGFR is a better estimate of renal impairment – see above.

Reference interval:

Sodium	135-145 mmol/L
Potassium	3.5-5.2 mmol/L
Chloride	95-110 mmol/L
Bicarbonate	22-30 mmol/L
Total protein	60-80 g/L
Urea	2.5-7.5 mmol/L
Creatinine	80-115 µmol/l (M) 53-97 µmol/l (F)

Other considerations (physiological variables): Both urea and creatinine rise with a protein meal and serum creatinine is related to muscle mass. Urea level falls in starvation and in pregnancy.

MICROBIOLOGY

Blood Culture

Indications: Blood culture is recommended on all patients with suspected septicaemias.

Samples to send: This must be collected using strict aseptic technique and should be collected before antibiotic treatment is commenced.

Other considerations (physiological variables): For patients with suspected endocarditis, three sets of blood culture in the first 24 hours (from separate venepunctures) are required. It is recommended that at least 30 ml of blood is cultured in total. In the patient who is acutely ill, three sets of blood cultures should be taken within 2 hours before starting empirical therapy.

References:

British Society for Antimicrobial Chemotherapy. Guidelines for the Antibiotic Treatment of Endocarditis in Adults. *Journal of Antimicrobial Chemotherapy* 2004; 54, 971-981.

Mid Stream Specimen of Urine (MSSU)

Indications: To detect urinary tract infections.

Ideally the specimen should be examined within two hours of collection. The specimen should be refrigerated if it cannot be examined promptly.

Perform dipstick analysis FIRST to detect leucocytes and nitrites.

Dipstick analysis	Sensitivity (%)	Specificity (%)
Leucocytosis	89	68
Nitrites	57	96

If both dipstick and direct microscopy are **NEGATIVE**, no need for formal culture of MSSU.

A positive culture is indicated by $>10^6$ colonies uropathogen.

Not indicated: No urinary symptoms.

Frequency to repeat: Repeat specimen is indicated if symptoms persist despite antibiotic treatment.

Urine Specimen collection: Clean catch in men or women, catheter specimens in women where difficulties with obtaining sample (British Urological Institute GP guidelines).

Other considerations:

In children – low threshold for referral and investigation.

In men – UTI much less common than women. Consider ultrasound scan of urological tract and referral.

In pregnant women – reagent strips in early pregnancy not always enough to identify asymptomatic bacturia in early pregnancy. Do not prescribe broad-spectrum antibiotics unless positive urine culture results.

A negative dipstick and direct microscopy result will give a negative predictive value of 98%. It is estimated to decrease the need for culture by 75% and the associated costs are reduced x20.

References:

1. Correlation between urine dipstick and urine culture in screening women with urinary incontinence for urinary tract infection.
Buschbaum G, Albushies D. ICS 2004.
2. The cost effectiveness of combined rapid tests (Multistix) in screening for urinary tract infections.
Fowles GA, Waters J, Williams G. J R Soc Med 1994 Nov; 87(11): 681-682
3. A study of microscopical and chemical tests for the rapid diagnosis of urinary tract infection in general practice.
Ditchburn RK, Ditchburn JS. Br J Gen Practice 1990 Oct; 40 (339): 406 -408

Sputum for Culture.

Indications: Sputum sample should be sent for culture and sensitivity from patients with pneumonias who are able to expectorate purulent samples and who have not received previous antibiotic therapy.

Not indicated: Specimens that are largely or wholly saliva yield misleading information and should not be sent for culture.

Minimum frequency to repeat: For investigation of tuberculosis, 3 consecutive specimens are required. A single negative smear does not exclude the diagnoses of pulmonary tuberculosis, as the release of infectious droplets can be intermittent.

Samples to send: They should be transported to the laboratory as quickly as possible. Sputum specimen should not be refrigerated.

References:

British Thoracic Society. Guidelines for the Management of Community Acquired Pneumonia in Adults. Thorax 2001; 56, Supp No IV: iv 1-64. 2004 update.
<http://www.brit-thoracic.org.uk/docs/MACAPrevisedApr04.pdf>.

British Thoracic Society Guidelines. Chemotherapy and Management of Tuberculosis in the United Kingdom: Recommendations 1998. Thorax 1998; 53: 536-548.

Stool for *C difficile*

Indications: Only diarrhoeal stools over 65 years should be sent to the microbiology laboratory for detection of *C. difficile* toxin.

Not indicated: Screening and treatment of asymptomatic patients is not necessary.

Minimum frequency to repeat: Once the diagnosis has been confirmed, *repeat specimens need not be taken* unless there is a relapse following treatment. This is because it is not uncommon for the faeces to remain toxin- positive for some time after the start of treatment, even when the patient's symptoms have settled.

Samples to send: Sample of stool.

References:

National *Clostridium difficile* Standards Group. Report of Department of Health. *Journal of Hospital Infection* (Supplement 1) 2004; 56: 1-38.

IMMUNOLOGY

Specific Allergy Testing

Indications: Identifying causative allergens in allergic disease. Please indicate suspected allergen on the request form.

Not indicated: Chronic fatigue syndrome, constipation, arthritis, depression. Screening for multiple food allergens not indicated.

Minimum frequency to repeat: Only if history changes significantly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Allergen scores do not reflect clinical severity of reactions.

Reference interval: 95% positive predictive values are available for selected food allergens.

ANCA

Indications: Investigation of glomerulonephritis (especially RPGN), pulmonary haemorrhage, cutaneous vasculitis with systemic features, multiple lung nodules, chronic destructive disease of the upper airways. Long standing sinusitis or otitis, subglottic tracheal stenosis, mononeuritis multiplex or other peripheral neuropathy, retro-orbital mass.

Not indicated: Large or medium vessel vasculitis.

Minimum frequency to repeat: Not more than 3 monthly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Literature provides conflicting evidence. Caution that infection may cause a rise in ANCA titre.

References:

ANCA testing – International consensus statement. Savige et al 1999. Am J Clin Pathol; 111 (4); 507-513.

Antiphospholipid /Anticardiolipin Antibody Testing

Indications: The identification of patients likely to have primary or secondary Antiphospholipid Antibody Syndrome (APS) i.e. all patients who present with a thrombosis with no clear provoking factors.

Investigation of adverse pregnancy outcome i.e.

- (a) Three or more consecutive miscarriages before 10 weeks gestation,
- (b) one or more morphologically normal foetal death after the tenth week of gestation and
- (c) one or more preterm births before the 34th week of gestation due to severe pre-eclampsia, eclampsia or placental insufficiency.

Arterial thrombosis

Not indicated: DVT after known provoking factor i.e. trauma, surgery, malignancy.

Timing of Investigation: The patient must have at least two positive tests at least six weeks apart for either Lupus Anticoagulant (LAC) or Anticardiolipin Antibodies (ACL) in medium or high titre.

Samples to send: See lab handbook.

Other considerations (physiological variables): The diagnosis of anticardiolipin syndrome can be difficult and may require input from a number of specialities. The assays may need to be repeated several times as there is assay variability. The diagnosis is a clinical diagnosis of which laboratory tests are only a part.

References:

The Investigation and Treatment of Couples with Recurrent Miscarriage. RCOG Green Top Guideline No 17: <http://www.rcog.org.uk>

Anti-ds DNA

Indications: Suspected Systemic Lupus Erythematosus (SLE).

Minimum frequency to repeat: Not more than 3 monthly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Yes, level reflects disease activity.

Anti-thyroid Autoantibodies

Indications: Confirmation of autoimmune basis of thyroid disease.

Not indicated: In non-specific illness.

Minimum frequency to repeat: Only if clinical history changes.

Samples to send: Clotted blood sample.

Value in disease monitoring: No.

Autoantibody Screen

Indications: Suspected non-organ specific autoimmune disease.

Minimum frequency to repeat: 3-6 monthly if clinical history changes significantly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Changes in titre are not necessarily indicative of altered disease activity.

Coeliac Serology (Endomysial and TTG Antibodies)

Indications: Suspected coeliac disease e.g. failure to thrive, malabsorption, unexplained anaemia, diarrhoea etc.

Minimum frequency to repeat: Only if clinical history changes significantly or to monitor compliance 3 monthly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Both autoantibodies may become negative on gluten free diet therefore there is value in repeat serology.

Complement C3, C4

Indications: Systemic autoimmune disease, cryoglobulinaemia, post-infectious glomerulonephritis.

Minimum frequency to repeat: Only if clinical history changes significantly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Yes for monitoring of post-streptococcal glomerulonephritis, SLE activity and activity for vasculitis and other connective tissue diseases.

Immunoglobulins

Indications: Suspected immunodeficiency or lymphoproliferative disease.

Minimum frequency to repeat: 28 days and usually not more than 3 monthly.

Samples to send: Clotted blood sample.

Value in disease monitoring: Yes in both primary immunodeficiency and myeloma.

Other considerations (physiological variables): Characteristic elevation of immunoglobulins may be seen in chronic infection, inflammatory and autoimmune disorders.

Rheumatoid Factor

Indications: Suspected rheumatoid arthritis.

Not indicated: For assessment of disease activity.

Minimum frequency to repeat: Only if clinical history changes significantly.

Samples to send: Clotted blood sample.

Value in disease monitoring: No value.

Total Serum IgE

Indications: Atopic status, parasitic infestation.

Not indicated: In non-specific illness.

Minimum frequency to repeat: Only if clinical history changes.

Samples to send: Clotted blood sample.

Value in disease monitoring: In monitoring resolution of parasitic infection.

Reference interval: < 120 kU/L (adults)

LABORATORY MONITORING REQUIRED FOR SPECIFIC DRUGS

Angiotensin Converting Enzyme Inhibitors (ACEI)

Indications: ACEI drugs can affect renal function. A Urea & Electrolyte (U & E) test is recommended.

Samples to send: Clotted blood sample (gel tube).

Minimum frequency to repeat: A U & E test is recommended before initiation of therapy, within 2 weeks of start and at least annually after commencement of a drug. Also a check should be done if blood pressure renal function or blood chemistry changes suspected.

Amiodarone

Indications: Amiodarone can affect thyroid and liver function. Monitoring tests should be carried out at intervals.

Minimum frequency of testing: A liver function test and a thyroid function test (including T₃, T₄, TSH) should be done before initiating amiodarone and at 6 monthly intervals. A chest x-ray is needed before initiating therapy and annually while on treatment.

Samples to send: See local laboratory handbook.

Digoxin

Indications: Serum digoxin level for monitoring, if required. A U & E test as well as serum magnesium and calcium levels. Digoxin levels are not routinely done unless clinically indicated, but if needed should be taken at least 6 hours post dose.

Minimum frequency to repeat: Tests should be done before initiation of therapy and then if clinically indicated.

Samples to send: See local laboratory handbook.

Other considerations (physiological variables): Maintenance dosage in atrial fibrillation should be guided by the ventricular heart rate, which should not be allowed to go below 60 beats per minute unless there is concomitant administration of a beta-blocker.

Diuretics

Indications: Diuretics can affect blood chemistry in many different ways.

Minimum frequency to repeat: If clinically indicated then a U & E, blood sugar, uric acid, magnesium, calcium and lipid profile may be appropriate to monitor. Primary and secondary care needs for these tests can vary markedly.

Samples to send: See local laboratory handbook.

Other considerations (physiological variables): Age of patient and concurrent pathologies and multiple drug usage would suggest a need for regular monitoring.

Statins

Indications: Liver function tests and creatine kinase.

Minimum frequency to repeat: Liver function tests should be done before initiating treatment, within 1-3 months of initiation and then 6 monthly thereafter for 1 year and also if clinically indicated by signs or symptoms suggestive of hepatotoxicity.

Other considerations (physiological variables): Treatment should be discontinued if serum transaminase concentration rises to and persists at x3 the upper limit of the reference range.

Hypothyroidism should be corrected before treatment considered.

Muscle effects are a rare complication of statin use and if myopathy is suspected and the Creatine Kinase is elevated above x5 the upper limit of normal then treatment should be stopped. Also in patients with a high risk of muscle effects, a statin should not be used if the Creatine Kinase is raised.

Lithium

Indications: Monitoring of serum lithium. Thyroid function testing and U & E are required at intervals.

Minimum frequency to repeat: A U & E test should be done before initiating therapy with lithium and also if there are any concerns over toxicity. A thyroid function test should be done every 6-12 months when on a stabilised regimen. Serum for lithium testing should be drawn 12 hours after dosing. When initiating therapy serum lithium should be tested on day 4-7 following, then weekly until dosage has been constant for 4 weeks and then every 3 months or if toxicity suspected.

Other considerations (physiological variables): Lithium salts have a very narrow therapeutic/toxic ratio. Lithium can affect thyroid function. Lithium toxicity can be made worse by sodium depletion as might occur with concomitant diuretic administration.

Appendix 1

Suggestions for audit of GAIN use of laboratory guidelines.

The tests referred to in this guideline are diverse and varied. These suggestions are some simple measures designed to improve test use.

1. Were there appropriate indications for the tests being requested?
2. Was a clinical history given on the request form?
3. Was the correct sample taken and were any extra sampling requirements adhered to?
4. If the test was repeated, was the retest interval adhered to?
5. Did the test contribute to the clinical management?
6. Did the laboratory give appropriate reference intervals and interpretative information?
7. Was the test result available in a timely manner?

Appendix 2

Membership of the GAIN Sub-Group on the Use of the Laboratory

Joint Chairman

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Members

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