Technical SOP

Users Handbook

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OWNER	**Andrew Chitolie**
AUTHOR	**Michael Foye**
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Quality Policy

"It is the policy of 21st Century Clinic Ltd trading under the name The PathLab to provide a customer focussed, high quality service, delivering integrity and reliability for all our users"

Commitment to Quality

The quality of results is of paramount importance to the business. As such results are monitored on a daily basis with the overall quality system overseen by the Management Team (Laboratory Director, Practice Manager and Quality Manager) and support is provided by a number of external consultants to ensure we are always compliant with best practice and in accordance to the standards stipulated by UKAS.

The quality policy is the overriding document, which describes the quality system in detail; a copy is available upon request.

Assessment of quality

Key performance and quality indicators are used to enhance operational performance and remove variation from laboratory processes. Internal Quality Control (IQC) and External Quality Assurance (EQA) is used as part of our overall assurance mechanism.

External QA schemes selected are chosen on the basis of suitability of the laboratory's needs. Where possible EQA schemes will be accredited to ISO 17043 international standard or hold equivalent markers of quality, participation in individual schemes is kept under regular review.

An internal annual audit schedule ensures the adequacy of operating procedures and effectiveness of the overall quality system is maintained.

Continual quality improvement is a philosophy strongly adopted by the Path Lab to better our progress and maintain the very best service to our customers. The Management Team utilises several tools for Incident Management such as Root Cause Analysis (RCA) and Trend Analysis to ensure effective corrective and preventive (CA/PA) actions are implemented.

Location, Contact Details and Opening Hours

This handbook provides key information for service users or potential service users of The Path Lab, which provides a clinical pathology service for general practitioners, consultant medical staff, and other laboratories with most routine reports available within one working day.

Any tests referred to in this handbook, which are not explicitly covered in the scope of practice (UKAS The Path Lab Schedule) are by definition NOT part of the laboratory's external accreditation. They should as far as practicable still be covered by the Laboratory Quality Management system, including QC and initial verification.

The information provided includes reference values or interpretative data where relevant, and specimen requirements and instructions for collection of specimens to comply with Health and Safety requirements.

Any errors, amendments, queries relating to this document or the service provided for the Path Lab should in the first instance be addressed by contacting the laboratory via telephone or email.

Our opening hours are:

Monday-Friday: 9.00am-6.00pm

Saturday: 9.00am-12.00pm

Sunday: By appointment only

Phlebotomy Service: By appointment only

We are based at:

10a Upper Wimpole Street, London, W1G 6LL

The nearest tube stations are:

Regents Park, Bond Street, Oxford Circus,

View the tube map here

The best buses to catch are the 205, 27, 30, 18.

If you're still having trouble finding us, why not contact us through one of the methods below:

Tel +44 (0)20 7935 6650

email: info@thepathlab.co.uk

Services

Enquires and Advice

Scientific and medical advice on issues within the laboratory's range and competence is available. Key contact personnel are listed below:

Position	Name in Position	Telephone or email
Medical Director and Consultant Microbiologist	Dr Anthony Elston	Tel +44 (0)20 7935 6650 email: info@thepathlab.co.uk
Deputy Medical Director	Professor TRC Boyde	
Consultant Chemical Pathologist	Dr Mike Louw	
Consultant Haematologist	Dr J Luckit	
Deputy Consultant Haematologist	Dr F Hiwaizi	
Laboratory Director	Andrew Chitolie	

Position	Name in Position	Telephone or email
Practice Manager	Yvonee Wysocka	
Quality Manager (Biomedical Scientist)	Details available on request	
Biochemistry Manager (Biomedical Scientist)	Details available on request	

Routine Service – Tests performed at The Path Lab

Please check Department sections for routine tests.

Referrals Tests

The laboratory has a procedure for referring specimens to other accredited laboratories for some specialist tests. Information can be obtained by contacting the laboratory. Some test results may take time to be come back, so please check the TAT on our webpage or phone the laboratory to speak with us.

Referrals will happen for one of the following reasons:

1. The test requires expertise or equipment that the department does not have currently
2. The low number of request's is such that, it would not be possible to maintain suitable skills or competence in the analytical method, so they are referred to another accredited referral laboratory
3. Only In extreme circumstances, routine tests may be referred in the case of catastrophic analyser failure, as part of the departmental service contingency plan.

Referring laboratories are chosen that provide equal performance to our own and are regularly asked to provide evidence of UKAS accreditation and acceptable EQA performance. Our main referral centre is The Doctors Laboratories (TDL) but other referral providers are also used. A list of the referring laboratories is held in the department and is available on request by the Management Team.

Referred samples will be sent off by the laboratory using appropriate postal or courier methods and the laboratory will manage the dispatch and return of results process. Referral laboratories are subject to internal audit and review of their accreditation status.

Add-ons and Urgent Samples

In accordance with local policies, the laboratory stores specimens for a period of time post analysis in conditions suitable for retrospective or additional test requests. With certain analysis however, there is a time limit outside of which the stored sample is likely to unsuitable for processing; therefore, add-on test availability is dependent upon test stability and the storage time and condition of the original sample.

If you need to add a further test request to a sample that we have previously received in the laboratory, please telephone the laboratory to check that the sample is still viable and an add-on test can be requested.

The following table will give information on such time limits for commonly encountered tests. For any tests that are not on this list, please contact the department for advice. Outside of the times stated on this list new samples will be required.

Time Restrictions
Please check Department sections for specific time restrictions on testing.

Phlebotomy Services

A phlebotomy service is available as part of the routine service by appointment only (see Location, Contact Details and Opening Hours)

Instructions for phlebotomy
Refer to:

- Phlebotomy Manual (LAB 03)

- The Phlebotomy Guidelines of the World Health Organization

Guidelines for Phlebotomists

The work of involves the collection of blood using aseptic techniques from patients whose history of infectivity may be unknown. Blood is collected by venepuncture or with a sterile disposable lancet. Staff will therefore be exposed to the risks associated with the handling of blood specimens in the presence of 'sharps. As well as following the general precautions outlined previously in this document, phlebotomists should in addition observe the following points:

a. Wear the coat, gown or coverall provided for your protection. Wear gloves and other protective equipment, as required by the Standard Operating Procedures and always when attending patients where a high risk of infection is suspected or known to exist. Blood samples should not be taken in offices or general workrooms in the laboratory. A special room should be set aside for taking blood specimens.

b. Discard the gown / coverall worn during sampling immediately if it becomes contaminated with blood, and / or at the end of each day.

c. Wash hands between attending patients and at end of each work period or if contaminated. Cover cuts, grazes and broken skin with impervious waterproof dressing.

d. Needles should never be re-sheathed.

e. Syringes, needles and disposable lancets should be disposed of safely – directly into a sharp's container, never into plastic waste sacks, ensure the sharps bin has its lid in place.

Procedure for obtaining blood samples from low risk patients

Personal hygiene: inspect your hands and make sure that any recent cuts or abrasions are covered with a waterproof dressing without visible air holes. Wear gloves if appropriate. Avoid needle pricks, spilling blood and contaminating with blood the outside or rim of the specimen container. Do not lick labels, envelope etc.

Tray: to reduce the risks of spillage make sure that all the equipment you need is to hand and safely held on a tray preferably in suitable holders or compartments. All parts of the tray should be either disposable, autoclavable or cleanable by surface disinfectant solution. Ensure this solution is to hand.

BD vacutainer blood collection system: this is the preferred blood collection system in The Path Lab and enables a variety of tube types to be used. If there is anticoagulant in the container dissolve it in the blood by inverting the tightly closed container slowly several times.

Needle: dispose of any needle, syringes etc. as a single unit. Keep all this equipment separate from all the other waste and discard it into a container approved and marked for disposal of “SHARPS”’.

Discards: mediswabs, gloves, cotton wool, and other blood-contaminated materials used for venepuncture should be placed into a clinical waste bin.

Spillage of blood: if any sharp items, e.g. broken glass, are involved, where possible, use thick, heavy duty gloves, otherwise use ordinary surgical gloves. In the event of broken glass, pick up all fragments carefully with forceps and discard them into a container approved and marked for the disposal of "sharps", never into a plastic bag. Dilute any spillages of blood with ready to use biocidal cleaner (Biocleanse) solution and mop it up with absorbent paper. Put the mopping up material into a yellow biohazard bag, close it securely,

e.g. by knotting it, and send it for incineration. Remove the gloves, put them in a yellow plastic bag, close it securely and send for incineration. **Then wash your hands.**

NB: Never attempt to re-sheath a needle. Never leave a needle, or "sharp" for someone else to clear away, discard it safely

Procedure for obtaining blood samples from suspected or known "high risk" patients.

Special precautions are needed for samples that are collected from patients who are at high risk of hepatitis B, C or HIV. Additional precautions for obtaining a blood sample from a suspected or known "high risk" patient: blood samples should only be taken by staff experienced in venipuncture. The following precautions MUST be taken:

Wear well-fitting surgical gloves and plastic apron.
If available, wear safety spectacles.
A yellow hazard-warning label must be put on the specimen container.
Blood samples should be double bagged and where possible sent in a robust screw-capped container with the cap securely tightened, and sealed in a plastic bag with an integral-sealing strip.
The request form, to which a yellow hazard label must be attached, should be placed in the external pocket of the bag.
The specimen should be transported in the upright position.

Disposal of blood contaminated items: all syringes, needles or BD systems should be disposed of as a single unit into a sharps bin. Mediswabs, gloves, cotton wool and any spilt blood must be dealt with at once by disinfecting with Biocleanse solution. (In collecting and transporting specimens from outpatients, the same precautionary measures must be taken as described above).

Action to be taken in the event of an accident involving blood or other body fluids from a suspected or known “high risk” patient: if there is personal injury from a needle prick or cut, the following action should be taken:

Make the lesion bleed freely at once to help wash away infection.
Wash it immediately and thoroughly with running tap water.
Apply a suitable dressing (as provided in first aid boxes).
If blood or other body fluid is splashed into the eye, nose or on the lips, wash it away immediately with running tap water.
Follow Needle Stick Injury Procedure applicable to your workplace.

Phoning of critical results

The Critical Values policy is described below:

Critical Value: - A Critical Value is defined as one which is such at variance with normal (expected values) as to be life threatening unless something is done promptly and for which some corrective action could be taken.

Abnormal results are not considered Critical Values: Most laboratory tests have established reference ranges which are the results that are typically seen in a group of healthy individuals. While results outside these ranges may be considered abnormal, that is not the same as “critical”.

Action taken when a result exceeds the Critical Values: In addition to normal reporting staff will attempt to telephone or otherwise contact the ordering clinician as quickly as possible. For this reason, each request should be accompanied by contact details to allow the laboratory to contact a referring clinician.

The following limits apply to patients at all times.

Critical Values for Biochemistry testing include:

- Amylase >600 U/L
- Bicarbonate <10 mmol/L (DKA = Glucose >15, HCO3 <15)
- Calcium Corrected <1.8 or >3.00 mmol/L
- CK (non cardiac) >1000 U/L
- Creatinine >850 umol/L
- Glucose (fasting/random,GTTO and GTT2) <2.2 or >15 mmol/L (non-diabetic); diabetic >30 mmol/L
- Phosphate <0.35 mmol/L
- Potassium <2.3 or >6.2 mmol/L (exclude haemolysis or delay in separation factors)
- Sodium <120 or >160 mmol/L
- Free T4 >75 pmol/L (new case)
- Troponin > cut-off value
- Uric Acid >550 mmol/L (pregnant)
- Urea >35.0 mmol/L

Critical Values for FBC include:

- Haemoglobin < 50g/l (when unexplained by clinical data/diagnosis)
- Platelet count < 30x10*9 /l (when unexplained by clinical data/diagnosis)
- Neutrophil count < 0.5x109 /l (when unexplained by clinical data/diagnosis)

Critical Values for Coagulation testing include:

- INR > 7.9 (patients on Warfarin)
- PT > 25.0 seconds (unless known to be receiving anti-coagulation therapy)
- APTT >50.0 seconds (unless known to be receiving anti-coagulation therapy)
- Fibrinogen <1.0 g/l (new presentation)
- D-dimer ≥230 ng/mL

Turn Around Times (TAT)

This document provides information on turnaround times for commonly encountered assays offered by the department. During routine processing, the department will endeavour to process samples to within these stated time limits. In situation of reduced staffing or unexpected analyser failure, processing times may be longer. The times stated are in-laboratory turnaround times and do not take any account of delivery of sample to department or delivery of report to final location. For any process not covered and for samples stated as urgent, we will attempt to process them as rapidly as practical, within operational constraints.

- The Laboratory has set target turnaround times for all tests performed.
- Turnaround times are governed by daily cut-off times.
- Turnaround times are calculated from the date and time of receipt of the sample in the laboratory to the date and time of authorization.
- It is anticipated that turnaround target times will be achieved for the majority of specimens, however the nature of microbiology investigations means that some results may take longer.

Turnaround times are subject to regular audit.

Business Contingency Plan

In the event of a local, regional or national disaster, The Path Lab has a comprehensive contingency plan (QMS 21) in place to ensure the impact on care and specifically on laboratory services is minimised. This is reviewed on a regular basis.

The Path Lab - Quality Manual

The Path Laboratory Quality Manual (QMS 01) a copy is available upon request.

Comments and Complaints

TELL US WHAT YOU THINK!

We will like to hear from clinicians, patients, laboratory staff or any other parties. All

comments and suggestions are dealt with without passing on any personal information.

Do you have a comment about the services we provide?
Do you have a suggestion for improving our services?

Please contact a member of staff who will guide you through our compliments/complaints procedures. If you would prefer to speak to someone independent, you can contact the Citizens Advice Bureau.

All feedback, incidents (including adverse incidents, accidents and near misses – both clinical and non-clinical) and complaints that are received or occur in the Clinical Laboratory that involve equipment, staff or processes connected to the laboratory are logged for timely investigation to help prevent further occurrences that could cause harm to staff, patient, processes or the Hospital.

The Clinical Laboratory has sought to develop and embed an open, just and non-punitive culture where all personnel feel able to report complaints, adverse incidents, near misses and hazards in the knowledge that incidents are not normally investigated through the disciplinary procedure. Staff investigating an incident has a positive approach to any investigation seeing it as an opportunity to learn and change things for the benefit of patients, staff, visitors and others who use our services and facilities.

Requesting Process

Requests should only be made by clinicians or health professionals and never by a patient using the service or indeed by someone working in the laboratory. In the event that a request form is received without an authorising clinician or medical professionals' signature it should be immediately taken to management who will be tasked with acquiring this authorisation or if this is not possible one of our consultants will provide this authorisation oversight and duty of care until the originating clinician can be contacted.

The Request Form

The laboratory has a number of test request forms controlling the ordering of laboratory tests. Request forms used are required to contain essential information in a legible manner. The request form used contains enough information to identify the patient and the requestor as well as pertinent clinical data. The request form and process allow the inclusion of the following items but not limited to:

- Sufficient information to allow unique identity of the patient (DOB, Sex, etc.)
- Identification(s) and the location of the requesting individual
- Date and time of specimen collection
- Type of specimen and, where appropriate, anatomical site of origin
- Date and time of receipt of samples by the laboratory
- Relevant clinical information
- Identification of priority status
- Laboratory accession number

Record Retention

The Laboratory retains requests sample material and test results for the retention periods recommended by the Royal College of Pathologists, in "Retention and Storage of pathological records and specimens 5th edition 2015"

Specimen Submission

All requests should be made to The PathLab in writing preferably using the laboratory specific request form. See the department section for the correct sample types and for further test information.

Date and time of collection should be provided on all samples; as certain assays can only be performed on fresh samples.

For further specimen requirement and protocols see ***Lab Tests Online-UK*** (*http://www.labtestsonline.org.uk/*). *Lab Tests Online-UK is supported by "The Royal College of pathologists" and "The Institute of Biomedical Science".*

Requirements for patient consent

"All procedures carried out on a patient need informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collection procedure, for example, venepuncture. Patients in a hospital bed should normally be given the opportunity to refuse" – BS EN ISO 15189:2012 26:5.4.4.1

"Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent" - BS EN ISO 15189:2012 27:5.4.4.1

"In emergency situation, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest" - BS EN ISO 15189:2012 27:5.4.4.1

If a sample is to be sent to a referral laboratory, it is essential that the requesting clinician obtain consent from the patient/patient's guardian to disclose relevant clinical history and family information.

Sample Acceptance and Rejection Policy

Request form with the minimum requirement must be met, otherwise sample will be rejected.

Sample label must contain the following as a minimum

- Full Name (first name and surname)
- Date of birth

Some of the common reasons a Pathology request may be rejected:

- Unlabelled and incorrectly labelled samples will be rejected. For precious and urgent samples, efforts will be made to contact the requestor, for them to have the opportunity to label samples – responsibility of the patient being correctly identified

remain the responsibility of the requestor (except Transfusion forms and samples – amendment to original sample NOT allowed).

- Samples collected in the incorrect container.
- Coagulation bottles not filled to the fill line – under -filled and over -filled samples will be rejected.
- Samples received by the laboratory, upon analysis that are haemolysed, lipaemic or Icterus, depending upon severity may affect some test parameters and as such the affected test results may not be available.
- Samples not collected following the laboratory procedure.
- Spurious results due to inappropriate collection.
- If 2 requests for different patients are placed on one request form.
- Leaked samples
- Out of date sample containers
- For Histology Samples, if clinical details incomplete or missing, at the Pathologist discretion the requestor may be contacted to provide this detail, samples would then be returned to requestor for the clinical details to be provided before sample will be accepted for analysis.

  Note: Addressograph labels are permitted on all laboratory samples except Blood Transfusion samples.

  Blood Transfusion (Blood Grouping) samples must be hand written immediately, in the presence of the patient with a positive patient identification, e.g. ask the patient to state their date of birth.

Protection of Personal Information

We recognise the confidentiality of information we hold on patients, donors and clients and allow accreditation and regulatory bodies appropriate access to the knowledge systems maintained to provide third party assurance to our clients and stakeholders.

The Path Lab complies fully with the provisions and obligations of the Data Protection Act 1998 in storing and processing patient information.

Guidance: Data Protection Act 1998

Guide to the General Data Protection Regulation (GDPR)

Order of Draw

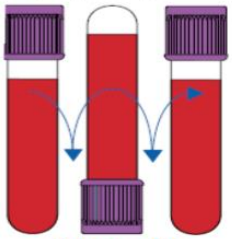
Blood Collection Order of Draw

Closure Color	Collection Tube	Mix by Inverting
Aerobic/Anaerobic	Blood Cultures*	8 to 10 times
Light Blue	Sodium Citrate Tube**	3 to 4 times
Red	Serum Tube	5 times
Gold	BD Vacutainer SST Gel Separator Tube	5 times
Light Green	BD Vacutainer PST Gel Separator Tube with Heparin	8 to 10 times
Dark Green	Heparin Tube	8 to 10 times
Lavender	EDTA Tube	8 to 10 times
Grey	Fluoride Tube	8 to 10 times

*** A Sodium Citrate tube must be drawn and discarded prior to the collection of blood cultures.**

**** When using a winged blood collection set, a Sodium Citrate discard tube must also be drawn.**

Mix gently, inverting as shown



= 1 inversion

References:

CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6. Wayne, PA; Clinical andLaboratory standards Institute; 2007.

BD Diagnostics (Becton, Dickinson and Co.) Pre-Analytical Systems, New Jersey, USA, www.bd.com

Guidance - Number of Samples
SERUM SAMPLES

Sample No	Tests Performed in	Tests		
1	The Path Lab	Renal profile Liver profile Bone profile Lipid profile CK Amylase Glucose HCG	CRP Paracetamol Salicylate TSH FT3 FT4 Troponin	Magnesium LDH Uric acid Iron Ferritin Vit B12 PSA
2	National Virus Reference Laboratory	Hepatitis screens VDRL HIV	All viral serology	
3	Referral - Biochemistry	*Tumour markers Specific hormone levels Lithium Methotrexate Caeroloplasmin	Theophylline Immunoglobulins Electrophoresis	Endocrinology
4	Referral - Immunology	*Autoantibodies Rheumatoid factor Specific antibodies	C1 Esterase inhibitor Anti phospholipid antibody Anti Reticulin antibody Thyroid antibody	
5	Referral - Toxicology	Caramazepine Epilim Phenytoin Phenobarbitone	Drug Screen	

Please state the specific required.

Other samples including high risk specimens

Please refer to the laboratory for advice where more than one test is required.

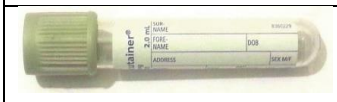
Factors affecting the Performance of Examinations

Although all analytical methods used by the department are appropriately controlled by internal and external quality assurance methods, there are some factors that can affect the specific analytical methods. This document will cover the factors affecting the most common tests; information on other tests is available from the relevant sections on request.

PROBLEM	COMMON CAUSES	CONSEQUENCES
Sample collection, storage and transport to the laboratory	Poor/delay collection, storage and transportation technique/procedure	Can increase sample degradation pre analysis. For any analysis that requires whole (EDTA) blood, samples which contain clots are unlikely to be suitable for processing.
Contamination by infused fluids	High MW dextrans Dextrose Crystalloid solutions	Elevated total proteins High glucose Spurious Na+, K+, Cl-, etc. Low calcium High Na+ Affect clotting tests
Haemolysis	Expelling blood specimen through a needle into container Over vigorous mixing of specimen Specimen stored in freezer Excessive delay in transit	High K+ High phosphate Low Na+ and Cl- High AST and LD High Mg^{2+}

PROBLEM	COMMON CAUSES	CONSEQUENCES
	Specimen left in hot temperature	
Incorrect container/ anticoagulant	No enzyme inhibitor EDTA tube Excess liquid heparin	Low glucose and ethanol High K+ Low Calcium, Iron, Magnesium Abnormal blood gases and analytes
Lipaemia	Taken before intra-lipid is cleared Taken after fatty meals Anxiety and stress	Interferes with many assays because of turbidity of specimen. May cause low sodium concentration
Recent infection of cytomegalovirus, leptospirosis, hepatitis A and parvovirus	Some patients do not develop heterophile antibodies (<20% adults and 50% children)	Glandular fever test false positive result
Serum or plasma separation delay	Overnight storage Delay in transit	High K+, AST, LD, Mg2+ Low Na+ (occasionally)

Primary Sample Containers: Capacity and Anticoagulant

Vacutainer	Anticoagulant	Capacity
	EDTA	4ml/10ml
	SST/Gel	5ml
	Citrate	4.5 ml
	Fluoride oxalate	2ml, 4ml

	Lithium heparin	6 ml

Incorrect Collection Tubes

- Sodium Heparin (tube): this will present as increased sodium with all other results being correct.
- Lithium Heparin (tube): an elevated Lithium result; these tubes contain about 1.0 mmol/L of lithium.
- Dipotassium EDTA (tube): EDTA chelates ALL divalent ions (Ca, Mg, Fe, Zn, Cu) to non-detectable levels. The potassium is raised often past the 20 mmol/L mark. EDTA also chelates the Zn and Mg needed in some enzyme systems giving a false suppression of enzyme rates. A low ALP is often easy to spot.
- Sodium Fluoride/Oxalate (tube): a very high sodium (over 220 mmol/L) and the fluoride interferes with the enzyme activity of most systems giving lower than normal enzyme levels. Not often easy to see.
- Sodium Citrate (tube): a high sodium (about 150 mmol/L) and a 10% dilution in all other results - with a low chloride-. The citrate complexes calcium and competes with the calcium method dyes so you get a low total calcium result, of about 1.55 mmol/L.

Broken or Leaking Samples

If a specimen is dropped or broken do not touch it or try to clear up the mess. Stay with the specimen to prevent other people touching it and send someone to the laboratory for help. If you spill the specimen onto your overall, you must remove it at once and then wash your hands and put on a clean overall. Report the accident to the laboratory staff as soon as possible.

Specimen Collection, Handling, Labelling and Transport

The PathLab does provide a specimen collection service to its clients. It does provide advice on collection tubes, collection conditions and limitations of testing.

Sample collection is available by prior arrangement or on an ad-hoc basis by telephoning the laboratory.

If samples are collected off site then the samples should be forwarded to the laboratory accompanied by a written request.

A procedure which focus on the transportation of specimens, is available.

This procedure covers;

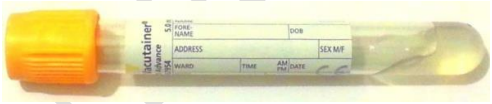
a) Ensuring the safety of the courier, the general public and receiving laboratory

b) Packaging, labelling and dispatch

c) Protection of the specimens from deterioration

Sample storage prior to sending to the laboratory

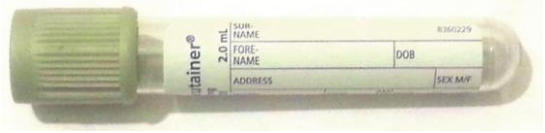
Routine biochemistry profiles



Do NOT store in the fridge - send to lab within 4 hours.

Keep at room temperature, potassium will be falsely elevated if samples are stored in a refrigerator. Samples should be stored at room temperature prior to transportation to lab.

Blood glucose / lactate



May store whole blood in refrigerator overnight.

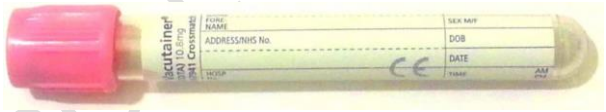
Routine haematology

Okay to store at room temperature awaiting transportation.
Store overnight in the refrigerator.
Clotted samples unsuitable for testing.
Flow Cytometry (cell markers) not available overnight or at weekends.
If Temporal Arthritis please send sample as soon as possible.

Coagulation

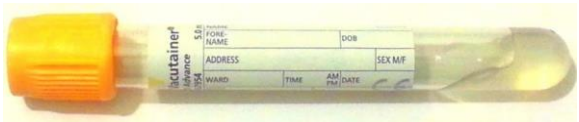
Do NOT store - send to lab within 4 hours.
Coagulation factors deteriorate rapidly and some factors are affected by cold storage.
Under filled and overfilled samples are unsuitable for testing.
Arrow on label indicates fill level and acceptable tolerance.
Clotted or haemolysed samples cannot be processed.

Blood groups



May store whole blood in refrigerator overnight.
Grossly Haemolysed or very small samples will be rejected.
Ensure that samples are fully labelled (Hand written) with patient's full name and date of birth

Serology



Can be stored overnight in the refrigerator

General Transportation of samples to the laboratory

Samples are received by hand by couriers or directly from patients**.** Besides EQA samples no samples are received via the post.

Sample should be transported to the laboratory in a plastic bag where possible, this will isolate and limit any potential spillage that may occur. Plastic polygrip bags are available from the laboratory by request and have a compartment for carrying the request form together with the sample which can help avoid their separation. Where more specific transport and storage information is needed it will be supplied by the laboratory,

Model Rules for Laboratory Messengers

Some of the work carried out by laboratory porters and messengers in the hospital may involve accidental contact with material that could be infectious. Consequently, they must follow the general precautions outlined below if working in the laboratory or when transporting clinical samples.

a) Wear your overall, properly fastened, especially when carrying specimens, even when you are not in the laboratory. Keep your overall separate from your outdoor clothing, not in your locker. Pegs are provided. Never wear your overall in the staff room or canteen. If you do you could spread infection.

b) Cover any cuts or grazes on your hands with a waterproof dressing.

c) Carry all specimens in the trays or boxes provided, not in your hands or pockets.

d) Touch specimen containers as little as possible. If you do touch them, wash your hands as soon as practicable afterwards.

e) Always wash your hands before meal breaks and at the end of a spell of duty.

f) If a specimen leaks into a tray or box, tell the laboratory reception staff and ask them

to make it safe.

g) If you drop and break a specimen, do not touch it or try to clear up the mess. Stay with the specimen to prevent other people touching it and send someone to the laboratory for help. If you spill the specimen onto your overall, you must remove it at once and then wash your hands and put on a clean overall. Report the accident to the laboratory staff as soon as possible.

h) If you drive a van, make sure that you have gloves, a bottle of freshly made disinfectant approved by the laboratory and some cotton wool with you in the vehicle. If a specimen leaks and runs out of the tray or box, put on gloves, pour disinfectant over the spillage and cover it with cotton wool. Do not mop it up. Drive to the laboratory for help. (Follow the advice in (g) above.)

i) If your vehicle breaks down or you have an accident, do not let anyone touch the specimens unless they come from a hospital and know the appropriate procedure.

j) Handle specimen containers gently at all times. Do not drop or manhandle specimens in a rough manner.

k) Take care when carrying waste or rubbish from the laboratory - there may be broken glass or needles. If you find these tell your supervisor. Special `sharps' containers are provided for glass, syringes and needles - these must be handled carefully as leakage or penetration by sharp objects can occur.

l) Do not remove specimens and or Laboratory Request Forms from the polygrip bag

Guidelines for Drivers

As part of your work you may have contact with blood and body fluid substances. By

following these standard infection control practices and precautions, you are unlikely to catch any infection.

List of items to be kept in a vehicle

- Spillage kit (Ensure bottle is filled with tap water. Check expiry date on tablets/granules container)
- Alcoholic hand rub (personal dispenser or bottle)

In the event of breakdown or accident, do not let anyone touch the specimens unless they are an employee from the Path Lab with appropriate responsibility.

Specimens must be carefully handled at all times.

Cuts/pricks and accidents to transport staff must be reported to the pathology laboratory, safety officer, or central reception manager and an incident report form must be filled in.

Transport staff must not eat, drink or smoke when carrying specimens.

Any spillage/accidents during transport must be reported as soon as possible to the pathology department and their supervisor.
Spillages must be dealt with using the Board Safe Handling of Body Fluid Spillage Policy. Spill kits should be available in the transport vehicle.
If specimens are spilt onto clothes/overalls, they must be removed at once and hands cleaned. The incident must be reported to a supervisor as soon as possible and an incident form completed.

Chain of Custody

Chain-of-Custody is a record of disposition of a specimen to document who collected it, who

handled it, who performed the analysis, is often required when results are to be used in a court of law, (e.g. in Paternity testing cases). The Path Lab does **NOT** provide this service. In certain appropriate cases with relevant consent, samples or test results originally used for clinical care would be released if no longer required for clinical testing.

General Guidelines and Infection Control

For microbiology investigations the prompt and accurate isolation of infecting agents is directly influenced by the quality of the specimen. With the exception of suspected meningitis, it is almost always possible to obtain appropriate specimens before commencing antibiotic therapy.

The following points should be adhered to:
Collect specimen before administration of antibiotic therapy
Specimen should be transported to the laboratory as soon as possible
Ensure that the specimen container is clearly labeled with the patient's details

Remember that you may be dealing with pathogenic microorganisms and care should be taken while obtaining and handling the specimen.

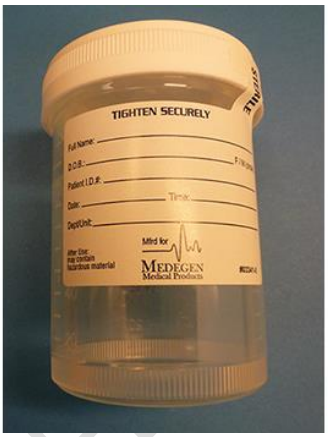
Infection control

Wash hands thoroughly or use sanitizer (the latter if hands are visibly clean) before obtaining the specimen and after it has been prepared for collection
Gloves should always be worn when handling bodily fluids
Do not overfill container
Ensure container is securely closed and outside of container is not contaminated by the specimen

Accidental Exposure to Blood Borne Pathogens

Procedure: any accident involving the puncture of the skin by a needle or scalpel contaminated with blood from ANY patient, or the spilling of such blood on broken skin must be reported as soon as possible to your superior. The member of staff concerned MUST attend the A&E department immediately.

Patient instructions for collecting Mid-Stream Urine (MSU)



1. Collect 20 mL of urine in a sterile specimen container.
2. Transfer urine to a Boricon urine transport container (red top container).
3. Transport to the microbiology laboratory.
4. If unable to collect 20 mL of urine, collect in sterile specimen container and Transport urine specimens to the microbiology laboratory immediately or refrigerate **within 30 minutes**.
5. Refrigerated specimens should be delivered to the lab as soon as possible, and *may be rejected if not received within 24 hours of collection*.

1. **Midstream clean catch method:** Patients should be instructed to wash hands prior to collection and offered exam gloves.
    a. **Female** patients should be instructed to sit on toilet with legs apart and spread labia with one hand. First void in toilet and then, continuing to void, hold specimen container in "midstream" to collect sample.

b. **Male** patients should be instructed to retract foreskin if uncircumcised. First void in toilet and then, continuing to void, hold specimen container in "midstream" to collect sample.

2. **Straight catheter:** Thoroughly cleanse the urethral opening with soap and water. Rinse area with wet gauze pads. Aseptically insert catheter into the bladder. After discarding initial 15 to 30 mL of urine, collect 20 mL of urine for submission in a Boricon urine transport container.
3. **Indwelling catheter**: Clamp catheter below port and allow urine to collect in tubing. Disinfect the catheter collection port with 70% alcohol. Use needle and syringe to aseptically collect 20 mL freshly voided urine though catheter port. Transfer to Boricon urine transport container. Do not collect urine from collection bag.

4. **Ileal conduit:** Remove the external device and discard urine within device. Gently cleanse the stoma with 70% alcohol followed by povidone-iodine swab stick (907172). Using sterile techniques, insert a double catheter into the cleansed stoma, to a depth beyond the fascial level, and collect the urine into a sterile container. Transfer to Boricon urine transport container. Use of a double catheter helps to minimize contamination of the specimen with skin flora.

Patient instructions for collecting Faeces / stool sample

General guidelines

1. Submit 10-20 g in sterile container.
2. Transport time ≤1 hour.
3. Refrigerate if transport is delayed.
4. *Stools are cultured to isolate* bacterial causative agents of diarrheal illness; *Salmonella, Shigella, Campylobacter,* and Shiga toxin producing *E. coli.*
5. *Stools for C. difficile* toxin detection must be transported to the laboratory immediately or refrigerated if transport is delayed.

Instructions for sample collection

1. Label the specimen container with your surname, forename, date of birth.
2. Place plenty of toilet paper in a clean potty of in the toilet bowl.
3. Make sure there is no trace of disinfectant or bleach present, as this will interfere with the testing.
4. Faeces should then be passed onto the toilet paper.
5. Open the specimen container. Place a sample of the faeces in the specimen container. There is no need to fill the container. Screw the lid firmly back on the container. **Note:** If you have severe diarrhea or a watery stool, a potty may be needed to collect the initial sample.
6. Place the container in the plastic bag attached to the form and seal the bag.
7. Flush away the remaining paper and faeces.
8. Wash your hands thoroughly with soap and water.
9. Check that the request form details the full name and date of birth of the person providing the sample and add the date and time of the sample collection.
10. The sample should be brought promptly to the laboratory for analysis. A report will be sent to the requesting doctor, usually within 3 working days.

a. Patient Information 24 hour urine 5HIAA
b. Patient Information 24 hour urine Acid
c. Patient Information 24 hour urine Catecholamines
d. Patient Information 24 hour Urine Plain
e. Transport of Blood by Taxi

1. Drivers must not remove or tamper with the consignment or its contents.
2. Ensure that the delivery is taken directly to the correct location within the hospital/organisation as identified on the transport box. Outside of normal working hours the box can be delivered to the Hospital Reception desk and the receptionist informed.
3. If there is a breakdown, driver must inform the hospital of the delay and give an estimated time of arrival. Any prolonged delays due to traffic conditions must be communicated to the hospital.
4. Drivers must inform the laboratory of any loss or damage to the consignment as soon as possible.
5. At all times, drivers must ensure compliance with all road traffic and transport laws and any request by the Police.
6. Drivers must have appropriate motor insurance which includes business cover declared for transporting specimens.

The Laboratory Report

The report will identify the patient, requesting clinician and then list the requested tests alongside the result, units and reference range.

Should a result be calculated (e.g. globulin) then this will appear on the report as test name (calc), e.g. globulin (calc)

The Path Lab currently issues paper results only on demand by the requestor. E-mailing of reports (pdf file) is the preferred means of delivering reports. The electronic transfer of The path lab reports are handled and transmitted confidentially in accordance with data

protection laws. A DTE information system regulates this Reporting of Results policy to ensure the confidentiality of patient data as required by law.

Reports are e-mailed as a pdf file or hand delivered to the requester.

All amended reports are referred to a Senior BMS as soon as possible.

A large number of tests are sent to referral laboratories from The Path Lab. All reports are issued to the requester directly from the referral laboratory in the form of a hard copy or electronically as a pdf file.

Biological reference intervals and clinical decision values are provided on result reports.

Clinical Biochemistry

Biochemistry tests, performance and limitations.

Assays which appear in **bold** are those which are performed in house whilst all others are performed at a suitable accredited laboratory.

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
17 alpha Hydroxyprogesterone	HPRO		3 working days	Quoted by referral laboratory	4 days	
ACTH	ACTH		7 working days	10- 50 nmol/L	Not available	**By appointment only** Must be separated immediately upon receipt and frozen
AFP	FETO		1 working day	Quoted by referral laboratory	3 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Alanine Aminotransferase	**ALT**		**1 working day**	**male 5 - 50 IU/L female 5 - 35 IU/L**	**4 days**	
Albumin	**ALB**		**1 working day**	**35 - 50 g/L**	**6 days**	
Alcohol	ETH		1 working day	Quoted by referral laboratory	1 day	Not suitable for medico-legal use
Aldosterone	ALDO		7 working days	Quoted by referral laboratory	7 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Alkaline phosphatase	**ALKP**		**1 working day**	**38 - 126 IU/L**	**4 days**	
Allergy screen, generally			3 working days		7 days	
Allergy screen, UK Panel VII	VIEE		3 working days		7 days	
ALP isoenzymes			7 working days		7 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Alpha 1-antitrypsin1			2 working days	Quoted by referral laboratory	7 days	
Alpha-1- acid glycoprotein			7 working days	Quoted by referral laboratory	4 days	
Amylase	**AMY**		**1 working day**	**30 - 110 IU/L**	**4 days**	
Androstenedione	ANDO		1 working day	Quoted by referral laboratory	1 day	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Angiotensin Converting Enzyme	ACE		1 working day	20 - 90 U/L	2 days	
Anti Mullerian Hormone	**AMH**		**1 working day**	**5.0 -25.0 pmol/L**	**1 day**	
Apolipoprotein A	APOA		1 working day	Quoted by referral laboratory	2 days	
Apolipoprotein B	APOB		1 working day	Quoted by referral laboratory	2 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Aspartate Aminotransferase	**AST**		**1 working day**	**male 17 - 59 IU/L female 14 - 36 IU/L**	**4 days**	
Basic chemistry	**BACH**		**1 working day**	**Please refer to individual tests**	**Please refer to individual tests**	**Screen includes renal, bone, lipid and liver profiles**
Basic chemistry & electrolytes	**BAEL**		**1 working day**	**Please refer to individual tests**	**Please refer to individual tests**	**As above plus electrolytes**
Bence Jones Protein	BJP		7 working days		2 days	Early morning urine preferred, more sensitive.

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Beta hCG	**HCG**		**1 working day**		**4 days**	
Beta hCG (urine)	**UHCG**		**1 working day**		**2 days**	**Early morning urine preferred, more sensitive.**
Bicarbonate	**CO**		**1 working day**	**22 - 30 mmol/L**	**1 hour**	**Routinely measure Total CO2**
Bile acids			1 working day	Quoted by referral laboratory	7 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Bilirubin (Conjugated / Direct)	**BC**		**1 working day**	**0 - 5 µmol/L**	**1 day**	
Bilirubin (Total)	**BILI**		**1 working day**	**3 - 22 µmol/L**	**1 day**	
BNP			2 working days	Quoted by referral laboratory	8 hours	
CA 19-9 (Pancraetic/colorectal)	**C19**		**1 working day**	**0 - 33 U/L**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
CA-125 (Ovarian)	**CA12**		**1 working day**	**0 - 35 U/L**	**2 days**	
CA-153 (Breast)	**CA15**		**1 working day**	**0 - 25 U/L**	**2 days**	
CA72-4 (Gstrointestinal)	CA72		1 working day	Quoted by referral laboratory	2 days	
Calcitonin	CALC		14 working days	Quoted by referral laboratory	Not available	**By appointment only as sample MUST be separated within 15 minutes**

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Calcium	**CA**		**1 working day**	**2.10 - 2.55 mmol/L**	**4 days**	
Carbamazepine			1 working day	Quoted by referral laboratory	7 days	
Carbohydrate Deficient Transferrin	CDT		5 working days	Quoted by referral laboratory	2 days	Sensitive marker of chronic alcohol abuse
CEA	**CEA**		**1 working day**	**0 - 5 ng/L**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Chloride	**CL**		**1 working day**	**98 - 107 mmol/L**	**1 day**	
Cholesterol (total)	**CHOL**		**1 working day**	**Desirable 3.2 - 5.2 mmol/L**	**4 days**	
CK	**CK**		**1 working day**	**24 - 173 IU/L**	**4 days**	
Complement C3	C3		1 working day	0.75 - 1.65 g/L	4 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Complement C4	C4		1 working day	0.14 - 0.5 g/L4	4 days	
Cortisol	**CORT**		**1 working day**	**10am - 12 pm 190 - 700 nmol/L**	**2 days**	
C-peptide			3 working days	Quoted by referral laboratory	Not available	Must be separated immediately upon receipt and frozen
CRP	**CRP**		**1 working day**	**0 - 10 mg/L**	**7 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Creatinine	**ECRE**		**1 working day**	**male 64-104 µmol/L female 49-90 µmol/L**	**6 days**	
DHEAS	**DHES**		**1 working day**	**male 2.2 - 15.2 nmol/L female 1.0 - 11.5 nmol/L**	**1 day**	
Digoxin	DIG		1 working day	Quoted by referral laboratory	7 days	Must be collected 6 - 8 hours post dose Dosage and time of last dose to be quoted on request form
Drugs of Abuse (Blood)	DOAX		10 working days		7 days	Urine is the preferred sample for routine screening

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Drugs of Abuse (urine)	DOAS		5 working days		7 days	Not to be used for medico-legal purposes
Endocrine screen (female)	**SENF**		**1 working day**	**Please refer to individual tests**	**7 days**	**Contains FSH, LH, E2, P4 and Prolactin**
Endocrine screen (male)	**SENM**		**1 working day**	**Please refer to individual tests**	**7 days**	**Contains Testosterone, PSA, FSH, LH & Prolactin**
Ferritin	**FERR**		**1 working day**	**male 30 - 400 ng/mL female 10 - 130 ng/mL**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Folate	**FOLA**		**1 working day**	**13.4 -56.2 nmol/L**	**1 day**	
Free T3	**FT3**		**1 working day**	**3.6 - 10.4 pmol/L**	**5 days**	
Free T4	**FT4**		**1 working day**	**7.5 - 21.1 pmol/L**	**5 days**	
Fructosamine	FRUC		1 working day	Quoted by referral laboratory	5 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
FSH	**FSH**		**1 working day**	**male 1.0 - 11.0 IU/L female Varies with cycle**	**7 days**	
Gastrin			7 working days	Quoted by referral laboratory	1 day	
GGT	**GGT**		**1 working day**	**5 - 55 IU/L**	**4 days**	
Glucose	**GLUC**		**1 working day**	**fasting 3.3 - 6.1 mmol/L non-fasting 3.3-7.8 mmol/L**	**2 days**	**Fluoride (grey stoppered tube) to be used if sample is to be stored overnight before sending to the laboratory**

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Growth hormone	GH		3 working days	Quoted by referral laboratory	1 day	
Haptoglobin			1 working day	Quoted by referral laboratory	7 days	
HbA_1c	**HBAC**		**2 working days**	**20 - 42 mmol/mol Hb**	**5 days**	
HCG			1 working day	male <5 mIU/L female <3 mIU/L	2 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
HDL Cholesterol	**HDLC**		**1 working day**	**0.9 - 2.2 mmol/L**	**2 days**	
Homocysteine	HOMO		1 working day	3.4 - 20.4 µmol/L	Not available	By appointment only due to analyte stability
IGF-1	IGF1		5 working days	Quoted by referral laboratory	Not available	Must be separated immediately upon receipt and frozen
Immunoglobulin A	IGA		1 working day	0.7 - 4.00 g/L	7 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Immunoglobulin G	IGG		1 working day	7.0 - 16.0 g/L	7 days	
Immunoglobulin G Subclasses	IG14		7 working days	Quoted by referral laboratory	7 days	
Immunoglobulin M	IGM		1 working day	0.4 -2.30 g/L	7 days	
Inorganic phosphate	**PHOS**		**1 working day**	**0.81 - 1.45 mmol/L**	**4 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Insulin	INS		2 working days	Quoted by referral laboratory	Not available	Must be separated immediately upon receipt and frozen
Iron	**FE**		**1 working day**	**male 12.0 - 32.4 µmol/L female 10.0 - 32.4 µmol/L**	**7 days**	
Iron Binding Capacity (Unsaturated)	**UIBC**		**1 working day**	**20 -62 µmol/L**	**7 days**	**Consider transferrin and ferritin as an alternative**
Iron Binding Capacity Total)	**FEBC**		**1 working day**	**46 - 85 µmol/L**	**7 days**	**Consider transferrin and ferritin as an alternative**

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
LDH	**LDH**		**1 working day**	**10 - 248 IU/L**	**4 days**	
Lead	LEAD		10 working days	Quoted by referral laboratory	7 days	
LFT	**LFT**		**1 working day**	**Please refer to indivdual tests**	**1 day**	**Includes Total protein, albumin, globulin, AST, ALT, Alkaline Phosphatase and Total Bilirubin**
LH	**LH**		**1 working day**	**male 1.0 - 8.4 U/L female Varies with stages of cycle**	**3 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Lipase	LIPA		1 working day	Quoted by referral laboratory	2 days	
Lipids	**LIP**		**1 working day**	**Please refer to indivdual tests**	**2 days**	**Includes Cholesterol, HDL Cholesterol triglycerides**
Lithium			2 working days	0.6 - 1.2 mmol/L	1 day	
Magnesium	**MG**		**1 working day**	**0.74 - 1.10 mmol/L**	**4 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Oestradiol	**OESB**		**1 working day**	**Varies with stage of menstrual cycle**	**2 days**	
Parathyroid Hormone	PTH		2 working days	Quoted by referral laboratory	If refrigerated stable for 48 hrs	
Pregnancy Associated Protein A	PAPA		5 working days	Quoted by referral laboratory	2 days	1st trimester risk. Stage must be **exact** and quoted on request form
Progesterone	**PROG**		**1 working day**	**Varies with stage of menstrual cycle**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Prolactin	**PROL**		**1 working day**	**male 32 - 399 U/L female 40 - 700 U/L**	**2 days**	
Protein Electrophoresis	PELE		5 working days		6 days	
PSA (Free & ratio)	**PSAF**		**1 working day**		**2 days**	
PSA (Total)	**PSA**		**1 working day**	**0 - 4.0 ng/mL**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Renal & Bone Profile	**REBO**		**1 working day**	**Please refer to indivdual tests**	**3 days**	**Includes urea, creatinine, urate, calcium and phosphate**
Renin			10 working days	Quoted by referral laboratory	Not available	By appointment only Must be separated immediately upon receipt and frozen
SHBG	**SHBG**		**1 working day**	**male 10 - 80 nmol/L female 35 -100 nmol/L**	**3 days**	
Testosterone	**TEST**		**1 working day**	**male 10 - 30 nmol/L female 0.5 - 4.2 nmol/L**	**1 day**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
TFT	**TFT**		**1 working day**	**Please refer to indivdual tests**	**5 days**	**Includes TSH and FT4**
Theophylline			1 working day	Quoted by referral laboratory	7 days	
Thyroid Peroxidase Antibody	TPOY		1 working day	<10 U/L	5 days	
Total protein	**PROT**		**1 working day**	**62 - 82 g/L**	**6 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Transferrin	TRAN		1 working day	2.0 - 3.2 g/L	7 days	
Triglycerides	**TRIG**		**1 working day**	**0.6 - 2.2 mmol/L**	**3 days**	
Troponin T	TRPT		1 working day	Quoted by referral laboratory	3 days	
TSH	**TSH**		**1 working day**	**0.3 - 5.0 mIU/L**	**5 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
UE	**UAE**		**1 working day**	**Please refer to indivdual tests**	**3 days**	**Include urea, creatinine, urate, sodium, potassium and CO2**
Urate	**URIC**		**1 working day**	**male 208 - 506 µmol/L female 149 - 446 µmol/L**	**7 days**	
Urea	**UREA**		**1 working day**	**male 3.2 - 7.1 mmol/L female 2.5 - 6.1 mmol/L**	**7 days**	
Urine Albumin (Microalbumin)	**UALB**		**1 working day**	**<2.3 mg/L**	**2 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Urine Creatinine (Random)	**UCRE**		**1 working day**		**2 days**	
Urine Protein	UPCR		1 working day	<13 mg/mol creatinine	2 days	
Valproate	VAL		1 working day	Quoted by referral laboratory	7 days	
Vitamin B12	**B12**		**1 working day**	**179 -1162 ng/L**	**1 day**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Vitamin D (1,25 Dihydroxy)	D3		7 working days	Quoted by referral laboratory	2 days	
Vitamin D (25 Hydroxy)	VITD		5 working days	51 - 200 nmol/L	2 days	D2 & D3 determined by mass spectrometry
Zinc	ZN		1 working day	Quoted by referral laboratory	2 days	

There are certain factors, which can affect the quality of test results produced. These can include Haemolysis, Lipaemia, Icterus, and time from sample collection to receipt.

- EDTA contamination severely affects results. Especially for potassium and calcium.
- The antibiotic assays for Gentamicin and Vancomycin: time of last dose and time of sample are essential for interpretation of the result. Detailed advice on initial dosing, timing of levels, interpretation of results and dosage adjustment is available (See Enquires and Advice section).
- Therapeutic Drug Monitoring requires samples to be taken at specific times e.g. pre-dose; 6 hrs post dose etc. Please provide this information in the clinical details section.
- Do not request a serum vitamin B12 if the patient is on cyanocobalamin.
- Samples that require centrifugation within certain timeframes are deemed unsuitable for analysis if they fail to meet the criteria (e.g. homocysteine, insulins etc)
- It is difficult to gauge the effects of transport delays on routine results. This is because the mode and temperature of transport cannot be gauged accurately and the effects on any sample can be individual. Potassium for example can be high in some patients where there is a delay of 4 hours before centrifugation whilst in others there is no appreciable change in potassium concentration at all.
- Urine Pregnancy Test: False negative results: very dilute urines or very early pregnancy. If pregnancy is still suspected, advise to perform a serum pregnancy test.
- Artefacts in Biochemistry: most familiar artefacts are caused by delayed separation or haemolysis and/or lipaemia (wrong collection tube may not be obvious).
- Haemolysis can happen post collection or during collection. Common reasons are a difficult collect (sample in needle for too long), sample kept against cold surface (ice brick in transit), accidentally frozen or haemolysis is due to a contaminant (alcohol swab and there is alcohol in the sample). Haemolysis can also occur in vivo but is often not visible. Haemolysis gives raise to artefacts under two scenarios
- The red cell releases an analyte of interest e.g. K+, AST, LD
- The absorption peaks of Hb interfere with the reading wavelengths of a method e.g.

creatinine, total bilirubin.

- Lipaemia: high concentrations of cholesterol and/or triglycerides lead to lipaemic samples. Lipaemia can be due to dietary input and/or disease states. Triglycerides tend to give more turbidity than cholesterol but the “milk” type samples contain more cholesterol. Lipaemia interferes with the test system in two ways:
- Dilutional errors e.g. indirect ISEs
- Wavelength blanking errors.
- Icterus: high concentrations of bilirubin interfere with the reading wavelengths of some methods and can interfere with the formation of alkaline picrate in the Jaffe creatinine method.
- High Total Proteins: high protein content can lead to dilutional errors (indirect ISE) and precipitation issues (some phosphate methods). High IgM levels can lead to high bilirubin answers so check high bilirubin and make sure the sample looks icteric.
- Age: old samples give a picture similar to haemolysis with one important factor. Small amounts of haemolysis will raise the potassium and leave the sodium largely unaffected. Old samples are an issue because the Na/K pump of the red cell fails and Na and K start to diffuse across the membrane in both directions. This can lead to high potassium with concomitant low sodium. Phosphates can be raised in old samples because of release of phospholipids from red cell membranes. Bilirubin will fall in centrifuged samples exposed to light over time. Bicarbonate will fall over time. In uncapped tubes bicarbonate may fall up to 2 mmol/L.

Biochemistry Reference Intervals

Ranges have been derived from several reputable sources including running patient samples as part of each respective method verification programme.

Oral Glucose Tolerance Test

The OGTT is indicated if fasting and/or random glucose measurements are equivocal i.e. 6.1-7.0 mmol/l. It should not be performed in individuals who fulfil the criteria for Diabetes Mellitus i.e. 1) fasting glucose >7.0 mmol/l on 2 or more occasions or 2) clinical symptoms of Diabetes with a random plasma glucose > 11.1 mmol/l.

This procedure tests all the homeostatic mechanisms involved in glucose homeostasis and can give useful information on the renal threshold. For the interpretation of test results, see the WHO publication "Definition, Diagnosis and classification of Diabetes Mellitus and its complications", WHO/NCD/NCS 99.2.

Patient Preparation

Patients should have been on a normal carbohydrate diet (>150g daily) for at least 3 days prior to the test.

Patients must be fasted for 10-14 hours prior to the test. Small volumes of water are permitted during this time.

Patients should refrain from smoking and exercising prior to and during the test.

Procedure

The test SHOULD BE CARRIED OUT IN THE MORNING and patients should remain at rest during the test.

At Time 0 min blood should be taken into a fluoride oxalate tube for a fasting plasma glucose level.

A 75g glucose load is given dissolved in 250-300mls of cold water. This should be drunk within 5 minutes. Children should be given 1.75g/kg body weight to a maximum of 75g.

A further sample for plasma glucose is taken at Time 120 mins.

Interpretation

The current WHO guidelines on interpretation are shown below:-

Indication/Time	Plasma glucose (mmol/L)	
	0 min	120 min
Non diabetic	<6.0	<7.8
Impaired glucose tolerance	6.1-6.9	7.8-11.0
Diabetic	≥7.0	≥11.1

Reference World Health Organization - www.who.int/diabetes/publications/en/

f. Short Synacthen® Test (Ward Protocol)

g. Therapeutic Drug Monitoring (TDM)

All requests forms should indicate the dosage, frequency of dosage and sampling time.. Timing of samples for TDM is critical, in relation to the time of an oral dose, as the patient may still be in the absorption/redistribution phase. For most purposes, it is safe to take a sample immediately prior to an oral dose.

Haematology

Haematology and Blood Transfusion tests, performance and limitations

Haematology Tests

Add-on test availability is dependent upon test stability and the storage time and condition of the original sample.
Please note samples are stored normally for a minimum of 7 days and therefore please use the tables below as a guide to the suitability for requesting add-on requests.

Each report will quote the appropriate age and gender related reference range or provide a clinical interpretation

Assays which appear in **bold** are those which are performed in house whilst all others are performed at a suitable accredited laboratory.

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Antithrombin III	AT3		3 working days	70 - 140 mg/L	1 days	Coagulation/thrombosis uses
Blood film	**FILF**		**1 working days**		**1 days**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Blood film for parasites	**FILP**		**1 working days**		**2 days**	We will collect sample if the patient can attend the laboratory at no extra charge
Blood group			**1 working days**		**7 days**	**Ensure sample fully labelled correctly (hand written)**
Bone Marrow Aspirate			5 working days		Not applicable	**By appointment only**
Clotting time	**CLOT**		**1 working day**		**Not applicable**	Sample to be collected by us

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Coagulation screen	COAG		1 working day	Please refer to individual tests	Not applicable	
Erythrocyte Sedimentation Rate	**ESR**		**1 working day**	**0 - 15 mm/H**	**Not applicable**	
Factor V Leiden	FVL		7 working days	Quoted by referral laboratory	Not applicable	
Fibrinogen	FIB		1 working day	Quoted by referral laboratory	Not applicable	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Full blood count	FBC		1 working day		Not applicable	
Full Blood Count plus ESR	**FBCE**		**1 working day**	**Please refer to individual tests**	**Not applicable**	
Haemoglobin	**HB**		**1 working day**	**male 13.0 - 18.0 g/dL female 11.5 - 16.5 g/dL**	**2 days**	
Haemoglobin Electrophoresis	HBEL		5 working days		2 days	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Haemoglobin S Screen	**HBS**		**1 working day**		**2 days**	
INR	INR		1 working day	1.0 - 1.2	Not applicable	
INR for Warfarin	INRW		1 working day	1.0 - 1.2	Not applicable	
Lupus anticoagulant screen	LUP		7 working days	Quoted by referral laboratory	Not applicable	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Lymphocyte subsets	CD48		2 working days	Quoted by referral laboratory	Not applicable	
Malarial parasites	**FILP**		**1 working day**		**1 day**	
Mononucleosis screen	MONU		1 working day		1 day	
Platelets	**PLAT**		**1 working day**	**140 - 400 x 10^9/L**	**Not applicable**	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
Protein C	PRC		7 working days	70 -140 IU/dL	Not applicable	
Protein S	PRS		7 working days	65 -140 IU/dL	Not applicable	
Prothrombin Time	PT		7 working days	7 - 12 seconds	Not applicable	
Red Cell Count	RBC		1 working day	male 4.50 _ 6.50 x 10^12 cells/µL female 3.80 - 5.80x 10^12 cells/µL	Not applicable	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
RBC Antibody Screen	BGA		1 working day		7 days	
Reticulocyte Count	RETI		1 working day	0.5 -2.5 %	Not applicable	
Thalassaemia screen	THAL		1 working day		Not applicable	
von Willebrand's screen	VWD		5 working days	Quoted by referral laboratory	Not applicable	

Test	Path Lab Request code	Sample Tube	Turnaround Time	Reference Range	Maximum age of samples for retrospective testing	Additional comments
White Cell Count	WBC		1 working day	3.5 - 12.0 x 10^9/L	Not applicable	

STRICTIONS FOR HAEMATOLOGY TESTING	
TEST	**TIME LIMIT**
APTT	< 4 Hours
BNP	
CLOT	
D-DIMER	
ESR	
INR	
FBC	Sample > 24 hours old

Coagulation screens before surgery or invasive procedures

In 2008 the British Committee for Standards in Haematology (BCSH) published guidance on the assessment of bleeding risk prior to surgery (Chee et al 'Guideline on the assessment of bleeding rick prior to surgery or invasive procedures). These recommendations can be summarized as follows:

- Indiscriminate coagulation screening prior to surgery or other invasive procedures for prediction of bleeding risk is not recommended
- A comprehensive bleeding history should be taken in all patients prior to surgery and invasive procedures
- If the bleeding history is negative, no further coagulation testing is indicated
- If the bleeding history is positive or there is a clear clinical indication (e.g. liver disease), a comprehensive assessment guided by the clinical features is required

Testing for Thrombophilia

Who to test for heritable thrombophilia

- Patient: consider testing those with a strong family history of unprovoked thrombosis; or women planning a pregnancy who have had a VTE due to a provoking factor should be tested and considered for antenatal prophylaxis if a thrombophilia is found
- Relative: consider testing asymptomatic relatives in selected thrombosis prone families with high risk thrombophilia (antithrombin, protein C or protein S deficiency). May be particularly helpful for counselling female relatives regarding COC and HRT; or women planning a pregnancy who have a family history of venous thrombosis should be tested if an event in a first degree relative was unprovoked, or provoked by pregnancy or COC exposure.

In patients, if testing is indicated it is usually performed one month after discontinuing anticoagulation with Warfarin. We do not recommend testing in the acute phase or when anticoagulated with warfarin.

Haematology Reference Intervals

Ranges have been derived from several reputable sources including running patient samples as part of each respective method verification programme.

Microbiology

Interpretation of Gram Films

If telephoning microbiology for clinical advice please ensure that you are familiar with the patient's clinical history and examination results - Drug allergies need to be defined as this determines antimicrobial choice.

Antibiotic sensitivity tests

If cultures are sterile, consideration should be given to stopping antibiotic treatment. Clinical advice can be obtained from the microbiologist.

Antibiotic sensitivity tests which cover the common antibiotics normally used are carried out on most bacteria isolated, apart from those regarded as normal flora. Other antibiotics are tested as required or on request.

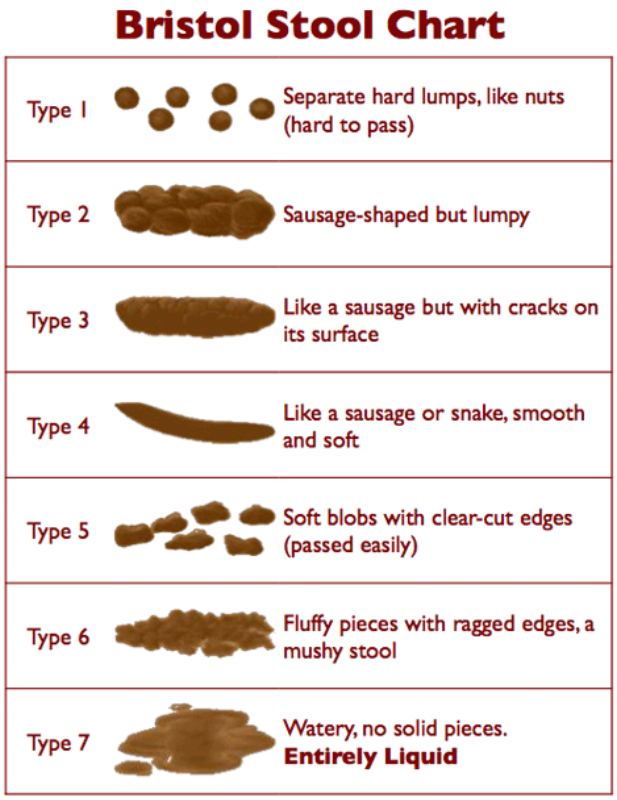
Results are usually available between 18-48 hours after receipt, depending upon type of specimen.

Consult the laboratory if antibiotic sensitivities are required urgently.

In special circumstances, e.g. treatment of endocarditis, the determination of the minimum inhibitory concentration (MIC) or minimum bactericidal concentration (MBC) of an antibiotic for a particular bacterial isolate may be required. Please consult the laboratory before ordering such tests.

Always consider rationalising antibiotic treatment on receipt of sensitivities. It is usually possible to switch to less toxic, more appropriate and often cheaper agents. Early switch to oral therapy should also be considered.

Bristol Stool Chart



Reference: Heaton, K W & Lewis, S J 1997, 'Stool form scale as a useful guide to intestinal transit time'. Scandinavian Journal of Gastroenterology, vol.32, no.9, pp.920 - 924. Retrieved on 2/3/2007

Virology and Immunology investigations

Where testing is for natural immunity from PAST infections or immunity after immunisation, testing is for antibody. Give date(s) of relevant immunisations. State clearly for which infection immunity is to be tested.

For CURRENT or RECENT infections, take specimens as early in the illness as possible. Give details of clinical symptoms with their duration, as well as a provisional diagnosis and what infection is suspected. State if the patient is immunocompromised. If there has been recent foreign travel, state countries visited and when, including date of return, and if any "unusual" immunisations have been given (e.g. Yellow Fever, Japanese Encephalitis, Tick-

borne encephalitis). Many diagnoses are made by detecting viral nucleic acid or viral antigen.

Serology is used as follows: -

- To demonstrate a recent infection by detecting IgM antibody e.g. hepatitis A, erythrovirus (parvovirus) B19, rubella, EBV and occasionally other infections e.g. toxoplasma.
- To detect persisting infection e.g. HIV, hepatitis B
- To detect natural immunity from previous infection OR immunity after immunisation.
- As diagnosing a recent infection by serology may require different tests to those used for determining immunity, the relevant clinical information is especially important. Interpretation of serology test results depends on the timing of the samples submitted and types of tests used.

Each report will quote the appropriate age and gender related reference range or provide a clinical interpretation.

Assays which appear in **bold** are those which are performed in house whilst all others are performed at a suitable accredited laboratory.

Test	Path Lab Request code	Sample Tube	Turnaround Time	Maximum age of samples for retrospective testing	Additional comments
Allergy screen, generally			3 working days	7 days	
Allergy screen, UK Panel VII	VIEE		3 working days	7 days	
Anti Cardiolipin Antibodies	CLY		7 working days	7 days	
Anti DNA Antibodies			7 working days	4 days	Single stranded DNA Abs
Anti dsDNA Antibodies	AUTZ		3 working days	7 days	Double stranded DNA Abs

Anti Neutrophil Cytoplasmic Antibodies	ANCY		3 working days	4 days	
Anti Nuclear Factor	ANFY		3 working days	4 day	

Measurement uncertainty (MU)

Measurement uncertainty for all tests performed in house (E.g: on multiple analysers) are available upon request.

Computer Systems & IT

Status of Laboratory Reports

All printed reports issued are final reports unless the report states otherwise

Examples of text used to designate other types of report are as follows:

- **Sent to reference laboratory**
  - Interim report
  - A further report will be issued on receipt of results of further investigations from a reference laboratory
- **Provisional report**
  - Interim report
  - A further report will be issued when additional results are available
- **Supplementary Report**
  - Additional report issued after a final report, giving additional information which was not available when the final report was issued
- **Amended Report**
  - Previously reported results have been corrected; the results which have been changed will be clearly identified
- **Copy Report**
  - Copy report issued which includes information on the individual who should receive the copy and the original requestor.
  - The report to the original requestor will also contain details of the

individual(s) who have received copy reports

Waste Management

Safe disposal of material used in the collection: all materials used in specimen collection should be treated as potentially hazardous and discarded using sharps containers and other appropriately colour coded bags. Please refer to the current Health & Safety Manual (QMS 12).