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Blood Sciences Handbook					

### Blood Sciences Stoke Mandeville and High Wycombe Hospitals

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Accepted by:	Blood Sciences Management Group



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### 1. Introduction

The Blood Sciences encompasses the disciplines of Biochemistry, Blood Transfusion, Coagulation, Haematology, Immunology and Serology.

The main 'Hub' laboratory is part of the Blood Sciences Laboratory at Stoke Mandeville Hospital. This is a purposebuilt laboratory suite with state of the art equipment facilitating the provision of a high quality service to the Buckinghamshire health community and beyond. SMH laboratory serve GP practices from Stoke, Wycombe and Amersham

There is also a smaller 'Spoke' laboratory in the Blood Sciences Laboratory at Wycombe Hospital. There is common, state of the art equipment across the two sites enabling direct comparison of any result analysed on either site. Biochemistry, Blood Transfusion, Coagulation and Haematology services operate at this site. Services are offered with limited repertoire and the Transfusion laboratory operates only between 8am to 8pm. There is daily communication between the sites for the transfer of samples as required.

The Clinical Immunology Laboratory provides the clinical diagnostic service for the entire Buckinghamshire Healthcare NHS Trust since the restructuring of laboratory services in 2005. The laboratory receives and processes samples from the three main hospital sites within the Trust as well as from GP patients living within a wide radius of the hospitals. The clinical lead for the laboratory is undertaken by the consultant medical staff at the John Radcliffe Hospital in Oxford who is available for clinical advice by telephone

This handbook aims to provide key information for the service users including specimen types, turnaround times and reference ranges.

### 2. The Departments

### 2.1 Departmental overview

**Stoke Mandeville** – The Blood Sciences department at Stoke Mandeville is located within the old part of the hospital site and is accessed by entrance 2 (see appendix 2 'Laboratory locations). The department comprises Biochemistry, Blood Transfusion, Coagulation, Haematology, Immunology and Serology. The majority of the sample analysis undertaken is performed via a Blood Sciences track system that includes Abbott Architect automated analysers for Biochemistry and serology, Sysmex XN and CS analysers for Haematology and Coagulation and Diasorin Liaison XL for Serology. Additional analysis is performed on Biorad D100, Biorad Variant II, Helena V8 and the Ortho Vision analysers.

**Wycombe** – The Blood Sciences department at High Wycombe is located in the main (Phase 1) hospital building with access via the main entrance (see appendix 2 'Laboratory locations). Common analysers are used across the Trust but there is no track system on the Wycombe site.

The Blood Sciences departments are clinically led by discipline specific Consultants:

Biochemistry: Dr Gayani Weerasinghe -- Consultant Chemical Pathologist (SDU co-lead) Dr Sureshni De Fonseka --Consultant Chemical Pathologist (Clinical lead - Point of Care)

Haematology: Dr Helen Eagleton (Divisional Chair) Dr Joe Browning (Laboratory, Haemoglobinopathy & Morphology lead)

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Dr Rachel Lacey (Bloo Dr Renu Riat Dr Liane Simons Dr Robin Aitchison Dr Beena Pushkaran (I Dr Jennifer Davies	d Transfusion) Paediatric Haematology)			

Dr Wenchee Siow (Thrombosis & Coagulation)

Immunology: Dr Liz Bateman (Consultant Clinical Scientist) Dr Ross Sadler (Consultant Clinical Scientist)

The department is managed by:

Head Biomedical Scientist for Blood Sciences - Venkat Nadella Lead Biomedical Scientists: Biochemistry& Immunology – Sola Okor Haematology & Blood Transfusion – Katy Cotton POCT – Saima Khan

### 2.2 Staffing and establishment

The departments employ a number of clinical, scientific and support staff thereby providing a full range of laboratory services for our users. Clinical support is provided by the consultant staff who are happy to answer any questions with regards to interpretation of results, patient management etc.

Scientific and managerial support is provided by the Head Biomedical Scientist, Lead Biomedical Scientists and Senior Biomedical Scientists. Analytical work is performed by a number of Biomedical Scientists (BMS) with administrative and technical support from Associate Practitioners (AP) and Medical Laboratory Assistants (MLA).

The department is recognised as a training laboratory by the IBMS with active training programmes designed to produce the next generation of multidisciplinary scientists.

Individuals within the programme have completed a recognised degree in Biomedical Science and complete the required Institute of Biomedical Sciences (IBMS) registration portfolio for registration with the Health and Care Professions Council (HCPC).

There is comprehensive Continuing Professional Development comprising of CPD seminars and competency assessment programme, including quality management.

There are phlebotomy services on the Amersham, Stoke Mandeville and Wycombe hospital sites.

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### 2.2.1 Pathology Service Delivery Model



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### 2.2.2 Blood Sciences Laboratory Organisational Structure



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### 2.3 Contact details

### Table 1: Clinical Staff

	Email address	Stoke Mandeville contact number	Wycombe contact number	
Biochemistry – available for consult	ation and clinical advice during normal w	orking hours		
Dr Gayani Weerasinghe (SDU Lead, Consultant Chemical Pathologist)	gayani.Weerasinghe@nhs.net In Oxford on Friday but contactable via email	01296 418333	01494 425069	
Dr Sureshni de Fonseka (Consultant Chemical Pathologist, POCT clinical lead)	sureshni.defonseka@nhs.net	01296 315353	01494 425069	
Haematology Consultants – contact	ctable through switchboard			
Dr Helen Eagleton – Divisional Chair, Specialist Services	haemsecssmh@nhs.net	01296 316053		
Dr Liane Simons (Consultant Haematologist)	lsimons@nhs.net	01296 315511		
Dr Jennifer Davies (Consultant Haematologist)	Jennifer.davies11@nhs.net	01296 315511 07980656642		
Dr Rachel Lacey (Lead for Blood Transfusion)	rachel.lacey3@nhs.net	01296 316053		
Dr Renu Riat (Consultant Haematologist)	r.riat@nhs.net	01296 316053		
Dr Robin Aitchison (Consultant Haematologist)	haemsecswh@nhs.net	01494 425224		
Dr Beena Pushkaran (Lead for Paediatric Haematology)	b.pushkaran@nhs.net	01494 425224		
Dr Joseph Browning (Laboratory, Haemoglobinopathy and Morphology Lead, SDU Lead for Haematology and Oncology	Joe.browning@nhs.net	01494 425224		
Dr Wen Chee Siow (Lead for Thrombosis and Coagulation)	Wenchee.siow1@nhs.net	01494 425224		
Immunology				
Dr Ross Sadler (Consultant Clinical Scientist)	rosssadler@nhs.net Ross.Sadler@ouh.nhs.uk	For non-urgent clini use the General En Immunology at the on 01865 225995 (9	cal enquiries please quiry line for Churchill Hospital 9:00-17:30 Monday	

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Dr Elizabeth Bateman (Consultant	Elizabeth.Bateman@ouh.nhs.uk	to Friday.
Clinical Scientist)		For urgent clinical enquiries a clinician can be contacted by bleep via the
		Churchill Switchboard (0300 3047777)

### **Table 2: Laboratory Management Team**

	Email address	Stoke Mandeville contact number	Wycombe contact number
Head Biomedical Scientist (Blo	od Sciences)		
Venkat Nadella	venkat.nadella@nhs.net	01296 315355	01494 425610
Lead Biomedical Scientist (Biod	chemistry)		
Sola Okor	sola.okor@nhs.net	01296 315355/315323	01494 425610
Lead Biomedical Scientist (Hae	matology and Transfusion)		
Katy Cotton	katy.cotton@nhs.net	01296 315454	01494 42 5627
Pathology Business Manager			
Vacant			
Pathology IT Services Manager			
Dave Green	dave.green@nhs.net	01296 315013	
ICE Manager			
Steven Foster	steven.foster@nhs.net	01296 316684	
Head of Diagnostics			
Andrew Wainwright	andrew.wainwright4@nhs.net	07833237420	
Divisional Director (interim)			
Isobel Day	isobel.day2@nhs.net	01296 315179	

### 2.4 Turnaround Times

- Target Turnaround Times (TAT) is largely dependent on the urgency of a specimen, the time of day received and also the requesting location.
- All of the times stated within the following table are from the time that the specimen is received in the laboratory.

### Table 3: Expected TAT

Request Type	Turnaround Time (within)
Urgent Specimens	One hour
Non-urgent hospital specimens (ward or outpatients)	Four hours
GP specimens	By 11am the day following blood collection

### 3. Opening Hours

- The Blood Sciences department at Stoke Mandeville and Wycombe Hospitals provide cover 24 hours a day, 365 days a year.
- The laboratories are fully staffed Monday to Friday from 09:00 17:30.

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- At other times there is reduced staffing to process urgent samples and provide an urgent Transfusion service for the hospital (on the Stoke Mandeville site only from 20:00 to 08:00).
- Service provision during the routine hours can accommodate any request made on the department as it is fully staffed and has capacity.
- Please ensure any routine or unusual analysis such as specialist assays are requested during routine working hours.
- Please check with the laboratory for specific instructions regarding specialist tests.
- Phlebotomy opening times available via Swan Live need to give URL link

https://www.buckshealthcare.nhs.uk/Our%20clinical%20services/A%20to%20Z%20of%20clinical%20services/Pathology/blood-tests.htm

### 3.1 Routine opening hours:

### Table 4: Routine working hours

Weekdays	Routine Service 09:00 to 17:30 daily
Weekends	As per section 3.2 'Urgent samples and out of hours'
Bank Holidays	As per section 3.2 'Urgent samples and out of hours'

### 3.2 Urgent samples and out of hours

The Blood Sciences departments at Stoke Mandeville and High Wycombe hospitals both offer services outside of the routine working hours of the laboratory.

The Wycombe laboratory does not provide an overnight service for Transfusion.

The service and contact details for out of hours personnel differ slightly between the sites and therefore it is essential to use the information pertinent to the hospital that is providing your service.

### Table 5: Restricted service hours

Weekdays	Out of hours service 20:00 to 08:00 daily
Weekends	Out of hours service: 20:00 Friday – 08:00 Monday
Bank Holidays	Out of hours service: 08:00 to 20:00

#### 3.3 Out of hours contact details

### Table 6: Out of hours contact details

Stoke Mandeville Hospital	Phone number	Bleep number
Blood Sciences Specimen Reception	01296 315354	
Biochemistry	01296 315356	783 (or via switchboard)
Transfusion and Haematology	01296 315461	784 (or via switchboard)
Switchboard	01296 315000	
Wycombe Hospital		
Biochemistry	01494 425398	3700

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Transfusion and Haematology*	01494 425237	3702
Switchboard	01296 31500	

\*The Blood Sciences department at WH is manned by one BMS overnight; please use the same contact number for Biochemistry.

After 20:00 please use the bleep number for Haematology & Transfusion as there is only one BMS covering both departments.

### 4. Specimen Information

### 4.1 Sample types

The correct specimen container is essential. A test may be contraindicated if an inappropriate container is used. Please note that many samples deteriorate rapidly, if in doubt about appropriate storage please contact the laboratory.

### 4.1.1 Biochemistry & Immunology testing

### a) Blood samples

- For non-paediatric patients the majority of common analysis is performed on SST II gel tubes (gold top) and a single tube is sufficient for most standard profiles of tests. Guidance is provided on all ICE requests.
- For paediatric samples please contact the department if in doubt about the correct sample container **before** venepuncture. The small lithium heparin (orange tube) is, at present, recommended for most of the common paediatric blood tests except for Immunology tests and for Protein Electrophoresis.
- For a list of tests and associated tube types see sections 7.1 'Biochemistry In house Tests' and 7.4 'Referral Tests'.
- Fasting patients: Fasts should be for 10 12 hours overnight with nothing to eat or drink except for water.
- For help with which test to use click on https://labtestsonline.org.uk/
- Blood collection sample guidance for peak time post therapeutic drugs.

Drug	Time post dose (hours)
Carbamazepine (Tegretol)	3
Digoxin	6-8
Lithium	12-14
Phenobarbitone (Primidone Or Mysoline)	6-18
Phenytoin/Epanutin	4-8
Theophylline (Slophylline Or Phyllocontin)	2
Valproate (pilim)	1-3

### b) Urine and stool samples

- All random and 24-hour urine and all stool samples must be clearly labelled with the minimum data set as below.
- Make sure lids are secure to prevent leakage.
- Random Urine samples must be collected in the approved sample tube to facilitate efficient processing
- For 24-hour urine collection always follow instructions and warnings on the containers if present.

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 Patient instructions for stool collection can be found on form: BS FORM311 and QFIT instructions in BS-EXT-B127. Instructions for 24-hour urine collection is in BS FORM312.

### • Urine sample collection

Mid-stream (Spot/Random) urine collection for Biochemistry tests:

- 1. Sample should be taken mid-stream. Do not collect the initial or last part of the urine sample.
- 2. Collect the urine from the morning's first sample using the cup supplied and then follow instructions below:

#### c) CSF sample collection

- **Sample 1&3** for CSF would be analysed by Microbiology for the tests requested.
- **Sample 2** is for CSF Protein, **sample 4** is used for Xanthochromia analysis and should be protected from light and should not be sent through the chute system.
- For CSF Glucose and Lactate analysis CSF **Sample 2** should be collected in a Fluoride/Oxalate tube (grey container)

#### d) Sweat collection

The department provides service for Sweat analysis for Cystic Fibrosis with conductivity and Chloride analysis.

The sweat collection is carried by the CF team at Bucks Healthcare NHS trust using the Elitech advanced macroduct system

Please refer to 2014 Guidelines on Sweat testing for further information.



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# Urine Monovette® User Guide



### 4.1.2 Haematology testing

- For non-paediatric patients the majority of Haematology analysis is performed on mauve top EDTA samples or blue top citrate samples. Some specialist testing will require numerous tubes so please contact the laboratory if you are not familiar with the test. (See Table 7.2 for further details related to sample requirements.)
- For paediatric samples please contact the department if in doubt about the correct sample container **before** venepuncture. The small EDTA (red or mauve top) is, at present, recommended for most of the common paediatric haematology tests. Paediatric citrate (blue top) samples are also available for coagulation and must be filled to the required line on the bottle or the sample will have to be rejected.

### 4.1.3 Blood Transfusion testing

- For Blood Transfusion, the majority of testing is performed on pink top EDTA samples.
- Reference testing may require multiple samples or possibly other sample types so please contact the laboratory for advice if required. (See Table 7.2 for further details related to sample requirements.)
- Small red or mauve top EDTA samples for paediatric patients will only be accepted until the age of four months; after this we must receive at least a mauve top EDTA, containing at least 2ml of blood for analysis.

### Tube guide and order of draw:

Cap colour	Anticoagulant	Assays	Mixing
			instruction

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	Sodium Citrate	Coagulation investigation INR D-dimer PT & APTT Thrombophilia Lupus	3-4 times
	Plain	Erythropoietin Fructosamine Thyroglobulin	5-6 times
	SST	All routine Biochemistry Immunology and Virology testing	5-6 times
_	Lithium Heparin	Ammonia Paediatric assays for Biochemistry Some referral tests (see referral table)	8-10 times
	EDTA	FBC, Malaria Screen HBA1c Haemoglobinopathy screen ESR PTH Some referral tests (see referral table)	8-10 times
	K3EDTA	Blood Group and Antibody screen	8-10 times
	Fluoride Oxalate	Glucose, Alcohol, Lactate	8-10 times
	Trace Element	Aluminium, Zinc, Selenium, any other trace metal.	8-10 times
	Trace Element	Chromium, Cobalt	8-10 times

### Correct handling of samples

EDTA

- Handle samples with care to avoid haemolysis.
- All blood tubes require immediate mixing by gentle inversion 8 –10 times.
- Insufficient mixing can lead to inaccurate results.
- All tubes should be filled to the capacity of the vacutainer to ensure adequate sample for analysis. When
  samples are taken for Coagulation studies this is especially important as underfilled samples will produce
  incorrect results and will not processed.

### 4.1.4 Immunology testing

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It is essential that the correct specimen container is used to collect samples for testing. The sample requirements for some assays are very restrictive and the assay may not be possible if an inappropriate container is used. The majority of samples can be stored in a refrigerator before dispatch to the laboratory, but this is not possible for all sample types. Please contact the laboratory if in any doubt about sample storage.

For paediatric samples please contact the department if in doubt about the correct sample container **BEFORE** venepuncture. The small lithium heparin (orange tube) is not recommended for many of the commonly requested paediatric blood tests where serum, and not plasma, is the required sample type.

Samples being sent for lymphocyte markers, *QuantiFERON*-TB Gold or functional assays must **NOT** be placed into the refrigerator but kept at room temperature. It is not possible to process these samples if they are collected on a Friday due to the restrictions of the reference laboratory. CSF samples must be collected into sterile sample containers, as used for Microbiology samples, and not collected into blood tubes.

Below is a table of common BD Vacutainer<sup>™</sup> tube types supplied by the laboratory.

BD Vacutainer Colour	Tube Name	Sample Produced	Routine Application
Gold	SST II Advance	Serum	All routine Immunology Investigations.
Lavender	Potassium EDTA	Plasma or Whole Blood - EDTA	Lymphocyte markers, functional and genetic studies.
Green	Lithium Heparin	Heparinised Plasma or Heparinised Whole Blood	Functional assays and Cytogenetic studies
	Various	Various	<i>QuantiFERON</i> -TB Gold Plus for detection of <i>Mycobacterium</i> <i>tuberculosis</i>

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### Key factors which may adversely affect test results

It is well accepted that the best possible results can only be achieved if the samples received are of the highest quality. The quality of the samples received remains a shared responsibility for both the laboratory and the requester to ensure that results are not adversely affected.

Acute Infections	It is not advisable to request auto-antibody testing on patients who have
	significant acute infections, bacterial or viral, as these patients will give weakly
	false positive reactions in many assays. This can lead to confusion and delay
	in diagnosis and treatment.
Cellular Assays	Cellular assays rely on the white blood cells remaining viable within the
	sample container, and so must be kept at room temperature and not
	refrigerated. These samples must reach the laboratory within 2 hours of
	collection and the laboratory should be contacted prior to sample collection to
	ensure that the collection plans are suitable.
Cryoglobulins	Samples for cryoglobulins can only be collected when a member of the
	laboratory staff is present to ensure that the temperature of the sample does
	not fall below 37°C. Samples that are not collected by the laboratory will not be
	processed as they will only provide very poor-quality results. Please contact
	the laboratory to make an appointment for the sample to be collected, we are
	unable to provide this service without an appointment being pre-made.
Drips & Infusions	Do not collect samples from the same arm as any intravenous infusion as this
	will dilute the peripheral circulation and lead to a poor-quality result.
EDTA	EDTA samples are only suitable for cellular phenotyping assays such as
	lymphocyte subsets, they should not be used for any other immunology
	assays.
Haemolysed Samples	Grossly haemolysed samples can adversely affect the immunology specific
	protein results and can make electrophoresis and paraprotein quantitation
	difficult to achieve.
Heterophile Antibodies	These are antibodies with non-specific binding properties which can cause
	confusion when looking for true autoantibodies. They are particularly common
	in patients who have received multiple blood transfusions of in women with a
	history of multiple pregnancies.
Immune Deficiency	Patients receiving replacement IV immunoglobulin cannot be tested for IgG,

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IgA or IgM responses, as they do not have a normal humoral immune		
response. All results will be falsely negative.		
Patients who are significantly immunocompromised do not demonstrate		
normal antibody responses, and all of their results must be interpreted with		
caution. Please discuss the testing requirements for these patients with the		
laboratory before undertaking any testing.		
Grossly lipaemic samples can interfere with antibody binding and either reduce		
the sensitivity of an assay or lead to weakly false positive results.		
Lithium heparin samples should only be taken when specifically advised. They		
will not be accepted for routine immunology assays.		
Results are unreliable on all patients who have recently received significant		
blood transfusions as the laboratory investigations will detect antibodies and		
antigens present in the transfused units.		
In order to maintain the confidence in the sensitivity and specificity of the		
laboratory results, all requests are reviewed by experience members of the		
laboratory staff. If the investigation is not indicated by the clinical information		
provided, then the request may be withdrawn, and additional information		
requested. Samples are stored within the laboratory awaiting the information		
and are not discarded.		
All laboratory results are issued electronically either onto the hospital Review		
system, ICE electronic requesting or via GP links. Every effort should be made		
to obtain the required results from these locations before contacting the		
laboratory for a verbal result. This reduces the likelihood of a verbal		
transcription error.		
If in any doubt, please contact the laboratory to confirm the specific sample		
type required for any specific investigations.		
Not all of the investigations performed in the laboratory produce numerical		
results which can be interpreted using fixed guidelines. The microscopic		
examination of immunofluorescence slides for autoantibodies and the		
interpretation of electrophoresis gels are performed manually and subject to		
individual interpretation. The inherent differences in interpretation has been		
minimised by adopting a double reading approach whenever possible and all		
staff training and competency with these tasks is closely monitored. It is		
expected that any variation in results due to differences between individual		
staff interpretations will be minimal and the user should have confidence in the		

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	reported results.
Tipped Samples	If a sample has been collected into the wrong tube, DO NOT tip it into the
	correct one. The sample will already have been adversely affected and then
	cause added complications as it appears to be in the correct sample tube.
Transport	All samples are transported to the laboratory as quickly as possible and in a
	way appropriate for the test request. There may be occasions when extreme
	or adverse conditions may affect sample integrity, and this will be documented
	on any reports.

### 4.2 Sample volume

Guidance on sample volume is given on ICE when a request is made. If more than one type of tube is required, for example two EDTAs, this will be indicated on the ICE system and the printed ICE form.

If for some reason ICE cannot be accessed, please contact the laboratory for advice on sample volume, tube type & pre-analytical requirements.

### 4.3 Labelling requirements

The following is the **minimum** requirement for the labelling of samples and request forms received within the Blood Sciences Department:

Table	8: Request	form and	sample	labelling	requirements

Request form	Sample tube
Full forename	Full forename
Surname	Surname
Date of birth	Date of birth
NHS/hospital number (MRN)	Transfusion only:
	NHS/hospital number (MRN)

### 4.3.1 Electronic requesting and results

- The laboratory utilises the ICE Order Comms system from Sunquest.
- Requests can be made electronically, increasing the accuracy and efficiency of the laboratory. Results can also be viewed on this system as can the progress of the sample.
- Request forms with printed labels are generated from your system that also shows the sample bottles required. The printed request form must still accompany samples to verify identification and requests in the laboratory.

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### 4.3.2 Sample labelling

- Prior to labelling a sample, ensure that you have asked the patient to confirm their full name and date of birth (positive identification of patient)
- The sample should be clearly labelled with the patient's surname, forename and date of birth as the minimum identification criteria.
- Other necessary information includes the date and time the sample was taken and the signature of the person taking the blood.
- Pathology samples must be labelled at the time the sample is taken after confirmation of the patient's identity; pre-labelling of sample tubes is an unsafe practice.

The development of the Trust's Clinical Risk Policy has highlighted the importance of applying minimum standards to the labelling of pathology samples and the provision of information on pathology request forms. This has been reinforced by reports on Serious Hazards in Blood Transfusion, where labelling errors have had fatal consequences.

Inadequately labelled samples will be rejected by the Pathology Laboratory unless the specimen is unrepeatable e.g., aspirate. In these cases, it is at the discretion of the Pathology Laboratory to ask the requesting clinician to **attend the laboratory** to positively identify the sample before it is processed.

ICE labels on Blood Transfusion samples are not acceptable. All Transfusion samples MUST be hand labelled to be accepted for processing\*.

\*The only samples that will be accepted in the Transfusion laboratory with ICE labels are those for maternal group and antibody screen samples from the GP surgery. The labels **must** be signed by the staff member taking the sample. If the patient subsequently attends hospital a new sample must be taken for issue of blood and/or blood products.

### 4.3.3 Unlabelled specimens

Samples that are unlabelled are NOT accepted for processing. Care must be taken during the labelling of all samples, especially those that would be very difficult to repeat

#### 4.3.4 Request form completion

All requests for Blood Sciences investigations should be made on the electronic Order Comms system, ICE. Request forms are printed directly from the system and include printed labels for the samples.

- Pre-printed addressograph adhesive labels from the notes can be used on handwritten Pathology request forms. Please do **not** use addressograph labels on the sample bottles; these will be rejected.
- Other information which should be added to the request form includes the requesting consultant, location of the patient, and address for copies, patient's GP, clinical details, the nature of the specimen for analysis and test required.
- Brief clinical details and drug therapy, where applicable, should be included on the request form to aid in the correct testing and interpretation of results.
- Illegible and incomplete request forms are a source of clinical risk and may not be processed.

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### 4.3.5 Adding tests

Adding tests to a request already sent to the laboratory is dependent on the laboratory accepting the request, the date of the addition relative to the date and time of the original sample, the test requested, and the sample type already received.

Where possible all tests required should be requested at initial request to ensure complete audit trails and effective workflow.

Currently specimens are stored for approximately three days before disposal unless specifically requested. Please discuss with the lab the validity of adding tests to existing samples.

The department in collaboration with primary care has developed an email-based system for Blood Sciences add on requests. Primary care clinicians can e-mail <u>BHT.Bloodsciences@nhs.net</u> requesting add on tests which will be actioned by the blood sciences team.

### 4.3.6 Patient consent

Once Request forms are sent to blood sciences laboratory and receipted on LIMS, it is classed as consent from patient and requester to share clinical information, family history (if provided) to relevant healthcare professional and referral laboratory.

#### 4.4 High risk specimens

Please indicate known 'high risk' (blood borne virus) samples by ticking the high-risk box on the request form, or add a high-risk sticker to the sample and request form

Samples from patients suspected of a Viral Haemorrhagic Fever diagnosis MUST be discussed with the Consultant Microbiologist before samples are sent to the laboratories.

The department operates a policy whereby all samples received are treated as potentially high risks and precautions are in place to handle and analyse them.

#### 4.5 Storage and Retention of samples

All initial laboratory testing, whenever possible, is undertaken from the primary sample tube which remains stored in the laboratory for the next 3 days.

The laboratory has a responsibility to store aliquots of antenatal booking bloods for 2 years to ensure that the samples remain available for additional testing if required during the pregnancy or post-natal period. A small volume of this original sample is transferred into a storage tube and is retained in the laboratory for 2 years, stored at -20°C.

The laboratory can be contacted at any time to request that additional tests are added to stored samples within the laboratory. The laboratory staff will confirm that a sample is available and then the additional requests can be made.

Contact the laboratory on 01296 315354/01494 425398 to discuss sample availability for additional testing.

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#### 4.6 Urgent specimens

Urgent samples will be analysed in preference to the routine workload and dealt with as quickly as possible. All work received out of hours will be processed in an order appropriate to urgency and patient location.

If the sample is sent with a porter, please indicate that the sample is urgent and the porter will bring the sample directly to the urgent request area of the Blood Sciences reception and will sign to confirm delivery.

#### Samples and form from A&E use a yellow form and red bags

#### 4.7 Sample Transport

- Electronically generated request forms must be attached to the sample bags provided as per the description on the form. Please ensure that the bags are sealed.
- Red sample bags are available for urgent requests from A&E to allow the laboratory staff to easily ascertain these samples amongst hundreds of other requests at peak times. These bags are restricted to A&E and its associated areas.
- Manual request forms supplied have a specimen bag attached to provide a secure link between request form and specimens for transport to the Pathology laboratories. These must be used for one patient only and sealed with the sample inside the bag.
- Secondary plastic courier bags are also supplied. Samples for transport to the laboratory are placed in these bags. Diagnostic specimens **only** must be placed in these bags.
- The courier bags are collected by the Brake driver or Porter and then placed in designated lidded carrier containers. Do not overfill these boxes by pushing samples hard down into the box, use another box when reasonably full. These are then delivered to the laboratory.
- Samples transported outside these provisions must be double bagged and placed in a secure rigid container to protect the sample and prevent contamination of any third party.
- Samples should be transported to the laboratory as quickly as possible and in a manner that is appropriate to the test requested.
- Samples from the GP or other non-hospital locations that are **time sensitive** or **urgent** must be clearly identifiable for Pathology Reception staff to locate easily. An example of this would be to use a courier bag specifically for the urgent sample, with a note stating the sample is urgent.
- If sample transport is delayed until later than your usual collection time please store samples between 18 25°C and away from any heat source or sunlight. Should samples be stored overnight please consult with the laboratory for appropriate storage and indicate storage conditions on the request form. Always remember to preserve patient confidentiality on samples waiting for transfer or in transit.

#### 4.8 Disposal of sample collection materials

Collection materials, such as needles, must be disposed of safely according to Trust or local procedures.

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### 5. Laboratory Quality Assurance

#### **5.1 Accreditation Status**

The Blood Sciences laboratories are subject to accreditation by the United Kingdom Accreditation Service (UKAS).

The Blood Transfusion laboratories are subject to inspection by regular inspections by the MHRA (Medicines and Healthcare Regulatory Agency) and are compliant with these standards.

#### 5.2 Quality Assurance Activities

It is essential to have confidence in the data and results produced by the laboratory.

- The Blood Sciences department runs a comprehensive Quality Management System, operating a schedule of internal quality audits, corrective action, and quality improvement.
- Each assay is verified by Internal Quality Control (IQC) procedures and the laboratories on both sites subscribe to the relevant External Quality Assurance (EQA) programmes. The EQA programmes are designed to give an estimation of the laboratory's performance against other users with the same instrument and also to highlight the performance of a particular instrument group against rival manufacturers. For further information on EQA scheme participation please contact the department.
- The department also carries out regular correlation studies between the sites and analysers ensuring that whichever site a sample is presented to, clinicians and patients can have confidence that a comparable result will be reported.
- Performance data, including measurement of uncertainty, is available on request to the laboratory.
- Clinically relevant changes to test performance and repertoire are communicated to clinicians if and as they
  occur. The department will contact the Trust Communications team for internal distribution of the
  communication; the CCG will be communicated to ensure distribution of communication to primary care. The
  department will carry out a change control process for the change to test performance/repertoire.
- When samples have been referred to other laboratories for testing, this will be indicated on the report form.

### **5.3 Confidentiality**

Information about service users and patients are treated confidentially and with respect.

- All laboratory premises are secure, and all computer systems are password protected as per the Trust's guidelines and Caldicott principles.
- Accuracy of data is audited by random sampling of records by our Quality Management programme.
- Confidential waste is disposed of securely.
- All staff members in the department undergo annual information governance e learning.
- Freedom of Information requests can be written to the FOI team or alternatively emailed to <u>bht.bhinfo@nhs.net</u>

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# 6. Analytical Information

### 6.1 Key factors adversely affecting test results

Factor	Impact on results/processing of sample
Patient not fasting	High glucose and triglyceride
Storage of whole blood in fridge	High potassium, phosphate, LDH, AST
Prolonged venous stasis	High protein, calcium, and cholesterol
Blood from drip arm	Dilution effects reflecting the composition of the infusion
Collecting sample into wrong vial or tipping from one vial to another	Various errors due to incorrect additives, especially low calcium from chelation with EDTA and raised potassium
Blood for glucose not in fluoride oxalate sample	Low plasma glucose, lactate, alcohol
Delay in processing sample	Low bicarbonate in blood gas samples (>15 minutes) High potassium, phosphate, magnesium (>4 hours) D dimer
Delay in separating and freezing plasma, delay to lab	Low ACTH, insulin, renin, aldosterone, gut hormones, plasma metanephrine Specialist coagulation
Haemolysed sample	As above but sample has been adversely affected & may not be viable. High magnesium & iron. Low ALP, High K, PO <sub>4</sub> , LDH, AST Cannot perform bilirubin
Lipaemic sample	Will cause false increases in glucose, protein, calcium, and phosphate, Will cause false decreases in sodium, chloride May be unable to process FBC, Clotting studies or Transfusion samples
Icteric sample	Unable to process clotting studies May be unable to process Transfusion samples
Clotted sample (EDTA or Citrate)	Unable to process FBC, clotting studies or HbA1c
Short sample	May be unable to process tests
Citrate sample not filled to line	Unable to process clotting studies
CSF for SAH	Sample should be protected from light Blood-stained samples Samples should be 12 hours post onset of headache but no greater than 2 weeks. Patient must have CT scan prior to collection

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### Table 9: Therapeutic drug timings

Drug	Sample collection requirements		
Digoxin	Sample must be taken 6 hours post dose		
Lithium	Sample must be taken 12 hours post dose		
Salicylate and paracetamol	Sample must be taken 4 hours post ingestion		
Other TDM	Sample just before the next dose (trough levels)		

Samples should be collected into the appropriate container for the test. Please contact the laboratory for the correct information.

### 7. In-house tests

### 7.1 Biochemistry In house Tests

### Table 10: in-house tests

Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Reference Range/Instruction	Site routinely processed on
Alanine Transferase	Serum	Gold	24 Hours	10-35 U/L	SMH & WH
Albumin	Serum	Gold	24 Hours	35-50 g/L	SMH & WH
Alkaline Phosphatase	Serum	Gold	24 Hours	Paediatric age dependent Over 16: 40 -150 U/L	SMH & WH
Alpha Fetoprotein	Serum	Gold	24 Hours	0-11.1 IU/ML	SMH & WH
Ammonia	Li Hep Plasma	Orange – paediatric	24 Hours	18 - 72 μmol/L	SMH & WH
Ammonia	Li Hep Plasma	Green – adult	24 Hours	18 - 72 μmol/L	SMH & WH
Amylase	Serum	Gold	24 Hours	25-125 U/L	SMH & WH
Angiotensin Converting	0.000	Qala	7	0-18 years 29-112 U/L	WH
Enzyme (ACE)	Serum	Gola	7 days	Adults 20 -70 U/L	
AST	Serum	Gold	24 Hours	5-34 U/L	SMH & WH
Beta hCG (pregnancy)	Serum	Gold	24 Hours	IU/L	SMH & WH
Bicarbonate	Serum	Gold	24 Hours	22-32 ml/L	SMH & WH
Bile Acids	Serum	Gold	24 Hours	<14 µm/L	SMH
Bilirubin – Direct	Serum	Gold	24 Hours	0-8.6 µm/L	SMH & WH

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Reference Range/Instruction		Site routinely processed on	
(conjugated)							
Bilirubin – Indirect (unconjugated)	Serum	Gold	24 Hours			N/A	SMH & WH
Bilirubin - Total	Serum	Gold	24 Hours		0	-21 μm/L	SMH & WH
CA125	Serum	Gold	24 Hours		(	) -35 U/L	SMH & WH
CA 153	Serum	Gold	24 Hours			<32 U/L	WН
CA 199	Serum	Gold	24 Hours		(	)- 37 U/L	SMH & WH
Carbamazepine	Serum	Gold	24hrs	2	1-12mg/	L 3hrs post dose	SMH
Carcino Embryonic Antigen (CEA)	Serum	Gold	24 Hours	<5 U/L Non-Smoker <10 U/L Smoker		SMH & WH	
Chloride	Serum	Gold	24 Hours		98-	107 mmol/L	SMH & WH
Cholesterol/HDL Ratio (Lipids)	Serum	Gold	24 Hours	N/A		SMH & WH	
Corrected Calcium	Serum	Gold	24 Hours		2.10	2.55 mmol/L	SMH & WH
Cortisol	Serum	Gold	24 Hours	Interpretative comments are available for individual report		SMH & WH	
C-Reactive Protein (CRP)	Serum	Gold	24 Hours			<5 mg/L	SMH & WH
Creatine Kinase (CK)	Serum	Gold	24 Hours	F:	29-168	U/L, M 30-200 U/L	SMH & WH
				Sex	Age	Reference Range	SMH & WH
					1d	27 - 50 µmol/L	
					4w	27 - 88 µmol/L	
		<b>a</b>			52W	18 - 35 µmol/L	
Creatinine	Serum	Gold	24 Hours		6y	24 - 66 µmol/L	
					12y 16y	39 - 82 μmol/L	
				F	>16v	50 - 98 µmol/L	
				M	>16y	63 - 111 µmol/L	
Creatinine Clearance	Urine - 24 Hours and Serum	Gold + Urine	24 Hours	90 - 130 ml/minute/1.73m <sup>2</sup>		SMH & WH	

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Reference Range/Instruction		Site routinely processed on
CSF Albumin	CSF	N/A	24 Hours		(mg/L)	SMH & WH
CSF Glucose	CSF	N/A	24 Hours	(01	2.2-3.3mmol/L r 60% of plasma glucose)	SMH & WH
CSF Lactate	CSF	Grey	24 Hours		<2.8 mmol/L	SMH & WH
CSF LDH	CSF	N/A	24 Hours		(U/L)	SMH & WH
CSF Protein	CSF	N/A	24 Hours		0.15-0.45 g/L	SMH & WH
Digoxin	Serum	Gold	24 Hours	(0.8 -	2.0 ng/ml; 6-8 hrs post dose)	SMH & WH
Estimated Glomerular Filtration Rate (eGFR)	Calculated from Creatinine result	Gold	24 Hours		>90 ml/min/1.73m <sup>2</sup>	SMH & WH
Ethanol	Plasma – Fluoride/EDT A	Grey	24 Hours		80 mg/dl	SMH & WH
Faecal Calprotectin	Faeces	N/A	<mark>3 Days</mark>		<50ug/g	SMH
Faecal Q-FIT	Faeces	Alpha lab kit	48 hours	Interpretative comment with negative and positive result. All positive results (=>10ug Hb/g faeces) have a numerical value		SMH
Fasting Glucose	Plasma – Fluoride/EDT A	Grey	24 Hours	3-6 mmol/L		SMH & WH
Ferritin	Serum	Gold	24 Hours	M	22 - 275 ng/ml	SMH & WH
				F	20 - 204 ng/ml	
Fluid Albumin	Aspirate / Fluid	N/A	24 Hours	N/A		SMH & WH
Fluid Amylase	Aspirate / Fluid	N/A	24 Hours	N/A		SMH & WH
Fluid Cholesterol	Aspirate / Fluid	N/A	24 Hours	N/A		SMH & WH
Fluid Glucose	Aspirate / Fluid	N/A	24 Hours		N/A	SMH & WH

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Fluid LDH	Aspirate / Fluid	N/A	24 Hours	N/A			SMH & WH
Fluid protein	Aspirate / Fluid	N/A	24 Hours			N/A	SMH & WH
Fluid triglyceride	Aspirate / Fluid	N/A	24 Hours			N/A	SMH & WH
Free Androgen Index	Serum	Gold	24 Hours		F	0.5 - 7.3	SMH & WH
				Age	R	eference Range	SMH & WH
Free T3	Serum	Gold	24 Hours	28d	2	2 - 8.5 pmol/L	
TIEE 15	Serum	Gold	24110015	11m	3.	1 - 10.6 pmol/L	
				> 1y	2.0	63 - 5.70 pmol/L	
				28d		15 - 34 pmol/L	SMH & WH
Free T4	Serum	Gold	24 Hours	11m		10 - 26 pmol/L	
				>1y	9.0	1 - 19.05 pmol/L	
				Sex	Age	Range	SMH & WH
				М	Зу	0.1 - 5.5 IU/L	
				М	9у	0.1 - 1.9 IU/L	
				М	>10y	1.0 - 12.0 IU/L	
				F	Зу	0.1 - 13 IU/L	
Follicle Stimulating	Serum	Gold	24 Hours	F	9у	0.1 - 1.6 IU/L	
				F	50y	Follicular phase: 3.0-8.1 Luteal phase: 1.4-5.5	
				F	>50y	Post- menopausal: 26.7-133	
Gamma Glutamyl	0	Qala	04.1.1	F	9 - 36	U/L	SMH & WH
Transferase (GGT)	Serum	Gold	24 Hours	M 12 - 64 U/L			
Gentamicin	Serum	Gold		Refe	r to micı	o/Trust guidelines	SMH & WH
Glucose	Plasma – Fluoride/EDT A	Grey	24 Hours	Non pregnant 3.0 - 7.0 mmol/L		SMH & WH	
Haemoglobin A1c (DCCT aligned)	Whole Blood - EDTA	Lavender	72 Hours	Inte ava	erpretativ ilable fo	ve comments are r individual report	SMH & WH

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	TAT	Ref	erence	Site routinely processed on	
HDL Cholesterol (Lipids)	Serum	Gold	24 Hours			N/A	SMH & WH
Iron	Sorum	Cold		F	4.4 - 2	27.9 mmol/L	SMH & WH
IION	Serum	Gold		М	5.5 -	25.8 mmol/L	
Lactate	Plasma - Fluoride Oxalate	Grey	24 Hours	0.5-2.2 mmol/L			SMH & WH
LDH	Serum	Gold	24 Hours		125	5 – 243 U/L	SMH & WH
LDL Cholesterol	Serum	Gold	24 Hours	N/A(m	mol/L)		SMH & WH
Lithium	Serum	Gold	24 Hours	0.3 - 0.8 mmol/L (12 hrs post dose)			SMH & WH
		Gold		Sex	Age	Reference Range	SMH & WH
				М		(0.6 - 12.1) IU/L	
				F	18m	(0 - 2.3) IU/L	
	Serum			F	9y	(0 - 1.3) IU/L	
Luteinising Hormone (LH)			24 Hours	F	50y	Follicular phase 1.8 - 11.8) U/L	
				F	50y	Luteal phase 0.6 - 14.0) IU/L	
				F	>50y	Post-menopausal 5.2 - 62.0) IU/L	
Macroprolactin	Serum	Gold	72 Hours		Reco	overy > 40%	SMH & WH
Magnesium	Serum	Gold	24 Hours		0.70	-1.0 mmol/L	SMH & WH
NT – Pro BNP	Serum	Gold	24hrs	Int ava	erpretat ailable fo	ive comments are or individual report	SMH & WH
				Sex	Age	Reference Range	SMH & WH
Oestradiol	Serum	Gold	24 Hours	F	<50y	Follicular phase 77 - 922 pmol/L	
				F	<50y	Luteal phase 77 - 1145 pmol/L	
				F	>50y	Post-menopausal	

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						< 103 pmol/L		
Osmolality	Urine - Random / Serum	Gold	24 Hours	Serum: 275-295 mOsm/KgH2O Urine: N/A			SMH & WH	
Paracetamol	Serum	Gold	24 Hours	C	Critical: >2 >50 n	SMH & WH		
Parathyroid Hormone (PTH)	Plasma – EDTA	Lavender	24 Hours	Adults 3 – 12 pmol/L (> 18 years) Paediatrics 1.6-7.2 pmol/L			SMH & WH	
Phenytoin	Serum	Gold	24 Hours		10	-20 mg/L	SMH & WH	
Phosphate - inorganic	Serum	Gold	24 Hours	Age 28d 12m	Refere	ence range 2.6 mmol/L	SMH & WH	
				15y >15y	0.9 - 1	.8 mmol/L .5 mmol/L	-	
Potassium	Serum	Gold	24 Hours	3.5-5.1 mmol/L		SMH & WH		
Progesterene	Sorum	Cold	24 Hours	Sex	Age	Reference Range >20 nmol/L:	SMH & WH	
Filgesterone	Serum	Gold		M	×30y N/A	ovulation likely 0.86 - 2.9 nmol/L		
				Sex	Referer	ce Range	SMH & WH	
Prolactin	Serum	Gold	24 Hours	M	73 - 407	<sup>7</sup> mIU/L	-	
				F	109 - 55	Poforonco Rongo	SMH & WH	
				M	-ye <50v	0.0 - 2.0 ng/ml		
Prostate Specific Antigen				M	50-60y	0.0 - 3.0 ng/ml		
(PSA)	Serum	Gold	24 Hours	М	61-69y	0.0 - 4.0 ng/ml		
				М	70-79y	0.0 - 6.0 ng/ml		
				М	>79	0.0 - 20.0 ng/ml		
Salicylate	Serum	Gold	24 Hours	То>	kic if Grea	ter than 300 mg/L	SMH & WH	
Sex Hormone Binding Globulin (SHBG)	Serum	Gold	24 Hours	Sex M F	Referen 13.5 - 7 19.8 - 1	ce Range 1.4 nmol/L 55.2 nmol/L	SMH	
Sodium	Serum	Gold	24 Hours	136 –	145 mmc	I/L	SMH & WH	

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Refe	erence	Site routinely processed on	
Sweat Chloride*	Westcor sweatcheck			Age	I	WH	
	chloride analyser	N/A	24 Hours	<6m	<6m Normal: <30		
					Inter		
				>6m	Norm	nal: <40	
					Inter	mediate: 40-60	
				All	Posit	ive: >60 mmol/L	
				ages	Asso comr with	ciated interpretative ments are aligned above reporting	
	Swoot	N/A		<	50 mmo assoc	ol/L- unlikely to be iated with CF.	WH
Sweat Conductivity	iontophoresis			> 90	) mmol	/L - diagnosis of CF	
			24 Hours	CF sh on con Confirn sweat all pa	ould no ductivit nation s chloride itients v		
Teicoplanin	Serum	Gold	24hrs	Refer to micro/Trust guidelines			SMH
				Sex	Age	Reference Range	SMH & WH
				М	9y	0.1 - 1.0 nmol/L	
				М	11y	0.1 - 9.5 nmol/L	
				М	13y	0.3 - 22.7 nmol/L	
				M	14y	0.7 - 26.2 nmol/L	
				M	18y	0.6 - 31.3 nmol/L	
Testosterone	Serum	Gold	24 Hours	M	49y	8.3 - 30.2 nmol/L	
					>00y	1.1 - 24.0 IIIIUI/L	
					109	0.04 - 1.12  nmol/L	
					1∠y 13v	0.2 - 0.0 IIII0//L	
					15y	0.5 = 1.4  mmol/L	
					18v	0.6 - 3.4 nmol/L	
				F	50y	0.5 - 1.9 nmol/L	

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				F	>50y	0.4 - 1.2 nmol/L	
Theophylline	Serum	Gold	24 Hours			8 -20 mg/L	SMH & WH
<b>T</b> I 100 I 0				Age		Reference Range	SMH & WH
I hyroid Stimulating Hormone (TSH)	Serum	Gold	24 Hours	28d	0.35	- 10.0 mIU/L	
				>1m	0.35	- 4.94 mIU/L	
Total Cholesterol	Serum	Gold	24 Hours		N/	A (mmol/L)	SMH & WH
Total Globulins	Serum	Gold	24 Hours		2	20-39 g/L	SMH & WH
Total Protein	Serum	Gold	24 Hours	64-83 g/L			SMH & WH
				Sex	R	eference Range	SMH & WH
Transferrin	Serum	Gold	24 Hours	М	1.6 - 3	]	
				F	1.7 - 3	.6 g/L	
Transferrin Saturation	Serum	Gold	24 Hours	М	20 - 50	)%	SMH & WH
				F	15 - 50	)%	
Triglycerides	Serum	Gold	24 Hours		Fasting < 1.7 mmol/L		SMH & WH
				Sex Reference Range		SMH & WH	
Troponin I (high sensitive)	Serum	Gold	24 Hours	F	Le	ss than 15.6 ng/L	
				Μ	Le	ss than 34.2 ng/L	
				Sex	Age	Reference Range	SMH & WH
Urea	Serum	Gold	24 Hours		16y	2.5 - 6.7 mmol/L	
				F	>16y	2.5 - 6.7 mmol/L	
				M	>16y	3.2 - 7.4 mmol/L	
	•			Sex	F	Reference Range	
Uric Acia	Serum	Gold	24 Hours		0.	15 - 0.35 mmol/L	-
	-	<b>a</b>		M 0.21 - 0.42 mmol/L			
Valproate	Serum	Gold	24 hours		50	D-100mg/L	SMH
Vancomycin	Serum	Gold	24 hours	Ref	er to mi	cro/Trust guidelines	SMH & WH
Vitamin B12	Serum	Gold	24 Hours		187	7- 883 pg/ml	SMH & WH
Vitamin D	Serum	Gold	24 Hours	Great	er than s 25-50 nr	50 nmol/L – Vitamin D ufficiency nol/L – Vitamin D	SMH & WH

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Ref	erence R	ange/Instruction	Site routinely processed on
				Less t	insu han 25 –	ıfficiency Vitamin D deficiency	
Xanthochromia	CSF protected from light	Plain universal	24 Hours	In av	terpretativ ailable for	SMH	
			24 hours	Sex	Age	Reference range (mmol/24hrs)	SMH WH
				F	40y	(90 - 130)	
				F	50y	(84 - 124)	
				F	60y	(77 - 117)	-
				F	>60y	(64 - 104)	-
24 hr Urinary Creatinine	Urine - 24			М	40y	(100 - 140)	
Excretion	Hours	Plain		М	50y	(94 - 134)	-
				Μ	60y	(87 - 127)	
				М	>60y	(74 - 114)	-
				U	40y	(90 - 140)	-
				U	50y	(84 - 127)	-
				U	60y	(74 - 117)	-
				U	>60y	(64 - 114)	
24 hr Urinary Protein Excretion	24-hour Urine	Plain	24 Hours		0.0 - 0	.15 g/24 hour	SMH & WH
24-hour Urine Calcium	24-hour Urine	Plain	48 hours		2.5 -7.5	mmol/24hrs	SMH & WH
24-hour Urine Phosphate	24-hour Urine	Plain	24 Hours		12.9 - 42	2 mmol/24hrs	SMH & WH
Urine Amylase	Urine - Random	3 mL urine tube	24 Hours		170-	2000 U/L	SMH & WH
Urine Calcium	Urine - Random	3.2 mL urine tube	48 Hours			N/A	SMH & WH
Urine Chloride	Urine - Random	3.2 mL urine tube	24 Hours			SMH & WH	
Urine Creatinine	Urine - Random	3.2 mL urine tube	24 Hours			N/A	SMH & WH
Urine Magnesium	Urine - Random	3.2 mL urine tube	24 Hours			N/A	SMH & WH

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Biochemistry Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Ref	erence Range/Instruction	Site routinely processed on
Urine Osmolality	Urine - Random	3.2 mL urine tube	24 Hours		(mOsm/kgH20)	SMH & WH
Urine Phosphate	Urine - Random	3.2 mL urine tube	24 Hours		N/A	SMH & WH
Urine Potassium	Urine - Random	3.2 mL urine tube	24 Hours		N/A	SMH & WH
Urine Protein / Creatinine ratio	Urine - Random	3.2 mL urine tube	24 Hours		0 – 30 mg/mmol	SMH & WH
Urine Sodium	Urine - Random	3.2 mL urine tube	24 Hours		N/A	SMH & WH
Urine Urate	Urine - Random	3.2 mL urine tube	24 Hours		N/A	SMH & WH
Urine Urea	Urine - Random	3.2 mL urine tube	24 Hours		N/A	SMH & WH
Urino Albumin / Croctining	Urino			Sex Reference range		SMH & WH
ratio	Urine - Random	3.∠ m∟ urine tube	24 Hours	F	0.0 - 3.5 mg/mmol	
				М	0.0 - 2.5 mg/mmol	

All reference range sources can be supplied by the laboratory on request.

### 7.2 Haematology and Transfusion in-house tests

Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	ТАТ	Reference Range/Instruction		Site routinely processed on	
					Age	Sex	Reference range (g/L)	
Ma				1d		140-220	-	
	Mauve			3d		150-210		
		TA Red or	24 Hours	24 Hours	1m		115-165	SMH & WH
Haemoglobin	EDTA				2m		94-130	
	(Paed)			1y		111-141		
					6y		110-140	
					12y		115-145	
					>12y	М	130-180	_

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Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	ТАТ	Refe	rence	Range/Instruction	Site routinely processed on
					>12y	F	115-165	
					Age	Sex	Reference range (10*9/L)	
					1d		10.0-25.0	
					3d		7.0-23.0	
		Mauve			1m		5.0-19.0	
WBC	EDTA	Red or	24 Hours	24 Hours	2m		5.0-15.0	SMH & WH
		Mauve			6m		6.0-18.0	_
		(Paed)			1y		6.0-16.0	_
					6y		5.0-15.0	_
					12y		5.0-13.0	_
					>12y		3.7-11.0	
					Age	Sex	Reference range (10*9/L)	
					1d		4.0-14.0	-
					3d		3.0-5.0	
		Mauve			1m		3.0-9.0	
Absolute Neutrophils	EDTA	Red or	24 Hours	24 Hours	2m		1.0-5.0	SMH & WH
		Mauve			6m		1.0-6.0	
		(Paed)			1y		1.0-7.0	-
					6у		1.5-8.0	
					12y		2.0-8.0	
					>12y		1.7-7.5	
					Age	Sex	Reference range (10*9/L)	SMH & WH
					1d		3.0-8.0	_
					3d		2.0-8.0	_
		Mauve			1m		3.0-16.0	_
Absolute Lymphocytes	EDTA	Red or	24 Hours	24 Hours	2m		4.0-10.0	_
, , , , , , , , , , , , , , , , , , , ,		Mauve			6m		4.0-12.0	_
		(Paed)			1y		3.5-11.0	_
					6у		1.5-9.0	
					12y		1.0-5.0	
					>12y		1.0-4.0	
		Mauve		0.4 L	Age	Sex	Reference range (10*9/L)	
Absolute Monocytes	EDTA	Red or Mauve	24 Hours	24 Hours	1d		0.5-2.0	

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Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	ТАТ	Refe	Site routinely processed on		
		(Paed))			3d		0.5-1.0	
					1m		0.3-1.0	
					2m		0.4-1.2	
					6m		0.2-1.2	
					1y		0.2-1.0	
					12y		0.2-1.0	
					>12y		0.2-1.0	
		Mauve Red or	24 Hours	24 Hours	Age	Sex	Reference range (10*9/L)	_
					1d		0.10-1.00	
Absolute Eosinophils	EDTA				3d		0.10-1.00	SMH & WH
		Mauve			1m		0.20-1.00	
		(Paed)			12y		0.10-1.00	
					>12y		0.04-0.50	
Absolute Basophils	EDTA	Mauve Red or Mauve (Paed)	24 Hours	24 Hours	0.00-0.10 (10*9/L)			SMH & WH
	EDTA	Mauve Red or Mauve (Paed)	24 Hours	24 Hours	Age	Sex	Reference range (10*12/L)	- - - - - SMH & WH
					1d		5.0-7.0	
					3d		4.0-6.6	
					1m		3.0-5.4	
RBC					2m		3.1-4.3	
					6m		4.1-5.3	
					1y		3.9-5.1	
					12y		4.0-5.4	
					>12y	М	4.5-6.0	
					>12y	F	4.0-5.5	
Haematocrit	EDTA	Mauve Red or Mauve (Paed)	24 Hours	24 Hours	Age	Sex	Reference range (L/L)	
					1d		0.450-0.750	
					3d		0.450-0.660	
					1m		0.330-0.530	SMH & WH
					2m		0.280-0.420	
					6m		0.300-0.400	
					1y		0.300-0.380	

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					6у		0.340-0.400	
					12y		0.370-0.450	_
					>12y	Μ	0.390-0.500	
					>12y	F	0.360-0.440	
		Mauve Red or	24 Hours	24 Hours	Age	Sex	Reference range (fl)	_
					1d		100-120	
					3d		92-118	
					1m		92-116	SMH & WH
Mean Cell Volume	EDTA				2m		87-103	
(MCV)		Mauve			6m		68-84	
		(Paed)			1y		72-84	
					6y		75-87	
					12y		77-95	
					>12y		80-100	
Mean Cell Haemoglobin (MCH)	EDTA	Mauve Red or Mauve (Paed)	24 Hours	24 Hours	Age	Sex	Reference range (pg)	SMH & WH
					1d		31.0-37.0	
					3d		31.0-37.0	
					1m		30.0-36.0	
					2m		27.0-33.0	
					6m		24.0-30.0	
					1y		25.0-29.0	
					6у		24.0-30.0	
					12y		24.0-30.0	
					>12y		27.0-32.0	
Mean Cell Haemoglobin Concentration (MCHC)	EDTA	Mauve Red or Mauve (Paed)	24 Hours	24 Hours	Age	Sex	Reference range (g/L)	- - - - - SMH & WH
					1d		300-350	
					3d		290-350	
					1m		290-350	
					2m		285-350	
					6m		300-350	
					1y		320-350	
					12y		320-350	
					>12y		320-360	
Nucleated RBC	EDTA	Mauve	24 Hours	24 Hours	0.00(10*9/L)			
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Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	TAT	Reference Range/Instruction		Site routinely processed on	
		Red or Mauve (Paed)						SMH & WH
					Age	Refere	nce Range	
					1d	120	- 400%	-
		Mauve			3d	50	- 350%	-
Reticulocytes	FDTA	Red or	24 Hours	24 Hours	1m	20	- 60%	
Reliculocytes	LUIX	Mauve	24110013	24110013	2m	30	- 50%	
		(Paed)			6m	40	- 100%	-
					12y	30	- 100%	-
					>12y	10	- 100%	
					Age	Refere	nce Range	r.
	EDTA	Mauve	24 Hours	24 Hours		Male	Female	- SMH & WH
		Red or Mauve (Paed)			<17	0 - ≤10	0 - ≤ 12	
ESR					17-50	0 - ≤10	0 - ≤ 12	
					51-60	0 - ≤ 12	0 - ≤ 19	r
					61-70	0 - ≤14	0 - ≤ 20	
					>70	0 - ≤ 30	0 - ≤ 35	
Morphology (blood film)	EDTA	Mauve	24 hours	Urgent – one hour Routine – 24 hours		N/A		SMH WH only if urgent
Malarial parasites	EDTA	Mauve	4 Hours	8 Hours		N/A		SMH
Bone marrow aspirate	EDTA	Mauve	2 hours	7 days		N/A		ѕмн
Haemoglobinopathy						A2 1.5-3.	5%	SMH
screen	EDTA	Mauve	1 Week	72 Hours		and F <3	3%	
Sickle screen	EDTA	Mauve	48 Hours	24 Hours		N/A		SMH
INR	Citrate	Blue	24 Hours	24 Hours	Specific to patient reason for Warfarin treatment		SMH & WH	
Prothrombin time	Citrate	Blue	24 Hours	24 Hours		8.5-13 Sec	onds	SMH & WH
APTT	Citrate	Blue	4 Hours	24 Hours		20-34 Sec	onds	SMH & WH
Thrombin time	Citrate	Blue	4 Hours	24 Hours		14-20 Sec	onds	SMH & WH

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Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	ТАТ	Reference Range/Instruction		Site routinely processed on
Fibrinogen	Citrate	Blue	4 Hours	4 Hours		2-4 g/L	SMH & WH
D-dimer	Citrate	Blue	4 Hours	4 Hours		0-500 μg/L	SMH & WH
Low Molecular Weight Heparin	Citrate	Blue	4 Hours	24 Hours		0.0-1.5 IU/ml	SMH
Protein C	Citrate	Blue	4 Hours	2 Weeks		70-150%	SMH
Protein S	Citrate	Blue	4 Hours	2 Weeks	Sex M F	Reference Range 75 - 140 % 55 - 125 %	SMH
Antithrombin III	Citrate	Blue	4 Hours	2 Weeks		85-115%	ѕмн
Lupus anticoagulant	Citrate	Blue	4 Hours	2 Weeks	Interp wheth Negativ	retive comments indicate ner results are Positive or ve for Lupus Anticoagulant	SMH
Apixaban	Citrate	Blue	4 Hours	24 Hours	Peak levels should be checked 4 hours after dosing and trough levels prior to the next dose. Results should be interpreted in the right clinical context. Please liaise with haematology clinical team if there are further queries.		SMH
Rivaroxaban	Citrate	Blue	4 Hours	24 Hours	Peak levels should be checked 4 hours after dosing and trough levels prior to the next dose. Results should be interpreted in the right clinical context. Please liaise with haematology clinical team if there are further queries.		SMH
Dabigatran	Citrate	Blue	4 Hours	24 Hours	Peak levels should be checked 4 hours after dosing and trough levels prior to the next dose. Results should be interpreted in the right clinical context. Please liaise with haematology clinical team if there are further queries.		SMH
Factor assays	Citrate	Blue	4 Hours	2 Weeks	Factor FII FV FVII VIII	Reference Range           0.5         -         2.0 IU/mI           0.5         -         2.0 IU/mI	SMH 

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Haematology and Transfusion Tests:	Sample Types:	BD Vacutainer Colour:	Sample stability	ТАТ	Reference Range/Instruction		Site routinely processed on
					FIX	0.5 - 2.0 IU/ml	
					FX	0.5 - 2.0 IU/ml	1
					FXI	0.5 - 2.0 IU/ml	1
					FXII	0.5 - 2.0 IU/ml	-
					XIII	0.5 - 2.0 IU/ml	-
					F2	50 - 150%	-
					F5	50 - 150%	1
					F7	0.5 - 1.5 IU/ml	-
					F8	50 - 150%	1
					F9	50 - 150%	-
					F10	50 - 150%	
					F11	50 - 150%	_
					F12	50 - 150%	
					F13	50 - 150%	
Group and save	EDTA	Pink	1 Week	Urgent-1hr defined by a requirement for blood or blood products Routine- 14hrs Complex investigation – 72 hrs		N/A	SMH/WH
Kleihauer	EDTA	Pink		72 hrs		N/A	SMH
DAT	EDTA	Pink	1 Week	Urgent – 2hrs Defined by clinical indications Routine – 14hrs			SMH/WH

Further testing in Transfusion TATs e.g. Phenotype are dependent on the requirements of the patient. All required testing provided in house will be completed within 12 hours.

# 7.3 Immunology in-house tests:

Immunology Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Reference Range/Instruction	Site routinely processed on

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Immunology Tests:	Sample Types:	BD Vacutainer Colour:	ТАТ	Reference Range/Instruction	Site routinely processed on
Complement 3	Serum	Yellow	1-2 Days	65-190 mg/dl	SMH
Complement 4	Serum	Yellow	1-2 Days	15-50 mg/dl	SMH
Rheumatoid Screen	Serum	Yellow	1-2 Days	<20 IU/mI	SMH
IgG	Serum	Yellow	1-2 Days	6-13 g/L	SMH
IgA	Serum	Yellow	1-2 Days	0.8-3.0 g/L	SMH
IgM	Serum	Yellow	1-2 Days	0.4-2.5 g/L	SMH
Total IgE	Serum	Yellow	1-2 Days	<120 Ku/L	SMH
B2 Macroglobulin	Serum	Yellow	2-5 Days	<3 mg/L	SMH
Alpha 1 Anti-trypsin	Serum	Yellow	1-2 Days	107-209mg/dl	SMH
Urine Electrophoresis	Urine	N/A	3-5 Days	N/A	SMH
Immunofixation	Serum	Yellow	3-5 Days	N/A	SMH
Serum electrophoresis	Serum	Yellow	2-3 Days	N/A	SMH

All reference range sources can be supplied by the laboratory on request.

# 7.4 Referral tests

Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
11 Deoxy Cortisol	Serum	Gold	Royal London	2 Weeks
		Gold /		2
17-OH Progesterone	Serum / Plasma	Green	Royal London	Weeks
24 hr urinary 5HIAA	Urine - 24 Hours	N/A	JRH	2 Weeks
Urinary 5HIAA	Spot Random preferred (Protected from light)	N/A	JRH	2 Weeks

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
24 hr Urinary free	Urine – 24 hours	N/A	JRH	2 weeks
24 hr Urinary Metanephrines NMET:Normetadrenaline	Urine-24 Hrs plain Acetic Acid spot preferred	N/A	JRH	2 weeks
MADR: Metadrenaline MYTR: 3 Methoxytyramine	Spot/randompreferred Urine 24 hrs Plain		JRH	2 weeks
Acylcarnitine	Guthrie Card	N/A	GOS	2 Weeks
Aldosterone	Serum / Plasma	Gold / Green	СХН	2Weeks
Alkphos Iso Enzymes	Serum (+ggt)	Gold	СХН	2 weeks
Aluminium	Serum - Trace Free	Dark Blue	КСН	2 Weeks
Amino Acids	Plasma	Orange / Green	GOS	2 - 3 Weeks
Androstendione	Serum / Plasma	Gold / Green	Royal London	2 Weeks
Apolipoprotein B and A1	Serum	Gold	Newcastle lab	2 weeks
B2 Transferrin (Tau Protein)	CSF / Nasal Fluid	N/A	Inst. Neuro	2 - 3 Weeks
Caeruloplasmin	Serum	Gold	СХН	2 weeks
Calcitonin	Plasma - Li Hep	Orange / Green	СХН	3 Weeks
Centromere Antibodies	Serum	Yellow	CHU	2-5 Days
DNA antibodies	Serum	Yellow	CHU	2-5 Days
Epidermal antibodies	Serum	Yellow	CHU	7-10 Days
ENA antibodies	Serum	Yellow	CHU	2-5 Days

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
Gastric Parietal Cell antibodies	Serum	Yellow	CHU	2-5 Days
Glomerular Basement Membrane antibodies	Serum	Yellow	CHU	2-5 Days
Chromium	Plasma	Dark Blue	СХН	2 Weeks
Citrate	Urine - 24 hours	N/A	UCL	2 Weeks
Clonazepam	Serum	Gold	CEU	1 Week
Clobazam	Serum / Plasma	Gold / Green	CEU	1 Week
Cobalt	Plasma	Dark Blue	СХН	2 Weeks
Copper	Serum	Dark Blue	СХН	2 Weeks
C-Peptide	Serum	Gold	Oxford	2 Weeks
CSF ACE	CSF	N/A	Queens Sq.	1 Week
Cyclosporin	Whole Blood - EDTA	Lavender	JRH	1 Week
Cystine	Urine - 24 hours	N/A	UCL	2 Weeks
DHEA	Serum	Gold	Royal London	2 Weeks
Cystatin C	Serum / Plasma	Yellow / Green	JRH	1 Week
Drugs of Abuse Screen (Tox Screen)	Random Urine	N/A	КСН	2 Weeks
DPD	Plasma -EDTA	Lavender	STH	1- 2Weeks
Ethylene Glycol	Serum	Gold	B'ham	1 day
Erythropoietin	Serum	Gold	КСН	2 Weeks
Faecal Elastase	Faeces	N/A	GOS	2 Weeks
Free Fatty Acids	Plasma	Orange / Green	GOS	2 - 3 Weeks
Fructosamine	Serum	Red	B'Ham	2 - 3 Weeks

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
G-1-Phosphate Uridyltransferase (G-1-GALYPUT)	Whole Blood – Li Hep	Orange / Green	GOS	2 - 3 Weeks
Gabapentin	Serum	Gold	Inst. Neuro	1 Week
Glucose 6 Phosphate Dehydrogenase G6PD	Whole Blood - EDTA	Lavender	B'Ham	2 Weeks
Urine glycosamine glycans (GAG)	Random Urine	N/A	GOS	2 - 3 Weeks
Gastrin	Contact Laboratory	N/A	CXH-H'smith	3 - 4 Weeks
Growth Hormone	Serum	Gold	JRH	2 Weeks
Gut Hormones	Plasma – EDTA Freeze sample STAT	Lavender	CXH-H'smith	3 - 4 Weeks
Haptoglobin	Serum Plasma - Li Hep /	Gold	SUH	2 Weeks 3 Weeks
IGF-1 (Insulin-like growth factor 1)	Serum	Gold	JRH	2 Weeks
IGF-2 (Insulin-like growth factor II)	Serum	Gold	GH	2 Weeks
Immuno Reactive Trypsin (IRT)	Guthrie Card	N/A	Addenbrooks	3 Weeks
Insulin	Serum / Li Hep	Gold	JRH	2 Weeks
Jo-1 antibodies	Serum	Yellow	CHU	2-5 Days
Liver Kidney Microsomal (LKM) antibodies	Serum	Yellow	CHU	2-5 Days
Mitochondrial antibodies	Serum	Yellow	CHU	28 Days
Smooth muscle antibodies	Serum	Yellow	CHU	2-3 Days

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
Lamotrigine	Serum	Gold	CEU	2 Weeks
Laxative Screen	Random Urine	N/A	St Thomas'	2 Weeks
Lead	Whole Blood EDTA	Dark Blue	CHX:TM	2 Weeks
Lipoprotein (a)	Serum	Gold	Newcastle lab	2 weeks
MCAD Screen	Guthrie Card & Random Urine	N/A	Sheffield	2 Weeks
Methotrexate	Plasma - Li Hep	Orange / Green	JRH	2 Weeks
Oxcarbamazepine	Serum	Gold	CEU	1 Week
P1NP	Serum	Gold	Liverpool	2 Weeks
P3NP	Serum	Gold	Manchester	2 Weeks
Placental AlkPhos	Serum	Gold	CHX:ONC	1 Week
Porphyria – Protect from light	Whole Blood – EDTA & random Urine & Faeces	Lavender	UHW	2 – 3 Weeks
Pseudocholinesterase (Apnoea Screen)	Serum	Gold	UHW	4 – 6 Weeks
Renin	Plasma – Li Hep	Orange / Green	СХН	2 Weeks
Selenium	Serum – Trace Free	Dark Blue	CHX:TM	2 – 3 Weeks
Serum Amyloid Protein	Serum	Gold	QS	4 – 6 weeks
Sflt:PLGF ratio	Serum	Gold	JRH	24hr
Steroid Profile	Urine - 24 hours /Random(Plain)	N/A	КСН	3 Weeks
Stone Analysis	Stone	N/A	UCL	2 Weeks
Sulphonylurea Screen	Random Urine	N/A	Birmingham	3 Weeks
Tacrolimus	Whole Blood - EDTA	Lavender	JRH / Patient's own	1 Week

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
			transplant centre	
Thiosulphate	Random Urine	N/A	Sheffield Childrens	3 Weeks
Thyroglobulin	Serum - SST	Gold	JRH	2 Weeks
Toxicology Screen	Random Urine	N/A	ViaPath/Kings	3 - 4 Weeks
ТРМТ	Whole Blood - EDTA	Lavender	STH	3 Weeks
Transferrin Isoforms / Electrophoresis	Serum	Gold	Inst. Neuro	2 Weeks
Urinary Copper excretion	Urine - 24 hours (Nitric acid washed)	N/A	CHX:TM	2 Weeks
Urine Amino Acids Glycine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Serine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Threonine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Proline	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Leucine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Isoleucine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Valine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Alanine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Glutamine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Arginine: creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Ornithine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Lysine: creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Cystine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids	Random Urine	N/A	GOS	3 - 4

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
Methionine:creatinine				Weeks
Urine Amino Acids Taurine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Phenylalanine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Tyrosine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Tryptophan:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Histidine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Aspartate:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Glutamate:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Amino Acids Homecystine:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Mercury	Random Urine	N/A	CHX:TM	3 Weeks
Urine Organic Acids Oratate:creat	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Organic Acids Methyl malonic acid:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Urine Organic Acids Methyl citrate:creatinine	Random Urine	N/A	GOS	3 - 4 Weeks
Very Long Chain Fatty Acids Docosanoate C22	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Very Long Chain Fatty Acids Tetracosanoate C24	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Very Long Chain Fatty Acids Hexacosanoate C26	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
Very Long Chain Fatty Acids C24:C22	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Very Long Chain Fatty Acids C26:C22	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Very Long Chain Fatty Acids Phytanate	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Very Long Chain Fatty Acids Pristanate	Plasma - Li Hep / EDTA	Orange / Green / Lavender	GOS	2 - 3 Weeks
Vitamin A	n A Serum / Plasma F		RGH	2 - 4 Weeks
Vitamin E	Serum / Plasma	Gold / Green Protect from light	RGH	2 - 4 Weeks
White Cell Enzymes Palmitoyl protein thioesterase	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes Galactocerebrosidase	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes Leucocyte b- galactosidase	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes arylsuphatase A	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes Hexosaminidase A	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes a-fucosidase	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White Cell Enzymes a-neuraminidase	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
White cell enzymes	Whole Blood – Li Hep	Orange / Green	GOS (enzyme Lab)	6 - 8 Weeks
Zinc	Serum - Trace Free	Dark Blue	JRH	2 Weeks

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Referral Tests Test Name	Sample Type	BD Vacutainer Colour	Referral Location	ТАТ
Factor V Leiden	EDTA	Mauve	OUH	Within 14 days
Von Willebrand	Citrate	Blue	OUH	Within 14 days
Factor assays	Citrate	Blue	OUH	Within 14 days
HLA typing	EDTA Pink/mauve		NHSBT	Within 7 days
Antibody identification & quantitation	EDTA	EDTA Pink		Within 7 days
NAIT screening	EDTA Pink/Mai Red		NHSBT	Within 7 days
HIT screening	SST & EDTA	Gold & mauve/pink	NHSBT	Within 7 days
Haemochromatosis	EDTA	Mauve	OUH	2 weeks
JAK 2	EDTA	Mauve	OUH	Up to 4 weeks
Acetylcholine receptor antibodies	EDTA	Mauve	CHU	21 Days
Adrenal antibodies	EDTA	Mauve	CHU	21 Days
Anti-IgA antibodies	EDTA	Mauve	CHU	21 Days

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# 7.5 Analytical stability

Samples should be sent to the laboratory as soon as possible as prolonged storage can affect cell morphology and the composition of the sample which may result in incorrect results.

For optimum results, routine coagulation samples should reach the laboratory within four hours of venepuncture. Samples from the community should be stored in an appropriate fridge until transport.

Specialist coagulation testing - please phone the laboratory for advice as different tests have different requirements.

Parasite studies should also be carried out as soon as possible to aid detection. The optimum time for receipt would be within four hours of venepuncture. Please phone the laboratory if you have any queries.

Currently specimens are stored for approximately three days before disposal unless specifically requested. Please discuss with the lab the validity of adding tests to existing samples.

# 7.6 Uncertainty of Measurement

All measured parameters are subject to a degree of measurement uncertainty. This may be due to range of factors, which include:

- Analytical measurement imprecision
- Pre-analytical factors
- Biological variation within individuals

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### 7.7 Laboratory Critical Ranges

Results outside of the following ranges will be telephoned by the laboratory to the requesting clinician or team by the laboratory. These are **not** reference (normal) ranges

#### Table 12: Critical ranges -

#### Biochemistry Results for Urgent Communication: Biochemistry Results for Urgent Communication:

Biochemistry Test	units	Telephone Results	
		Less than	Greater than
Sodium	mmol/L	120 (130 if <16 yrs)	160
Potassium	mmol/L	2.5	6.5
Adjusted Calcium	mmol/L	1.80	3.5
Glucose	mmol/L	2.5	25 (≥ 11.1 if < 16 yrs)
Urea	mmol/L		30 (>10 if <16 yrs) *
Creatinine	mmol/L		354 (>200 if < 16yrs) *
Magnesium	umol/L	0.4	
Phosphate	mmol/L	0.3	
AST	mmol/L		15 X ULN
ALT	U/L		15 X ULN
Total CK	U/L		≥ 5000
Digoxin	ug/L		2.5 (6hrs post dose)
Theophylline	mg/L		25
Phenytoin	mg/L		25
Lithium	mg/L		1.5
Amylase/Lipase	U/L		>5 X ULN
CRP	mg/L		300
Troponin I	mg/L		Only if it is a GP request
AKI alerts			AKI-3
			AKI-2
			AKI-1***
Ammonia	µmol/L		100
Bicarbonate	mmol/L	10	
Cortisol 9 am	mmol/L	50	
Cortisol (SST 30 min)	mmol/L	250	-
Ethanol	mg/l		4000
Paracetamol	mmol/L		All detectable levels
Neonatal Bilirubin	µmol/L		
(conjugated)			25
Triglyceride	mmol/L		>10
HbA1c	mmol/mol		>86 Only for New onset diabetes

\* Exception- rule for the renal patients.

\*\* AKI-1 Please note this needs to be telephoned if Potassium  $\geq$  6 mmol/L. Results should be phoned to both primary and secondary care locations. If it is out-of-hours the GP locations should be communicated the next day or OOH GP services (on weekends)

AKI 2 and 3 to be phoned irrespective of potassium result to both primary and secondary care locations. \*\*\*Please note primary care requests with results triglyceride >10 mmol/L can be telephoned the same day if during working hours and communicate the GP surgery next day if out-of-hours. Communication to OOH GP service requires if it is associated with acute pancreatitis and amylase > 5 x ULN

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# 7.8 Haematology Results for Urgent Communication:

Haematology	Unit	Telephone Results	
Test		Level	Comments
Hb	g/L	<50 <70	Microcytic or macrocytic anaemia Normochromic, normocytic as this might suggest blood loss or bone
		>190	Or haematocrit above 0.55 L/L, only requires urgent referral if there appears to be a compounding medical problem
Neutrophils	x 10 <sup>9</sup> /L	<0.5 >50	Requires urgent but not immediate referral
Lymphocytes	x 10 <sup>9</sup> /L	>50	Requires urgent but not immediate referral
Platelets	x 10 <sup>9</sup> /L	<30 >600 >1000	Requires assessment and referral Requires urgent referral for assessment
Blood film		Presence of blasts or diagnosis suggestive of Chronic Myeloid Leukaemia (CML)or Acute Myeloid Leukaemia (AML)	Discuss with covering haematologist prior to deciding what action to be taken - please check first on WinPath if the patient is already known to department with CML or AML
Malaria parasites		All positive results > 5.0 for patients on Warfarin	Requires urgent assessment
INR		> 1.6 for patients <b>not</b> on Warfarin	
		lf > 8.0	Requires urgent assessment

Due to the diverse range of potential results that may arise within Haematology, any abnormal results where early notification may affect or improve patient care should be telephoned promptly. This is within the scope of the BMS finding the abnormal result. More in depth details regarding reporting and telephoning abnormal results are available in the relevant local SOPs.

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# Immunology Results for Urgent Communication:

Autoimmunity

Laboratory Myeloma Investigation - detection of new monoclonal bands exceeding defined quantitative levels (by densitometry) and/or abnormal free light chain ratios with accompanying features suggestive of a new diagnosis of myeloma e.g. background immunosuppression, impaired renal function

Analyte-serum/plasma	Units	Action limits	Additional comments	How was this derived
IgG paraprotein	g/L	>15	Further testing should be added for serum free light chain	BSCH
IgA or IgM paraprotein	g/L	>10	Further testing should be added for serum free light chain	BSCH
Any monoclonal free light chain found in urine or serum	n/a	n/a	Further testing should also be added for IgE and IgD fixation as well as Serum free light chain	BSCH

# Autoimmunity

Analyte- serum/plasma	Units	Action limits	Additional comments	How was this derived
New Anti GBM Ab patient	IU/mI	*		Consensus with local Clinical teams

\*positive GBM as further action to alert Dr Ross Sadler /Dr Elizabeth Bateman and Authorise promptly.

Immunoloav	Results for	Urgent	Communication:	only	examples	aiven i	n RCPath
anology	1.00041.0101	ergene	oominamoutom	<u> </u>	onampioo	9	

Autoimmunity	Action limits	Additional comments
SCID/ new severe lymphopenia	T cell (absolute numbers)	Any new lymphopenia reviewed in the context of clinical details and actioned as appropriate

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# 8.0 Standard reference ranges

Please refer to ranges on printed or electronic reports that will be up to date. Ranges are specific to the laboratory and technique used for analysis and do not automatically apply to results from other laboratories

When interpreting reference ranges please take account of age and/or gender specific ranges. The above reference ranges state for in-house tests are adopted mainly from the manufacture's package insert whereas clinical guidelines have been used for some specialised tests (eg; sweat test, CSF xanthochromia).

If a particular reference range is no longer relevant to the population served, and is therefore changed, the laboratory will communicate that change via the results report.

#### 9.0 Reporting

#### 9.1 Laboratory reporting

The Blood Sciences Laboratories at Stoke Mandeville and High Wycombe hospitals have the ability to deliver results to locations electronically via ICE.

All results are available throughout the Trust by means of the ICE system on the Hospitals Intranet.

- Results are released for reporting after all the results appropriate to an individual report have been authorised either by registered Biomedical Scientists or an appropriate laboratory clinician.
- Once results have been authorised, they are released and held in queues for electronic release as appropriate.
- Electronic transmission of fully authorised results happens in a timely manner with deliveries to ICE and GP Links occurring at five-minute intervals.

**Immunology reporting:** The Immunology Laboratory at Stoke Mandeville has the ability to deliver results to locations either in printed format, electronically via GP messaging systems or the Trust internal results viewing system (Review). Results are released for reporting after all the results appropriate to an individual report have been authorised by registered Biomedical Scientists or a Consultant Clinical Immunologist. Once results have been authorised they are released and held in queues for printing and electronic release as appropriate.

Electronic transmission of fully authorised results happens in a timely manner with deliveries to Review and GP Links occurring at five minute intervals. Print runs are produced at various intervals throughout the day and the reports are sorted and then sent to the appropriate location for delivery with the next day's transport services.

Abnormal results which the Immunology staff consider urgent are automatically phoned to the requesting clinician. Where the result may influence immediate management, results may be phoned to the Wards. If requesting results by telephone, please have the patient's date of birth and NHS/unit number available and indicate when the sample was taken. Approximate test turnaround times, in working days, are given with each test listed below. If a test result is required more rapidly please contact the laboratory to discuss the result availability. The staff will do everything possible to provide the results in a timely manner.

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### 9.2 Telephone results

There is a very high risk associated with the transcription of results when taken over the phone.

Analysis of this risk and a number of clinical near misses resulted in the Trust investing a great deal of money and time implementing what is now the ICE electronic results system.

Given the availability of access and the associated risk, preferred practice is not to give out results over the phone.

Always check on ICE or GP systems for results before phoning.

Should for any reason the results be unavailable results will be given orally but must be repeated back to ensure accuracy, then verified electronically (once working) or against a printed report (available from the laboratory on request) before starting any clinical action.

Email result communication is acceptable through nhs.net accounts.

#### 9.3 Amended results

If a result needs to be amended due to new information or a correction, the requesting clinician or representative will be advised via the updated report available on ICE.

A comment will be added to the report saying that it is an amended report and to disregard the previous report associated with that specimen, identified by the unique laboratory number.

If any further clarification is needed please contact the laboratory immediately.

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# Appendix1: Feedback, Compliments and Complaints

Any feedback or complaints should be directed to the Clinical or Laboratory Managers - please make any reservations you may have about the quality of any aspect of the service known to us as soon as possible; we take your complaints very seriously.

In particular, let us know of any untoward delay in receipt of reports, any discrepancies between results and clinical picture, and any errors in patient or clinician name or location on the report.

Please also let us know about new services you would wish to see developed.

You can also utilise the Trust's complaints system:

- Email your complaint to <a href="https://www.bht.complaints@nhs.net">bht.complaints@nhs.net</a>
- Telephone the complaints team on 01494 734958

The Patient Advice and Liaison Service (PALS) provide support and advice to patients, their families and friends.

Contact PALS on 01296 316042 or send an email to <a href="https://www.bht.pals@nhs.net">bht.pals@nhs.net</a>

The department will also accept any feedback, compliments and complaints via the following e mail address. <u>BHT.Bloodsciences@nhs.net</u>

The department initiates an annual Pathology user survey for all service users of Pathology and welcomes any feedback, compliments and complaints via the survey.

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# **Appendix 2: Laboratory locations**

# Stoke Mandeville laboratory





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# Wycombe laboratory





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# Amersham Hospital – Phlebotomy service only

Use main entrance (entrance C) to locate phlebotomy, which is located near outpatients department.



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### Appendix 3 - Thrombophilia Screening

Avoid testing in the acute situation in A&E. Results of these tests rarely influence management of an individual patient in arterial disease. Test for antiphospholipid antibodies only (lupus anticoagulant and anticardiolipin antibodies).

- 1. Whom to Test
  - a. Personal History and;
    - i. Family history of venous thromboembolism
    - ii. Personal history in young women (potential pregnancy)
    - iii. Proven Recurrent Venous thrombosis
    - iv. Unusual site of venous thrombosis i.e. cerebral
  - b. Family history only:
    - i. Test only if there is a known defect (1 test only)
  - c. Anti-phospholipid antibodies:
- 2. Testing may be appropriate in;
  - a. All patients with spontaneous venous thromboembolism
  - b. Stroke /Peripheral Artery disease <50 years if other common risk factors not prominent
  - c. SLE
  - d. Miscarriages (>/=2 consecutive, >/=3 non-consecutive).
  - e. Any loss of normal foetus in 2<sup>nd</sup>/3<sup>rd</sup> trimester.
  - f. Severe Pre-Eclampsia /severe placental insufficiency

Samples required;

- Full Blood Count (EDTA tube) if not already known to be normal
- Electrolytes and Urea and Liver function tests (gel tube), if not already known to be normal
- Anticardiolipin Antibody (Clotted tube, yellow form, serology test)
- Clotting Screen including APTT, PT and TT one citrate (blue top) tube, correctly filled.
- Prothrombotic Screen four citrate (blue top) tubes, correctly filled.
- Samples for Protein S and Lupus screening MUST be separated within four hours of venepuncture.
- Please provide full clinical information
- Requests will be rejected if clinical information is not provided or is inadequate.

Please phone the laboratory should you have any questions.

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# **Appendix 4- Autoantibody Tests**

Acetylcholine receptor antibodies (CHU) Reported in titres: <2 x 10<sup>-10</sup>M

Negative Equivocal

 $5-50 \times 10^{-10} M$  Positive

2 – 5 x 10<sup>-10</sup>M

50 – 500 x 10<sup>-10</sup>M Strongly positive

A highly sensitive and specific marker for patients with generalised myasthenia gravis (80 - 90% sensitivity). Up to

40% of patients with pure ocular myasthenia may be antibody negative.

Type of sample required: Serum

Turn-around time: 21 days

Adrenal antibodies (CHU) Reported as: Positive or Negative

Present in 60% of patients with isolated autoimmune hypo-adrenalism. This prevalence rises to 90% in patients with

hypo-adrenalism and primary ovarian failure.

Type of sample required: Serum

Turn-around time: 21 days

Anti-IgA antibodies (SHE)

Anti-IgA antibodies occur in IgA deficient patients who have received blood-products containing IgA. Their presence

in high titres indicates increased risk of adverse reactions to blood products containing IgA.

Type of sample required: Serum

Turn-around time: 21 days

C3 Nephritic factor (CHU)

C3 nephritic factor is an IgG autoantibody which stabilises the alternative pathway C3 convertase and leads to continuous C3 breakdown. This is associated with type II Glomerular nephritis and also with partial lipo-dystrophy. This test will only be performed on patients who show a low C3 and normal C4 level. A fresh serum sample is required, reaching the lab within 4 hours of venepuncture. Type of sample required: Serum Turn-around time: 28 days

Cardiolipin & Beta-2 glycoprotein 1 IgG and IgM antibodies (CHU)

Reported in: Units/ml (IgG reference range 0-10)

These antibodies are associated with thrombosis (arterial and venous) in patients with systemic lupus erythematosus, often in conjunction with a lupus anticoagulant. They may also occur in isolation in patients with thrombosis and no evidence of lupus. Antibody levels do not correlate with extent or severity of thrombosis. Moderate rises in anticardiolipin antibodies may occur transiently following infection. Lupus anticoagulant studies are performed by Haematology. Beta-2-Glycoprotein 1 IgG antibodies are also performed as part of this lupus antibody screen. Type of sample required: Serum Turn-around time: 3 days

Centromere antibodies – please request "ANA" (CHU) Reported as: Positive or Negative

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ey are detected on standard HEp-2 ti ne 'CREST' Syndrome (Calcinosis, F ns of Scleroderma. ne of sample required: Serum	ssue substrate used for scro Raynaud's, oEsophageal dy	eening antinuclear antibodi smotility, Sclerodactyly, Te	es. They are a mar langiectasia) and li		

Coeliac antibodies (CHU)

Request Anti-Tissue transglutaminase (TTg) IgA

Reported as: Negative, <20 or as a numerical value in units/ml

Untreated coeliac disease in adults is characterised by the presence of IgA endomysial antibodies (EMA) (sensitivity 70 – 90%, specificity 90 – 100%) or anti-Tissue transglutaminase antibodies. There is a good correlation with disease activity, and relapse or poor compliance with a gluten free diet is often associated with a return to antibody positivity. IgA endomysial antibodies may be 'falsely negative' in patients with coeliac disease and total IgA deficiency. Simultaneous measurement of serum IgA ensures that these cases are not missed. Patients with positive TTg antibodies will be reflexed tested for EMA. Type of sample required: Serum

Turn-around time: 7 days

DNA antibodies (Double stranded DNA) (CHU)

Reference range: IU/mI (0 - 30).

A highly sensitive and specific marker for SLE, with raised levels found in 70 – 90% of patients with SLE. Antibody levels tend to correlate with disease activity. Raised levels may also be seen in a small minority of patients with chronic active hepatitis.

Type of sample required: Serum Turn-around time:7 days

Epidermal antibodies (CHU) Pemphiaus

Reported as: Positive (titres) or Negative

Serum antibodies directed against the cell surface of epidermal keratinocytes are found in 90% of patients with Pemphigus and correlate with disease activity. Direct immunofluorescence staining of skin biopsies reveals intra epidermal IgG & C3 deposition in 90% of patients.

**Bullous Pemphigoid** 

Reported as: Positive or Negative

Serum antibodies directed against the basement membrane are present in 70% of patients. Immunofluorescence staining of skin biopsies reveals basement membrane IgG & C3 deposits in 90% of patients. Antibody levels do not correlate with disease activity. Type of sample required: Serum

Turn-around time: 14 days

ENA antibodies (Extractable Nuclear Antigens: Ro (Ro52/Ro60), La, Sm, RNP (U1-snRNP, RNP70), Scl – 70, Jo – 1 (CHU)

Reported as: Positive or Negative

Present in patients with SLE, Lupus overlap syndromes (Mixed Connective Tissue Disease), Sjogren's syndrome and Scleroderma. The sensitivity and specificity of individual antibodies for these diseases is variable e.g. Sm and Scl70 antibodies are specific for SLE and Scleroderma respectively, whilst Ro and La antibodies occur in lupus and Sjogren's syndrome. The isolated presence of anti-RNP antibodies is suggestive of MCTD. The presence of a speckled ANA (> 1/80) is often a clue but not specific to the presence of anti-ENA's. Conversely a negative ANA on HEP-2 cells precludes the presence of anti-ENA antibodies.

Type of sample required: Serum

Turn-around time: 7 days

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Aspe Refe Usec Conc Type Turn	ergillus IgG levels (CHU) erence range – 0-79mgA/L d to assist in investigations for allerg ducted using Phadia 250 Immunoca e of sample required: Serum -around time: 14 days	gic broncho-pulmonary asp ap method.	ergillosis (ABPA) and hype	rsensitivity pneumonitis.
Anti- Repo Antik sens Type	GAD antibodies (CHU) orted as: Positive, sometimes with a oodies to glutamic acid decarboxyla itivity), a rare neurological disease of sample required: Serum Turn-around time: 14 days	a numeric value, or Negativ se in high titre are a reliabl characterised by muscle rig	e e marker of the stiff-person gidity and spasms.	syndrome (60%
Gang Anti- GM1 Type Turn	glioside antibodies (CHU) ganglioside antibodies are associat (IgM) with multifocal motor neurop of sample required: Serum -around time: 28 days	ed with several immunolog athy, GQ1b (IgG) with the l	ically mediated peripheral Viller-Fisher syndrome.	neuropathies e.g. anti-
Gast Repo An a Test antib Type Turn	ric Parietal Cell antibodies (CHU) orted as: Positive or Negative. ntibody marker of pernicious anaen ing for Pernicious anaemia should b oodies). e of sample required: serum -around time: 14 days	nia that is present in 90% o be primarily conducted with	f cases. It is highly sensitiv intrinsic factor antibodies (	re, but not very specific. (see anti-intrinsic factor
Glon Repo This activ If rec Type Turn	nerular Basement Membrane antibo orted as: Positive or Negative U/ml. antibody is a highly sensitive and s ity and often predict clinical outcom quired urgently, please contact the la e of sample required: Serum -around time: 3 days	odies (CHU) pecific marker of Goodpast le. aboratory.	ure's syndrome. Levels co	rrelate well with disease
Intrin Repo This uptal an in Type Turn	nsic Factor antibodies (CHU) orted as: Negative or with a Numeric is a highly specific marker for perni- ke of vitamin B12 by either binding to idicator of a disease process that re e of sample required: Serum -around time: 7 days	cal Value in U/ml cious anaemia that is found to the vitamin complex and equires further investigation	d in 75% of patients. The a preventing its uptake, or b	ntibodies can prevent the locking the binding. It is
Jo-1 Repo Four pane Type Turn	antibodies (see ENA antibodies) (C orted as: Positive or Negative nd in 25% of cases of polymyositis, i el of myositis specific antibodies is a e of sample required: Serum -around time: 7 days	CHU) it correlates well with the p available following discussio	resence of interstitial lung on with the laboratory.	disease. An extended

Liver Kidney Microsomal (LKM) antibodies (CHU) Reported as: Positive or Negative

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LKM induc Type Turn-	antibodies are found only in a small n ed hepatitis, but are highly specific fo of sample required: Serum around time: 7 days	umber of patients with auto r these diseases.	immune chronic active hepa	atitis and drug
Mitoc Repo A hig with a Type Turn-	chondrial antibodies (CHU) orted as: Positive or Negative hly sensitive and specific marker of Plautoimmune chronic active hepatitis. of sample required: Serum around time: 7 days	rimary Biliary Cirrhosis, it is	also found in a small perce	ntage of patients
Neura Anti- Repo Thes e.g. s neuro Initial Requ Type Turna	onal antibodies (anti-Hu, anti-Yo,anti- Tr, Anti-Titin & Anti-Recoverin) (CHU) rted as: Positive or Negative e antibodies occur in a variety of para mall cell lung carcinoma, lymphoma, plogical antibodies are available by sp testing is performed by immunofluore ests for primary testing by the immun of sample required: Serum around time: variable, but approximate	Ri, Anti-Ma2, Anti-CV2/CRM -neoplastic neurological syn breast carcinoma & ovarian becial request. escence, with follow-on testi oblot method can also be m	IP5, Anti-Amphiphysin, Ant ndromes associated with va a carcinoma. A wide range c ing by immunoblot panel if r nade.	i-Zic-4, Anti-Sox-1, rious malignancies of additional eactivity is seen.
Neutri Repo If pos If req The a prote Prese untre corre e.g. in ANC/ glome The la conta Type Turn-	Neutrophil Cytoplasmic antibodies (ANCA) (CHU) Reported as: Positive or Negative If positive, the titre and staining pattern is also reported as: cytoplasmic (c-ANCA) or perinuclear (p-ANCA). If required urgently, please contact the laboratory on ext 5323 The antigenic specificity of all positive ANCA samples is characterised by performing ELISA assays for anti- proteinase3 (PR3) and anti-myeloperoxidase (MPO) antibodies. Presence of high titre (>1/80) c-ANCA in the appropriate clinical setting, directed against PR3, is highly suggestive of untreated necrotising vasculitis e.g. Wegener's granulomatosis or Microscopic polyarteritis. Antibody titres tend to correlate well with disease activity. Note 'false positives' may occur in diseases which may mimic systemic vasculitis e.g. infective endocarditis, tuberculosis, non-Hodgkin's lymphoma and acquired immune deficiency syndrome. P- ANCA (of anti-MPO specificity) are found in up to 50% of patients with microscopic polyarteritis and pauci-immune glomerulonephritis, in addition to rheumatoid arthritis, SLE and ulcerative colitis. The laboratory operates a gating policy to reduce un-necessary requests or those with limited clinical value. Please contact the laboratory if you require further guidance. Type of sample required: Serum Turn-around time: 3 days			
Nucle Repo A ser nega speci sclerc antibo Clinic The I conta Type Turn-	Nuclear antibodies (ANA) (CHU) Reported as: Positive Titre or Negative A sensitive marker of systemic lupus erythematosus; which occurs in virtually all patients with untreated disease. A negative ANA on HEp-2 cells effectively excludes untreated SLE. Presence of ANAs in significant titre (>1/80) is not specific for SLE, occurring in up to 15 – 50% of patients with other autoimmune diseases e.g. rheumatoid arthritis, scleroderma, Sjogren's, dermatomyositis. The ANA titre is of little value in monitoring SLE disease activity, as the antibodies have an in-vivo half -life of 3 – 4 weeks. Clinically relevant, positive ANA results will have ENA screening and dsDNA ab screening reflexed on to them. The laboratory operates a gating policy to reduce un-necessary requests or those with limited clinical value. Please contact the laboratory if you require further guidance. Type of sample required: Serum Turn-around time: 5 days			
Ovari	an antibodies (CHU)			

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Reported as: Positive or Negative Present in patients with either isolated pr endocrinopathies such as Hypo-adrenalis Type of sample: Serum Turn-around time: 21 days	imary ovarian failure or it i sm, insulin dependent dial	s associated with other auto betes and pernicious anaem	pimmune nia.	
Pancreatic Islet cell antibodies (PICA) (C Reported as: Positive or Negative. Present in 90% of patients with insulin de relatives of patients with IDDM. Type of sample required: Serum Turn-around time: 21 days	HU) ependent diabetes mellitus	at presentation. There is ir	ncreased prevalence in	
Parathyroid antibodies (SHE) Reported as: Positive or Negative Present in up to 10% of patients with idio autoimmune poly-endocrinopathies with a Type of sample required: Serum Turn-around time: 21 days	pathic hypo-parathyroidis antibodies to both adrenal	n. Many of these patients h cortex and ovarian tissue.	ave multiple	
Rheumatoid Factor (SMH) Reported as: Negative or Positive Rheumatoid factor (usually IgM) is presen disease. The presence of RF is not essen (SLE, scleroderma, Sjogren's), and chror normal population. Type of sample required: Serum Turn-around time: 2 – 3 days for screen	nt in approximately 70% o ntial for the diagnosis of R nic bacterial infection. Rho	f patients with RA and corre A. RF also occurs in other eumatoid factors are preser	elates with more seven autoimmune diseases at in low titre in 5% of	
Ribosomal antibodies (SHE) Reported as: Positive or Negative. Present in a minority of patients with SLE Type of sample required: Serum Turn-around time: 2-5 days	Ξ.			
ScI-70 (see ENA antibodies) (CHU) Reported as: Positive or Negative Present in 15 – 20% of cases of sclerode panels are available by special request. Type of sample required: Serum Turn-around time: 7 days	erma, it forms a marker of	systemic disease. Additiona	al extended testing	
Smooth muscle antibodies (CHU) Reported as: Positive (titre) or Negative Present in up to 70% of patients with auto with primary biliary cirrhosis. The antibod Type of sample required: Serum Turn-around time: 5 days	oimmune chronic active h y frequently occurs as a 'f	epatitis and in approximatel alse positive' in patients wit	y 25 – 50% of patients h viral infections.	
Antibodies to Striated Muscle (CHU) Reported as: Positive or Negative. Found in 60% of patients with Myasthenia the presence of a thymoma.	a Gravis, the presence of	striated muscle antibodies i	n myasthenia sugges	

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Type o Turn-ai	f sample required: Serum ound time: 21 days			
Protein Alpha- Report Measu adults. levels v Type o Turn-at	Immunochemistry I anti-trypsin (1 Proteinase inhibitor ed as mg/dl (107 – 209mg/dl) rement of $\alpha$ -1 anti-trypsin level is us In paediatric practice $\alpha$ -1 anti-tryps vill be sent for Phenotyping to deter f sample required: Serum round time: 3 days	) (SMH) seful in the investigation of sin deficiency is associated rmine homo or heterozygo	<sup>:</sup> emphysema and unexplain d with neonatal jaundice. Pa sity.	ed liver disease in tients with low $\alpha$ 1-AT
B2-Mic Report As an i Levels Type o Turn-ar	roglobulin (SMH) ed as mg/L NR <3.0mg/L ndex of cellular turnover and renal t are raised in renal tubular dysfunct f sample required: Serum round time: 2-5 days	tubular function, this test c ion irrespective of cause.	an be a useful prognostic m	arker in myeloma.
C1 inhi Quantit Functic C1 inhi heredit collecte Conver Type o Turn-ar	bitor (formerly termed C1 esterase atively Result: as mg/dl (reference anal Activity (reference range 70 – 1 bitor deficiency (antigenic or function ary angioneurotic oedema. Acquire ad during an acute attack of angioed sely, a normal C4 level virtually exc f sample required: Serum round time: 7 days	inhibitor) (CHU) range 0.15 – 0.35) 130u/ml) onal) is transmitted as an a ed C1 inhibitor deficiency m dema due to C1 inhibitor d cludes all forms of C1 inhib	autosomal dominant disorde hay also occur with B-cell lyr leficiency are characterised bitor deficiency.	r resulting in nphomas. Samples by a low C4.
Comple Report C3 Rar C4 Rar Measu SLE. C inflamn Type o Turn-ar	ement levels (C3 & C4) (SMH) ed as: Unit value in mg/dl nge: 65 – 190 mg/dl nge: 15 – 50 mg/dl rement of serum complement levels omplement levels act as acute pha natory and infective disorders. f sample required: Serum round time: 1 – 2 days	s is useful in the diagnosis se proteins and may be no	and monitoring of immune o ormal, despite complement o	complex diseases e.g. consumption, in some
Cerebr Report Oligocl sugges the cer Type o Turn-a	o-spinal fluid Oligoclonal banding & ed as: Oligoclonal bands Present o onal bands, confined to the CSF, a tive, but not pathognomonic of mul- tral nervous system e.g. viral ence f sample: Paired CSF & serum sam round time: 21 days	a IgG / Albumin (CHU) r Absent re indicative of intrathecal tiple sclerosis, being also f phalitis, bacterial meningiti pples	immunoglobulin synthesis. found in infective and inflam is, neurosyphilis, sarcoid an	Oligoclonal bands are matory diseases of d lupus.
Functic Report Normal These if any c Sample disease	anal complement, CH100 (previousled as: Normal or percentage of nor range is equal or >70% of control. investigations form a test of integrit omponent is absent. a needs to reach the laboratory with a particularly if recurrent, should be	ly CH50) and AP100 (CHU mal y of classical and alternate hin 1 hour of venepuncture e screened in convalescen	<ul> <li>I)</li> <li>Iytic pathways of complem</li> <li>Patients with any form of n ce with a CH100.</li> </ul>	ent. Low levels occur neningococcal

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Type of sample: Serum Turn-around time: 28 days

Cryoglobulins (CHU)

Reported as: Positive or Negative.

For Cryoglobulin testing, clotted blood (2 tubes) should be taken and immediately placed in a thermos flask containing water at 37 to 39°C. Please organise this sample collection with the laboratory who will arrange to be present when the samples are collected. If there are any questions or doubts about taking blood for this test, contact Immunology on 01296 315323.

Cryoglobulins are immunoglobulins which reversibly precipitate in the cold. Type I (monoclonal) cryoglobulins are associated with B cell lymphoma and myeloma whilst mixed cryoglobulins (type II & III) are associated with infective and inflammatory disorders. Type II cryoglobulins exhibit rheumatoid factor activity and are invariably associated with marked consumption of C4. Consider cryoglobulinaemia in any patient with unexplained renal or skin disease and a low C4.

Type of sample required: Serum (Kept at 37°C) Turn-around time: 14 days

Serum electrophoresis (SMH)

Electrophoresis is essential in the investigation of suspected paraproteinaemia and immune deficiency. Characteristic patterns are also seen in the presence of an acute phase response, nephrotic syndrome and  $\alpha$ 1-antitrypsin deficiency. A polyclonal increase in the gamma region is seen in inflammatory and infective disorders, often with a concomitant acute phase response. A decrease in the gamma region indicates either primary or secondary hypogammaglobulinaemia. This test is performed in conjunction with immunoglobulins. Type of sample required: Serum Turn-around time: 2 – 3 days Urine electrophoresis (SMH) Urine electrophoresis is most useful in detecting the presence of Bence Jones proteins (monoclonal free light chains) in patients with suspected myeloma. Polyclonal free light chains may occur in the urine of healthy elderly people as well as in inflammatory disorders. All serum and urine samples with suspected paraprotein bands will be investigated by immunofixation electrophoresis. Type of sample required: Urine & Serum Turn-around time: 3 to 5 days Immunofixation electrophoresis (SMH) Result is reported descriptively as presence or absence of paraprotein. All serum samples with suspected paraprotein bands on electrophoresis are typed by immunofixation and quantified by densitometry scanning. Haemolytic complement activity - classical pathway / alternative pathway (CH100, AP100) (CHU) See 7.6. Functional complement, CH100 (previously CH50) and AP100 Immunoglobulins (SMH) NR: (Adult) IgG 6.0 – 13g/L IgA 0.8 - 3.0g/L IgM 0.4 - 2.5g/L Paediatric ranges are applied to children's results. This forms an essential investigation for 'failure to thrive', recurrent infections and lymphoproliferative diseases including myeloma. IgA deficiency occurs in 1 in 700 people and may not be associated with disease (but beware of transfusions). Polyclonally raised IgG occurs in chronic infection and inflammation, especially HIV infection, chronic liver disease and to a lesser extent in connective tissue diseases. Reduced immunoglobulins - predominantly IgG may be due to loss (protein - losing enteropathy, nephrotic syndrome), reduced synthesis (lymphoproliferative

disorders; primary immune deficiency) and excessive catabolism. Low levels always warrant further investigation, as serious infective complications may occur.

Type of sample required: Serum

Turn-around time: 1 – 2 days

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IgG subclasses (CHU) Reported in g/L Adult reference range: IgG1 3.2 – 10.2 IgG2 1.2

lgG2 1.2 – 6.6 lgG3 0.2 – 1.9 lgG4 0.1 – 1.3

For children age matched reference ranges are provided. IgG subclass measurements are only useful in the investigation of selected cases of suspected immune deficiency. Levels vary with age. IgG2 levels are physiologically low in infancy and may not reach adult levels until 10 – 12yrs of age.

Type of sample required: Serum

Turn-around time: 21 days

Specific antibodies to Tetanus toxoid, Haemophilus type B and Pneumococcal Polysaccharide (CHU) Reported quantitatively – levels vary with age.

Measurement of specific antibody production (spontaneous and post immunisation levels) is useful in the assessment of patients with suspected immune deficiency. Assays are only undertaken following prior discussion with immunology medical staff.

Type of sample required: Serum

Turn-around time: 21 days

. Total IgE (SMH)

Reported as: Units ku/L (adult reference range <120).

Total IgE levels are elevated in atopic eczema, allergic asthma bronchopulmonary aspergillosis, invasive helminthiasis and some forms of immunodeficiency. Measurement of total IgE levels is not essential for the diagnosis of allergy. Type of sample required: Serum

Turn-around time: 1-2 days

Specific IgE antibodies ('RAST' tests) (CHU, SHE)

Reported as: a numerical value, with descriptive interpretation of grade 0 – 6 reactivity

Specific IgE tests are available to a wide range of antigens. However, they are not a substitute for proper history taking and skin prick tests except in small children, those with extensive skin involvement that precludes skin testing or where there is a risk of anaphylaxis.

Blanket requests for 'RAST testing' will NOT be processed.

Please give details of suspected allergens and symptoms. Samples with insufficient details will be stored for 1 month awaiting the required information Tests for specific IgE to penicillin are not reliable in diagnosing immediate type hypersensitivity to this drug. If in doubt, please contact the laboratory on ext 5323 to discuss. Type of sample required: Serum Turn-around time: 21 days

Venom Specific IgE Specific IgE to bee, wasp and hornet venom are available Type of sample required: Serum

Turn-around time: 21 days

Component Resolved Specialist Allergens (CHU) These assays are available for peanut, hazelnut, birch, insect venoms and egg antigens and may provide additional information regarding severity of any allergic response. Type of sample required: Serum Turn-around time: 21 days

Serum Free Light Chain Assay (CHU)

A specific measure of renal capacity to remove monoclonal free light chains from a patient's circulation as an indication of disease activity or myeloma relapse. Requests are only processed from Haematology.

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Type of sample required: Serum Turn-around time: 21 days

Cellular Investigations

Lymphocyte surface marker analysis (CHU)

Please ensure that a full blood count is performed simultaneously. Indicated in the investigation of immunodeficiency and monitoring of HIV infection. The use of CD4 counts as a surrogate marker for the diagnosis of HIV infection is unhelpful and constitutes poor medical practice. A low CD4 count is not diagnostic of HIV infection, occurring in a wide variety of other conditions including primary immunodeficiency, viral and bacterial infection, lupus, steroid therapy. All requests for lymphocyte surface marker analysis, other than for HIV monitoring, should be discussed with the departments' medical staff.

It is not possible to process these samples if they are collected on a Friday due to the restrictions of the reference laboratory

Special samples required – discuss with Laboratory Type of sample required: EDTA (5ml) Turn-around time: 7 days

Neutrophil function (CHU)

Special samples required - discuss with Laboratory.

Neutrophil function tests are available through the department. These are useful in the diagnostic work-up of patients with suspected primary immunodeficiency, particularly those patients with recurrent deep-seated bacterial and fungal infections. Primary neutrophil defects are exceedingly rare. Tests are only available by special arrangement with the Laboratory's medical staff.

QuantiFERON-TB Gold Plus Testing (CHU)

Quantiferon is a gamma interferon stimulation assay that is used to look for latent TB in individuals who have visited areas with higher endemic risks or who have been in contact with known cases. The samples MUST be returned to the laboratory on the day of collection as the antigen stimulation stage of the assay must be initiated within 16 hours of collection.

Samples to be kept at Room Temperature after collection and NOT refrigerated

It is not possible to process these samples if they are collected on a Friday due to the restrictions of the reference laboratory

Special samples required – discuss with Laboratory

Type of sample required: Quantiferon collection kit available from immunology

Turn-around time: 7 - 10 days

Guidelines on the appropriate use of tests

Diagnosis and monitoring of Systemic Lupus Erythematosus

Diagnosis: ANA, antibodies to dsDNA, ENAs, antibodies to cardiolipin, C3,

C4 and immunoglobulin levels should be requested at presentation. A negative ANA performed on HEp-2 cells effectively excludes the diagnosis of untreated SLE.

Monitoring: Since the half-life of antibodies is 3 weeks, serial measurement of antibodies at weekly or fortnightly intervals is unhelpful. At each visit measurement of C3, C4 and CRP is advised with intermittent measurement of ANA and dsDNA binding antibodies.

Systemic Vasculitides At presentation, the following investigations are useful for baseline assessment: ANA ANCA C3 and C4 CRP RF Immunoglobulins Cryoglobulins Diagnosis of Wegener's granulomatosis and Microscopic polyangiitis

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Diagnosis: In patients with active untreated Wegener's granulomatosis, c-ANCA / p-ANCA (anti-PR3) is present in > 90% of cases. Although p-ANCA occurs in microscopic polyangiitis, idiopathic pauci-immune glomerulonephritis and in a few patients with Wegener's, they are also present in a range of other autoimmune diseases as well e.g. SLE, RA and ulcerative colitis.

Monitoring: Wegener's, Microscopic polyangiitis – at each visit CRP and ANCA. In view of antibody half-life of 3 weeks, frequent ANCA measurement i.e. weekly / fortnightly is unlikely to provide clinically useful information. In patients in remission, a rising ANCA titre often heralds a relapse.

Investigation of renal failure

At presentation, the following investigations are useful for baseline assessment: ANA C3, C4 CRP ANCA Anti-GBM Cryoglobulins Serum immunoglobulins and electrophoresis Urine electrophoresis

Suspected immunodeficiency At presentation, the following investigations are useful for baseline assessment: C3, C4 Immunoglobulins and Electrophoresis Subclasses Functional Antibody levels Further investigations should be undertaken only after discussion with the laboratory staff.

Investigation of Allergy

Selective testing for specific IgE antibodies tailored to the clinical history. All encompassing 'blanket' screens for specific IgE antibodies cannot be accepted (see under specific IgE antibodies).

Investigation of Anaesthetic Reactions

Consult Laboratory as soon as possible.

Take 10ml clotted blood immediately after the onset of the reaction and collect 3 further samples over the next 24 hours and test for mast cell tryptase, i.e. 1hour, 6 hours and 24 hours post reaction.

Label each one clearly with the time taken.

Please send full details of the agents used and relevant previous drug history, type of operation, clinical manifestations, management and outcome. Patients with suspected anaesthetic allergy will need to be assessed in an allergy clinic during convalescence.

Type of sample required: Serum

Turn-around time: 10-14 days

#### Monoclonal Therapy Biologics Monitoring

The measurement of Adalimumab and Infliximab is a useful tool in managing patients who fail to respond or who go on to lose response (secondary failure) to treatment. Monitoring drug levels allows for a personalised approach to drug optimisation by appropriate dose escalation/de-escalation or drug switching/withdrawal. Tumour Necrosis Factor alpha (TNF- $\alpha$ ), is a pro-inflammatory cytokine involved in the establishment and maintenance of tissue inflammation in chronic diseases such as ulcerative colitis and Crohn's disease. Neutralisation of the biologic activity of TNF- $\alpha$ , using monoclonal antibodies such as Infliximab, has been shown to be an effective strategy for the reduction of tissue inflammation and induction of disease remission. However, during therapy, some patients may generate antibodies to Infliximab, termed anti-drug antibodies (ADAs). High levels of ADAs may negate Infliximab efficacy. The serum concentration of Infliximab immediately prior to re-infusion (trough level) provides important information and should be used to inform dosing, clinical management and appropriate ADA testing; trough drug levels should be monitored during any changes in dosing regimen.

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Type of sample required: Serum

Turn-around time: 21 days

#### Reference Laboratories

The majority of samples received in the laboratory are tested in-house, but investigations that are less commonly requested or those that require specialist equipment are referred to specialist laboratories for processing. The laboratory in which the testing is undertaken is indicated by a three letter code in brackets, after the test description. SMH refers to the in-house laboratory. The other referral laboratories used routinely are listed below:

Code:	Reference Laboratory & Address
СНИ	Department of Immunology
	Oxford University Hospitals NHS Trust
	Churchill Hospital
	Headington
	Oxford. OX3 7LE
SHE	Sheffield Protein Reference Unit
	Immunology Department
	P.O. Box 894
	Sheffield S5 7YT
CAR	Cardiff Protein Reference Unit
	Medical Biochemistry & Immunology
	University Hospital of Wales
	Heath Park
	Cardiff. CF14 4XW
KIN	Viapath
	Kings College Hospital
	40 Denmark Hill,
	London
BAT	Bath Institute for Rheumatic Disease
	Allan Dixon Building

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	1 Trim Bridge
	Bath BA1 1HD
SJI	St John's Institute for Dermatology
	St Thomas' Hospital
	Lambeth Palace Road
	London
NHN	National Hospital For Neurology and Neurosurgery
	Queen Square
	London
	WC1N 3BG
VIA	St Thomas' Hospital
	Westminster Bridge Road
	London
	SE1 7EH

# Appendix 5 – Supplies & Logistics

Pathology Supplies

Supplies of sample tubes request forms and specimen bags are available as follows:

#### Chiltern CCG Request forms, Sample bags and Biochemistry urine tubes from: Prep Room, Cellular Pathology Laboratory, Wycombe Hospital, Queen Alexandra Road, High Wycombe HP11 2TT

Tel: 01494 425248 (09:00 - 12:00) answerphone outside these hours

Blood sample tubes from Bunzl- direct ordering and delivery as per your practice

Aylesbury CCG, Tring, Leighton Buzzard GP practices Request forms, Sample bags, Blood tubes and Biochemistry urine tubes from:

Pathology Reception Stoke Mandeville Hospital

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Mandeville Road Aylesbury HP21 8AL

Email: BHT.Bloodsciences@nhs.net

Tel: 01296 315 333 (11:30 – 14:00) answerphone outside these hours

For **immunology supplies** (i.e. forms, containers and swabs) please telephone the appropriate extension and leave a message on the answer phone for Wycombe and send an email with an attached supplies form to Stoke Mandeville.

Stoke Mandevillebht.pathologysupplies@nhs.netWycombe5248

#### Logistics

Brake runs transport samples to the lab and take supplies and reports to the community locations.

They run by our logistics partners under contract to the Trust.

- From Stoke Mandeville Hospital Sodexo
- From Wycombe & Amersham Hospitals Medirest

# Appendix 6: Clinical indications and frequency of requesting.

# National minimum retesting intervals in pathology

http://www.acb.org.uk/docs/default-source/guidelines/acb-mri-recommendations-a4-computer.pdf

The ICE order comms system provides further guidance on test profiles available and frequency of testing.

# **Guidance on Acute Kidney Injury (AKI)**

• Think Kidneys:

https://www.thinkkidneys.nhs.uk/aki/wp-content/uploads/sites/2/2014/12/AKI-Warning-Algorithm-Best-PracticeGuidance-10.03.16.pdf

• Acute kidney injury NICE clinical guideline 169:

www.nice.org.uk/guidance/cg169