viapath

PATHOLOGY USER GUIDE

BEDFORD HOSPITAL NHS TRUST

Version 8 – Effective from December 2016

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General Information

Handbook Preface

This manual outlines the Pathology Service offered by Viapath at Bedford Hospital NHS Trust.

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

Should you have queries in connection with any aspect of the Pathology Service, our staff will be pleased to discuss these with you. Errors, amendments and suggestions for the next edition should be brought to the attention of the Customer Service Manager or General Manager, Viapath Bedford.

This handbook is also available on Bedford Hospital website – www.bedfordhospital.nhs.uk

Key Contacts

Clinical Director, Viapath Bedford

Dr Fraser Mutch (fraser.mutch@bedfordhospital.nhs.uk)
01234 792325
Ext 4725

Interim General Manager, Viapath Bedford

Guy Humphrey (guy.humphrey@bedfordhospital.nhs.uk)
01234 792156
Ext 4656

Customer Service Manager:

Anne Strong (anne.strong@bedfordhospital.nhs.uk)
01234 792628
Ext 4658

Results Hotline
01234 355122 Ext 4811

Further pathology contacts can be found within discipline specific sections.

Services

The pathology laboratories offer a comprehensive range of pathology services, fully supported by consultant-grade staff.

Service Objectives

Viapath Group LLP – the UK's leading independent provider of pathology services – is a unique and innovative joint venture between Kings College Hospital, Guy's and Thomas'

Hospitals NHS Foundation Trust and Serco plc. Viapath (formerly GSTS Pathology) contracted with Bedford Hospital to provide its Pathology Services in December 2009. Laboratory services are provided by Viapath Analytics LLP.

Viapath is an exemplar of public private partnership in the health sector. The result is a unique clinically-led, customer-focused and scientifically-driven pathology service.

Viapath is transforming the way pathology is delivered, providing an end-to-end service that draws upon innovative processes and technology to improve outcomes for patients. Customers have access to one of the most extensive ranges of tests and support services. The company is a leading national diagnostic referral service, providing a wide range of specialist tests and routine services to support all healthcare organisations.

Viapath's customers include GPs, referring clinicians, the NHS and the private sector – both domestically and internationally.

Commitment to Quality

All Viapath laboratories are currently registered or working towards registration with UKAS United Kingdom Accreditation Service and previously Clinical Pathology Accreditation (CPA) Ltd. The Blood Transfusion service is compliant with the Blood Safety & Quality Regulations (BSQR) as regulated by the Medicine and Healthcare Products Regulatory Agency (MHRA). The Cytology department within Cellular Pathology is compliant with Cytology External Quality Assurance. The laboratories accreditation status is contained on our website (currently under review) and can be accessed via the accreditation link.

Each department within the Pathology Service holds a Quality Manual describing all aspects of their department's Quality Management System. This is available for inspection by users.

Quality Policy

This statement of purpose constitutes the quality policy for Viapath Group LLP and is applicable to both Viapath Analytics and Viapath Services. Viapath is an independent pathology provider registered with the Care Quality Commission. The quality policy can be found at http://www.viapath.co.uk/our-quality-policy

The management system incorporates the requirements of the Health and Social Care Act, Health and Safety and Environmental legislation, and BSQR amongst others.

Scope

Viapath is a clinically led, customer focused and scientifically driven full service pathology provider of accurate, timely and clinically useful prognostic, diagnostic and screening results, blood and blood products, with clinical advice to the NHS and private sector locally, nationally and internationally. Services include core pathology such as Blood Sciences, Tissue Sciences and Infection Sciences, typically delivered from each operational site and specialised tests delivered from centres of excellence. Services participate in research, development and clinical trials.

Aims and Objectives

The Viapath management system supports the business vision to be the leading pathology provider of high quality, cost effective pathology services and ensures that:

- Viapath has a business reputation based on safety, quality and customer service, using innovation to build a competitive advantage in chosen market sectors so that Viapath becomes the provider of choice.
- Viapath identifies its resource requirements through an effective management structure to ensure that risk and improvement opportunities are identified and acted on to protect or improve the health and safety of patients, staff and visitors.
- Viapath services operate above the minimum level of quality and compliance set by legislation and professional standards in the environment we operate.
- Viapath integrates its organisational structure, processes and procedures required to fulfil this policy and demonstrate improved quality outcomes.
- Viapath has an effective governance system that ensures accountability and provides internal and external assurance through reliable and relevant evidence.
- Viapath engages stakeholders to understand, meet and exceed their needs and requirements for patient safety, clinical effectiveness and operational performance.
- Viapath maintains an ethical culture and environment to underpin the business values. High standards of behaviour, staff engagement and empowerment with accountability are maintained to allow excellence in our services to flourish.

Quality Improvement

Viapath has established continuous quality improvement as a business philosophy for all processes and services to support safe and effective patient care. Viapath continually monitors its activity, annually reviews this policy for its suitability and effectiveness and publishes a quality account which defines our quality improvement objectives. Services complete an Annual Management Review (AMR) to ensure objectives are monitored locally and changes or new systems, processes or procedures are implemented effectively. Satisfaction of Users of the service is seen as a key indicator of success in improvement of services. Viapath is proactive in managing its business risks and has plans in place to ensure service continuity in all events.

Workforce

Viapath will maintain a high quality flexible workforce that are committed, engaged, trained and supported to provide the highest level of service to our users in accordance with relevant good professional guidance. Through recruitment, induction and training, staff will be made familiar with this policy and relevant content and procedures of the management system. Each staff member holds a personal responsibility for the quality of the work that they perform. Competency assessment and appraisal is used to ensure ongoing capability and identify individual personal development.

Managers and supervisors provide effective leadership and create a culture and working environment that allows operational performance and change management to be achieved by staff that are empowered to make suggestions and take decisions.

Assessment and Monitoring

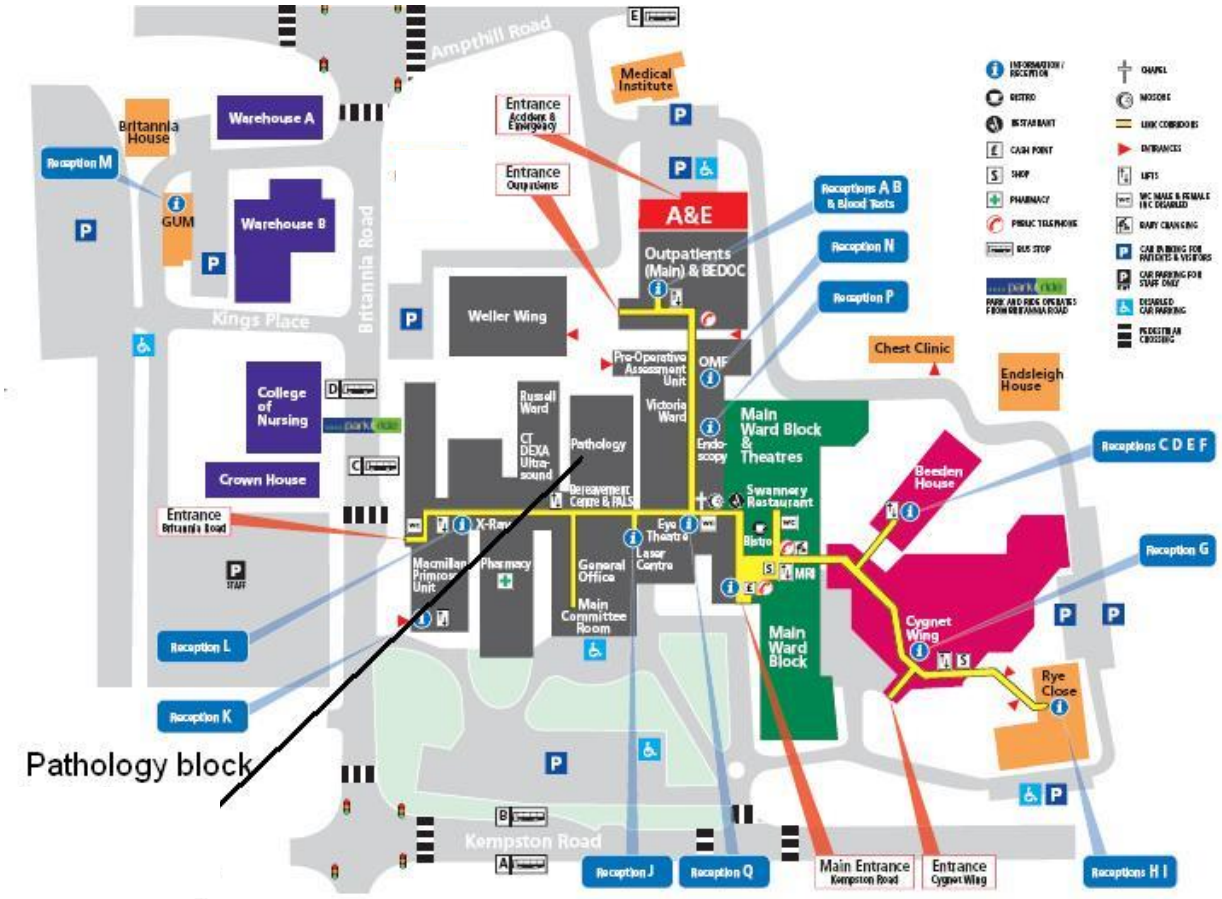
Key performance and quality indicators are used to enhance operational performance and remove variation from laboratory processes. Internal Quality Control (IQC) and assurance with External Quality Assurance (EQA) is used as part of the overall assurance mechanism along with clinical and internal audit to monitor adequacy of operating procedures and effectiveness of the quality system. Quality tools such as Root Cause Analysis (RCA) are used to ensure effective corrective actions are implemented. We recognise the confidentiality of information we hold on patients, donors and clients and allow accreditation and regulatory bodies appropriate access to the knowledge systems maintained to provide third party assurance to Viapath and our stakeholders.

Viapath is registered with the Care Quality Commission (CQC) as an independent healthcare provider at all locations on which it operates for the provision of diagnostic and screening services and blood and transplant services.

Pathology Block is located in the South Wing of Bedford Hospital

(See map below)

Pathology can only be accessed via security swipe cards out of hours, but during the hours of 8:00am – 5:30pm (Mon – Fri) and 08:00 – 12:30 (Sat) personnel can access the department from the hospital main corridor by pressing the pad on the left hand side of the main doors and reporting to Pathology Reception using the stairs or lift to the first floor. The pathology block does not have the facilities for any phlebotomy service. The pathology block (indicated on the map) contains the Mortuary and Bereavement Service on the ground floor, Clinical Biochemistry, Serology, Haematology and Blood Transfusion on the first floor, Cellular Pathology on the second floor and Microbiology on the third floor.



Pathology Opening Hours: Please refer to individual departments

Blood Sciences Laboratory incorporating Clinical Biochemistry and Haematology /Transfusion operate a full 24/7 shift service.

The full range of tests are available 08:00 – 20:00 Monday – Friday and 08:00 – 12:30 Saturday.

At all other times a reduced staffed core service will be available

Reduced Core Service hours:

Haematology/Blood Transfusion:
Between 17.00 and 20.00 may be contacted on extensions 4833/4653.

	Haematology/ Blood Transfusion	Biochemistry/ Serology	Microbiology
Monday to Friday	**20.00 – 08.00**	**20.00 – 08.00**	**17.00 – 08.45**
Friday to Saturday	**20.00 – 08.00**	**20.00 – 08.00**	**17.00 – 08.45**
Saturday to Sunday	**12.30 – 08.00**	**12.30 – 08.00**	**12.00 – 08:45**
Sunday to Monday	**08.00 – 08.00**	**08.00 – 08.00**	**08:45 – 08.45**
Bank Holidays	**08.00 – 08.00 next day**	**08.00 – 08.00 next day**	**17:00 – 08:45**

Please be aware that there will be limited number of staff available during the hours listed above. Please be patient when contacting the laboratory as staff may be busy dealing with emergencies or liaising with other clinical teams.

Haematology, Blood Transfusion and Clinical Biochemistry samples will be processed at regular intervals.

It is only necessary to contact the duty BMS if the work is considered urgent.

Clinical Biochemistry **Bleep 432** [If no response please
Haematology/Blood Transfusion **Bleep 474** contact switchboard]

Both the Clinical Biochemistry and the Haematology/Blood Transfusion BMS also carry DECT phones for use by the **Accident and Emergency Department only**

Microbiology **Contact via switchboard**

The On-call Microbiology BMS is usually off-site and should always be contacted before urgent work is sent.

Work sent after midnight without bleeping the relevant personnel will be processed with the next urgent/batch of work.

ALL critical results produced out of hours will be telephoned or hard copy sent in the air tube to the requesting location. All other results will be available on the ward reporting system

available on all Trust computers connected to the Intranet. In the event of ICE system failure, an interim report will be sent to the ward.

Consultant staff may be contacted via switchboard if clinical advice is required.

Requesting Investigations

All pathology requests should be made electronically using the Sunquest ICE system. All Hospital and GP users have been trained in requesting Pathology electronically.

However, if a request is made manually then the following should be adhered to as detailed below:

Request Forms

If a pre-printed patient label is used, please ensure that a label is also placed on all copies of the request form.

It is essential that specimens are correctly identified otherwise:

- a patient may receive the wrong treatment
- a patient may not receive the treatment that they require

If request forms are being handwritten please ensure that they are legible.

A correctly completed request form must state:

- the patient's name (Surname and Forename)
- date of birth
- hospital number or NHS number (if known) (exceptionally the patient's address)
- Gender
- nature of the specimen
- date and time the sample was collected
- clinical diagnosis and relevant clinical signs/symptoms (including travel history if indicated)
- examination required
- Consultant or GP name caring for the patient.
- Name and bleep or contact number of requesting doctor
- Location to send report
- Risk status (If Known)
- Date and time of sample collection
- The identity of the individual collecting the sample

Adequate clinical information and current drug treatment must be given to facilitate the interpretation of results, to establish the need to do further laboratory investigations on a specimen and to identify possible drug/test interactions, etc. Drug timing and dosages are also necessary to provide reliable therapeutic drug monitoring. If a test requires special collection conditions (e.g. fasting, timing) it should be clearly stated that the conditions have been met.

Please ensure that the correct consultant/GP code is used and that the destination for delivery of results is accurately and clearly stated. If request forms are not correctly and legibly completed then the laboratory reserves the right to cancel requests for the safety of patients.

We attempt to inform and advise users of such problems as they arise but may not always be able to contact those concerned.

Add-on Test Requests

If you need to add a further test request to a sample that we have previously received in the laboratory, please telephone the relevant department to check that the sample is still viable and an add-on test can be requested. Any add-on requests must be made within 72 hours, tests will be performed if the assay is still valid and sample integrity has not been compromised. If this is possible, please send an email request with patient details and tests to be added on to the following secure email address – Viapath.Bedford-Addontest@nhs.net. Please note that faxed requests will not be accepted. Please note that only requests from a secure nhs.net account will be accepted. Any other form of email accounts used will not be accepted. Within the hospital, to request an "add-on test" please send a request card outlining the test stating it is an "add-on".

Private Work

All such work must be identified on the original request form. With private GP, outpatients and day-patient requests the appropriate invoicing address must be written on the form. The laboratory will advise on the procedures and charges.

Specimen Collection

All specimens must be labelled as detailed above. Accompanying request forms must contain the same information.

Waste generated as a result of sample collection must be disposed of in accordance with local waste management policies. Phlebotomy sharps must be placed in a sharps container and waste contaminated with bodily fluid or excretions must be disposed of via a clinical waste stream.

Samples for blood group and cross match must be **hand written** with surname, first name, date of birth, hospital number and signed by the person taking the sample.

All specimens must be transported inside a sealed polythene bag.

The person collecting the specimen is responsible for positively identifying the patient. Ideally, the patient should be asked to state their name and date of birth, and this should then be checked against the information on the patient's wristband. If the patient is unable to speak, their identity must be ascertained from their wristband.

The sample tubes must be labelled with ballpoint pen as soon as the samples are collected, and before leaving the patient or bleeding any other patient. Labelling must be clear and legible. Unlabelled or mislabelled specimens cannot be accepted, for the safety of patients and for the medico-legal protection of hospital staff.

Please also see Acceptance Criteria for Cellular Pathology Samples (Page 77)

Transport of Specimens to the laboratory

Hospital Sites

Samples should be sent to the laboratory by either the pneumatic tube system or arranging collection by a hospital porter. High-risk samples, blood gas samples, blood culture samples, unrepeatable samples e.g. CSF and any samples in formalin **must not** be sent through the pneumatic tube system.

General Practitioner Surgeries

Pathology samples are collected from surgeries by our courier service.

High Risk Specimens

Separate procedures are used in the laboratory for the safe handling and examination of samples from patients known, or suspected, to have infections caused by certain pathogens (see below) that pose a risk to laboratory workers and others if handled incorrectly. It is the responsibility of the person taking such a specimen from a patient and sending it to the laboratory to ensure that the request forms and specimen container are labelled to indicate a danger of infection.

The request forms should be flagged with a **self-adhesive "high risk" label**.

The request form must give sufficient clinical information to enable experienced laboratory staff to know what special precautions are necessary. In the interests of confidentiality, only the warning label needs be clearly visible to others. Specimens from V.R.E. and M.R.S.A. positive patients do NOT require flagging.

Identification of high risk specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a **known or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

- HIV 1
- HTLV1 and 2
- Hepatitis B virus
- Hepatitis C virus
- Salmonella typhi & paratyphi
- *Brucella spp*.
- And the causative agents of:-
- Anthrax
- Creutzfeldt-Jakob disease
- Rabies
- Yellow Fever
- Plague

Please see individual departmental guidelines for high risk specimen types.

To ensure valid results are obtained:

1. Avoid prolonged venous stasis when collecting blood. Consult Tube Guide (Page 89) for order of drawing samples.
2. Avoid contamination of sample with i.v. fluids.
3. Do not mix blood from one specimen container with another.
4. Ensure that urine collections are timed correctly and kept cool.
5. Fill in clearly what tests are required. Only ask for what you really need.
6. Avoid sending samples outside the routine working hours unless they are urgent and laboratory staff are expecting them.

Do not contaminate request forms with sample.

Special Tests

Patients requiring phlebotomy for tests with 'special' requirements, see individual discipline section.

Reporting of Results

Printed reports

Printed reports are sent out to hospital wards, hospital clinics and GPs daily.

Electronic reporting

Access to completed pathology results is available on all wards, departments and GP surgeries via the hospital electronic reporting system (Sunquest Anglia ICE).

Please **LOOK** on the **ICE system** before telephoning for results. CSF, Glucose, Protein and antibiotic levels (Gentamicin/Vancomycin) are reported onto the ICE system.

Critical results

These will always be telephoned. GP requests marked urgent will be telephoned.

Telephoning for results from outside the Hospital:

Under the requisite of the Patient Data Protection and Information Governance Guidelines, it is **mandatory** that a pre-determined Phone Code is provided by callers seeking Pathology results by telephone. Phone Codes are in place for all external users of the service e.g. GP Practices, Mental Health Trust, and have been communicated to such users. To obtain a code please contact Customer Service Manager, Anne Strong on 01234 792628.

Other Services

Viapath is able to provide a range of services and information to wards, departments and GP practices. If you wish to discuss any service developments or require information relating to or derived from the Pathology service then please contact the Customer Service Manager or General Manager, Viapath Bedford.

User Satisfaction and Complaints

Viapath is committed to providing the public with what it needs, not only in respect of excellent clinical care and safe and efficient diagnostics and screening, but also in passing on their thanks, providing them with information, answering their questions and concerns, or resolving their complaints, in an open, efficient and timely way to ensure that they receive an

appropriate response to whatever their specific needs are. It will provide a focal point for the provision of accurate, effective and sensitive information, supporting all patients, their representatives or anyone who may be affected by the actions of Viapath or need information from it.

Compliments, comments, concerns and complaints should be made to the General Manager or the Customer Service Manager, Viapath Bedford (contact information is provided within this user guide). Further information regarding the procedure can be found on the Viapath website http://www.viapath.co.uk/customer-service

Data Protection

All personal data is held in accordance with the Data Protection Act 1998 and the NHS Confidentiality Code of Practice. Closed files will be stored securely in the relevant department until archived within secure archive facilities provided by Viapath.

2. Clinical Biochemistry (CPA Accredited Laboratory)

Key contacts

Telephone (Result Enquiries) Direct Lines 01234 792148 / 792160

Consultant Chemical Pathologist	Dr W S Wassif	Tel. 01234 792167	Ext 4661
Principal Clinical Scientist	Dr Louise Ward	Tel. 01234 355122	Ext 4747
Blood Sciences Service Delivery Manager	Mr S Hyare	Tel. 01234 792165	Ext 4722
Clinical Biochemistry Laboratory		Tel. 01234 792166	Ext 4654
Out of hours		Tel. 01234 355122	Bleep 432
Secretary		Tel. 01234 355122	Ext 4625
Serology Laboratory		Tel. 01234 355122	Ext 4814
For Serology Clinical queries, please contact:			
Consultant Microbiologist	Dr Simantee Guha	Tel. 01234 795845	Ext 4603

Laboratory Service

Specimens for all pathology departments should be left at Specimen Reception located on the 1st Floor of the pathology building. Access is via the hospital main corridor. Outside of normal working hours only personnel with security badges can access, but at all other times this door is unlocked. A lift is available.

The laboratory provides a wide range of tests for the diagnosis and follow-up of patients, the results of most being available within 24hr of receipt of samples. Results from samples sent to specialist laboratories will take longer. Some of the in-house specialised tests are done in batches and results are available within one week. Turnaround times are indicated in the assay service table.

If you need to add a further test request to a sample which we have previously received in the laboratory, please telephone the relevant department to check that the sample is still viable and an add-on test can be requested. Any add-on requests must be made within 72 hours, tests will be performed if the assay is still valid and sample integrity has not been compromised. If this is possible, please send an email request with patient details and tests to be added on to the following secure email address – viapath.Bedford-Addontest@nhs.net. Please note that faxed requests will not be accepted. Within the hospital, request cards received with “add-on tests requested” will also be accepted.

Requests received from Accident & Emergency, Acute Assessment Unit, Neonatal Unit and Critical Care Complex are treated urgently. Any other urgent requests, the laboratory needs to be telephoned in normal hours or bleeped after 5pm (Bleep 432). Requests marked as urgent, but not accompanied by a telephone call will be assayed as soon as possible. ‘Critical’ results, which need immediate intervention, will also be telephoned. Results of GP requests marked urgent will be telephoned.

The Consultant Chemical Pathologist or Principal Clinical Scientist is available on site during working hours (and by mobile phone at other times when on call). Doctors are encouraged to discuss the investigation and management of individual patients with the Consultant Chemical Pathologist.

Sample Requirements

Becton Dickinson (BD) Vacutainer System:

Most routine tests can be performed on:	3.5ml Serum Separating Tube SST (sand cap)
Except: Glucose	2 ml Fluoride Oxalate (grey cap)
HbA1c:	2 ml EDTA (translucent lavender cap)

Fluoride Oxalate preservative (grey capped vacutainer) enables stable and accurate glucose measurements to be performed. Glucose measurements on unpreserved clotted serum samples can also produce accurate measurements if the sample is received and processed in the laboratory promptly (within two hours). Therefore glucose will be analysed on clotted serum samples received from inpatients and South Wing phlebotomy including outpatients. Blood samples received from other locations are required to take a fluoride oxalate (grey vacutainer) for glucose analysis.

Phlebotomy collections from small children and babies:

A 2 ml paediatric green lithium heparin bottle can be used for these patients instead of an SST to yield a better volume of plasma for analysis, **except** for the following tests where an SST is necessary:

Anti tissue transglutaminase	Lithium
C1 esterase inhibitor	Protein electrophoresis
CEA	Vancomycin
Folate	Gentamicin
Anti GAD and Anti Islet abs	Alpha-1-antitrypsin

For a 17hydroxyprogesterone (17OHP), Androstenedione and DHEAS a sample collected into a tube **without** gel is required. Serum or lithium heparin plasma is acceptable. These assays are not part of the standard profile available to general practice.

A minimum of 1 ml of blood is required for a routine biochemistry profile.

A 2 ml paediatric grey fluoride oxalate bottle can be used for glucose analysis.

Some of the more specialised assays may require different samples – please contact laboratory before bleeding the patient. See assay services table.

Some important notes to help us give you a good service:-

1. Always ensure minimum delay between venepuncture and sending samples to the laboratory. Delays can cause changes in some analytes, particularly artefactual increases in serum potassium, phosphate and some enzymes.

   Haemolysis, lipaemia and icterus samples that may affect some analytes, will be noted on the report.

   Grossly haemolysed samples will not be analysed. However, if prompt delivery is not possible some tests are still valid on serum samples stored overnight (see list of tests below for further information).

   Further details of assay interference are available from the laboratory on request.

76. Please fill Vacutainer tubes (3.5 ml) even if few tests are requested – 'economising' on samples can cause processing problems and changes to some analytes. In general, multiple analyses can be performed on a single sample. Exceptions are indicated in the list of assays.

Pathology laboratories will not assay samples without the following minimum data set on **both** request card and sample container:

SURNAME
FIRST NAME
DATE OF BIRTH
HOSPITAL NUMBER OR NHS NUMBER

It is also desirable and frequently essential for results interpretation to include:

DATE OF SAMPLE
TIME OF SAMPLE
ADEQUATE CLINICAL INFORMATION

Inappropriately labelled or unlabelled samples will not be analysed.

A report will be issued stating-: "Unlabelled sample received, unsuitable for analysis. Consider repeat if still needed."

This will also be conveyed by phone for urgent requests.

Specimen Transport

All specimens must be in blood collection tubes of approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers must be further contained within the specimen transport plastic bag with the request card kept separate in the front pocket. Leaking specimens are hazardous and may be destroyed. The Pneumatic Tube system may be used to transport specimens in accordance with the rule of use of the system. *(Pneumatic Tube Policy is available on the Hospital Intranet – online facilities).*

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations. Specimen transport bags, and request forms, which are supplied to the GPs, have an absorbent pad which will immobilise the entire leakage of a liquid specimen. These used in combination with the hospital courier service will ensure compliance with the regulations.

ASSAY SERVICES OFFERED BY CLINICAL BIOCHEMISTRY DEPARTMENT

Test Name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn-around time (routine tests are carried out the same day if received before midday)
ACE		Not for diagnosis of sarcoidosis. Only for monitoring patients known to have sarcoid disease [a]	15 days
ACTH	EDTA on ice	Send to lab immediately, subject to inhouse protocol. Must be accompanied by a cortisol request [a]	21 days
AKI alert		Calculation added by laboratory	
Alanine transferase (ALT)			Same day
Albumin			Same day
Alkaline Phosphatase (ALP)			Same day
Alpha fetoprotein (AFP)			3 days
Alpha-1-antitrypsin	Serum only	*** [a]	10 days
Amino acid chromatography	Li Hep		10 days
Ammonia	EDTA on ice	Ring lab first	On receipt
Amylase			Same day
Aspartate Transaminase (AST)		Not routinely available, please call the laboratory.	Same day
Beta- 2- microglobulin			14 days
Bicarbonate		Cannot be added on	Same day
Bile Acids			8 days
Bilirubin (total & conjugated)			Same day
Blood Gases	Heparin syringe	Send on ice (not via pneumatic tube)	On receipt
Caeruloplasmin	Special bottle Obtainable from lab [a]	*** [a]	10 days
Calcium			Same day
Carbamazepine		Prior to oral dose	3 days*
Carboxyhaemoglobin	Li Hep		On receipt
Carcino embryonic antigen (CEA)		Tumour markers are not recommended for screening	3 days
CA 125			3 days
CA 199		Tumour markers are not recommended for screening	3 days
CA 153		Tumour markers are not recommended for screening	3 days
C1 esterase inhibitor			10 days
Cholesterol			Same day
Cholinesterase & phenotyping			21 days
Complement C3 & C4			3 days*
Copper	Special bottle Obtainable from lab	*** [a]	10 days
Cortisol	Timed sample	See adrenocortical function protocol	3 days*
Creatine kinase (CK)			Same day
C reactive protein (CRP)		No indication to repeat within 24hrs, these requests will be blocked.	Same day
Cryoglobulins	Plain bottle	Arrange with lab	7 days

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn-around time (routine tests are carried out the same day if received before midday)
Cyclosporin	EDTA or Li Hep		7 days
DHEAS		Serum or lithium heparin plasma with no separating gel [a]	14 days
Digoxin		6-8 hours post dose	3 days*
Electrolytes		See renal function	Same day
Estimated GFR (eGFR)		See guidance notes	Same day
Ethanol	Li Hep	Arrange with Consultant Chemical Pathologist	Same day
Ferritin			Same day
Folate			Same day
Free light chains		Part of serum electrophoresis profile	14 days
Follicle stimulating hormone(FSH)		See infertility protocol	Same day
Fructosamine		Subject to in house protocol	8 days
Gastrin	Special tube – available in lab	Arrange with lab. Must be fasting and patient not taken PPIs in the last two week [a] s	14 days
Gentamicin	Serum sample ONLY	Please state time of last dose & regime. Contact Microbiology for clinical interpretation	Same day
Glucose	Fluoride Oxalate (Flu Ox) timed sample	State fasting/ random or if known DM	Same day
Glucose tolerance test (GTT)	Flu Ox timed samples	Arrange with phlebotomy (SW or NW)	2 days
γ glutamyl transferase (GGT)			Same day
Haemoglobin A1c	EDTA	Available only for known DM. Please allow at least 3 months before repeat test,	1 – 2 days
HDL cholesterol			Same day
Human chorionic gonadotrophin (HCG)		Not available for pregnancy testing. If ectopic pregnancy suspect, refer patient to Accident and Emergency	Daily but not week-ends
Human Growth Hormone		Subject to in house protocol, of limited clinical use in the diagnosis of acromegaly or growth hormone deficiency [a]	8 days
17 hydroxyprogesterone	SST not suitable	NO tube containing gel, serum or lithium. Heparin plasma is acceptable	10 days
Immunoglobulins (IgA, IgG & IgM)			3 days
Immunoglobulin IgE			7 days
Insulin / C peptide	Fl Ox & SST	Arrange with lab, subject to in house protocol [a]	15 days
Iron			Same day
K+			Same day
Lactate	Fl Ox	Send to lab immediately	Same day
Lamotrigine		Subject to in house protocol	8 days
LDH		Due to sample integrity this assay cannot be added on	Daily, weekdays
Lead	Li hep or EDTA		21 days

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn-around time (routine tests are carried out the same day if received before midday)
Lipids (cholesterol & Triglyceride)		Please allow at least 3 months before repeat test, unless triglyceride above 10 mmol/L	Same day
Lithium		12 hrs post dose	Same day
Liver function tests (LFT) Bilirubin, ALT Alk Phos & albumin			Same day
Luteinizing Hormone (LH)			Same day
Magnesium			Same day
Manganese	Special tube available from lab	Prior laboratory approval is required [a]	15 days
Na+			Same day
NT Pro BNP		Available for GP Only	8 days
17B Oestradiol		See HRT monitoring	2 – 3 days
Osmolality			Same day
Paracetamol		Not available to General Practice	Same day
Paraprotein typing			14 days
Parathormone (PTH)		Subject to in house protocol, see guidance in the Clinical Services Section	7 days*
Phenobarbitone		Prior to oral dose	3 days*
Phenytoin		Prior to oral dose	3 days*
Porphyrins	Full porphyria screen requires EDTA blood, random urine and stool sample.	Protect all samples from light	14-21 days
Potassium			Same day
Progesterone		7 days before next cycle is due (day 21)	Same day
Prolactin			Same day
Prostate specific antigen (PSA)			Same day
Proteins (Total protein, albumin & globulin)			Same day
Protein electrophoresis			14 days
RAST (Specific IgE)			21 days
Renal profile (Na^+ K^+ & creatinine)			Same day
Salicylate			Same day
Sodium			Sample day
Testosterone			2 – 3 days
Theophylline		Prior to oral dose	3 days*
Thyroglobulin		For monitoring thyroid cancer patients only	15 days
Thyroid stimulating hormone (TSH)			Same day
Thyroxine (Free T4)			2 days
TPMT	4ml EDTA	Pre azothioprine	14 days
Transferrin			Same day
Tri-iodothyronine (Free T3)		Subject to in house protocol	3 days*
Troponin T		6 hrs after onset of chest pain [a]	Same day
Urate			Same day
Urea			Same day
Valproate		Prior to oral dose	3 days*

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn-around time (routine tests are carried out the same day if received before midday)
Vancomycin	Serum sample ONLY	Please state time of last dose & regime. Contact Microbiology for Clinical Interpretation.	Same day
Vitamin B12			Same day
Vitamin D		Subject to in-house protocol, see guidance in the "Clinical Service" section	7 days
Zinc		Special bottle obtained from lab. Must be a fasting sample [a]	15 days

* Can be carried out urgently if agreed with Consultant Chemical Pathologist/Principal Clinical Scientist.

** Protect from light. Please send both cells and separated plasma (it is not necessary to wash the cells).

*** Not available as part of standard liver test profile.

[a] Not part of standard profile available to general practice

Test name (Tests highlighted in blue denote test sent away)	Sample	Special Requirements	Expected turn-around time (routine tests are carried out the same day if received before midday)
Urine			
Albumin Creatinine Ratio (ACR)	EMU		Same day
Amino acid chromatography	Fresh MSU	Not provided as part of a metabolic screen	10 days
Bilirubin	MSU		3 days
Calcium	24hr collection		Same day
Calcium creatinine clearance ratio (CCCR)	Urine and serum		Same day
Copper	24 hr collection	Special container required, subject to in house protocol	12 days
Cortisol	24 hr collection		21 days
Cystine	24 hr collection	Available as part of a bilateral/recurrent stone protocol	15 days
Drugs of addiction (In house screen)	MSU		Same day
Drugs of addiction (Confirmation)	MSU		7 days
5 HIAA	24 hr collection	Acid preservative required – contact the lab for bottle	15 days
Homocystine	EMU	[a]	7 days
Metadrenalines (Phaechromocytoma screen)	24hr collection	Acid preservative required – contact the lab for bottle	17 days
Mucopolysaccharides (GAGs)	MSU	[a]	19 days
Osmolality	MSU		Same day
Porphyrins	Fresh EMU*	Protect from light	14 days
Porphobilinogen (PBG)	Fresh EMU*	Protect from light	14 days
Potassium	24 hr collection		Same day
Sodium	MSU		Same day

EMU: Early morning urine
MSU: Midstream urine
* Protect from light

** 24 urine protein is not routinely available. We recommend ACR in accordance with NICE Guidelines. In non-diabetic, consider clinically significant proteinuria to be present if ACR is 30mg/mmol or more (this is approximately PCR of 50mg/mmol or more, or a urinary protein excretion of 0.5g/24hr or more). Heavy proteinuria should be considered present when the ACR is 70mg/mmol or more (PCR of 100mg/mmol or more, or a urinary protein excretion of 1.0g/24hr or more).

Test name (Tests highlighted in blue denote test sent away)	Sample	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
Faeces			
Calprotectin	Small plain stool		15 days
Elastase	Small plain stool sample	Must be received in lab within 30 minutes. Subject to in house protocol [a]	15 days
Porphyrins	Small plain stool sample	Protect from light	14 days
Sweat Tests			
Sweat chloride	Collection performed by paediatric department		Same day
Cerebrospinal Fluid (CSF)			
Protein	Plain universal (Bottle 2)	Samples must be received within 2 hours	
Glucose	Fluoride Oxalate		
Lactate	Fluoride Oxalate (plain acceptable)	Paediatric patients only, send to the laboratory promptly	
Xanthochromia	Plain universal CSF SST for serum	Only for ?, SAH, if CT head negative and LP >12 hours post onset of symptoms. Protect from light. Minimum 0.5ml CSF. Serum sample also required	2 working days
Oligoclonal Bands	Plain universal CSF serum also required within 5 days of CSF collection.	Subject to in house vetting procedure. Minimum volume 1ml CSF, 2 ml serum [a]	16 days.

Send away tests are indicated in blue.

[a] Not part of standard profile available to general practice

Add on tests, for inpatients within the Trust, are generally not recommended unless the additional tests are important for immediate patient management or a repeat sample will not be relevant e.g. a paracetamol level on an additional sample taken much later after the overdose. Laboratory staff who receive telephoned add on requests will inform the requestor to send an additional request card, stating that the sample is already in the laboratory and providing clinical information to justify the request. Specialist assays may be vetted for sanctioning by the Consultant Chemical Pathologist or Clinical Scientist. Add-on test requests from General Practice should be requested via the secure email address – **GSTS.Bedford-Addontest.nhs.net.**

If other assays are required, please contact Consultant Chemical Pathologist Dr W. Wassif or Clinical Scientists to discuss.

The following hospitals are routinely used to refer specialist tests for analysis.

Viapath – London (GSTT & Kings)
Royal Free Hospital – London
Imperial College Hospitals – London
Protein Reference Unit – Sheffield
Addenbrooke's Hospital – Cambridge
Great Ormond Street Hospital for Children – London
UCLH Hospital – London

VIAPATH CLINICAL BIOCHEMISTRY REFERENCE RANGES FOR ASSAYS CARRIED OUT ON SITE

Analyte	Clinical Guidance
Albumin	35 – 50 g/L
Urine Albumin/Creatinine Ratio (ACR)	Male <2.5mg/mmol creatinine Female <3.5mg/mmol creatinine
Alkaline Phosphatase (ALP)	Adult 30 – 120 iu/L 0 – 17 yrs 40 – 390 iu/L
Alphafetoprotein (AFP)	< 7 iu/mL
Alaninne Transferase (ALT)	0 -40 iu/L
Ammonia	Male 15 – 55 mmol/L Female 11 – 48 mmol/L
Amylase (Serum)	< 100 iu/L
Aspartate Transferase (AST)	10 – 50 iu/L
Bicarbonate (serum)	22 – 29 mmol/L
Bilirubin (Total) (conjugated)	3 – 20 µmol/L 0 – 5 µmol/L
Beta-2-microglobulin	0.80-2.20 mg/L
Blood Gases:	
PH pCO_2 pO_2 Bicarbonate CO_2 content Base excess Standard Bicarbonate % O_2 saturation	7.35 – 7.45 4.7 – 6.0 kPa 10.0 – 13.3 kPa 22 27 mmol/L 24 – 32 mmol/L $\pm$ 2 mmol/L 22 – 27 mmol/L No reference range

Analyte	Clinical Guidance
Calcium (serum)	>2 – 150 yrs 2.20-2.60 mmol/L 0 – 2 yrs 2.35 – 2.72 mmol/L
Corrected Calcium	± 0.02 mmol/L of Calcium for every g/l variation from an Albumin of 40 g/L. eg. Ca 2.80 Alb 35 Corrected Ca 2.90 Ca 2.80 Alb 45 Corrected Ca 2.70 (Invalid if albumin is <20 g/L)
Calcium (urine)	2.5 – 7.5 mmol/d
Carbamazepine	4 – 12 mg/L
Carboxyhaemaglobin	< 1.5 % of Total Hb (smokers <6.5%)
Chloride	95 – 108 mmol/L
Chloride (sweat)	Less than 40 mmol/L
Cholesterol	See Lipid interpretation
C3 complement	0.75 – 1.65 g/L
C4 complement	0.20 – 0.65 g/L
CA 125	0 – 35 u/mL
CA 153	0-28 u/mL
CA 199	0-34 u/ml
CEA	0 – 4 ug/L
Cortisol(serum)	REFERENCE RANGES/INTERPRETATION 9.00 am: 135-550nmol/L Midnight: Less than 80 nmol/L Short Synacthen test Ideally it should be started about 9am Samples to be taken pre, 30 and 60 minutes post synacthen Adequate response if Cortisol level at 30 mins is greater than 420 nmol/L(not on oestrogen/pregnant) or 640 nmol/L (on oestrogen preparation) Overnight Dexamethasone suppression Test 9.00 am post dexamethasone A Cortisol concentration of less than 50 nmol/L excludes Cushing's Syndrome, but most normal individuals achieve suppression to less than 30 nmol/L
Creatinine(serum)	0 – 1 month 30 – 80 umol/L 1m – 6 years 15 – 40 umol/L 6 y – 12 years 25 – 60 umol/L Over 12 years 60 – 110 umol/L

Analyte	Clinical Guidance
Creatinine Clearance	80 – 120 ml/min
Creatine Kinase (CK)	Male: 40-320 iu/L Female:25-200 iu/L
C-Reactive Protein	< 5 mg/L
Cryoglobulins	Not detected
Digoxin	0.5-1.0 ugl/L
eGFR	See interpretive information in this document
Electrolytes (Na, K and Creatinine)	
Serum	See individual Test
Urine	See individual Test
Ferritin	Male: 20 yrs + 30-400 µg/L Female: 15-50 yrs 15-150 µg/L 50 yrs + 30-400 µg/L
Free light chains	Kappa 3.3-19.4 mg/L Lambda 5.7-26.3 mg/L K/L ratio 0.26-1.65
FSH (Follicle Stimulating Hormone)	Male: 2.0 – 12.0 iu/L Female: Follicular 2.0 – 12.0 iu/L Luteal 3.0 – 9.0 iu/L Levels high mid cycle Post Menopause > 25.0 iu/L
Gentamicin	Refer to normogram for dosage interval. Antibiotic policy is available on the Trust intranet. For endocarditis patients only, maintain pre-dose <1mg/L and post dose (1-2 hours) between 3-5 mg/L
Gamma Glutamyl Transferase (GGT)	5 – 55 iu/L
Globulin (calculated)	15 – 35 g/L
Glucose (sugar) plasma Serum	3.0 – 6.0 mmol/L
CSF glucose	normally 60 % of plasma glucose
Haematinics: Serum B12 and Folate	B12: >150 ng/L Folate: > 4.6-18.7 ug/L
Haemoglobin A1c (Glycated Hb, HbA1c)	< 53 mmol/mol (<7%) suggests good glycaemic control 53-64 mmol/mol (7-8%) suggests fair control, though improvement of glycaemic control is desirable. 64-75 mmol/mol (8.1-9%) suggests inadequate glycaemic control >75 mmol/mol (>9%) suggests poor glycaemic control

Analyte	Clinical Guidance
HDL Cholesterol	See lipid interpretation
ßHCG (human chorionic gonadotrophin)	Non pregnant 0-4 iu/L
Immunoglobulins (IgA, IgG and IgM)	Adult IgA 0.5 – 4.0 g/L Adult IgG 5.0 – 14.0 g/L Adult IgM 0.5 – 2.0 g/L See Protein Electrophoresis SOP book for child ranges.
Iron	Male 10 – 30 µmol/L Female 9 – 27 µmol/L
Lactate	0.50 – 2.00 mmol/L
Lactate Dehydrogenase (LDH)	240 – 480 iu/L
LDL Cholesterol	See lipid interpretation
Lithium	0.50 – 1.20 mmol/L Suggested therapeutic range Therapeutic range of 0.5-0.8 mmol/L may be adequate in prophylaxis.
LH (Luteal Hormone)	Male 2.0 – 9.0 iu/L Female:Follicular 2.0 – 12.0 iu/L Luteal 1.0 – 11.0 iu/L Post menopause >12.0 iu/L Levels high at mid cycle
Magnesium	0.7 – 1.0 mmol/L
Microalbumin (ACR Urine)	Male <2.5 Female <3.5 mg/mmoL creatinine
NT Pro BNP	Units = pgl/mL Interpretation: Normal: <400pg/mL (Heart failure unlikely, consider alternative diagnosis) Intermediate: 400 – 2000pg/mL (Echocardiograph and clinical management plan required. If heart failure confirmed, refer to heart failure clinic) High: >2000pg/mL (refer to rapid access heart failure clinic)
Oestradiol	Premenopausal female 110 -1450 pmol/L, depending on stage of cycle. Untreated post-menopausal female: less than 100 pmol/L Although the test is of limited clinical value in the diagnosis of menopause. Male: less than 160 pmol/L

Analyte	Clinical Guidance
Osmolality (Serum) (Urine)	275 – 295 mOsmol/Kg. Interpret in light of clinical features, serum osmolality and random urine sodium.
Parathyroid hormone (PTH) (Calcium, albumin, phosphate & total protein also to be assayed)	15 – 65 pg/ml
Paracetamol (Serum)	Available for suspected overdose
Phenobarbitone	15 – 40 mg/L
Phenytoin	Adult 10 – 20 mg/L
Phosphate	0-1 mth 1.2-2.8 mmol/L 1-6 mths 1.2-2.1 mmol/L 6 mth – 1 yr 1.2-1.9 mmol/L 1-7 yrs 1.3-1.8 mmol/L > 7 yrs 0.8-1.5 mmol/L
Primidone	Assayed as phenobarbitone
Porphobilinogen	Customised Porphyria report
Porphyrins	Customised Porphyria report
Prolactin (+ Macroprolactin)	Male < 450 mu/L Female < 550 mu/L Customised report
Protein (Serum) (CSF)	60 – 80 g/L < 0.4 g/L
Protein Electrophoresis	Normal Pattern
Potassium (Serum) (Urine)	3.5 – 5.3 mmol/L 25 – 125 mmol/d
PSA	0.5 – 4.0 ug/L Normal, although does not absolutely exclude a localised prostatic cancer. PSA is also raised in other conditions, e.g. BPH, prostatitis, prostatic infarction, UTI, transuretheralresection of prostate (TURP) and prostate biopsy. A rise of >20%/year refer for further investigation.
Progesterone	Levels of <20 nmol/L, probably non-ovulatory. Ovulation likely if level >30 nmol/L. These interpretations apply only for samples taken 7 days before the next cycle.

Analyte	Clinical Guidance
Rheumatoid Factor	< 14 iu/ml
Salicylate	Available for suspected overdose
Sex hormone binding globulin	Male 15-55 nmol/L Female 20-120 nmol/L
Sodium (Serum) (Sweat) (Urine)	 133 – 146 mmol/L < 60 mmol/L Interpret in the light of clinical features + plasma and urine osmolality and serum sodium.
Testosterone	Male 9-29 nmol/L Female 0.2- 1.8 nmol/L
Testosterone/SHBG ratio Free Testosterone Index (FTI)	Male 25-90 Female 0.2 – 5.6 In males low FTI indicates androgen insufficiency In females high FTI indicates androgen excess.
Theophyline	Adult 8 – 20 mg/L Neonate 5 – 10 mg/L
Thyroxine (FT4)	12 –22 pmol/L
Tri-iodothyronine (FT3)	3.1 – 6.8 pmol/L
TSH (Thyroid stimulating hormone)	0.25 – 4.00 mu/L
Transferrin	23-43 umol/L
Troponin T	The following interpretive comments only apply if the sample is taken at least 6 hours after the onset of chest pain: <14 ng/L Myocardial damage may be ruled out. >= 50 ng/L Myocardial damage present. Consider cardiology opinion 14-49ng/L Borderline Troponin T concentration. It would be prudent to repeat test after a further 6 hours. If the clinical picture is that of acute coronary syndrome, consider cardiology opinion.
Urate (Serum) (Urine)	0.1 – 0.4 mmol/L 1.5 – 4.5 mmol/d
Urea (Serum) (Urine)	2.5 – 7.8 mmol/L 250 – 600 mmol/d

Analyte	Clinical Guidance
Valproate	50 – 100 mg/L Some patients are effectively controlled with concentrations below 50 mg/L and others require concentrations far in excess of 100 mg/L
Vancomycin	Maintain dose between 5-15 ug/L. Antibiotic policy is available on the Trust intranet.

LIPID INTERPRETATION

Cholesterol Triglyceride HDL Cholesterol LDL Cholesterol Non-HDL Cholesterol	Fasted sample Calculated test. Valid if patient fasted and Triglyceride does not exceed 4.5 mmol/L	In patients at very high cardiovascular risk (established CVD, type 2 diabetes, type 1 diabetes with target organ damage, moderate to severe CKD or SCORE equal or greater than 10%) target concentrations: - LDL cholesterol less than 1.8 mmol/L - HDL cholesterol ideally greater than 1.2 mmol/L - Non-HDL cholesterol less than 2.6 mmol/L - Fasting Triglyceride less than 1.7 mmol/L

Non Core hours Service

The following tests are available if requested:

Electrolytes and creatinine	CRP
Urea	Bilirubin on paediatric samples (total & direct)
Glucose	Calcium (inc albumin)
Amylase	Magnesium
Bicarbonate	Paracetamol
Chloride	Salicylate
CSF protein	LFT
CSF glucose	CK
Vancomycin	Lactate (grey/white topped vacutainer)

Blood Gases & Carboxyhaemoglobin

Other routine analytes may also be available on the Trust ICE system. Critical results will be telephoned to the requesting physician or to the ward.

Iron and Lithium for overdose cases.

Gentamicin will be analysed if the sample is between six to fourteen hours post dose and the patient is on an 'extended interval regimen', or they are on an alternative regimen.

Anti-epileptic drugs, theophylline and digoxin are not routinely available on call.

Ethanol (dark green topped lithium heparin vacutainer sample) analysed by arrangement with the consultant chemical pathologist.

Osmolality – needs to be specifically requested by a doctor, ICU requests will be analysed on a Sunday between 08:00 and 19:00hrs

Insulin and C-Peptide (red topped vacutainer), will not be processed out of hours (send away tests) but will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP), an insulin request MUST be accompanied by a glucose request.

PTH will not be analysed out of hours but it will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP). A PTH request must be accompanied by a calcium request.

ACTH (2 x translucent lavender topped vacutainer), will not be processed out of hours (send away test) but it will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP). An ACTH request must be accompanied by a cortisol request (sand topped vacutainer).

Ammonia – on call staff in the laboratory need to be contacted, sample (translucent lavender topped tube) needs to be taken on ice and received immediately to the laboratory.

Screening for urine drugs of abuse is part of the on-call profile.

For any other biochemistry tests the Clinical Scientist on call needs to be contacted via switchboard.

For requests for out of hours serology testing, please contact the on-call Consultant Microbiologist, contactable via switchboard.

Clinical Service

The department runs a metabolic clinic and has an active role in the management of patients with dyslipidaemias, porphyrias and other metabolic disorders.

Further information

Additional information, useful suggestions and guidelines of services provided by the Clinical Biochemistry department are described in the following section. (This is by no means a comprehensive list, but if there are any specific problems please phone the laboratory or consultant chemical pathologist to discuss).

Adrenocortical function

Random cortisol measurement is of limited clinical value. If hypersecretion is suspected (i.e. Cushing's Syndrome) then we recommend that cortisol should be measured in a 9am blood sample (SST tube) collected after giving 1 mg of dexamethasone orally at 2300hr the previous evening. If hyposecretion is suspected (i.e. Addison's) then we recommend performing a short synacthen test.

Please note that prednisolone and hydrocortisone suppress the adrenal gland and interfere with cortisol assays. Please contact the laboratory or seek an endocrinological opinion if you need to investigate these patients.

Diabetes Mellitus (DM)

Random Blood Glucose

	Capillary Blood mmol/L	*Venous Plasma mmol/L*
Diabetes likely	≥ 11.1	≥ 11.1

Fasting Plasma Glucose

Diabetes likely	≥ 7.0
Impaired Fasting Glycaemia (IFG)	6.1 – 6.9

> If random plasma or blood glucose ≥11.1 or fasting plasma glucose ≥ 7.0 and the patient has symptoms (polyuria, polydipsia or unexplained weight loss), then further tests are unnecessary and DM is confirmed.
>
> If symptoms are not present, another raised fasting or random plasma glucose concentration is needed to diagnose DM.

Individuals with IFG should have their fasting plasma glucose checked annually. All those with a repeat non-diagnostic fasting plasma glucose (in the IFG range) should have oral glucose tolerance test (OGTT) to exclude/diagnose DM.

If in doubt an oral glucose tolerance test should be performed. A fasting glucose alone may not be diagnostic.

Criteria for gestational DM Fasting glucose sample greater or equal to 5.6 mmol/L and/or 2 hour glucose greater or equal to 7.8 mmol/L (Post glucose load)

Oral Glucose Tolerance Test (OGTT)

Advise patient to fast for about 12 hours overnight following three days of unrestricted carbohydrate diet. 75g of glucose (in the form of Lucozade) is given and blood samples taken at 0 mins and 120 mins.

Glucose meters should not be used for glucose assay during OGTT and a reliable laboratory glucose assay should be used to exclude/diagnose Diabetes Mellitus (DM) with confidence.

The phlebotomy department at South Wing (Tel: 01234 792160) will make appointments for OGTTs within one week if required.

Diabetes Mellitus is diagnosed if:

0 min	plasma glucose	≥ 7.0 mmol/l
120 min	plasma glucose	≥ 11.1 mmol/l

Impaired Glucose Tolerance is diagnosed if:

0 min	plasma glucose	< 7.0 mmol/l
120 min	plasma glucose	≥ 7.8 - < 11.1 mmol/l

Glycated Haemoglobin (HbA_{1c}) is not provided at present for the diagnosis of diabetes mellitus. Glycated Haemoglobin is useful in monitoring treatment. As the life span of red cells is usually about 3 months we would like Glycated Haemoglobin assays requested not less than 10 weeks apart, except in pregnancy or under special circumstances.

Ante-natal

Random plasma glucose is checked between 26-28 weeks gestation. Glucose tolerance test is required for diagnosis/exclusion of gestational diabetes if random plasma glucose ≥ 6.5 mmol/L.

Pregnancy

It is advisable to refer all patients with pre-existing diabetes to the antenatal clinic at the hospital where adequate measures will be taken to monitor the patient during her pregnancy.

Acute Kidney Injury (AKI)

AKI is associated with considerable harm and represents a significant risk to patient safety. AKI is a sudden decline in kidney function and when this happens in the context of acute illness it is associated with significant harm to patients. Because of its silent nature, AKI is often poorly recognised by patients and clinicians alike; as such AKI is associated with high rates of morbidity /mortality and is a major patient safety issue facing the NHS. In line with recommendations and best practice guidance of NHS England and NICE guidelines [CG169] Published in August 2013, AKI alert is reported on Clinical Biochemistry reports.

Microalbuminuria

All adults and children with known diabetes over the age of 12 years not previously diagnosed with microalbuminuria or proteinuria should be screened annually for microalbuminuria. Send a clearly labelled early morning urine to the Clinical biochemistry laboratory. The laboratory will measure the urinary albumin:creatinine ratio (ACR).

Reference values are:

Males <2.5mg/mmol

Females <3.5mg/mmol

If the urinary albumin is found to be grossly elevated (>3800mg/L) then urinary total protein will be reported instead of microalbumin. The patient should be investigated for gross proteinuria in the usual way, to exclude urinary tract infection etc.

A normal microalbumin requires no further action until the next annual routine screen is performed. If the microalbumin is raised then the patient should be asked to provide a further two samples, preferably one week apart within the following three months which will be tested in sequence. Two positive results are required to make a diagnosis of microalbuminuria. If the second sample is positive (result above the reference range) then the third sample will not be analysed. Once a patient has been diagnosed with microalbuminuria, treatment should commence, and the patient's condition should be monitored by submitting urine samples for ACR assay every six months (only a single sample should be sent on each occasion).

Estimated Glomerular Filtration Rate (eGFR)

National Service Framework (NSF) on chronic kidney disease (CKD) recommends eGFR to monitor/diagnose CKD. Consider requesting eGFR as an alternative to creatinine clearance.

eGFR is not validated for use in children <18 years old, acute renal failure, pregnancy, oedematous states, muscle wasting disease states, amputees or malnourished patients.

Reference ranges

Estimated GFR (eGFR) ml/min/1.73m^2

>90 Indicates normal GFR, unless there is a structural abnormality or a functional abnormality such as persistent proteinuria or microscopic haematuria.

60-89 Does not indicate chronic kidney disease unless there is other existing laboratory/clinical evidence of disease.

30-59 Indicates moderate renal impairment. Consider monitoring eGFR 6 monthly.

15-29 Indicates established renal impairment. Consider monitoring eGFR monthly.

15-30 <15 Indicates established renal failure. Consider monitoring eGFR 3 monthly.

For African-Caribbean people only – eGFR should be multipled by 1.212

Further information can be obtained from: Department of Health. National Service Framework for Renal Services. Part Two: Chronic Kidney Disease, Acute Renal Failure and End of Life Care. 2005.

Available at: www.dh.gov.uk/renal.

HRT monitoring

Oestradiol assays are useful to monitor patients on implants. They are of little or no value in patients on oral preparations, as these are first conjugated in the liver, and hence may give a false indication of serum oestradiol levels. Furthermore, conjugated oestrogen preparation produce metabolites which interfere with oestradiol assays.

Serum oestradiol assay is available to investigate postmenopausal bleeding, suspected gonadal / hypothalamic / pituitary disorders and to monitor oestradiol implants.

Human Chorionic Gonadotrophin (hCG)

We do NOT provide this test for the routine diagnosis of pregnancy. If ectopic pregnancy is suspected then we recommend urgent referral of the patient to the accident and emergency department.

hCG is a useful marker to monitor molar pregnancies.

Menopause

We recommend only FSH as the appropriate test to monitor ovarian oestrogen secretion around the time of menopause. Serum oestradiol is not recommended for investigating menopausal symptoms.

Menopause can be identified with certainty a year or more after the LMP.

A wide variety of hormonal patterns of LH, FSH, and oestradiol can occur in the serum during peri-menopause, with raised FSH being the most consistent feature.

However, post-menopausal biochemical parameters are no guarantee of post-menopausal state.

Prostate Specific Antigen (PSA)

Serum PSA values tend to increase gradually with age. It is not unusual to find values of up to 6.5 µg/litre in those over 70 years.

PSA values	Interpretation
0.5 – 4 ug/L	Normal, although does not absolutely exclude a localised prostatic cancer
4 – 10 ug/L	20-25% chance of cancer
10 –59 ug/L	overall 66% of patients will have prostatic cancer
> 60 ug/L	Usually indicates metastatic prostatic cancer
A rise of >20% / year	Refer for further investigation

PSA is also raised in other conditions, e.g. BPH, prostatitis, prostatic infarction, urinary tract infection, urethral catheterisation, retention of urine, transuretheral resection of prostate (TURP) and prostate biopsy.

Despite the lack of specificity of PSA for prostate cancer, at present it is the best tumour marker for the disease. Follow up PSA tests are valuable to monitor the management of prostate cancer, and to monitor men with equivocal results.

It is normally recommended to wait at least 6 weeks after prostate biopsy or TURP before obtaining a serum PSA level.

Prostate cancer can progress very slowly and it is often said that more elderly men die with prostate cancer than from it. Perhaps PSA testing should only be considered for men with a life expectancy of 10 years or more.

Digital rectal examination (DRE) provides the cornerstone of the physical assessment for prostatic disease. A PSA should not be carried out without a DRE, and all patients with abnormal DREs should be referred to an urologist.

Changes in PSA usually take place fairly slowly and steadily and it is usually unnecessary to repeat PSA more frequently than every three months. A sudden rise in PSA to unexpectedly high levels should be confirmed before any action is taken as coincidental conditions such as prostatitis can occur in men with prostate cancer.

Finasteride, a 5-α reductase inhibitor used in the treatment of BPH, reduces PSA by 50% after 12 months of therapy. If a patient has a PSA level determined before starting finasteride and a subsequent level after 12 months does not fall below 75% of the pre-treatment level, it would be prudent to re-evaluate for prostate cancer.

Parathryoid Hormone (PTH)

PTH assay is available to investigate

Rhabdomyolysis

Request a serum Creatine Kinase (CK) and a renal profile. In acute rhabdomyolysis, there is severe muscle destruction and serum CK activities may exceed 50 times the upper limit of the reference range.

Subfertility investigations for females

First line biochemical investigations include FSH, LH, Prolactin, Testosterone and Progesterone if the patient is menstruating.

Blood for FSH/LH should be taken during the follicular phase (days 1 – 5).

Progesterone assays are useful in detecting ovulation or anovulatory cycles. Best done during mid luteal phase (7 days before the next cycle is due). It has no place in other conditions.

Subfertility investigations for males / erectile dysfunction

The most useful biochemical investigations are serum FSH, LH, Testosterone, SHBG and Prolactin.

Tumour markers

Tumour markers are non-specific and are not useful as screening tests. High concentrations may occur in many benign conditions and in the absence of a tumour. If a tumour has not been identified it may be inappropriate to randomly request tumour markers to identify the primary tumour. Generally tumour markers are valuable in monitoring treatment of patients known to have malignancies and in follow up to detect recurrence.

CA 125

There are a variety of conditions in which raised values are obtained, e.g. endometriosis, pelvic inflammation etc. CA 125 is useful in monitoring treatment for carcinoma of the ovary. If there is a family history of carcinoma of the ovary (1 or more members of the family) or if ovarian mass is present then full screening procedures, including assay for CA 125, need to be done. The Department provides CA125 analysis in line with ovarian care NICE guideline 122 (April 2011)

Clinical utility of other tumour markers

Other tumour markers useful in monitoring therapy and follow up include:α–fetoprotein (AFP, hepatocellular iphtheri and testicular tumours), human chrionic gonadotrophin (hCG, choriocarcinoma and testicular tumours), carcinoembryonic antigen (CEA, colorectal cancer), CA19-9 (adenocarcinoma of pancreas) and CA15-3 (carcinoma of breast).

Therapeutic drug monitoring

Usual blood sampling times for oral preparations

Anti Epileptics	Collect just prior to the oral dose
Digoxin	Collect at least six hours post dose
Lithium	Collected approximately 12 hrs post-dose
Theophylline: Peak	* 2 hours after rapid release preparations * 4 hours after sustained release preparations
Trough	* Immediately before oral dose

Thyroid function tests

	Reference range
TSH = Thyroid Stimulating Hormone	0.25 – 4.00 mU/L
FT4 = Free Thyroxine	12 – 22 pmol/L
FT3 = Free Triodothyronine	3.1 – 6.8 pmol/L

Screening

TSH is the first line of investigation. If TSH is less than 0.60 mU/l, a FT4 will be organised.

If TSH is high, greater than 4.0 mU/L but less than 50.0 mU/L, a FT4 will be organised.

T3 thyrotoxicosis will be excluded where appropriate by assaying FT3 in those patients with suppressed TSH but normal FT4.

In patients with compensated/borderline hypothyroidism who are not on thyroxine replacement and are being monitored it is prudent to check thyroid antibodies and monitor TFT every two to three months.

Patients on replacement therapy

TSH will be performed in all patients.

FT4 will be organised in patients on thyroxine replacement with abnormal TSH

FT3 will be organised in patients on T3 replacement with abnormal TSH

It is usually unnecessary to monitor TFT more frequently than every two to three months. Less frequent long-term monitoring is needed in patients who are clinically and biochemically euthyroid.

Patients on suppressive therapy

TSH and FT4 will be assayed in all patients on suppressive therapy.

> Thyroid Function Tests may be misleading when requested in patients who are ill from non-thyroidal illness. It is usually unnecessary to screen for thyroidal illness in these situations and TFT should be organised when patient is well.

Vitamin D

Recently the focus has shifted to the importance of Vitamin D plus or minus calcium supplements rather than testing for Vitamin D status. NICE Guidelines of November 2014 recommend Vitamin D supplements in groups at risk of Vitamin D deficiency and do not routinely recommend Vitamin D testing in these groups. Similarly the National Osteoporosis Society guideline recommends Vitamin D supplements in these groups and do not recommend routine Vitamin D testing. Vitamin D assay is available if corrected calcium is <2.25mmol/L (ref range 2.2 – 2.6mmol/L) and is not recommended to monitor patients on Vitamin D replacement. In this situation monitoring serum calcium is recommended.

High risk samples

All 'high risk' samples should be clearly identified with a tick √ in the high risk box □ on the request card. The card, sample and bag in which the sample is transported in should have a 'high risk' sticker or a label clearly identifying 'high risk sample' on them to alert the user for additional precautions that need to be taken when handling the sample.

Overnight storage of blood samples

Every effort should be made to send the sample to the laboratory on the same day. However in exceptional circumstances, some useful information may be obtained after overnight storage of blood sample if the following are observed.

Fluoride Oxalate tubes (grey cap) for glucose or EDTA (translucent lavender cap) for HbA1c may be unaffected by overnight storage at room temperature.

Serum Separation Tube samples (sand cap) stored upright at room temperature i.e. 20 ºC overnight may well be suitable for some routine tests. However, artefactual elevation of serum potassium, phosphate and some liver enzymes are expected and make these assays unreliable.

However if Serum Separation Tube samples are stored in:

a) a refrigerator (which may be close to 0 ºC)
b) a hot place e.g. near a radiator or on a sunny window sill
c) a car boot (which may be either hot or cold)

Considerable changes to some analytes will occur, e.g. high potassium, high phosphate, low sodium and low calcium etc. etc. In short, results will be unreliable.

As storage conditions are beyond laboratory control and any changes to analytes cannot be quantified the laboratory will merely comment as follows:

1) Date of specimen collection (if known) and date received will be documented.
2) Haemolysed – this can be caused by poor or prolonged storage or difficulty with venepuncture and will cause increase in potassium, phosphate and some enzymes.

If your surgery has a centrifuge the following procedure will enable SST samples to be stored in a refrigerator (4 ºC – 6 ºC) for 24 hours perhaps without significant change to routine analytes.

Centrifugation of blood samples in SST tubes

1. Take blood sample from patient using normal Vacutainer procedure.
2. Mix blood by gentle inversion 6 times.
3. Allow sample to clot for 15–30 minutes.
4. Centrifuge for ten minutes at 3000 rpm.

(Time and speed may vary for different capacity centrifuges. The laboratory would be happy to advise; please telephone Service Delivery Manager 01234 792165).

NOTE: The gel in the tube has now formed a barrier between cells and serum.

5. Store the sample upright in a refrigerator at +2.0'C to +4.0'C

NB – **Never** centrifuge an SST more than once for any reason

2a. Serology (A CPA Accredited Laboratory)

The Microbiology department offers a range of serological screening tests and a referral service for investigations not performed 'in-house'.

Serology tests can be used to diagnose infections by assessing the patient's antibody response to a particular infective agent. IgM is the first to rise, and presence is indicative of a present or recently acquired infection. Some IgM tests are available but for other infections tests for IgG are used. The IgG antibody response will usually take 10-14 days to occur (but may sometimes be longer). If the duration of a patient's illness is <10 days then an 'acute' serum sample should be collected at this time and a convalescent sample taken 10-14 days later.

A serological diagnosis can be made when the following can be demonstrated:

- There is an increase in antibody titre from the acute to the convalescent serum samples (usually fourfold or greater).
- A stationary but high antibody titre in both samples.
- A fall in titre of antibodies can be regarded as evidence of recent infection.
- IgM is detected.

The following details should be included with <u>ALL</u> serological requests:

- Date of onset of symptoms.
- Relevant clinical details including history of travel, contact dates and any other appropriate information including vaccination history.
- Risk factors

The laboratory cannot process specimens or interpret the result without sufficient clinical information.

Label all specimens and request forms with HIGH RISK stickers if patient known or suspected to be high risk. For investigation of HIV a SIGNED request form is essential.

Serology, bacterial, viral, parasite and fungal

For all serological procedures it is important that all relevant clinical details including the date of onset of symptoms, and any risk factors are stated on the request form.

Samples will be processed according to the details stated on the form or in line with laboratory protocol.

The following tests are available on-site:

- Syphilis serology (*Treponema pallidum* antibodies)
- *Helicobacter pylori* serology (Serum IgG only)
- ASO titre
- *Toxoplasma gondii* Total antibody (IgM,IgG) (screening assay)
- Hepatitis B virus surface antigen and surface antibody
- Hepatitis B Total core antibody

- Hepatitis A virus IgM and Hepatitis A Total antibody (IgM, IgG)
- CMV IgM & IgG
- Hepatitis C virus antibody/antigen
- HIV 1 & 2 antigen/antibody
- Rubella virus IgG
- Rubella virus IgM
- Varicella-zoster virus IgG (to check for immunity to chicken pox)
- Measles IgG

In house assays are generally available two to three working days from receipt.

Many other serological tests are referred to specialist laboratories e.g. Colindale HPA. The following are some of the commonly requested specialist investigation:

- Amoebic serology
- Aspergillus serology
- Atypical pneumonia screen
- Avian precipitins
- Borrelia serology
- Cryptococcal serology
- EBV serology
- Hydatid serology
- Leptospira serology
- Mumps serology
- Parvovirus B19 serology
- Schistosoma serology
- Staphylococcal serology
- Toxocara serology

Any enquiries regarding specialist investigations please contact the laboratory on Ext. 4814. All serological tests require clotted blood samples.

In case of any molecular investigations such as HIV, HBV and HCV viral loads, CMV PCR, and neonatal HIV diagnosis, EDTA sample is required (see specimen requirements and containers section below).

Turnaround time for sendaway serology – generally 10-14 days from receipt in laboratory.

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
Amoebiasis/Hyatid/Schistosomal	5ml clotted blood– red and yellow top	Reference laboratory request – will only be sent if full travel history and risk factors are given	2-3 weeks
ASOT	5ml clotted blood – red and yellow top	Fairly non-specific test of limited value	Once daily
Aspergillus precipitins	5ml clotted blood– red and yellow top	Reference laboratory request – risk factors and date of onset must be given.	10-14 days

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
Atypical Respiratory Screen– Legionella, Chlamydia (Psittacosis), Mycoplasma, Influenza A &B, Q Fever (Coxiella)	Acute and Convalescent serum samples required taken 10-14 days apart. 5ml clotted blood – red and yellow top	If atypical pneumonia is suspected and sputum samples are negative for culture. Sent to Reference laboratory Samples will NOT be sent unless date of onset is given and any travel history.	10-14 days
AVIAN antibodies	5ml clotted blood– red and yellow top	Reference laboratory request – risk factors must be given e.g. keeps birds	10-14 days
BRUCELLA ANTIBODIES	5ml clotted blood– red and yellow top	Reference laboratory request – details of travel history must be given as well as risk factors e.g. eating unpasteurised cheese. Date of onset and clinical history must be given.	10-14 days
CAMPYLOBACTER SEROLOGY	5ml clotted blood – red and yellow top	Reference laboratory request – Please give full clinical details e.g. Guillain-Barre syndrome	10-14 days
CMV IgG/M Screen	5ml clotted blood– red and yellow top. Citrated blood required for PCR	Infection usually only of clinical significance in immunocompromised or pregnant patients.	1-2 days during working week
DENGUE FEVER, RICKETTSIA, ZIKA VIRUS, HAEMORR-HAGIC FEVER, TYPHUS, WEST NILE VIRUS, SARS etc	DO NOT TAKE SAMPLE without contacting Consultant Microbiology	CONTACT Consultant Microbiologist	
EBV	5ml clotted blood – red and yellow top.	Suggest send sample for Monospot in the first instance. If negative and EBV remains a differential diagnosis send sample for EBV testing.	Sent to reference laboratory – 7 – 10 days
Enterovirus (including Coxsackie)	5ml clotted blood – red and yellow top.	Reference laboratory request – Please give full clinical details –only available if diagnosis is pericarditis.	1-2 weeks

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
Haemophilus, Pneumococcal,Tetanus Antibodies		Sent to reference lab	2 weeks
HEPATITIS A IgG	5ml clotted blood with gel – red and yellow top	Immunity check.	1-2 days during working week
HEPATITIS A IgM	5ml clotted blood – red and yellow top	Transmission usually occurs enterically through: Person to Person contact Ingestion of contaminated food or water	1-2 days during working week.
HEPATITIS B Surface Antibody	5ml clotted blood – red and yellow top	Post vaccine	1- 2 days during working week
HEPATITIS B Core Total Antibody	5ml clotted blood – red and yellow top	Indicator of current or previous HBV infection. Should be requested in cases of household contact. Automatically performed on non-responders to Hepatitis B vaccine.	1-2 days during working week. Confirmation from ref lab usually 10-14 days
HEPATITIS B Surface Antigen	5ml clotted blood – red and yellow top	Transmission routes: Percutaneous, Permucosal, sexual.	1-2 days during working week. Confirmation from ref lab usually 10-14 days.
HEPATITIS C antibodies	5ml clotted blood – red and yellow top	Transmission routes: Percutaneos Permucosal PLEASE NOTE – incubation period is 2-26 weeks.	1-2 days during working week. Confirmation from ref lab usually 1-4 weeks
HERPES SIMPLEX antibodies	5ml clotted blood – red and yellow top	Herpes simplex antibodies of little value in diagnosing current infection. VIRAL SWAB of lesion preferred. Reference laboratory request.	Sent to reference laboratory daily. 7 -10 working days.
HERPES SIMPLEX PCR	Swabs (Green viral Swab)	Sent to reference laboratory.	7 – 10 working days
HIV 1 & 2 Ag/Ab	5ml clotted blood – red and yellow top Confirmatory sample should be taken in EDTA.	Transmission routes: Percutaneous Permucosal Sexual	1-2 days working days. Confirmation from ref lab usually 10-14 days.

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
HIV REQUEST NEONATE BORN TO HIV POSITIVE MOTHER	EDTA Sample within 24 hours of birth. Repeat at 6 weeks, 3 months and 6 months.	EDTA sample must also be taken from mother at time of birth so that primers can be checked.	10-14 days
LYMES DISEASE – Borrelia burgdorferi	5ml clotted blood – red and yellow top	Reference laboratory request – risk factors such as insect bites and travel history must be given as well as onset and nature of symptoms.	10-14 days
Meningococcal PCR and antibodies	EDTA sample for PCR	PCR request sent to Ref lab. Antibody sample should be collected 3 weeks after onset of infection – is only of value for retrospective diagnosis.	PCR 3 – 5 working days Antibody – several weeks
MUMPS antibodies	5ml clotted blood – red and yellow top If current infection is suspected Saliva testing kit should be requested from Colindale 020 8200 6868 ext 4412	Reference laboratory request suitable for 'at risk' contacts of confirmed cases only. Post vaccination antibody levels will not be tested as are not appropriate.	10-14 days
NEEDLESTICK INJURIES/ HUMAN BITES etc	5ml clotted blood – red and yellow top	MUST state whether donor or recipient of injury. Should discuss such cases with Consultant Microbiologist and/or CCDC. Hepatitis B antibodies and serum save will be run on recipient's serum. Tests on donor blood will only be run if permission is given.	1-2 days during working week. Service not available over weekend or bank holidays.
PARVOVIRUS IgG / IgM	5ml clotted blood – red and yellow top	Please give full clinical details and date of onset. Sent to reference laboratory	7-10 days during working week.
RUBELLA IgG	5ml clotted bloodl – red and yellow top	Antibody levels >10 iu/ml considered as immune	1- 2 days during working week
RUBELLA IgM	5ml clotted blood – red and yellow top	Please give full clinical details and date of onset of symptoms	1-2 days during working week
SYPHILIS SEROLOGY	5ml clotted blood – red and yellow top		1-2 days during working week Positives sent to

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
			ref lab for confirmation. 10 - 14 days
TOXOPLASMA IgG	5ml clotted blood with gel – red and yellow top.	Animal transmission. Particular concern in pregnancy.	Tested daily (Mon-Fri) Positives sent to ref lab for confirmation
VZV IgG	5ml clotted blood – red or yellow topped	Please state whether patient is pregnant or immune-compromised. Date of contact MUST be given.	Run daily (Mon-Fri)
VZV PCR	Fluid for vesicle – Green viral swab		7 – 10 working days
VZV IgM – very rarely indicated as Chicken pox is a clinical diagnosis.	5ml clotted blood – red and yellow top	Sent to Reference laboratory. Rarely necessary as Chicken Pox is essentially a clinical diagnosis	Positive results phoned Negative results 10-14 days
WEILS DISEASE – Leptospira antibodies	5ml clotted blood – red and yellow top	Reference laboratory request. Full details of risk factors e.g. sewage worker, ingested river water etc must be given. Date of onset and clinical details also required.	10-14 days

Specimen requirements and containers

General viral serology***	5ml clotted blood in plain tube.
HIV antibodies	5ml clotted blood in plain tube.
CMV PCR	5ml blood in EDTA
CMV (in urine)	Universal, half filled
HIV viral load	7-8ml blood in EDTA
Meningococcal & Pneumococcal PCR	1-2ml blood in EDTA
Herpes simplex	Swab from vesicle fluid in 1ml HSV transport medium from Microbiology
HIV maternal transmission	1-2ml blood in EDTA (baby and mother samples should be sent in tandem)

***For most viral serology paired sera are required, an acute, as early during the illness as possible and a convalescent 10 days afterwards.

Due to the large number of serological tests and groups of tests, and the number of different reference laboratories to which they are sent, it is not possible to state exactly the volume of serum required. Please telephone ext. 4814.

3. Haematology (MHRA Compliant Laboratory)

Key contacts

	Direct line (01234)	Internal Ext.
Haematology Results and General Enquiries	792150	4811
Consultant Haematologist	792145	2446/Bleep 264
Consultant Haematologist		2385
Consultant Secretary	792145	2445
Mr S Hyare, Blood Sciences SDM	01234792165	4722
Ms A Nubi, Operational Manager	01234 355122	4657
Ms A Nubi, Blood Transfusion Manager		Bleep 331
Referral Laboratory	01234 355122	4668

Location.

The Haematology and Blood Transfusion laboratories are located on the first floor of the pathology building on the South Wing site. Access is via the hospital main corridor. Phlebotomy services are **only** available in the Outpatient Department, South Wing and Gilbert Hitchcock House at North Wing. Paediatric phlebotomy services are available from Riverbank children's ward. The laboratory is unable to offer phlebotomy services.

Opening times.

Routine services.

	Enquiries	Specimens
Monday to Friday	8.00 am – 8.00 pm	8.00 am – 8.00 pm
Saturday	8.00 am – 12.30 pm	8.00 am – 12.30pm Urgent specimens only

Specimens for all pathology departments should be left at specimen reception located on the first floor of the pathology building. Access is via the hospital main corridor. A lift is available.

Blood Sciences Laboratory incorporating Clinical Biochemistry and Haematology /Transfusion operate a full 24/7 shift service.

The full range of tests are available 08:00 – 20:00 Monday – Friday and 08:00 – 12:30 Saturday.

At all other times a reduced staffed core service will be available

Reduced Core Service hours:

Haematology/Blood Transfusion:
Between 17.00 and 20.00 may be contacted on extensions 4833/4653

A consultant haematologist is available via hospital switchboard for clinical advice and interpretation.

Urgent samples will always be processed by the department.

Only contact the on-call staff for any work after midnight or for any cross-matching request. All other specimens will be processed as timely as possible. The Biomedical Scientist may be contacted via switchboard or on bleep 474.

Turnaround times and sample requirements

Turnaround time for Haematology and Blood Transfusion specimens may depend on the tests required.

It is the responsibility of the doctor to arrange for blood samples to be taken into the correct sample tube and arrive at the pathology department in good time to be analysed. GPs may send their patients to be bled by the phlebotomists Monday to Friday during normal working hours. Please note that after 12.30 pm waiting times will be considerably shorter. At present a satellite phlebotomy station is available at North Wing where arrangements are similar, except on Fridays when the station is closed.

A collection service for those GP Practises that provide phlebotomy services is in operation.

Samples for **full blood counts** are normally analysed on the day of receipt and results returned via electronic link (Sunquest ICE) and/or by paper result. Samples taken after the Courier collection can be stored overnight at room temperature with no significant deterioration in quality.

Urgent or very abnormal results will be telephoned as soon as possible. Relevant clinical information is of value in interpreting results e.g. in patients on chemotherapy. Failure to give this may generate unnecessary additional tests and delay the issue of results.

In the event of an **unexpected abnormal result** the laboratory will usually carry out further relevant haematological tests, e.g. Direct Antiglobuilin Test (Coombs Test) when the blood film suggests possible haemolysis. The Consultant Haematologists are available for advice or interpretation of results.

The following tests are performed and the results will normally be available within one working day, except where indicated:

Test	Sample required
FBC	**EDTA** (1 X 3ml mauve top)
ESR	**EDTA** (1 X 3ml mauve top)
I M screen	**EDTA** (1 X 3ml mauve top)
Reticulocytes	**EDTA** (1 X 3ml mauve top)
Sickle-cell screen	**EDTA** (1 X 3ml mauve top)
R A test (3 working days)	**Serum** (1x 6ml red top)
Rhesus immunisation tests (incl. Kleihauer)	**EDTA** (1 X 3ml mauve top)
Malaria identification	**EDTA** (1 X 3ml mauve top)
Direct Antiglobulin test ("Coombs Test")	**EDTA** (1 X 3ml mauve top)
G 6 P D screening test	**EDTA** (1 X 3ml mauve top)
Coagulation Screening	**CITRATE** (1 X 3ml blue top)
INR	**CITRATE** (1 x 3ml blue top)
Atypical Blood Group antibody ID (normally within 2 working days)	**EDTA** (4 X 6 ML pink top)
Blood Group & Antibody screen	**EDTA** (1 X 6 ml pink top)

The following tests are batched and performed on a batch basis and results are normally available within one week.

Haemoglobinopathy screening (for thalassaemia and abnormal haemoglobins)	**Serum plus 2 EDTA samples**

The following tests are normally available only after arrangement with the haematologist:

Bone marrow aspiration and related cytochemistry

Trephine biopsy

Requests for other tests should be directed to either the Clinical Haematologists or Service Delivery Manager. Thrombophilia screening, HLA identification and cytogenetic studies are sent to specialist centres. Information regarding turnaround times and specific sample requirements can be obtained from the laboratory

Immunology testing is performed at another centre; samples are received in Haematology for onward travel. Most immunology testing is performed from **SST** tube (sand top). Further details regarding Immunology may be obtained from the referral department in Haematology.

Limitations and special precautions

Coagulation screens and D-Dimers **MUST** be tested within four hours of being taken. Additional coagulation testing may require processing within 2 hours from Phlebotomy – seek advice from the laboratory

ESR may be added to a sample taken the same day

Blood film requests may be added to samples taken the same day

I.M screening may be added to samples taken the same day

Group and Save samples are kept for six days for cross-matching

Samples must never be stored in direct sunlight, carried on the parcel shelf of a car, or left near a radiator as these factors will directly interfere with results. Samples should reach the department on the same day. Where this in unavoidable, please contact the laboratory for specific storage instructions.

Completion of request forms.

All samples must be accompanied by a fully compliant request form. Information from the request card is transferred to the laboratory computer system. Illegible handwriting may lead to poor data transfer and incorrect filing of patient results.

Addressograph and other pre-printed labels must not be used on any sample sent to the Blood Transfusion department. They can however, be used on the request form. Unsatisfactory Blood Transfusion request forms may in some cases be returned to the ward for correction and may lead to a delay in blood issue

Identification of high risk specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a **known or suspected** infection due to Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

HIV 1 and 2
Hepatitis B virus
Hepatitis C virus
Brucella spp.
Salmonella typhi & iphtheri (typhoid)
Mycobacterium tuberculosis (TB)
HTLV 1 and 2

And the causative agents of:-

Anthrax
Rabies
Plague
Creutzfeldt-Jakob disease and vCJD
Yellow Fever

Sample labelling.

It is essential that specimens are correctly identified otherwise:

- a patient may receive the wrong treatment
- a patient may not receive the treatment that they require

All specimens **must** be labelled with:

- The patient's first name
- Surname
- Date of birth
- Hospital or NHS number
- The date/time of specimen.

Inadequately labelled specimens will not be examined and a report will be produced

"Inadequately labelled specimen received. Not processed. Please repeat."

Where there are clerical errors, omissions or quality issues with the sample, this will lead to immediate rejection by the laboratory.

Unrepeatable specimens

It is unlikely that samples for Haematology are genuinely unrepeatable
In the unlikely case of poorly labelled, unrepeatable specimens such as bone marrow aspirates, the requesting doctor will be given the opportunity to identify the specimen. The doctor will be asked to sign to accept responsibility for identification.

Re-Labelling of samples for Blood Transfusion is not permitted.

Sample transport

All specimens must be in blood collection tubes of approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers must be further contained within the specimen transport plastic bag attached to request card. Where mini-grip bags are used, the request card must be placed in the appropriate pocket away from possible sample leakage. Leaking specimens are hazardous and may be destroyed. The pneumatic tube system may be used to transport specimens in accordance with the rules of use of the system. *(Pneumatic Tube Policy is available on the Hospital Intranet – online facilities).*

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations.

Haematology transport bags, which are supplied to GPs, have an absorbent pad. These, used in combination with the hospital courier service, will ensure compliance with the regulations.

Normal ranges.

HAEMOGLOBIN g/dl	Men	130-180
	Women	115-165
	Child 3 months	95-135
	Child 1 year	105-135
	Child 3-6 yrs	120-140
	Child 10-12 yrs	115-145
MCV fl	Adult	76-96
	Child 3 months	95 (mean)
	Child 1 year	70-86
	Child 3-6 yrs	73-89
	Child 10-12 yrs	77-91
MCHC g/dl	Adult and Child	310-360
MCH pg	Adult	27-32
	Child	24-31
RDW	Adult and Child	11·5-14·5%
WHITE CELLS TOTAL		
	Adult	4·0-11·0
	Child 1 year	6·0-18·0
	Child 4-7 yrs	5·0-15·0
	Child 10-12 yrs	4·5-13·5
Neutrophils	Adult	2·0-7·5
	Child 6 yrs	2·0-6·0
Lymphocytes	Adult	1·5-4·0
	Child 6 yrs	5·5-8·5
Monocytes	Adult	0·2-0·8
	Child 6 yrs	0·7-1·5
Eosinophils	Adult	< 0·4
	Child 8 yrs	0·3-0·8
PLATELETS		150-400
RETICS		up to 2%
E.S.R.	Men < 50 yrs	1-7 mm
	> 50 yrs	2-10 mm
	Women< 50 yrs	3-9 mm
	> 50 yrs	5-15 mm

The International Normalised Ratio (INR) is performed for routine Warfarin treatment control and APTT for the control of heparin therapy.

Normal therapeutic ranges are as follows:

		INR
Routine anticoagulation following DVT or PE		2·0 – 3·0
High risk patients (prosthetic valves and grafts, recurrent thromboembolism)		3·0 – 4·5
		APTT
Control of Heparin therapy (by iv pump) (LMW heparin is not monitored)		40 – 60 secs
Prothrombin Time	normal:	9.5 – 12.5 secs
APTT	normal:	23 – 31 secs
D-Dimer (for PE & DVT diagnosis):	normal:	up to 0.55FEU mg/L
Clotting factor inhibitor tests	normal:	not present
Fibrinogen	normal:	2·0 – 4·0 g/l
Anti Xa assay (for control of LMWH)	Available for specific patients only.	

Seek advice from the Consultant Haematologist.

The advice of the Consultant Haematologist should be requested for patients with more serious coagulation defects – particularly if surgery is planned – or for investigation of bruising.

More detailed clotting studies, including factor assays (e.g. Factor VIII, Factor IX), are also available but only after discussion with a Consultant Haematologist.

Tests for thrombophilia and platelet function are sent to a reference laboratory. If required please refer to Consultant Haematologist.

Clinical Haematology

Bedford Hospital NHS Trust provides a Clinical Haematology Service covering all aspects of blood disease.

Inpatients

Inpatients are managed jointly with Consultant Physicians. Patients are admitted for blood transfusion, platelet transfusion, chemotherapy for chronic leukaemias, myeloma and some lymphomas, treatment of some coagulation disorders, treatment of thrombocytopenia, management of sickle cell crises and other haemoglobinopathy problems. An increasing number of patients can be managed as day cases. This would include simpler chemotherapy, i.v. immunoglobulin therapy, venesection and clotting factor replacement and blood transfusion.

Outpatient referrals

Outpatient referrals are all seen by a Consultant Haematologist. Advice on the suitability of a referral can be obtained by telephone throughout the working day.

Suitable cases might include:

Iron deficiency

Iron deficiency which is unexpected or unusual – most cases will be due to bleeding which should be investigated unless obvious. Many such patients may be better served by direct referral to a physician for endoscopy etc. “Failed iron therapy” is often due to inadequate therapy (two to three months may be needed to get iron stores back to normal) – or due to an inadequate iron preparation (slow-release types e.g. Feospan and Ferrogradumet).

Unexplained macrocytosis

Unexplained macrocytosis (MCV>100) or persistently low B12 or Folate levels; Patients with severe macrocytic anaemia (Hb<8·0) should be referred immediately. Mild macrocytosis is quite common and is often due to excessive alcohol consumption – a high urate and GGT will confirm this in most. However in the elderly dietary folate deficiency seems to be common and macrocytosis is also a feature of the Myelodysplastic Syndrome (MDS) – see below. Other causes of a high MCV include liver disease, myeloma, COPD, hypothyroidism and treatment with cytotoxic drugs.

Unexplained anaemias

Other unexplained anaemias. Note that many chronic conditions and diseases lead to a mild to moderate anaemia which may be normochromic or mildly hypo-chromic and needs no investigation. Patients leading sedentary lives can often cope very adequately with moderate anaemia (Hb 8-10).

Neutropenia

Neutropenia in young patients may be due to a recent virus infection but if persistent or severe further investigation is essential. SLE can present in this way and tests for ANF may be appropriate.

Low platelet counts

Low platelet counts are increasingly common. Immediate referral is advised if very low (<20). Counts below 100 may require further investigation. Counts between 50 and 100 are unlikely to cause any bleeding/bruising but may be a problem for surgeons. Usually spontaneous bleeding does not occur until the count is significantly less than 20. Possible causes are: ITP, alcoholic and other liver disease, drug therapy (diuretics may be an important cause in the elderly). Incipient leukaemia and MDS are important causes but usually there will be other indications (neutropenia, anaemia, blasts). Pregnancy is often accompanied by mild thrombocytopenia in the last trimester – the principles already indicated apply.

The cause of a **High WBC** will usually be obvious but consider the following if in doubt:

Neutrophilia –	early stage of Glandular Fever ,steroid therapy previous splenectomy
Monocytosis –	often occurs in recovering phase of infection may be CMML (MDS)
Lymphocytosis –	viral infection, previous splenectomy

Lymphocytosis

Lymphocytosis may be the first indication of underlying CLL, however unless there is marked lymphadenopathy or splenomegaly, anaemia and/or low platelets only observation is necessary. A FBC every two to three months will be adequate in most cases. Treatment is rarely needed in the early stage and many patients will not require intervention for many years particularly if the lymphocytosis was discovered by chance. Confirmation of C.L.L. requires Immunophenotyping. Now that differential counts are carried out routinely it is clear that transient lymphocytosis occurs in many “traumatic” situations and does not indicate bone marrow disease. If in doubt, repeat.

Lymphopenia

Lymphopenia is common in the elderly and also occurs after chemotherapy (sometimes persisting for many months) and in patients with chronic renal failure. It is often seen in HIV+ve people. **Chronic Myeloid and Acute Leukaemias** will usually be easy to diagnose, often by the laboratory first but if in doubt please refer.

Chronic and acute myeloid leukaemia

Chronic and acute myeloid leukaemias will usually be identified first by the laboratory but if in doubt please refer to the Consultant Haematologist.

Myelodysplasia

Myelodysplasia or the Myelodysplastic Syndrome (MDS) seems to be increasing, possibly due to an increasingly aged population but also an increasing awareness of its subtleties. Characteristic changes are often seen on the blood film but many patients will have only anaemia/neutropenia/low platelets in varying degree. A bone marrow will often be diagnostic but in view of the limited therapy options at present it may be sensible to delay this until intervention is necessary – usually this will be the need for transfusion. The outlook in MDS is very variable.

All patients with **Hodgkin’s Disease or Non-Hodgkin’s Lymphoma (NHL)** require specialist attention, however a “tissue diagnosis” will usually be necessary. Isolated enlarged lymph nodes will require excision and referral without delay to a surgeon is essential. Other patients with probable lymphoma will almost certainly need complex diagnostic procedures and should be referred to the Consultant Haematologist.

Myeloma

Myeloma may present with bone pain, symptoms which suggest a high calcium level (nausea, constipation, thirst, confusion), or just a high ESR (usually >100). Protein electrophoresis, urine analysis for protein or X-ray of the painful bone will often suggest the diagnosis. Bone marrow aspiration is mostly needed. Most patients can be treated in the OPD but hypercalcaemia is a medical emergency. Radiotherapy is often useful for bone pain.

Polycythaemia

Polycythaemia may be secondary to cyanotic heart disease, COPD or diuretic therapy. Occasionally it will be due to a renal tumour. Heavy smoking and alcohol consumption may lead to a high haematocrit but the level is not usually more than 0·55 (HB 18·0) Patients with

levels significantly higher than this may have a myeloproliferative disorder (PRV) and should be referred. They will also often have high neutrophil and platelet counts and uric acid level. The spleen may be enlarged. Some will appear to have iron deficiency and the high Hb will not become apparent until iron therapy is given.

Thrombocythaemia

Thrombocythaemia may be secondary to a number of unrelated conditions. This "reactive" change often parallels the ESR. If the count is very high (>1000) it may be due to a primary bone marrow disorder. As with PRV there is a tendency towards TIA and stroke and these patients should be referred for investigation and therapy.

Anticoagulant clinics

Anticoagulant clinics are held Mondays to Thursdays. Patients are seen by the anticoagulant specialist nurse. Referrals are usually from local clinicians or provider cardiovascular units. Referrals from General Practitioners are accepted if patients are being transferred from elsewhere and are already on therapy. A postal system which operates every day is available for patients with busy lifestyles who cannot attend the clinic and is also suitable for many other patients. Much valuable clinic time can be saved in this way.

A computerised system for both records and dosing has been introduced. This has allowed the present resources to cope with an increasing workload. Advantages are: reliable record keeping, improved statistical analysis, and more stringent follow-up of non-attenders. The dosing programme (not used for all patients) tends to be cautious and some patients may be recalled sooner than they would like. In some cases this is an advantage.

Interactions between anticoagulants and other drugs are a common problem. Safe alternatives should be chosen if possible. If there is no alternative patients should be asked to seek an earlier appointment at the clinic – remember that it will usually take several days for any change in the INR to occur after introducing a conflicting drug.

Generally patients with **Thrombophilia** (a thromboembolic tendency) will be referred by physicians or surgeons. However, it is now possible to identify some at-risk individuals using blood tests. Many of these will already be seen in other hospital departments but the following should be referred if not otherwise tested:

Unexpected PE/DVT in patients <45 yrs age
DVT/PE occurring in several family members
DVT/PE in young women on the "Pill"
Women with a clear history of recurrent miscarriage

The identification of the Factor V Leiden genetic defect has led to a great deal of public interest in thrombophilia. Much anxiety can be generated if inappropriate tests are carried out. In general the guidelines described above should be followed. If in doubt telephone the consultant haematologists.

Easy bruising

Patients with a serious defect of clotting will normally have been identified early in life. Easy bruising in later years however is common but in most patients no clear diagnosis emerges. Many will have taken aspirin or other drugs or preparations which affect platelet function and

this possibility should be excluded. Others with a clear history of bruising or bleeding should be referred preferably after the following have been carried out:

FBC including platelet count
Clotting screen
Urea and liver function tests

Patients with **Haemophilia and other clotting disorders** will usually know where to obtain help. An advice service for Haemophilia is available for local patients and visitors.

The Consultant Haematologist is willing to discuss clinical problems related to Haematology throughout the working day (telephone numbers at top of section).

Refer to the hospital switchboard for advice on urgent clinical matters out-of-hours.

Referral laboratories

Where testing is not available on site, samples are referred to the following CPA Accredited laboratories.

Red Cell Immunohaematology ,North London BTS, Colindale Ave, London
Department of Clinical Biochemistry, Kings College Hospital, Denmark Street, London
Department of Haematological Medicine, Kings College Hospital, Denmark Street ,London
Histocompatibility & Immunogenetics, NHS Blood and Transplant, 500 North Bristol Park, Northway, Filton, Bristol
Institute of Neurology, Queen Square, London
Cytogenetic department Kennedy-Galton Centre, Northwick Park Hospital, Watford
Molecular Genetics Department Kennedy-Galton Centre, Northwick Park Hospital, Watford
East Anglian Medical Genetics Service, Level 6 Addenbrooke's Treatment Centre, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge
Blood Coagulation Laboratory, Viapath Laboratories, GSTT
Immunology Laboratory St Thomas' Hospital London
Haemoglobinopathy Ref Lab St Thomas' Hospital London

3a. Blood Transfusion (MHRA Compliant)

Specific Information for Blood Transfusion requests

Telephone requests always require confirmation by a valid form (plus sample where necessary).

Samples must include the following mandatory information:

- **SURNAME**
- **FIRST NAME**
- **HOSPITAL NUMBER (or EMERGENCY NUMBER or FULL ADDRESS or NHS No.)**
- **DATE OF BIRTH** (not age)
- **GENDER**
- **DATE /TIME OF SAMPLE COLLECTION /SIGNATURE (**person taking sample**)**

Request forms must include the following mandatory information:

- **THREE POINTS OF ID** (As per sample labelling)
- **GENDER**
- **WARD**
- **CONSULTANT**
- **DRS SIGNATURE**
- **DATE/TIME OF BLOOD OR BLOOD COMPONENT/PRODUCT REQUIRED**
- **REASON FOR REQUEST**
- **SPECIAL REQUIREMENTS** (where applicable)
- **HIGH RISK STICKER** (where applicable)

Failing to disclose special requirements such as CMV- neg or Irradiated products may result in major morbidity.

A bleep number and notification when a patient has atypical blood group antibodies is important. Failure to supply this information may delay blood issue

In emergency circumstances when the patient is unconscious or unknown, a **UNIQUE NUMERIC IDENTIFIER** (A&E number), **GENDER** & **DATE/TIME/SIGNATURE can be accepted.**

In the case of a suspected transfusion reaction or adverse transfusion event immediately telephone the lab (Ext 4833 or bleep 474 on-call) for advice/appropriate documents required.

Blood and Blood Product/Component Issue.

Blood Transfusion risks to the patient are significantly greater during the out-of-hours period. Therefore, it is essential that non-urgent requests are limited during this period. This is in accordance with National Guidelines (SHOT) and local Trust Policy *(this is available on the intranet under policies and guidelines).*

Blood must ONLY be stored at 2-6° in a validated blood bank

Routine cross-matching takes about 55 mins but it is important to give as much notice as possible (preferably 24 hrs) due to possible blood shortages or the unexpected presence of atypical antibodies. 48 hrs minimum may be required when the patient is known to have atypical antibodies

Where the patient has had two recent group and negative antibody screens (<72hrs), blood can normally be issued safely using an abbreviated method within 5-10 mins.
The laboratory will automatically withdraw unused issued blood after 24-48 hrs unless an extension to this time has been requested by the doctor.

Anyone collecting or transporting blood or blood products must only do so if they have attended the mandatory Trust Transfusion training session within the last year. In order to enter pathology an access card will be required and all persons collecting should only do so if given three points of patient ID (porter's collection slip), the product required and the number of units required.

Full and unambiguous traceability of blood and blood products is a legal requirement in accordance with the Blood Safety & Quality regulations (2005). The tear off section of the bag label must be completed as required and returned to the laboratory after transfusion. Where the label has not been returned, it will be the responsibility of senior ward staff to provide documented evidence. Failure to comply is a criminal offence and may be subject to disciplinary action.

Platelets must be stored 20-24°C and kept gently agitated. Collect from Lab immediately before use together with a platelet giving set.

One unit of A RhD positive platelets is stocked for emergency purposes and will be issued dependent upon the clinical circumstances, age and gender of the patient. In all other cases, platelets will be ordered from the National Health Blood and Transplant Service at Colindale, North London.

In cases of massive bleeding or trauma laboratory staff can order up to two units directly. If quantities greater than this are thought to be required contact the consultant haematologist.

Fresh Frozen Plasma (FFP) and Cryoprecipitate are stored at -40°C and will be thawed in quantities of one unit at a time except for massive bleeding or trauma where up to four may be issued at the same time.

In cases where multiple units are being transfused, telephone the Transfusion Laboratory (Ext 4833) 15 mins before the next unit is required to allow time for defrost. Transfusion of these packs must ideally be completed within 4 hours for maximum therapeutic effectiveness. Where there are unavoidable delays, FFP may be given up to 24 hours after thawing if kept in a validated blood bank at 2-6*C.

Anti-D immunoglobulin (1500iu & 250iu) is kept in the Delivery Suite Blood Bank. A small contingency stock is retained in the lab.

This product is for eligible RhD NEGATIVE patients only and must not be given unless indicated by appropriate laboratory tests.

All Anti-D removed for use must be entered in the Anti-D register next to the Blood Bank

200 g/L Human Albumin Solution (H.A.S) is only available on request, laboratory staff can issue up to 400ml per patient. Where a greater volume is anticipated, contact the Consultant Haematologist.

50 g/L H.A.S is stocked in minor quantities in some satellite blood banks. Large volumes can be collected directly from the laboratory.

Details must be written in the appropriate register.

Beriplex (PCC) is only available after discussion with the Consultant Haematologist. It is available in 500iu & 250iu packs. A fully compliant request card is required and details must be recorded in the blood bank register.

4. Microbiology

Key Contacts

Consultant Microbiologist: Dr Simantee Guha

Direct line: 01234 795845
Internal extension: 4603
E-mail: simantee.guha@bedfordhospital.nhs.uk

Interim Service Delivery Manager: Helen Gough

Direct line: 01234 792208
Internal extension: 4613
E-mail: helen.gough@bedfordhospital.nhs.uk

Bacteriology results and general enquiries

Direct line: 01234 795913
Internal extension: 4703/4708

These notes are provided for clinical staff using the microbiology laboratory; they are not intended to be a complete or authoritative document but merely a guide to some of the services available. If you need further information about specimens, availability or suitability of tests, interpretation of results, or any other matter relating to the microbiology service, please phone the department. Laboratory staff will be pleased to help.

Opening hours	Enquiries	Specimens
Monday – Friday	8.45am – 5pm	8.45am – 4.30pm
Saturday	9.00am – 1pm	9.00am – 12.00

Specimens for all pathology departments should be left at specimen reception located on the first floor of the pathology building. Access is via the hospital main corridor. A lift is available.

For clinical advice outside of these hours please contact the Consultant Microbiologist through Bedford Hospital Switchboard.

The on-call Biomedical Scientist must be contacted through Bedford Hospital Switchboard if urgent specimens require processing outside of these hours.

The microbiology department is a UKAS accredited medical laboratory No. 8839. The schedule of accreditation can be found at:
http://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8839%20Medical%20Single.pdf

Specimens and Tests

Sample acceptance criteria

If request forms are being handwritten please ensure that they are legible.
Correctly labelled samples and request forms must state:

- The patient's name
- Date of birth
- NHS number and/or Hospital number
- Date and time the sample was collected
- Nature of the sample and the site from where it was taken

In addition the request form must state:

- Identity of the individual collecting the sample
- Clinical diagnosis and relevant clinical signs/symptoms (including travel history if indicated)
- Date of onset of symptoms (vital for serological tests – sample may not be processed without this information)
- Examination required
- Names of any recent, current or intended antibiotics
- Consultant caring for the patient
- Name and bleep or contact number of requesting doctor

Samples which do not meet the above criteria will be rejected. Samples must be sent to the laboratory without delay; samples should be refrigerated (except CSF and blood cultures) if there is a delay in transporting the sample to the laboratory. Undated samples and samples over 48 hours old on receipt will be rejected.

Unrepeatable samples:

In the case of unlabelled, unrepeatable, samples e.g. CSF; blood cultures; pleural fluids the requesting doctor will be given the opportunity to identify the sample. The doctor will be asked to sign to accept responsibility for identification.

Sample Transport

All samples must be in approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers should be placed in the sample transport plastic bag with the request card kept separate. Leaking specimens are hazardous and may be rejected. Please ensure that the outside of the container is not contaminated by the sample at the time of collection; contaminated containers may be rejected.

The pneumatic tube system may be used to transport samples in accordance with the pneumatic tube policy available on the Hospital Intranet. Unrepeatable samples and blood culture bottles **must not** be sent using the pneumatic tube system.
Samples transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations.

Identification of high risk samples

For the protection of laboratory workers the request form and any samples collected from a patient with a **known or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'.
These agents include:

HIV 1 and 2 *Salmonella typhi & paratyphi*
Hepatitis B virus *Mycobacterium tuberculosis*
Hepatitis C virus HTLV 1 and 2
Brucella spp.
And the causative agents of:-
Anthrax Creutzfeldt-Jakob disease
Rabies Yellow Fever
Plague

Hazard Group 4 biological agents

Samples known or suspected to contain biological agents in Hazard Group 4 **MUST NOT** be sent to the laboratory without discussion with, and the permission of, the consultant microbiologist. This includes the causative agents of Viral Haemorrhagic Fevers (Lassa fever, Ebola fever and Marburg disease)

Limitations of tests and uncertainty of results

Internal quality control and internal quality assurance are performed within the laboratory to minimise the risk of erroneous results on a daily basis.

For information on the limitations of tests performed please contact the laboratory.

Test repertoire

Microbiology test repertoire:

- Antibiotic Assays (Amikacin/ Teicoplanin/ Tobramycin)
- Blood culture
- *Chlamydia trachomatis/Neisseria gonorrhoeae* antigen detection
- CSF examination
- Eye, ear, throat and oral Infections
- Fungal infections
- Lower respiratory tract Infections
- *Mycobacteria* spp culture
- Genital tract infections
- Samples from other normally sterile sites
- Stool culture
- Urine culture
- Wound infections
- Screening samples (CRE, ESBL and MRSA)
- Antimicrobial susceptibility testing (EUCAST methodology is currently not accredited by UKAS to ISO 15189:2012 standards).
- *Helicobacter pylori* IgG (This test is not accredited by UKAS to ISO 15189:2012 standards in this laboratory).

If any tests other than the listed ones are required please contact the laboratory.

Bacteriology

Sample collection methods

For all samples:

- Collect specimens before antimicrobial therapy where possible; the timing of the specimen in relation to antimicrobial therapy may affect the interpretation of the result.
- Perform hand hygiene prior to and post specimen collection.
- Place specimens and swabs in the appropriate, correctly labelled containers.
- Ideally swabs should be cultured immediately. If processing is delayed, refrigeration (2-8°C) is preferable to storage at ambient temperature. Delays may affect the interpretation of the result.

Antibiotic assays

5ml clotted blood – red or yellow top. Please ensure that the dosage, frequency and timing of samples are stated on the request form.

Antibiotic	Timing of samples	Expected levels (mg/L)	Re-assay interval†
Amikacin	A pre dose sample is recommended for either iv/im administration	Once daily: Pre <5, Post >50	6-8 days
		BD or TDS: Pre <10, Post >20	3-7 days
Teicoplanin*	Ensure that the container is 2/3 -3/4 full. A pre dose sample is recommended	Skin and soft tissue: Pre 15-30 but <60	6-8 days
		Bone and joint: Pre 20-40 but <60	
		Infective endocarditis: Pre 30-40, but <60	
		OPAT on 25mg/kg 3x/week: Pre 20-30	
Tobramycin	A pre and post dose, taken 1h after the end of iv/im administration is recommended	Once daily: Pre <1, Post >10 8h post (4.5mg/kg) 1.5-6 or follow Hartford nomogram (note this is for 7mg/kg)	6-8 days
		Pre <2, Post >7	3-7 days

*Expected levels are for *S. aureus* infections
†Assuming initial results are within the expected range
Please contact the Consultant Microbiologist if advice is required.

Blood cultures

Blood cultures must be transported, by porter, to microbiology without delay. Out of hours blood cultures must be placed in the incubator situated in the lift lobby on the third floor of the pathology building.
Full instructions for collection of blood cultures are available on the Trust intranet:
See BHT policy
http://intranet/Policies/Clinical_Guidelines_Document_Library/Venous%20Blood%20Sampling%20and%20Peripheral%20Blood%20Culture%20Procedure.pdf

Cerebro-spinal Fluid (CSF)

CSF is always treated as an urgent sample; the laboratory must always be informed when a CSF sample is being sent.

Transfer 1mL CSF into each of three sequentially numbered, sterile 28-mL universal containers labelled '1', '2' and '3' (1mL is about 20 drops) and mmune . 0.2mL into the fluoride oxalate bottle for glucose estimation. Smaller volumes will be accepted however it may not be possible to perform additional tests e.g. viral PCR. The minimum required for protein estimation (universal 2) is 0.2mL (mmune . 4 drops). For investigation of Tuberculous meningitis a large volume (>6mL) should be collected.

The following samples should also be sent to the **Clinical Biochemistry laboratory**:

- Sterile universal No 2 (minimum 0.3ml CSF) for protein estimation
- Fluoride oxalate bottle (minimum 0.2ml CSF) for glucose estimation
- Fluoride oxalate bottle (blood) for blood glucose estimation.

In suspected meningitis please send:

- Blood in EDTA bottle to microbiology for PCR test for meningococcus and pneumococcus
- Blood Culture set
- Throat swab for microscopy, culture & sensitivity
- Urine for pneumococcal antigen test

In suspected viral meningitis/encephalitis send:

- CSF for viral PCR for VZV, HSV and enteroviruses, (at least 1ml is required by the reference lab)
- If possible collect 1mL in a 4th sterile universal container

Chlamydia trachomatis/Neisseria gonorrhoeae assay

Please use the APTIMA specimen collection tubes in the table below. Please follow the manufacturer's specimen collection instructions.

Colour of specimen tube	Specimen type
white	Endocervical swab or male urethral swab
orange	Vaginal swab
yellow	Unisex urine sample – the collection tube must be filled between the 2 lines

Please note that extra-genital swabs such as throat and rectum are not validated for this assay. If orange swabs are sent they will be tested but the technology is not validated for these sites. An additional blue topped swab for *Neisseria gonorrhoeae* culture and susceptibility is recommended prior to treatment.

Rectal samples which are positive for *Chlamydia trachomatis* rRNA are referred to Microbiology Department St Thomas' Hospital, North wing – 5th Floor, Westminster Bridge Road, London, SE1 7EH for testing for lymphogranuloma venereum (LGV).

Eye, ear, throat and oral infections:

Eye swabs: A swab should be gently rotated against the conjunctiva in the lower eye lid and placed in transport medium. Any visible pus should be sampled. Eye swabs are cultured for appropriate pathogens including *Neisseria gonorrhoeae* and thus it is important that such specimens reach the laboratory promptly after collection. Examination for *Chlamydia trachomatis* is also indicated in a neonate with a purulent eye discharge (use the swabs designated for the detection of *C. trachomatis* from the male genital tract).

Corneal scrapes: These samples should be collected by an ophthalmic surgeon. Agar plates (chocolate, fastidious anaerobic and Sabouraud) and a microscope slide are supplied by the microbiology department to enable inoculation at the patient's side. The agar plates should be inoculated first; if there is sufficient material then prepare slides. A separate set of plates should be used for each eye. Material should be spread from the scalpel blade or swab directly onto the surface of the plates using short streaks. Spread material directly onto the surface of the glass slides. Culture plates and microscope slides should be sent back to the laboratory promptly. All plates and slides should be labelled with the patient details.

Acanthamoeba culture: Corneal scrapings should be collected into a small (200µl) volume of sterile water (supplied by the microbiology department). These vials should be labelled with the patients details and transported promptly to the laboratory. Contact lens washing fluid or lenses in contact lens fluid sent in sterile containers will also be accepted.

Ear swabs: A swab in transport medium or fine wire swab with small bud may be used. The swab should be inserted into the outer ear and gently rotated.

Per-nasal swab: Per-nasal swabs should be used for the investigation of whooping cough (*Bordetella pertussis).* Pass the swab along the floor of the nasal cavity to the posterior wall of the nasopharynx and gently rotate the swab.

Throat swabs: are cultured for haemolytic streptococci and *Corynebacterium diphtheria (*if clinically indicated). The patient's tongue should be depressed using a spatula, before quickly and gently rubbing the swab over the tonsillar fossa or any region with a lesion of visible exudates. Touching other areas of the mouth should be avoided. Swabs should be transported in transport medium.
If culture for *Candida spp*. Is required, please state this clearly on the request form

Faeces culture

Please state if:

- The patient has returned from abroad
- Food poisoning is suspected
- The patient is on antibiotics or has been on antibiotics in the last four weeks

All specimens will be investigated routinely for:

- *Salmonella*
- *Shigella*
- *Campylobacter spp*.
- Verotoxic *Escherichia coli* 0157

Additional investigations for other enteric pathogens are performed based on the age of the patient, the clinical picture, and travel history.

Investigation for Rotavirus and Adenovirus is routinely performed on all stools on patients <5 years of age.

Requests for ova, cysts and parasites

If parasites are of particular concern, send three separate samples in sterile universal containers (as parasites may be intermittently excreted), requesting a concentration for ova, cysts and parasites (OCP). Tapeworm ova are rarely found in faeces; please send a segment or suspected parasite whenever possible. For the investigation of *Enterobius vermicularis* (Threadworm), a sellotape slide is the most appropriate sample.

If investigation of urine for Schistosomiasis is required, 10mL of terminal urine (including the last few drops) should be collected between 10am and 2pm or alternatively a 24hr collection of terminal samples of urine may be obtained. Samples should be collected in sterile universal containers.

Clostridium difficile toxin testing

All samples from hospital patients which are unformed or liquid will be reviewed by the infection control nurses prior to testing.

Samples requesting *Clostridium difficile* will not be processed if:

- A previous positive result was reported within 28 days of the new request
- If clearance of *C. difficile* is requested
- A previous negative result has been reported within 7 days of the new request
- The sample is NOT liquid and does not take the shape of the container (i.e. the sample is semi- formed or formed)

Faecal occult blood

Samples should be collected into a labelled sterile universal container.

Samples for testing should be no greater than 48 hours old on receipt in the laboratory as this can adversely affect the quality of the results.

Genital tract infections

High/Low vaginal swab: The swab should be used to obtain a sample from the mucosal membrane of the vaginal vault after removal of secretions or discharge. The swab should be placed in transport medium
For the investigation of PID a cervical and a Chlamydia swab should be sent to the laboratory.
For the investigation of *Neisseria gonorrhoeae* a cervical swab should be sent to the laboratory.
For the investigation of urethritis a urethral swab and a Chlamydia swab should be sent to the laboratory.

Penile swabs: After retracting the prepuce the swab should be gently rotated to collect any secretions in the urethral meatus. The swab should be placed in transport medium

Semen for culture: Collect the sample in the container provided. Open the lid of the container when ready to produce the specimen. Specimen should be collected by masturbation directly into the container. Fasten the lid of the container securely. Write

patients full name, date of birth, and hospital number/NHS number along with the date of collection on the container.

Where a sexually transmitted disease is suspected, it is recommended that the patients are referred to the department of Genito-Urinary Medicine (GUM) for follow up and contact tracing.

Lower Respiratory Tract Infections

Sputum samples: should contain material from the lower respiratory tract, expectorated by deep coughing. When the cough is dry, physiotherapy, postural drainage or inhalation of an aerosol before expectoration may be helpful. A minimum of 1mL should be collected into a sterile universal container.

Broncho-alveolar lavage (BAL) samples: A segment of lung should be 'washed' with sterile saline after insertion of a flexible bronchoscope. As large a volume as possible should be collected. BAL samples will be cultured for routine pathogens, *Mycobacterium tuberculosis* and fungi.

Mycobacteria, microscopy and culture

Sputum: should contain material from the lower respiratory tract, expectorated by deep coughing. When the cough is dry, physiotherapy, postural drainage or inhalation of an aerosol before expectoration may be helpful. 3 samples of ≥ 5mL should be collected mmune . 8- 24 hours apart with at least one from early morning. Samples should be sent to the laboratory within 48 hours. Urgent auramine phenol staining for acid fast bacilli (AFB) is available during normal working hours.

Urine: When sterile pyuria is noted, three early morning urines (EMU) should be collected in the containers available from the laboratory. The entire voided urine should be collected as soon as possible after waking and at the same time each morning if more than one specimen is being collected. Samples should be sent to the laboratory on a daily basis.

Biopsy samples, sterile fluids (CSF, pleural fluid) etc. should be sent in sterile universal containers to the laboratory. A minimum of 1mL (ideally >6mL) of CSF or sterile fluid is required.

Mycology (for investigation of dermatophyte infection)

Skin scrapes: Should be taken from the active edge of the lesion
Nail scrapes: Should be deep enough to include invaded tissue, ideally base of the nail
Hair: Should be plucked to include scalp scales.

Urine Culture

Midstream urine (MSU): Peri-urethral cleaning is recommend (water is considered sufficient) before sample collection. The first part of voided urine is discarded and, without interrupting the flow, approximately 10mL is collected in to a sterile universal container. A minimum of 5mL is required for automated microscopy and culture.

Clean catch urine: In young children clean catch urines are preferable to bag urines which are almost always contaminated by perineal flora. Peri-urethral cleaning is recommended

before sample collection. A minimum of 5mL is required for automated microscopy and culture.

Supra-pubic aspirates (SPA): Samples should be collected aseptically, directly from the bladder by aspiration with a needle and syringe and transferred into a sterile universal container. Ultra sound guidance should be used to show the presence of urine in the bladder before carrying out SPAs. The use of this invasive procedure is usually reserved for clarification of equivocal results from voided urine (e.g. in infants and small children).

Catheter specimen urine (CSU): Samples should only be sent if infection is suspected as colonisation of catheters is common and does not require treatment. The sample may be obtained either from a transient catheterisation or from an indwelling catheter. Samples should be obtained aseptically from a sample port in the catheter tubing or by aseptic aspiration of the tubing of indwelling catheters and transferred into a sterile universal container. The specimen should not be obtained from the collection bag. Microscopy is not performed on CSU samples.

Pad Urine: This is an alternative to bag urines from infants and young children. After washing the nappy area thoroughly, a pad is placed inside the nappy. As soon as the pad is wet with urine (but no faecal soiling), push the tip of a syringe into the pad and draw urine into it. Transfer into a sterile universal container. Pad urine samples may be contaminated with perineal flora. Microscopy is not performed on these samples.

Wound Infections

Pus samples: If frank pus is available, always send this in a sterile universal container and not a swab with pus on it.

Tissue: Should be sent as a priority sample without delay; please telephone the laboratory if urgent microscopy is required. The sample should be placed in a sterile universal container.

Wound swabs: Wounds should be cleaned with sterile water before taking the swab to prevent contamination of the specimen. The entire wound should be swabbed if practical ensuring the swab is rotated. Swabs should be transport in transport medium.

Intravascular cannulae: Disinfect the skin surrounding the cannula entry site and remove the cannula using aseptic technique. Cut off the 4cm of the tip and place into a sterile universal container. Cannulae should only be sent if there is evidence of infection. If catheter infection is suspected at least 2 sets of blood cultures should be obtained by peripheral venepuncture.

Animal bite or scratch acquired outside the UK: Please discuss the patient with the Consultant Microbiologist on call via switchboard immediately if anti-rabies treatment indicated.

Screening Specimens

Extended spectrum β-lactamase (ESBL) screening: Swabs should be inserted into the anal canal and rotated ensuring visible faecal material is present on the swab. Swabs should be transported in Amies transport medium.

Carbapenem resistant enterobacteriaceae (CRE) screening: Swabs should be inserted into the anal canal and rotated ensuring visible faecal material is present on the swab. Swabs should be transported in Amies transport medium.

Faeces specimens may be passed into a clean, dry, disposable bedpan or similar before being transferred into a sterile leak-proof container. The specimen is unsatisfactory if any residual soap, detergent or disinfectant remains in the pan.

MRSA: Samples should be collected in accordance with Bedford Hospital Trusts Infection control MRSA policy. Swabs should be transported in Amies transport medium.

Helicobacter pylori IgG

A 5mL clotted blood (red or yellow top) should be collected in individuals with symptoms suggestive of gastrointestinal disease. A negative *H. pylori* serology test confirms the absence of infection in the majority of cases. Samples obtained too early during infection may not contain detectable antibodies. Patients may test positive for months to years after eradication, and serological testing is therefore unable to distinguish between active and inactive infection. *H. pylori* serology testing is therefore unsuitable for patients with previous *H. pylori* infection.

Procurement of consumables for Bedford Hospital Trust

From Stores
Swabs for bacterial culture (blue-caps)
Blood culture bottles
Universal containers (MSU pots)
60mL wide neck containers (for sputum, faeces and IUCDs)
Dermapak
Faeces containers (60mL pots)
Hospital Request forms (no absorbent pad)
GP Request forms (with no absorbent pad)

Directly from Microbiology
EMU pots for AFB
Per-nasal swabs
Chlamydia trachomatis detection swabs
Herpes simplex detection swabs
Viral culture swabs

For consumables for GP surgeries please contact the pathology department.

Reference laboratories

Isolates which require further work such as identification, typing and antimicrobial sensitivity testing are routinely referred to:

Public Health England
Microbiology Services Colindale
76 Colindale Avenue
London
NW9 5EQ

Other reference laboratories used are detailed in the table below.

Test	Specimen requirements and containers	Method/ Comments/ Reference laboratories	Turnaround times
Acanthamoeba culture	Corneal scrapings should be collected into a small (200µl) volume of sterile water. Contact lens or washing fluid.	Samples referred to the London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E 7HT	10-14 days
Amikacin, tobramycin and teicoplanin	5ml clotted blood – red or yellow top. Samples should be taken pre dose and 1 hour post dose for most agents.	Samples referred to Antimicrobial Reference Laboratory, Department of Medical Microbiology, Southmead Hospital, Bristol, BS10 5NB	Verbal results next working day
Ascitic and Peritoneal dialysis fluid	20ml maximum in sterile universal	Contact Microbiology if urgent microscopy is required.	Microscopy same day, culture 2-3 days.
Aspirates and fluids form normally sterile sites, pus, tissues	20ml maximum in sterile universal	No formalin Contact Microbiology if urgent microscopy is required. Please state if replacement joints are in situ at the site of sampling	Microscopy same day, culture 2 -3days (may be extended when appropriate)
Aspirates and fluids from normally sterile sites, pus, tissues for acid fast bacilli (AFB)	20ml maximum in sterile universal. Ideally a minimum of 6mL should be received for CSF samples.	No formalin AFB isolates are referred to National Mycobacterium Reference Service- South (NMRS- South), PHE Colindale, 61, Colindale Avenue, London, NW9 5HT	Microscopy 1-2 working days Culture 6 – 8 weeks
Blood cultures	Aerobic bottles 8 – 10ml Anaerobic bottles 8 – 10ml Paediatric bottles 1 – 3ml	Remove the centre portion of the barcode and place on the request form. Blood culture bottles should be collected by porters and delivered to pathology specimen reception or placed in the incubator located on the 3rd floor of Pathology if out of hours. Please provide relevant clinical information including differential diagnosis, appropriate travel history, possible contact with infectious disease or predisposing condition. Samples are incubated using the BD BacTec™ FX blood culture system	48 hour interim report, 5 day final, 7 days for suspected bacterial endocarditis
Bronchial aspirate/trap for routine and fungal culture	Sealed trap or Sterile universal		2-3 days

Bronchial aspirate/trap for acid fast bacilli (AFB)	Sealed trap or Sterile universal	Processing of isolates is performed using the Bactec MGIT 960. AFB isolates are referred to National Mycobacterium Reference Service- South (NMRS- South), PHE Colindale, 61, Colindale Avenue, London, NW9 5HT	Microscopy 1-2 working days Culture 6-8 weeks
Chlamydia	• Aptima vaginal swab specimen collection kit • Aptima unisex swab specimen collection kit for endocervical and male urethral swab specimens • Aptima urine specimen collection kit for urine specimens	Processed using the APTIMA® Combo 2CT/GC assay. This assay is a transcription mediated amplification nucleic acid probe test that utilises target capture for the *in vitro* qualitative detection and differentiation of ribosomal RNA for CT and GC. This assay is performed on the Hologic Gen-Probe Panther analyser.	5 days
Corneal Scrapings	Smear scraping on clean labelled microscope slide and place in slide box. Spread scraping onto a Chocolate agar plate, fastidious anaerobic agar plate and Sabouraud agar plate.	Plates should be inoculated first, if there is sufficient material then prepare a slide.	Microscopy available same day if requested Culture 2-3 days
Contact lens –Routine bacterial	Contact lens in lens fluid		Routine –2-3 days
CRE Screening	Swab in transport medium (with visible faecal material) or faeces specimen in sterile universal container	CRE isolates are referred to AMRHAI, PHE Colindale for confirmation of carbapenem resistance	3-4 days
CSF for bacteriology / virology	Sterile universal containers	Send the 1st and 3rd universals to Microbiology. The laboratory **MUST** be informed once the sample has been taken. Out of hours contact the on call Biomedical Scientist via switchboard. Samples requiring viral PCR are referred to Microbiology Department St Thomas' Hospital, North wing – 5th Floor, Westminster Bridge Road, London, SE1 7EH.	Microscopy – same day Bacterial Culture 2-3 days Fungal culture 7 days AFB 6 – 8 weeks Viral PCR 3-5 working days
Ear, nose, mouth and throat swabs	Swab in transport medium or fine wire swab with small bud (ears only)	Please supply relevant clinical information including differential diagnosis, appropriate travel history, possible contact with infectious disease or predisposing condition to aid in the correct processing and interpretation of each specimen.	2-3 days
ESBL Screening	Rectal swab with visible faecal material in transport medium		3-4 days

Eye swabs	Swab in transport medium		2- 3 days
Faeces for faecal occult blood	3 faeces specimens in sterile universals collected on 3 consecutive days	Samples should be sent to the laboratory within 48 hours of collection. Samples > 48 hours will not be processed. Samples are processed using the hema-screen specific immunoassay.	1 day
Faeces for routine culture	Sterile universal container, half filled.	Include relevant clinical details including any history of foreign travel.	2-3 days
Faeces for the detection of *Clostridium difficile*	Sterile universal container, half filled.	Do not send repeat specimens within four weeks if positive or 1 week if negative.	1-2 days
Faeces for the detection of ova, cysts and parasites (OCP)	Sterile universal container, half filled.	Send 3 specimens collected on different days. Clinical details must be provided. Tapeworm ova are rarely found in faeces; please send a segment or suspected parasite whenever possible	1-2 days
Genital tract swabs/ HVS	Swab in transport medium	Please supply applicable clinical information including differential diagnosis, pregnancy status, and possible contact with infectious disease or predisposing condition to aid with the correct processing and interpretation of each specimen. For examination for *N. gonorrhoeae* in females, a cervical swab should be sent.	1-3 days
Helicobacter pylori IgG	5ml clotted blood – red or yellow top	Processed using the Premier H. pylori IgG on the DS2 workstation. This test cannot distinguish between active and inactive infection.	1 week
Intravascular line tips	Cut off the tip of last 4cm of the line tip with sterile scissors and place in a sterile universal container.		2- 3 days.
IUCD's for *Actinomyces spp* culture	Send entire device in sterile 60ml wide necked container		Minimum 2 weeks

Meningococcal PCR	EDTA blood (2.5-5ml) CSF (>0.5ml) 5ml clotted blood	EDTA whole blood and CSF are the preferred specimens. CSF samples, if available, should be sent in addition to an EDTA blood sample. Samples referred to the Meningococcal Reference unit, Manchester Medical Microbiology Partnership, PO Box 209, Clinical Sciences building 2, Manchester Royal Infirmary, Oxford Road, Manchester, M13, 9WZ	2-3 days
MRSA screen	Swab in transport medium	See Bedford Hospital Trust Infection Control MRSA Policy	1-2 days
Mycology	Skin scrapes from active edge of lesion. Nail scrapes in sterile universal deep enough to include invaded tissue, ideally base of nail. Hair should be plucked to include scalp scales and placed in a sterile universal or 60 ml container.	Universals or Dermapak Samples referred to Mycology laboratory at St Thomas' Hospital, North wing – 5th Floor, Westminster Bridge Road, London, SE1 7EH	Microscopy 1 week Culture 2 – 4 weeks
Norovirus PCR	Sterile universal container, half filled.	Discuss with Infection control or the Consultant Microbiologist before sending Samples referred to Microbiology Department St Thomas' Hospital, North wing – 5th Floor, Westminster Bridge Road, London, SE1 7EH	3-5 working days
NPA for Respiratory Synctival Virus (RSV)	Place tube containing aspirate in sterile container		1-2 days
Sellotape slide for Threadworm (*Enterobius vermicularis)*	Apply clear sellotape to the perianal region, in the morning before washing. Smooth the tape back onto the slide adhesive slide down.	Ensure slide is labelled with the patient details.	1-2 days
Seminal fluid for culture	Sterile universal container		2-3 days
Sputum for routine bacterial culture	Deep cough specimen (not salivary) in 60ml wide neck sterile container	State if patient suffers from bronchiectasis, COPD, Cystic Fibrosis or is mmune-compromised.	2-3 days
Sputum for acid fast bacilli (AFB)	Deep cough specimen (Not saliva) in 60ml wide neck sterile container	Processing of isolates is performed using the Bactec MGIT 960. AFB isolates are referred to National Mycobacterium Reference Service- South (NMRS- South), PHE Colindale, 61, Colindale Avenue, London, NW9 5HT	Microscopy 1-2 working days Culture 6 – 8 weeks (cultures may take up to 12 weeks)

Swabs for routine bacterial culture	Swab in transport medium	Please supply relevant clinical information including differential diagnosis, appropriate travel history, possible contact with infectious disease or predisposing condition, to aid with the correct processing and interpretation of each specimen.	2-3 days
Swab for Whooping cough	Pernasal swab – fine twisted wire swab with small bud	Specimens should be transported to the laboratory immediately after collection.	7 days (further 7-10 days for confirmation by reference laboratory).
Urine for routine bacterial culture	10 – 20 ml midstream urine in a sterile universal.	CSUs are of very limited value. Samples must be labelled with the date of collection. Automated urine microscopy is performed using the SediMax analyser.	1-2 days
Urine for Schistosoma	10 ml terminal urine including last few drops collected between 10am and 2pm or alternatively a 24hr collection of terminal samples of urine may be obtained. Sample should be collected in a sterile universal container	Consider sending serum for serological investigation.	1 working day
Urine for Legionella and pneumococcal antigen	10 – 20 ml urine in sterile universal		Same day
Urine for acid fast bacilli (AFB)	3 consecutive early morning samples each in a 500 ml sterile container	Processing of isolates is performed using the Bactec MGIT 960. Sterile containers available from Pathology. AFB isolates are referred to National Mycobacterium Reference Service- South (NMRS- South), PHE Colindale, 61, Colindale Avenue, London, NW9 5HT	Culture 6 – 8 weeks

Infection control

Advice is available at all times. Infection Control policies are available in all wards and departments, and on the Trust Intranet.

Notifiable diseases

Acute encephalitis	Paratyphoid fever
Acute poliomyelitis	Plague
Anthrax	Rabies
Cholera	Relapsing fever
Diphtheria	Rubella
Dysentery (amoebic or bacillary)	Scarlet fever
Food poisoning (or suspected food poisoning)	Smallpox (eradicated in 1979)
Leprosy	Tetanus
Leptospirosis	Tuberculosis
Malaria	Typhoid
Measles	Typhus
Meningitis (viral, bacterial or fungal)	Viral haemorrhagic fever
Meningococcal septicaemia	Viral hepatitis (A,B,C,D,E)
Mumps	Whooping cough
Ophthalmia neonatorum	Yellow fever

5. Cellular Pathology (CPA Accredited Laboratory)

Cellular Pathology comprises Histology and Cytology. The laboratory offers the following services:

Histopathology

Histopathology provides a comprehensive tissue diagnostic service to Bedford Hospital and local General Practitioners, including immunocytochemistry and referral for molecular diagnostics. Also provides tissue diagnosis for the Bowel Cancer Screening Programme.

Cervical Cytology

The cytology department provides the NHSCSP Cervical Screening Service for NHS Bedfordshire and since April 1st 2010 has provided the same service for NHS Luton; processing and screening in excess of approximately 35,000 cervical liquid based cytology specimens annually.

HPV Testing

Since April 2012, the department has offered HPV testing on samples in line with the NHSCSP Cervical Screening Programme Guidelines. Testing is routinely performed in our molecular diagnostics suite.

Diagnostic Cytology

Cytopathology also provides a comprehensive Fine Needle Aspiration (FNA) and diagnostic cytology service.

This includes evaluation of body cavity fluids, and washings and brushings from various sites in the body.

Fine Needle Aspiration Cytology

This is a quick, minimally invasive and cost-effective method of reaching a cellular diagnosis on mass lesions. The Consultant Cytopathologist offers an on-demand FNA service.

Semen Analysis

This includes routine semen analysis for infertility cases as well as evaluation of post-vasectomy specimens.

Key Contacts

	External	Internal
Dr M Wilkins. Consultant Histopathologist, Clinical Lead	01234 792094	4729
Mr N Cully, Service Delivery Manager, Cellular Pathology	01234 792092	4694
Dr F Mutch. Consultant Cytopathologist	01234 792325	4725
Hospital Based Co-ordinator		
Mrs J Tyler, Advanced Practitioner Cytology	01234 355122 x 4734	4734
Failsafe Officer	01234 355122 x 4616	4616
Admin & Clerical Office		
Office Team Leader		4625
Histology enquiries	01234 792149	4607
Cytology enquiries	01234 355122 x 4611	4611

Opening times

	Enquiries	Specimens
Monday to Friday	8.30 am – 5.00 pm	8.30 am – 4.30 pm

During working hours, specimens are to be delivered to the 2nd floor laboratory. Specimens can be left at the Specimen Reception Desk situated on the First Floor of the Pathology Block off the main corridor of the Hospital when the Cellular Pathology Department is closed.

Clinical Advice

Clinical advice for any of the tests / investigations undertaken within Cellular Pathology can be obtained by contacting the department.

ACCEPTANCE CRITERIA FOR CELLULAR PATHOLOGY SAMPLES

The information required on the sample is essential and samples will be rejected if there is missing or discrepant information.

Minimum Data Set for Histology, Diagnostic Cytology Fluid and Sputum Samples and Request Forms

These samples MUST have 3 patient identifiers which match on the sample label and the request form or the specimen will be rejected:

NAME
DATE OF BIRTH
NHS NUMBER (preferable) or HOSPITAL REFERENCE NUMBER

Additional Information

To allow the efficient processing of the sample the following additional information should also be present on either the sample or the request form:

REQUESTING CLINICIAN
LOCATION
SPECIMEN TYPE AND CLINICAL DETAILS
COLLECTION TIME AND DATE
PATIENT ADDRESS (where applicable)

Minimum Data Set for Diagnostic Cytology FNA Samples and Request Forms

These samples MUST have 2 patient identifiers which match on the slide and the request form or the specimen will be rejected. This can be 2 out of the following 3 identifiers:

NAME
DATE OF BIRTH
NHS NUMBER or HOSPITAL REFERENCE NUMBER

Additional Information

To allow the efficient processing of the sample the following additional information should also be present on either the sample or the request form:

REQUESTING CLINICIAN
LOCATION
SPECIMEN TYPE AND CLINICAL DETAILS
COLLECTION TIME AND DATE
PATIENT ADDRESS

Minimum Data Set for Cervical Cytology Samples and Request Forms

These samples MUST have 2 patient identifiers which match on the specimen and the request form or the specimen will be rejected. This can be 2 out of the following 3 identifiers:

NAME
DATE OF BIRTH
NHS NUMBER or HOSPITAL REFERENCE NUMBER

Additional Information

To allow the efficient processing of the sample the following additional information should also be present on either the sample or the request form:

REQUESTING CLINICIAN
SPECIMEN TYPE AND CLINICAL DETAILS
COLLECTION TIME AND DATE
PATIENT ADDRESS
SAMPLE TAKER CODE

Gynae LBC samples will be accepted with 2 of the 3 patient identifiers in accordance NHSCSP guidelines.

Gynae LBC samples should be submitted on pre-populated A5 Open Exeter HMR101 (2009) forms. Other versions of the HMR 101 form will be accepted, if complete. Please include the sample taker code.

Minimum Data Set for Andrology Samples and Request Forms

These samples MUST have 3 of the following patient identifiers which match on the specimen and the request form or the specimen will be rejected.

NAME
DATE OF BIRTH
NHS NUMBER or HOSPITAL REFERENCE NUMBER

Additional Information

To allow the efficient processing of the sample the following additional information should also be present on either the sample or the request form:
Patient Address
Sex
Purpose of investigation (Sub-fertility or post-vasectomy)
Clinicians name in capitals and signature on the bottom of the form.
Date of production
Time of production
Complete days since last ejaculation (infertilities)
If entire sample was collected (infertilities)

Request Forms with missing Information

After a reasonable attempt has been made to ascertain missing information, a decision (based on risk) will be recorded on the request form, as to whether the sample can be accepted. Request forms with missing information may not necessarily be rejected, however it may delay the diagnosis if further enquiries are necessary.

In the case of unlabelled, unrepeatable, specimens such as most histology samples, CSF, etc the requesting doctor will be given the opportunity to identify the specimen and asked to sign to accept responsibility for identification. These will be followed up by an email, phone call or samples will be returned to sender for amendments).

Identification of High Risk Specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a known **or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

HIV 1 and 2
Hepatitis B virus
Hepatitis C virus
Brucella spp.
Salmonella typhi & paratyphi
Mycobacterium tuberculosis
HTLV 1 and 2

And the causative agents of: -

Anthrax
Rabies
Plague
Creutzfeldt-Jakob disease
Yellow Fever

Uncertainty of Results

Internal Quality Assessments (IQA) will minimise the risk of erroneous results on a daily basis: IQA:

- Will help to ensure that the process used to achieve the result is of the highest standard.
- Plays a large part in controlling internal control materials, and variable factors such as supplies and reagents.
- May look at a series or sequence of results over short or long periods to show consistency or improvement, and provide certainty of results.
- Will enable staff to probe and analyse any reasons for uncertainty.

Internal Quality Assurance implies that the whole examination process should be assessed.

The following hospitals are routinely used to refer specialist tests for analysis.

Referral Lab	Routine Tests requested by Bedford	Address
Addenbrookes Histopathology	2nd / specialist opinion on Histology cases, medical liver biopsies for specialist reporting	Department of Histopathology, Box 235, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 2QQ
Charing Cross Histopathology	2nd / specialist opinion on Histology cases.	Pathology Department, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF
Kings Histopathology & Advanced Diagnostics Laboratory	KRAS, NRAS, MSI, ALK, HER2, ICC testing	Histopathology, Pathology Department, King's College Hospital, Bessemer Wing, Denmark Hill, London, SE5 9RS
Kings Liver Unit Histopathology	2nd / specialist opinion on Histology cases.	Liver Unit, King's College Hospital, Cheyne Wing, Denmark Hill, London, SE5 9RS
Luton & Dunstable Histopathology	2nd / specialist opinion on Histology and Cytology cases.	Histopathology, Pathology Department, Luton & Dunstable Hospital, Lewsey Road, Luton, LU4 0DZ
Stanmore Orthopaedic Hospital Histopathology	2nd / specialist opinion on Histology cases.	Pathology Department, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, Middlesex, HA7 4LP
Papworth Histopathology	2nd / specialist opinion on Histology cases.	Pathology Department, Papworth Hospital, Papworth Everard, Cambridge, CB23 3RE
QEII Histopathology	2nd / specialist opinion on Histology cases.	Pathology Department, Queen Elizabeth II Hospital, Howlands, Welwyn Garden City, Hertfordshire, AL7 4HQ
Royal Marsden Histopathology	2nd / specialist opinion on Histology cases.	The Royal Marsden Hospital, Fulham Road, London, SW3 6JJ
St John's Dermatology Histopathology	2nd / specialist opinion on skin Histology cases.	Histopathology Department, St John's Institute of Dermatology, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH
St John's Dermatology Immunoflourescence Laboratory	Immunoflourescence (IMF) testing	Immunoflourescence Laboratory, St John's Institute of Dermatology, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH
St Thomas' Histopathology	2nd / specialist opinion on skin Histology cases, immunocytochemistry (ICC), placenta for specialist reporting	Histopathology Department, 2nd Floor North Wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH

UCLH Histopathology	Immunocytochemistry (ICC)	Pathology Department, 3rd Floor East, University College London Hospital, 3rd Floor East, 250 Euston Road, London, NW1 2PG
Moorfields Histopathology London	Opthalmic specimens for specialist reporting	Moorfields Eye Hospital, 162 City Road, London, EC1V 2PD
Cheltenham General Hospital Histopathology	Gastrointestinal specimens for 2nd / specialist opinion	Histopathology Department, Cheltenham General Hospital, Sandford Road, Cheltenham, Gloucester, GL53 7AN
Backlogs	Histology specimens for Histology reporting	
Norfolk & Norwich	HPV Genotyping	Norfolk and Norwich University Hospital Colney Lane Norwich NR4 7UY

Requesting Additional Tests

Additional tests can be requested by contacting the department, the timeframes for each test type are:

Andrology – the day the sample is produced

Cervical Cytology – 2 weeks after the specimen collection date.

Diagnostic Cytology – 1 week after the specimen collection date.

Histology – is dependent on the test that is being requested – please contact the department for further details.

Histology Laboratory

Surgical Pathology

Fixation

The tissue fixative used routinely is **formalin** (10% neutral buffered formalin solution). On request, labelled specimen containers of various sizes, containing formalin, are provided by the laboratory to all users as required.

All tissue samples should be placed in fixative as soon as possible after removal from the patient. With small biopsies in particular, it is important not to let the specimen dry out. The recommended volume of fixative is at least ten times the volume of the specimen, so it is important not to squeeze a specimen into too small a container. If in doubt, choose a larger container. Poor fixation can hinder or prevent accurate histological diagnosis.

The temptation to slice open or dissect an excised specimen before it is sent to the histopathology department should be resisted. Subsequent fixation of a partly incised specimen may cause distortion and hinder anatomical orientation. In the case of excised tumours, it may then be impossible to identify surgical planes of excision.

Containers of formalin should be securely closed and transport should be in line with the Trust Policy on the transport of specimens in formalin. Formaldehyde vapour is a well-recognised respiratory irritant. Skin contact with formalin solution should be avoided, as repeated exposure may cause dermatitis in some individuals.

Formalin spillage kits should be available to each department that stores formalin.

On no account should **unfixed** specimens be sent to the histopathology laboratory without prior consultation with one of the Consultant Histopathologists.

SAMPLES IN FORMALIN MUST NOT BE SENT VIA THE PNEUMATIC TUBE SYSTEM.

Turnaround times

Urgent samples are prioritised. Routine results are usually available within 3-7 working days but every effort is made to make the results available sooner. Complex specimens requiring further investigation may take longer.

Specimens containing bone:

Specimens that contain bone will take longer than one week.

Cytology Laboratory

Cervical Cytology – ThinPrep Liquid Based Cytology (LBC) samples
Diagnostic Cytology – Cytology of fluids and aspirates

Note that NHS Luton and NHS Bedfordshire as local purchasers of the Cervical Screening Programme determines the policy on cervical screening, including interval between samples.

The laboratory actively manages inadequately labelled samples, late deliveries of samples, and out of programme samples in order to ensure patient safety and to deliver the 14 day patient pathway.

Out of Date Vials

Dates on all vials must be checked before taking an LBC sample as this will prevent a woman receiving an invalid cytology result, and if necessary, an invalid HPV result and having an unnecessary repeat test.

Out of programme samples which cannot be processed by the laboratory are:

1. Patient is under 24.5 years old and not scheduled from a previous test
2. Patient on three yearly recall and sample received less than 30 months since previous test
3. Patient on five yearly recall and sample received less than 54 months since previous test
4. Patient aged 65 and over with 3 consecutive routine negative tests, 2 of which were in the last 10 years
5. This sample is not clinically appropriate
6. Repeated <90 days from a previous sample.

Liquid Based Cytology (LBC)

Procedure for submitting a liquid based cytology sample:

Equipment: request form HMR101 OPEN EXETER Version 2009 (printed on A5)
LBC vial with collection fluid (pre-filled) – Thinprep only
Cervex brush

After taking the sample with the Cervex brush, **place brush in vial and agitate** to ensure all the cervical material is released into the fluid. **Dispose of brush** and send vial and form to laboratory in a pathology pouch bag. Use clear pathology bags to submit batches of samples.

Vials are transported to the laboratory in transport boxes provide by the hospital courier.
Sample takers are requested to submit the sample with an A5 size HMR101 2009 version Request Form generated by the Open Exeter computer system. Instructions for printing the correct format of HMR101/5 form from Open Exeter are available on request from the cytology department. If senders are unable to print the HMR101 form then request forms are available from the cytology dept. Request forms must be completed in full. This includes **name** and **previous names, address, date of birth, NHS number, reason for the smear, sender and source details, time and date of test** and any **relevant clinical information including sample taker code**. Relevant clinical information includes any history of CIN and previous biopsy results. If the patient has had a hysterectomy please indicate the reason as this will determine the need for further vault samples.

The laboratory works to all guidance and protocols issued by the NHS Cancer Screening Programmes, including those found in the following publications:

Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology. *NHSCSP Publication No.1 Third edition including revised performance indicators January 2013.*

Guidelines on Failsafe Actions for the Follow-up of Cervical Cytology Reports *NHSCSP Publication No 21 December 2004*

Audit of Invasive Cervical Cancers. *NHSCSP Publication No 28 (April 2012)*

Please Note: Copies of NHS Cervical Screening Publications can be obtained from:-

The Department of Health Publications Orderline
Tel: 08701 555 455
Fax: 01623 724 524
Email: doh@prolog.uk.com

Copies are also available as PDF files on the NHS Cancer Screening Programme website – www.cancerscreening.nhs.uk.

Diagnostic Cytology

The laboratory processes a wide variety of specimens, much of which is unfixed and requires processing promptly to prevent deterioration of the cells. **Specimens should therefore be sent to the laboratory without delay.**

Request form and specimen should be delivered to the cytology laboratory in plastic transport bags.

High risk specimens must be labelled as such to ensure that laboratory staff when handling these specimens take appropriate precautions.

Body fluids e.g. pleural fluid, ascites, synovial fluid, ydrocele fluid, breast cyst fluid should be put in a dry 60ml plastic specimen container. Please provide at least 25ml of fluid from body cavity fluids to enable full analysis to take place, including immunocytochemistry when appropriate.

Sputum. Specimens of early morning "deep cough" sputum should be submitted on three consecutive days. The specimens should be put in a 60ml. plastic specimen container.

Further advice on any aspect of specimen collection, transport, or suitability for examination can be obtained from the cytology laboratory, (01234) 792623 – Monday – Friday 9am – 5pm.

- Please note. Cells degenerate rapidly. Samples for cytological examination must be sent to the laboratory as soon as possible.
- Any high- risk specimens, e.g. HIV infection, Hepatitis B or C, should be identified clearly on both the sample and request form.

FNA Samples

Direct Slides
Microscope slides should be labelled clearly at the frosted end. Please label in PENCIL as ink is dissolved by the laboratory staining techniques.
The preparations can either be air dried or alcohol wet fixed. When air drying slides they must be air-dried quickly and placed in a plastic slide carrier. The slide carrier and request form (see Request Form Acceptance Criteria) should be promptly transported in a plastic sample bag pouch/pocket to the laboratory.

For discussion on alcohol fixed FNA slide preparations please contact the laboratory who will be able to give up to date advice on how to fix them and where to obtain fixative.

Needle Washings
Needle washings should be collected in saline (injection type). The needle can be flushed through with saline. The washings should be sent in a universal container labelled with the patient's forename, surname, date of birth and NHS number or Hospital number. The universal container and request form (see Request Form Acceptance Criteria) should be promptly transported in a plastic sample bag pouch/pocket to the laboratory.

Direct slides and needle washing samples should be sent together

Results

Diagnostic cytology reports are typically available twenty-four to forty-eight hours from receipt of the specimen, unless ancillary studies are required.

Andrology Service

In order to enable improvements to the Andrology Service the Cellular Pathology department at Bedford Hospital NHS Trust operates an appointment system for its Infertility and post-vasectomy semen sample analysis.

1. The Infertility semen analysis service **runs Tuesday and Wednesday by appointment only**. There will be x 2 time slots, which will be allocated and specified on the proforma sent out to the patient: these are 08:30-09:30 or 11:00-11:30.
2. The Post-vasectomy semen analysis service will **run on Thursday by appointment only** between from 08:30-10:30 (see page 88)

How to book an appointment:

Send a pathology request form, clearly stating "semen analysis for infertility" or "semen analysis for post-vasectomy" to:

Appointments Office, Administration and Clerical Office, Viapath, Bedford Hospital, Kempston Rd, Bedford MK42 9DJ.

Please ensure the correct and full patient address is included on the request form.

The request can be made on ICE, however the form **must** be printed and sent to the address above.

On receipt of the form, the laboratory will post a patient information sheet and sample pot to the patient and will allocate the next available appointment date, but allowing a fortnight for delivery of the information. A contact telephone number will be provided to allow the patient to rearrange the appointment date if it is inconvenient. The patient must bring the sample to the laboratory on the appointed date stated on their paperwork. The sample should be delivered **within 30-45 minutes** of production. Please note that there are NO facilities on-site for sample production.

Following Infertility semen analysis if all values are within reference ranges then no further appointments will be issued by the laboratory. If any values are outside reference ranges in the first sample then the laboratory will request a second sample and send a second information sheet and pot to the patient. Once the second sample has been examined and a report issued the laboratory will not request any further samples.

If a patient fails to attend:
A letter will be sent to the requesting clinician. If the test is still required please inform the laboratory by using the telephone number stated below.
If the patient fails to attend a second time and the test is still required please re-refer the patient to the laboratory at the above address.

If you have any questions regarding the provision of the Andrology service please contact the appointments office, Viapath on (01234) 792149, Monday – Friday 9am – 5pm.

Advice for patients:

Please ensure that adequate instruction is given to the patient on production of the semen specimen. **The date & time of specimen collection must be recorded on the request form and specimen container.**

Semen specimens must be delivered to the laboratory within 30-45 mins of production as these samples deteriorate rapidly and results will be impaired, particularly the motility assessment. Please note that there are NO facilities on the Hospital site suitable for the production of semen samples.

Please ensure patients are reminded of the importance of writing the date & time of specimen production on the request card and specimen container before delivery to the laboratory in addition to general information required for labelling specimen containers and request cards. The patients are asked to remain in the pathology specimen reception area for a short while after delivering the sample pot and form to ensure all information required has been provided.

Instructions to patients:

The following information is provided by the laboratory to patients:

Patient instructions and helpful information

Please produce the sample at home, carefully following the instructions provided below.

You should abstain from sexual intercourse or masturbation for a minimum of two days and a maximum of seven days before producing the sample for examination; this will ensure the sperm are at their best for testing.

The specimen must be produced by masturbation (stimulation by hand) directly into the specimen container provided. It is very important that only the container provided is used as this has been confirmed as being suitable for the test. Do not use an ordinary condom to collect the sample, or use lubrication, as either will seriously affect the test results.

It is important that the entire sample is collected in the specimen pot. If any of the sample is lost please telephone the laboratory on the number provided to arrange a repeat test on a convenient date.

Ensure the lid is tightly secured, and record your surname, forename, date of birth and date / time of sample collection on the pot.

Keep the sample warm, for example in an inside pocket, during delivery to the department. Excessive heat (greater than 37C) or excessive cold (below 20C) will seriously affect the test result.

The sample must be delivered to the laboratory as soon as possible, but within 30-45 minutes of production to ensure the sample is received at its best. Please note there are no suitable facilities at Bedford Hospital in which to produce the sample.

Please deliver the sample pot and this form to:

Pathology Specimen Reception,
Floor 1, Viapath,
South Wing, Bedford Hospital,
Kempston Road, Bedford
MK42 9DJ.
Tel: 01234 792149

On delivering the sample we would appreciate if you could wait a short time at the specimen reception to ensure the information on your paperwork and pot are completed before leaving the department.

The sample will be examined immediately on receipt by the laboratory and the result will be sent to the requesting doctor within seven days. Please do not telephone the laboratory for results as we are not authorised to give results to patients directly.

The laboratory examines the sample and reports it according to the latest reference ranges. If any parameters are outside the reference ranges, or if the laboratory is unable for technical reasons to complete all test, a repeat sample will be requested by the laboratory and you will receive a pot and new documentation for this in the post.

Copies of the above instructions for patients are available from the laboratory on request.

Reporting of semen samples:

Semen reports for the investigation of infertility include the following:

- Sample volume
- pH
- assessment of viscosity
- presence of agglutination or aggregation of sperm
- sperm concentration
- total number of sperm in the sample
- assessment of sperm motility and of sperm morphology.

It is helpful to include the name of the partner and the NHS/Hospital number on the request form for the correlation of results from both partners. If provided, this will be included on the report.

Recommendations for measurements and reference values for semen analysis in infertility investigation have been made by the World Health Organisation (WHO), whose standards are employed by most Andrology laboratories. WHO recommendations changed in 2010 and this laboratory reports semen samples in line with the current WHO recommendations (5th Edition).

Reference Ranges for Human Semen Samples

The following normal reference ranges are used for human semen:

1. Motility

Sperm motility is assessed in four categories and the percentage falling into each category calculated. The categories of motility are:

A. Rapid progressive
B. Slow/sluggish progressive
C. Non-progressive
D. Non-motile

The normal reference ranges are:

Progressive sperm motility (A+B)	:	>32%
Total sperm motility (A+B+C)	:	>40%

2. Morphology

Sperm morphology is assessed against published WHO criteria and the percentage of **normal** forms reported.

WHO guidelines recommend a lower reference range of 4% normal forms.

3. Other values:

Semen volume:	>1.5ml
Total number of sperm in ejaculate:	>39 Million
Sperm concentration:	>15 Million per ml
Sperm vitality (live sperm)	> 58%
pH:	>7.2

ref: WHO laboratory manual for the examination and processing of human semen (5th Ed.).

If you have any queries regarding semen analysis for infertility investigation, please contact the Andrology Service Manager, Histology Department.

Uncertainty of Results in Diagnostic Semen Analysis

Uncertainty in relation to laboratory testing simply means the existence of doubt or a level of error associated with a particular measurement. A degree of biological uncertainty exists when only a single semen sample is tested. Procedural uncertainty also exists from errors associated with specimen collection, to sample testing (method bias, sampling error and operator error) through to final reporting.

The steps taken by the laboratory to ascertain uncertainty include:

- Semen analysis methodologies are based on WHO (fifth edition) recommendations
- There is robust confirmation of the patient's identity and details on the specimen container(s), request and report forms are matched
- Strict 'specimen acceptance criteria' are applied with samples accepted in appropriate specimen containers
- The period of abstinence is defined
- The interval between collection and analysis is defined and semen analysis is commenced within an appropriate timeframe
- All laboratory equipment is appropriate and regularly serviced and maintained
- Samples are well-mixed prior to analysis
- Measurement of motility is carried out at 37°C
- Sampling error is ascertained by assessing large numbers of sperm wherever possible
- Staff are trained and their competency is assessed at intervals
- Robust Internal and External Quality Control measure are in place

Post vasectomy sample analysis:

Patients will be able to drop off their sample anytime within 08:30-10:30 on the Thursday morning stated on their form**.** Although we recommend that the sample should be received by the laboratory within an hour of the production time, to assess motility, we will not reject the sample if it is received within 4 hours from the production time.

As mentioned in the guidelines if non-motile sperm are observed later than an hour from production time then you may wish to repeat the test so that it can be analysed within the hour for the assessment of motility. In this case, the laboratory would require another request form to be sent to us to book another appointment.

Post vasectomy reversal samples: Patients requiring testing of semen following a post vasectomy *reversal* procedure should submit a sample via the appointment system to allow full analysis of a fresh sample. A request form should be sent to the appointments office indicating **"post vasectomy reversal semen analysis",** following which an appointment will be made for submission of a sample.

Patient information sheets

The following patient information sheets are available on the Bedford Hospital website, *www.bedfordhospital.nhs.uk/clinical-biochemistry*

- Appointment for a Glucose Tolerance test

- Patient instructions for Collecting a 24 hour urine sample.

- Patient instructions for Collecting a 24 hour urine sample for HMMA (VMA) Catecholamines, Metadrenalins and 5HIAA

BD Vacutainer®

BD Diagnostics - Preanalytical Systems

Tube Guide & Recommended Order of Draw*

* Clinical and Laboratory Standards Institute (Formerly NCCLS) Guidelines H3-A6, 6th Edition

Bedford Hospital NHS Trust - Printed 04.14

Blood samples should be taken in the following order:

Cap Colour	Cat. No.	Additive	Determinations	Special Instructions
		Blood Culture	Aerobic followed by anaerobic- if insufficient blood for both culture bottles, use aerobic bottle only.	
	Cat. No. 368380/KFK359 Draw Volume 6ml	Trace Element	Trace Elements.	Mix 8-10 Times
	Cat. No. 367956/KFK112 Draw Volume 3.5ml	SST™ II	Routine Biochemistry, B12 Folate (Haematinics) Immunology.	Mix 5-6 Times
	Cat. No. 363095/KFK119 Draw Volume 2.7ml	Sodium Citrate	INR, Clotting Studies.	Ensure tube is filled above minimum fill line. Mix 3-4 Times
	Cat. No. 367837/KFK168 Draw Volume 6ml	Serum	Microbiology, Serology, RA, Latex.	Mix 5-6 Times
	Cat. No. 367883/KFK281 Draw Volume 4ml	Lithium Heparin	Chromosomes, Genetic tests, Specialist Bio-chemistry Assays, Alcohol.	Genetic Tests only on Tuesday mornings. Mix 8-10 Times
	Cat. No. 368860/KFK042 Draw Volume 4ml	EDTA	FBC, ESR, Cyclosporin, Lead, Ammonia, PCR viral load.	HLAB27 needs 4 tubes Ammonia Assay - send to lab on ice. Mix 8-10 Times
	Cat. No. 367836/KFK279 Draw Volume 2ml	EDTA	HbA1c, FBC (difficult to bleed).	Mix 8-10 Times
	Cat. No. 367941/KFK277 Draw Volume 6ml	Cross Match	Cross Match, Group and Screen.	4 tubes required for antibody investigation. Mix 8-10 Times
	Cat. No. 367934/KFK250 Draw Volume 2ml	Fluoride Oxalate	Glucose and Lactate.	Mix 8-10 Times

IMPORTANT MIXING GUIDELINES Mix 8-10 Times

All BD Vacutainer® tubes require immediate mixing following collection. Insufficient mixing can result in inaccurate test results and the need to re-draw. Correct mixing technique is to invert each tube by the recommended number of times shown on the right hand side of the table.

BD

BD Diagnostics - Preanalytical Systems
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford OX4 4DQ
Tel: 01865 781603
Fax: 01865 781528

Amendments to the Pathology User Guide

Amend No	Date	Page No	Current		Replaced by		Approved by	Date amended electronically	Amended by
1	23/8	65	FAECES –Routine culture & Parasitology	Sterile 60 ml container	FAECES –Routine culture & Parasitology	Sterile universal half filled container	GH	23/8	AS
2	23/8	65	FAECES –For C. DIFFICILE TOXIN A&B	Sterile 60 ml container	FAECES –For C. DIFFICILE TOXIN A&B	Sterile universal half filled container	GH	23/8	AS
3	7/9/11	74	Cyto Enquiries	01234 792623	Cyto Enquiries	01234 355122 X4611	AS	19/10	AS
4	2/7/12	51	GH – Phone No	01234 792208	GH – Phone No	01234 792611	GH	2/7/12	AS
5	2/7/12	65	Urine Pregnancy Test		Remove		GH	2/7/12	AS
6	2/7/12	38	Return of FBC results		Now returned on same day by electronic link		AN	2/7/12	AS
7	2/7/12	39	Results available in one working day		Exceptions to IM Screen and RA Screen		AN	2/7/12	AS
8	2/7/12	42	Haematology ref Ranges		Changes to Haemoglobin		AN	2/7/12	AS
9	2/7/12	42	As above		Changes to MCHC ref ranges		AN	2/7/12	AS
10	2/7/12	47	Referral Laboratories	Immunology Addenbrookes	Referral Labs	Immunology St Thomas'	AN	2/7/12	AS
11	2/7/12	47	Referral Laboratories	Haemoglobinopathy Oxford	Referral Labs	Haemoglobinopathy St Thomas'	AN	2/7/12	AS
12	10/9/12	73	HPV Testing		INSERTED: HPV Testing	Since April 2012, the department has offered HPV testing on samples in line with the NHSCSP Cervical Screening Programme Guidelines	NC	10/9/12	AS
13	10/9/12	74	Dr M Wilkins	Consultant Histopathologist	Dr M Wilkins	Consultant Histopathologist, Clinical Lead	NC	10/9/12	AS
14	10/9/12	76	users are recommended to read the		transport should be in line with the		NC	10/9/12	AS

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15	10/9/12	76			Formalin Spillage Instructions		NC	10/9/12	AS
16	10/9/12	76	Turnaround times of samples		Amended		NC	10/9/12	AS
17	10/9/12	76	Bone Marrow Trephines require decalcification and the **minimum** turnaround time for a report is five days.		Removed	Specimens which contain bone will take longer than one week.	NC	10/9/12	AS
18	10/9/12	77			Out of Date Vials	Information added	NC	10/9/12	AS
19	10/9/12	77	Remove brush		Dispose of brush		NC	10/9/12	AS
20	10/9/12	79	Urine Samples		REMOVE		NC	10/9/12	AS
21	10/9/12	79			ADD	RESULTS: unless ancillary studies are required.	NC	10/9/12	AS
22	10/9/12	80	Amendment to paragraph			Operates an appointment system	NC	10/9/12	AS
23	20/9/12	13	Additional Tests	May be added by the requesting physician phoning the lab	Change	“the receipt of an “add on” request card or fax.	MS	20/9/12	AS
24	20/9/12	16	Alpha1 Antitrypsin		Change	Not available as part of standard liver test profile	MS	20/9/12	AS
25	20/9/12	16	Caeroplasmin		Change	Not available as part of standard liver test profile	MS	20/9/12	AS
26	20/9/12	17	Gastrin	Special Tube	Change	Serum only sample	MS	20/9/12	AS
27	20/9/12	17	Porphyrins		Add	EDTA – Protect from light	MS	20/9/12	AS
28	20/9/12	17			Add Vancomycin assay		MS	20/9/12	AS
29	10/9/12	21			Add ACR	Clinical Guidance	MS	20/9/12	AS

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30	10/9/12	24	Microalbumin		Change	Microalbumin (ACR)	MS	20/9/12	AS
31	10/9/12	24			Add NT Pro BNP assay	Clinical Guidance and Units of measure	MS	20/9/12	AS
32	10/9/12	28	Unusual drug assays		REMOVE		MS	20/9/12	AS
33	10/9/12	28	PTH (red topped 94acutainers)		Remove red topped vacutainers	PTH	MS	20/9/12	AS
34	10/9/12	28	Ammonia	Lavender/white	Change	Translucent	MS	20/9/12	AS
35	10/9/12	34			Add	The Department provides CA125 analysis in line with ovarian care NICE guideline 122 (April 2011)	MS	20/9/12	AS
36	10/9/12	34	Digoxin		REMOVE		MS	20/9/12	AS
37	18/10/12	87			Add	Blood Tube Guide	GH	18/10/12	AS
38	18/10/12	81	Samples to be delivered to the laboratory within 1 hour of production		Change	Samples to be delivered to the laboratory within 30-45 minutes of production	NC	18/10/12	AS
39	07/11/12	56	Chlamydia swab		Add/change	…or urine	GH	27/11/12	AS
40	07/11/12	62	Gen Probe Chlamydia		Add/change	…or urine kit	GH	27/11/12	AS
41	20/11/12	76			Add	Uncertainty of Results	NC	27/11/12	AS
42	20/11/12	75			Add	Referral Hospitals for Cellular Pathology	NC	27/11/12	AS
43	27/11/12	10			Add	Add-on Test Requests	GF	27/11/12	AS
44	27/11/12	13			Change/Add	Add-on Test requests	GF	27/11/12	AS
45	12/12/12	As necessary	Pathology Services Manager		Divisional Manager, Viapath Bedford		GF	12/12/12	GF

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46	02/09/13	3	Gillian Flack		Adrian O'Keeffe		AOK	19/09/13	AS
47	02/09/13	14	Glycated Hb		HbA1c		LW	19/09/13	AS
48	02/09/13	16	Bicarbonate		Cannot be added on		LW	19/09/13	AS
49	02/09/13	19	Cortisol Turnaround Time 7 days		Turnaround Time 21days		LW	19/09/13	AS
50	02/09/13	19	Microalbumin		Remove		LW	19/09/13	AS
51	06/09/13	83	Uncertainty of results – Histology		Amended		NC	19/09/13	AS
52	06/09/13	74	Clinical Advice		Comment added		NC	19/09/13	AS
53	06/09/13	76	Requests for additional tests		Information added		NC	19/09/13	AS
54	11/09/13	81	Sample storage		Temperature amended		NC	19/09/13	AS
55	11/10/13	82			FNA Samples	Additional information added	NC	18/10/13	AS
56	11/10/13	78			Add referral hospital	PAH	NC	18/10/13	AS
57	11/10/13	80			ThinPrep	Technology used	NC	18/10/13	AS
58	11/10/13	11			Acceptance criteria Cell Path	Addition	NC	18/10/13	AS
59	11/10/13	74			Acceptance criteria Cell Path	Addition	NC	18/10/13	AS
60	11/10/13	56	Pad Urine			TAT Amend	HG	18/10/13	AS
61	11/10/13	56	Parasites			On request	HG	18/10/13	AS
62	11/10/13	57	Outbreak investigations			TAT Amend	HG	18/10/13	AS
63	11/10/13	58	Bacterial Culture			TAT Amend	HG	18/10/13	AS
64	11/10/13	58	Bacterial Culture			Amend processing	HG	18/10/13	AS
65	11/10/13	61	Per-nasal swab			TAT Amend	HG	18/10/13	AS
66	11/10/13	61	Mycology			TAT Amend	HG	18/10/13	AS

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67	11/10/13	62	Serology Contact Number	5251	Amend	4814	HG	18/10/13	AS
68	11/10/13	63	Vanc & Gent		Amend	See Biochem Guide	HG	18/10/13	AS
69	11/10/13	64	Vanc & Gent		Remove		HG	18/10/13	AS
70	11/10/13	65	Ref Labs		Amend and update		HG	18/10/13	AS
71	11/10/13	66	Contact Lens		Amend		HG	18/10/13	AS
72	11/10/13	67	Urine Cultures			TAT Amend	HG	18/10/13	AS
73	11/10/13	67	Perianal swab		Remove		HG	18/10/13	AS
74	11/10/13	68	Mycology		Amend	TAT Amend	HG	18/10/13	AS
75	11/10/13	68	Child Abuse		Amend	Remove Woodlands	HG	18/10/13	AS
76	11/10/13	71	Cat Scratch Fever		Amend		HG	18/10/13	AS
77	11/10/13	87	Instructions for patients		Amend		JT	18/10/13	AS
78	11/10/13	84			Amend Instructions	Date & Time of specimen	JT	18/10/13	AS
79	11/10/13	13			Change time	9.40 – 5.10	LW	18/10/13	AS
80	11/10/13	13			Amend add on tests		LW	18/10/13	AS
81	11/10/13	13			Amend hospital add-on tests		LW	18/10/13	AS
82	11/10/13	13			Add	Urgent samples	LW	18/10/13	AS
83	11/10/13	14			Add	17OHP	LW	18/10/13	AS
84	11/10/13	16			Amend Bicarbonate	Special Bottle	LW	18/10/13	AS
85	11/10/13	16			Amend Copper	Special Bottle	LW	18/10/13	AS
86	11/10/13	16			Amend CRP	No indication to repeat	LW	18/10/13	AS
87	11/10/13	17			Amend Glycated Hb	Remove	LW	18/10/13	AS

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88	11/10/13	17			Add 17 hydroxyprogesterone	SST not suitable	LW	18/10/13	AS
89	11/10/13	17			Change Immunoglobulin	Now done in house	LW	18/10/13	AS
90	11/10/13	17			Change Immunoglobulin	TAT now 7 days	LW	18/10/13	AS
91	11/10/13	17			Lamotrigine	Cannot be added on	LW	18/10/13	AS
92	11/10/13	17			Porphyria screen	Full screen requires……	LW	18/10/13	AS
93	11/10/13	17			RAST	TAT is 21 days	LW	18/10/13	AS
94	11/10/13	18			Vit D	Now done in house	LW	18/10/13	AS
95	11/10/13	18			Protect cells	Protect from light	LW	18/10/13	AS
96	11/10/13	20			NEW CSF TABLE		LW	18/10/13	AS
97	11/10/13	20			GP add-on tests	Request through secure email address	LW	18/10/13	AS
98	11/10/13	33			PTH	Additional information	LW	18/10/13	AS
99	11/10/13	35			Vitamin D	Additional information	LW	18/10/13	AS
100	11/10/13	87			Post Vascectomy Samples	Courier information	KW	18/10/13	AS
101	13/12/13	80			Cellular Pathology	Specimen acceptance criteria	NC	13/12/13	AS
102	13/12/13	81			Cellular Pathology	Specimen acceptance criteria	NC	13/12/13	AS
103	13/12/13	83			Cellular Pathology	Specimen acceptance criteria	NC	13/12/13	AS
104	24/02/14	51	Platelets are not stocked in the laboratory and any request must normally be made through the Clinical Haematologist. As all platelets are collected from the NHSBT at Colindale, North London, they are not immediately available. The journey takes at least 90 mins.		Blood Transfusion	One unit of A RhD positive platelets is stocked for emergency purposes and will be issued dependent upon the clinical circumstances, age and gender of the patient. In all other cases, platelets will be ordered from the National Health Blood and Transplant Service at Colindale, North London.	PL	24/2/2014	AS

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105	24/02/14	51	Platelets should be stored at ****		Blood Transfusion	Platelets should be stored at 20-24^{0}		24/2/2014	AS
106	Aug 14		FULL REVIEW AND UPDATE OF WHOLE HANDBOOK DUE TO REBRANDING AND CHANGES TO SERVICES Including Order of Draw Card				GN	August 2014	AS
107	Aug 14	40	CPA Status updated				MS	August 2014	AS
108	Dec 14	85	Updated Andrology Infertility operating times.	0800hr – 1130hr	08:30 to 10:00 Mon-Wed.		AS	19/12/2014	SH
109	Feb 15	60	Dr Ahmed listed as a Consultant Microbiologist		Removed		HG	Feb 15	SH
110	Feb 15	12			Data Protection	Information added	HG	Feb 15	SH
110	Feb 15	12			User satisfaction and complaints	Additional information added	HG	Feb 15	SH
111	Feb 15	64			Chlamydia collection methods	Information added	HG	Feb 15	SH
112	Feb 15	70	Chlamydia samples referred to St Thomas		Chlamydia samples now processed in-house. Method stated		HG	Feb 15	SH
113	Feb 15	69-73			Added further information on methods used		HG	Feb 15	SH
114	Feb 15	69	Blood culture incubation time for endocarditis	10 days		7 days	HG	Feb 15	SH
115	Mar 15	3	Divisional Manager		General Manager		AS	Mar 15	SH
116	Apr 15	3	LLP	Viapath	Viapath Group	Lab services Viapath Analytics	SG	Apr 15	AS
117	Apr 15	62	Antibiotic assays		Teicoplanin/Amikacin/Tobramycin levels		SG	Apr 15	AS
118	Apr 15	64	CSF Information		Refer to BHT Website		SG	Apr 15	AS
119	Apr 15	65	Faeces Culture		**Clostridium difficile toxin testing** Must be requested on the laboratory form or when using electronic ordering		SG	Apr 15	AS
120	Apr 15	65	Throat Swabs		Remove other occasional pathogens		SG	Apr 15	AS

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121	Apr 15	66	Genital Tract Infections		Information added		SG	Apr 15	AS
122	Apr 15	67	Atypical Pneumonia		Removed		SG	Apr 15	AS
123	Apr 15	67	Biopsies		Addition information added		SG	Apr 15	AS
124	Apr 15	67	Outbreak investigations		Removed		SG	Apr 15	AS
125	Apr 15	67	Urine Culture		A minimum of 3mL is required for automated microscopy and culture.		SG	Apr 15	AS
126	Apr 15	68	Consumables		Amended chart		SG	Apr 15	AS
127	Apr 15	10	Add on tests		Only accepted from an nhs.net email account		SG	Apr 15	AS
128	Apr 15	68	Reference Laboratories		Table Added (to add)		SG	Apr 15	AS
129	Apr 15	All	Old header + footer		ISO compliant header+footer		SG	Apr 15	AS
130	June 15	73			Added information on specimen container for schistosoma		HG	June 15	SH
131	June 15	69			Added information on timing of specimens		HG	June 15	SH
132	June 15	4			Updated quality policy		HG	June 15	SH
133	July 15	14	Old paediatric bottle colours		Amended bottle colours		MB	July 15	SH
134	Jan 16	3	Gary Nicholson General Manager		Guy Humphrey		SH	Jan 16	AS
135	Jan 16	7	Department accessible using door pad from 8:00-6:00		8:00 – 5:30		SH	Jan 16	AS
136	Jan 16	80-81	Old table replaced		New table with referral lab info		SH	Jan 16	AS
137	Jan 16	76-90	Cellular Pathology Section		Rewritten		SH	Jan 16	AS
138	May 16	66	FOB patient instructions		Removed as no longer applicable		HG	May 16	SH
139	May 16	62			Added information on limitations		HG	May 16	SH
140	May 16	67	Salivary specimens not cultured		Removed		HG	May 16	SH

141	May 16	61	Guy Humphrey SDM		Helen Gough interim SDM		HG	May 16	SH
142	Aug 16		Full rewrite of the Clinical Biochemistry section due to assay changes and laboratory protocol changes				LW	Aug 16	AS
143	Aug 16	12	User Satisfaction		GM or Customer Service Manager		GH	Aug 16	AS
144	Aug 16	49	Opening times for Haematology		Amended to reflect 24/7 working		IA	Aug 16	AS
145	Sep 16	18	Remove SST or red top from folate sample requirement				IA	Sep 16	AS
146	Sep 16	59	Add clinical advice and how to contact on-call BMS		Addition		SA	Sep 16	AS
147	Sep 16	67	Insert ESBL and CRE screening details		Addition		SA	Sep 16	AS
148	Sep 16	69	Insertion into table for ESBL and CRE screening sample requirements		Addition		SA	Sep 16	AS
149	Sep 16	69	Insertion – MRSA screening details		Addition		SA	Sep 16	AS
150	Oct 16	41	Remove Helicobacter Pylori from Clinical Biochemistry		Remove		SH	Oct 16	AS
151	Oct 16	61	Add Helicobacter Pylori to Microbiology		Addition. Not yet accredited by UKAS		SH	Oct 16	AS
152	Oct 16	67 & 70	Add Helicobacter Pylori to both tables		Addition		SH	Oct 16	AS
153	Oct 16	18	Remove SST or red top from folate samples		Correction		IW	Oct 16	AS
154	Oct 16	40 – 43	Amend TAT for MCV, EBV, Hep A, Parvovirus, VZV		Amend TAT		IW	Oct 16	AS
155	Oct 16	43	Add VZV PCR		Addition		IW	Oct 16	AS
156	Oct 16	42	Herpes Simplex – add swab type		Add swab type		IW	Oct 16	AS
157	Oct 16	4	Quality Report		Micro already accredited to ISO		HG	Oct 16	AS
158	Oct 16	4	Quality Report		Website under review		HG	Oct 16	AS
159	Oct 16	37	Remove M Seaman		Insert SDM		AS	Oct 16	AS

160	Oct 16	All	Repagination				AS	Oct 16	AS
161 V 7.2	Oct 16						AS	Oct 16	AS
162	Nov 16	9 and 60			Added to include identity of specimen collector		HG	Nov 16	SH
163	Nov 16	59	Microbiology UKAS accreditation references		Removed reference to accreditation in title, amended sentence on accreditation		HG	Nov 16	SH
164	Nov 16	62	CSF sample volume		Add information on the volume required for TB		HG	Nov 16	SH
165	Nov 16	63			Add information on placing swabs in transport medium		HG	Nov 16	SH
166	Nov 16	65			Added information on volume of fluids for TB		HG	Nov 16	SH
167	Nov 16	66 and 69	CRE screening		Added need for visible faecal material on swab		HG	Nov 16	SH
168	Nov 16	64			Section on parasitology added		HG	Nov 16	SH
169	Nov 16	59-74			Microbiology section reviewed		HG	Nov 16	SH
170	Dec 16	84	Andrology Information		Andrology Service Updated		KW	Dec 16	AS
171	Dec 16	10	Sample collection		Added information regarding safe disposal of collection waste		SA	Dec 16	SA