NHS
Black Country Pathology Services

Black Country Pathology Services Supporting: The Dudley Group NHS Foundation Trust

GUIDE TO PATHOLOGY SERVICES

NHS Pathology Serving the Black Country
Provided by Sandwell and West Birmingham NHS Trust, The Dudley Group NHS Foundation Trust, The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trust.

CONTENTS

1 INTRODUCTION

Welcome to Pathology provided by the Black Country Pathology Services supporting The Dudley Group NHSFT. The Black Country Pathology Services (BCPS) partnership will integrate pathology services at The Royal Wolverhampton NHS Trust (RWT), with Sandwell West Birmingham Hospitals NHS Trust (SWBH), Dudley Group NHS Foundation Trust (DGH) and Walsall Healthcare NHS Trust (WHT). The BCPS will be hosted by RWT on behalf of the partnership.

The aim is to create a shared pathology service, with the hub based at New Cross Hospital, Wolverhampton and Essential Service Laboratories (ESL) at each of the remaining hospital sites (SWBH, DGH and WHT). The planned transformation project is well underway to consolidate services at the hub laboratory site. To facilitate this transformation, the building which houses the current RWT pathology services (Pathology Centre, C37 New Cross Hospital, Wolverhampton) has been expanded to meet the needs and requirements of BCPS. The BCPS has developed a single laboratory information management system (LIMS). To enable effective communication during this transformation period, a shared IT solution has been developed to enable secure sharing of data between all sites within the BCPS relating to the project.

All four Trusts (stated above) have signed the BCPS Partnership Agreement, which took effect on the 1 October 2018. Employees working within the pathology services at SWBH, DGFT and WHT have become employed by RWT in accordance with Transfer of Undertakings (Protection of Employment) Regulations 2006.

Dr Branko Perunovic is the Chief Medical Officer (CMO) for the BCPS. Graham Danks is the BCPS Operational Manager.

Clinical Leads and Discipline Leads have been appointed for each Pathology Discipline

Discipline	Job Title
BCPS	Chief Medical Officer Deputy Clinical Director Operations Manager Deputy Operations Manager Quality Manager Deputy Quality Manager
Chemistry	Clinical Lead Discipline Lead
Specialist Chemistry	Clinical Lead Discipline Lead
Haematology	Clinical Lead Discipline Lead
Blood Transfusion	Clinical Lead Discipline Lead
Immunology	Clinical Lead Discipline Lead

Microbiology	Clinical Lead Discipline Lead
Histology	Clinical Lead Discipline Lead
POCT	Clinical Lead Discipline Lead
Cytology/ Cervical Screening Programme	Histopathologist Lead Discipline Lead Cervical Screening Programme Lead Histopathologist Lead non- gynae
IT	IT Manager

To ensure the continued provision of pathology to all service users across the Black Country during the transformation period, no changes to individual laboratory quality management (QMS) and risk management systems (incident, risk reporting and managing complaints etc.) in place prior to the partnership agreement be amended, unless stated otherwise. The quality manuals and quality policies therefore, of the individual pathology services operating at each Trust site continue to be active documents. The BCPS quality manual shall outline the relationship of the pathology services within the Black Country during the transition phase. The quality manual will be revised at each key milestone during the transformation process in line with the BCPS project.

Pathology comprises of 5 functional sections which provide a comprehensive range of clinical services and diagnostic investigations: For an up-to-date list of all our tests which are accredited against ISO 15189:2012 by the United Kingdom Accreditation Service (UKAS) please go to www.ukas.com and click on the following icon:

Which provides the following:

Then type in the accreditation number for the department's tests you wish to search:

- **Biochemistry 9482**
- **Haematology 9578**

- **Immunology 9580**
- **Histology 8665 (accreditation as part of BCPS Cellular Pathology at the Hub New Cross Hospital)**
- **Andrology 8665 (accreditation as part of BCPS Cellular Pathology at the Hub New Cross Hospital)**
- **Microbiology 8655 (accreditation as part of BCPS Microbiology at the Hub New Cross Hospital)**

The document provided will show all current accredited tests.

The department also provides a wide range of POCT services which are not yet accredited.

This guide is designed to provide practical information and guidance to help you make the best use of the services we provide.

Whilst Phlebotomy is no longer part of the Pathology services supported by the BCPS, it does contribute significantly to the production of a safe and quality Pathology service. This guide contains the necessary information to support this.

2 GENERAL INFORMATION

2.1 LOCATION

The Department of Pathology is located on the 1st floor of the West wing of the hospital.
All visitors should report to Pathology Reception on arrival.
The postal address is: Department of Pathology
Russells Hall Hospital
Dudley
West Midlands
DY1 2HQ

2.2 OPENING HOURS

Department	Monday – Friday	Saturday	Sunday
Pathology Reception	09:00 – 17:00	Closed	Closed
Biochemistry	OPEN 24/7		
Haematology	OPEN 24/7		
Immunology	08:00 – 16:30	Closed	Closed

An out of hours system operates for some departments outside of the above hours (see Section 3.5 below).

2.3 CONTACT DETAILS (GENERAL ENQUIRIES)

Department	Enquiry type	External number (01384)	Internal (extension only)
Main hospital (switch board)		456111	0
Pathology Reception	General enquiries **(not results / not extra tests)**	244055	2055
Blood Science	Blood results	244086	3300
	Antenatal results		
	Additional / extra Biochemistry test		
	Blood bank		
	Appointment with clinical secretaries		
	To book a glucose tolerance test		
	Any other enquiry		
Blood bookings	For patients to book a blood test	244330	
Phlebotomy	Outpatient services	244946	2946
Biochemistry	Laboratory enquiries **(not results)**	244482	2482
Haematology	Laboratory enquiries **(not results)**	244487	2487
Blood Bank	Laboratory enquiries **(not results)**		2488
Cellular Pathology	All enquiries and results	01902 307999 ext 88277	
Immunology	All enquiries and results	456111 ext 2447	2447
Microbiology	All enquiries and results	01902 307999 ext. 88775	
Andrology	Semen analysis appointments	01902 695287	
Point of care testing (POCT)	All enquiries (use blood sciences number and select option for Any other enquiry)	01384 244299 ext.2299	
Pathology IT Support	All IT related enquiries	456111 ext 2896	2896

For other contact details, please refer to individual department and Key Contacts' sections in this guide.

2.4 CONCERNS, COMPLAINTS AND COMPLIMENTS

Whilst we take pride in the service we deliver and endeavor to make it the highest quality service we can, sometimes things can happen that are out of our control. We appreciate that our service users may want to inform us and the Trust of any poor service/treatment they receive, this is a useful process for us as it can enable us to identify ways to prevent recurrence of the same problem. Please be assured your care will not be affected adversely if you make a complaint. Let us know your comments as soon as possible and where necessary, we will do our best to put things right for you.

In addition, we want to know what you think of our services generally, what your suggestions are for the future and when you are pleased by the efforts of our staff. We are grateful when our service users take the time to send in compliments on good service, which we will pass onto the staff concerned who appreciate the feedback on their hard work. There are a number of ways you can do this:

- You can contact the Patient Advice and Liaison Service or PALS at rwt-tr.pals@nhs.net
- Phone 01902 695368 / 695362 / 07880601085
- By post to@
  Patient Experience Team
  Royal Wolverhampton NHS Trust
  New Cross Hospital
  Zone C, location C2
  Wolverhampton Road
  Wolverhampton
  WV10 0QP
- Or access the online feedback form at https://www.royalwolverhampton.nhs.uk/contact-us/compliments-feedback-and-complaints

2.5 INFORMATION GOVERNANCE

The Trust recognises the need for an appropriate balance between openness and confidentiality in the management and use of information. The Trust fully supports the principles of corporate governance and recognises its public accountability, but equally places importance on the confidentiality of and the security arrangements to safeguard both personal information about patients, staff and commercially sensitive information. The Trust also recognises the need to share patient's information with other health organisations and other agencies in a controlled manner consistent with the interests of the patient, and in some circumstances, the public interest. Any sharing will be done lawfully within RWT's Information Sharing Protocols.

The Trust believes that accurate, timely and relevant information is essential to deliver the highest quality health care. As such it is the responsibility of all clinicians, managers and staff to ensure and promote the quality of information and to actively use information in decision making processes.

Detail can be found in RWT policies:

OP12 Information security policy
OP13 Information governance policy
PRO02 Corporate records management procedure
OP85 Information sharing policy
OP90 Freedom of information policy and procedure
OP97 Confidentiality code of conduct for staff

3 USE OF THE LABORATORY

3.1 REQUESTING

We provide a wide range of tests, details of which may be found in each particular section within this document. Please contact us if you require any specific advice or guidance regarding your requests.

To avoid any unnecessary delays, please ensure that:

- Request forms are completed accurately and legibly with enough information to definitively identify the patient
    - Name
    - DOB
    - NHS number
    - Address
    - Who requested the test (the GP and / or consultant)
    - Clear / readable barcode for electronic requests
- Specimens are clearly and accurately labelled, packed correctly and where applicable lids securely fastened.
- Separate specimens have been collected when the same specimen type is required for different tests (see 'Specimen Collection' below for further guidance)
- All requests requiring a phlebotomy service should be on Sunrise by 7am
- Tests are ordered for departments separately as cross department orders will cause delays to testing.

Specimen Labelling

Specimens must be clearly labelled, with details matching those on the associated request form, after confirmation with the patient. As a minimum requirement, specimens must be labelled with:

- Patient's full name – surname & first name
- Date of birth
- Hospital / NHS number
- Clear / readable barcode for electronic requests

(Excluding Blood Transfusion specimens)

Pathology request rejection criteria:

- Samples or requests without the minimum essential identification criteria will be rejected without analysis

- Specimens will also be rejected for the following reasons, although exceptions may be made for specimens that cannot be easily repeated. In these circumstances the sample may be processed at the discretion of a senior BMS.
    - A delay in transit which could significantly affect the result.
    - An inappropriate sample for the investigation requested.
    - An inappropriate request for the sample provided

- Some Pathology disciplines will reject samples received in:
    - Leaking or broken container – please ensure lids are secure and specimens are safely packaged.
    - Incorrect specimen container.

- The laboratory will attempt to notify the requestor, ward, department or GP by telephone and the reason for rejection explained so that a repeat sample can be initiated. If the requestor cannot be contacted then the unsuitable report will be issued as soon as possible so the information about the rejected sample is available to requestors via Sunrise or Review.

Please note that in some circumstances the laboratory may not be able to accept mislabelled specimens or inaccurate request forms as this can lead to errors.

The provision of relevant clinical details is also encouraged wherever possible to ensure that the most appropriate tests are performed and to aid interpretation.

NB The date and time of collection must be entered clearly on all request forms.

3.1.1 Electronic Requesting

The facility to electronically request pathology tests is available to local GP surgeries for all routine Haematology, Biochemistry, Immunology, Serology and Microbiology requests. This is done through an electronic requesting system called 'ICE'. Any enquiries regarding the use of this system should be made to dgft.terafirmaservicedesk@nhs.net or call 01384 456111 ext. 2376.

Electronic requesting within the hospitals of The Dudley Group NHSFT is done through Sunrise. All test requestors have training from the IT team in the trust and this can be arranged by contacting dgft.terafirmaservicedesk@nhs.net or calling ext. 2376.

Training information and supporting documents and videos can be found on the Hub by following the link: http://thehub/digital-trust/SitePages/ORM.aspx

You should continue to use paper-based requesting for the following which cannot yet be raised on Sunrise:

- Histology

Transfusion requests are currently **not** available to request electronically.

When requesting through Sunrise, Pathology asks you:

- To ensure that your Zebra printers are working correctly and print clear bar codes, the tests that you have requested and all necessary patient information.
- To submit your specimen in the sample request bag. The sticker must not be stuck to the bag but must be placed in the external pocket.

- Only the large labels printed with a bar code are request labels (out patients can print a non-barcoded label to give to the patient for phlebotomy, this is not a request label).
- The large request label must not be stuck to the collection bag nor folded over on itself.
- The large request label should be put in the pocket of the collection bag away from the sample not stapled to the bag.
- When 'collecting' samples it is better to tick every test at once thus minimising the number of request labels that will be printed (a label for each tube will be printed anyway)
- If a request label has missing vertical banners or is very faint then IT need to be informed to adjust the printer.
- When ordering tests we recommend selecting common tests from the common orderables menu which each department has identified (easier than using the full menu).
- When placing the stickers/barcodes onto samples, please ensure that you are labelling them correctly.
- Please stick the right sample label to the right tube/specimen container e.g. the label will say grey top and it should be stuck to the grey top tube.

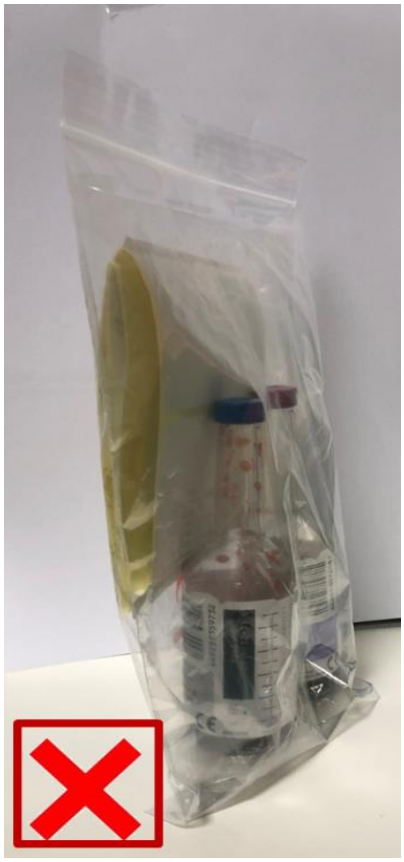
- To ensure that forms are kept flat in the specimen bags and not overly folded as this is causing them to stick to themselves and vital information (including the barcode) becomes obliterated preventing the request being processed.
- Not put forms, labels and samples into the same pocket of the specimen bags. Please put the samples in the sealable pocket and the forms and labels in the open pocket. This prevents contamination of the form if the specimens leak in transit and protects vital information from being obscured by leaked fluids.
- Hand written amendments to electronic request forms cannot be accepted.
- Have sufficient stocks of paper request forms to ensure that you can carryon requesting tests in the event of the Sunrise system failing (planned or unplanned downtime).
- Ensure that samples are labelled with at least the essential identification criteria, barcodes on the samples do not replace full sample labelling.

All tests are listed by disciple below.

- Clinical Biochemistry
- Haematology and Blood Transfusion
- Cellular Pathology and Mortuary Services
- Immunology
- Microbiology

NB – Blood Transfusion requests are not yet available electronically through Sunrise.

If you are unsure of the process please contact dgft.terafirmaservicedesk@nhs.net or calling ext. 2376.



DON’T DO THIS
The label and specimens MUST NOT be in the same area of the request bag.

DO THIS
Place the sample into the request bag and put the label into the external pocket on the back of the bag. This prevents the label from being ruined if the samples were to break.

In the event of planned or unplanned downtime, the Sunrise Business Continuity Plan can be accessed via http://thehub/digital-trust/SitePages/Home.aspx and please have sufficient stocks of paper request forms to ensure that you can carryon requesting tests in the event of the Sunrise system failing (planned or unplanned downtime).

Pathology request labels for the new Zebra printers have been set up within the Trust's catalogue on IB Solutions for re-order. The code to use when searching is DAK-3012597-T.

This code is under the catalogue name Pathology Labels and the items can be ordered as one box of 10 rolls at a value of £80.60 exc. VAT as a minimum quantity.

Please note that departments will need to re-order as required and it will not be possible to set these items up as standing orders. This is due to the monitoring of cross-charging requirements as a large bulk order has been placed on behalf of the Trust as implementation stock. Departments are, therefore, requested to ensure they monitor stock levels on-going.

3.1.2 Request forms

It is essential that correct and relevant information is provided clearly on the request form. This includes:

Patient's full name, date of birth and NHS or hospital number

Clinical details where appropriate

Specimen collection time / date

Sufficient contact details for correct reporting of results, including name and bleep number where appropriate and if needed 'copy to' details.

Requests can be made using the following request forms:

Haematology and Clinical Biochemistry use a single, combined request form. This form is split into colour-coded sections corresponding to each particular department – red, & green respectively.

Blood Transfusion – red and white request form with integral specimen bag

Immunology – light blue and white form

Microbiology – blue and yellow request form with integral specimen bag

Histology – A4 white form

Cytology (non-gynaecological) – A4 white form

The use of printed (use an addressograph label) rather than hand-written information on forms is encouraged wherever possible. Forms must be signed by the requesting GP or consultant unless previously agreed. Exceptions would include specialised screening, such as urology pre-op assessments, and MRSA screens.

3.2 BLOOD TRANSFUSION REQUESTS

3.2.1 Transfusion Request forms

All request forms must include the following details:

Patients full name

Date of birth

Unique identification number (e.g. NHS or Hospital Number)

Address

Location of patient (ward and area)

Consultant directing care

Requesting MO (signed and printed)

Contact number (telephone or bleep)

Pre-printed Addressograph-type labels are permitted on the request form providing the patient's full name is also handwritten on the label to confirm the patient's identity.

Once a suitable sample has been collected, the sample collector section must be completed. The collector must sign and print their name on the request form, a stamp may be used in-lieu of printing but it must be accompanied by a signature.

3.2.1.1 Transfusion Samples

All specimens must be labelled by hand with the following details:

Patients full name

Date of birth

Unique identification number (e.g. NHS or Hospital Number)

Ward

Date and time of collection.

The person collecting and labelling the specimen person must check all patient details to ensure they are correct, by asking the patient to confirm their identity and checking the details given match those on the wrist-band. The person labelling must sign the specimen to confirm the labelling is accurate and that the correct process has been followed.

Pre-printed labels must NOT be used on Blood Transfusion specimens.

3.3 SPECIMEN COLLECTION

Where more than one blood specimen is to be taken, the order of collection must be as stated - failure to do so may result in specimen contamination:

1. Blood culture bottles
2. Blood tubes – in the order stated in the table below

Table 1: Order of collection and type of tubes for blood specimens

Volume	Cap colour	Cap ring colour	Tube type	Tests	Special instructions
3.5 mL	 Blue	 Black	Sodium citrate	All routine coagulation, prothrombin time, APTT, Fibrinogen, INR, D-Dimer, lupus anticoagulant (2 tubes)	Fill to the line and mix well (Smaller volume tubes available on request. Under/over filled tubes will be rejected).
6 mL	 Red	 Black	Clotting accelerator	All routine Serology – including rubella, viral studies, hepatitis, HIV Biochemistry: Calcitonin, PIIINP	Send separate tube for Biochemistry
4 mL	 Ochre	 Ochre	Clotting accelerator and separation gel	All routine Biochemistry (except glucose) now including PTH, B12, Folate, Ferritin. Haematology: Erythropoietin. All routine Serology – including rubella, viral studies, hepatitis, HIV	Fill to the line and mix well Send separate tube for Haematology and Send separate tube for erythropoietin. Send separate tube for Serology
4 mL	 Ochre	 White	Clotting accelerator and separation gel	All routine Immunology	Send separate tube for Immunology
4 mL	 Green	 Black	Lithium heparin	High potassium study Chromosome studies (separate tube required), Microarray (also include EDTA specimen) Serology: T Spot (collect 2 tubes)	Fill to the line and mix
4 mL	 Lavender	 Black	EDTA	Haematology: FBC, ESR, Retics, Glandular Fever, HbS, G6PD, Hb electrophoresis, Malarial parasites, Factor V Leiden, antenatal screening (+ 2 x 6ml EDTA (pink)), cord blood for Kleihauer. Biochemistry: ACTH*, ciclosporin, Genetic tests, Gut hormones* (2 x EDTA), renin*, tacrolimus, TPMT Immunology: T/B/NK (Lymphocyte subsets), CD4, HLA B27, CD34 and HLADQ2/DQ8 Serology: Hepatitis B, Hepatitis C and HIV Quantification, Viral Loads (collect 2 tubes), Meningococcal PCR	Fill to the line and mix *Plasma must be frozen within 10 minutes Send separate tube for Biochemistry Immunology EDTA samples must **not** be refrigerated Send separate tubes for Serology
6 mL	 Pink	 Black	EDTA	All routine blood bank tests including group and antibody screen, crossmatch and maternal blood for Kleihauer Haematology: Plasma viscosity (separate tube required)	Blood Bank tube must be handwritten and labelled with **Name**, **Date of birth**, **Unit number/NHS number, date & time of collection** and **signed.**
2 mL	 Grey	 White	Fluoride oxalate	Glucose, HbA1c, alcohol, lactate	Mix the tube well

Volume	Cap colour	Cap ring colour	Tube type	Tests	Special instructions
6ml	 Dark Blue	 Black	Sodium Heparin	Trace elements (manganese, zinc, copper, selenium, cobalt, chromium)	Mix the tube well

All tubes must be filled to the appropriate level. Once collected, specimens should be put into appropriate specimen bags, with the specimens and form in separate pockets.
More detailed guidance on specimen collection can be found in the relevant sections below.

3.3.1 Paediatric tubes

Paediatric tubes are the tubes of choice to be used in neonates and paediatrics when only a small amount of blood has been obtained. They are not intended to be used for adults with poor venous access.
Advice is available from the laboratory on volumes required for each test.

Table 2: Paediatric tubes

Cap colour	Tube type	Tests	Special instructions
 Pink	EDTA	Haematology: FBC, retics, HbS, G6PD, Hb electrophoresis, malarial parasites, glandular fever screen ESR – 3 tubes minimum Serology : Meningococcal PCR Biochemistry: genetic tests	Fill the tube and mix well.
 Red	Plain	Biochemistry: Zinc, alpha-1-antiptrypsin Serology: all routine Serology including rubella, viral studies, hepatitis, HIV (not thumb prick). Immunology: all routine Immunology; for allergy testing please contact Immunology. Note that Heparin tube is not suitable for Coeliac screen.	Please use blue Microbiology request form. Fill the tube
 Green	Heparin	All routine Biochemistry (except glucose), including ammonia, Haematinics (including; B12, folate and ferritin Haematology: Chromosome studies. Serology: T Spot collect 3 full tubes	Fill the tube and mix well.
 Grey	Fluoride Oxalate	Biochemistry: Glucose, HbA1c, alcohol, lactate.	Fill the tube and mix well.
 Pink	EDTA	Haematology: Group, cross match, antibody screen, DCT.	Tube must be hand-written labelled with **Name**, **Date of birth**, **Unit number/NHS number and signed.**
 Pink	EDTA	Immunology: T/B/NK (Lymphocyte subsets), HLADQ2/DQ8	Fill the tube and mix well. Must **not** be refrigerated

3.3.2 Avoiding sharps injuries

- Never place any sharps in specimen bags. All sharps must be discarded into sharps containers at the site of use
- Management of needle stick injuries should include immediate first aid, washing the injury in running water and encouragement of bleeding. Exposure to HIV must be dealt with urgently with post-exposure prophylaxis.
- All needle stick injuries involving DGH staff must be dealt with in accordance with Trust infection control policies, including immediate referral to Occupational Health for consultation.

3.4 SPECIMEN TRANSPORTATION

There are a number of transport routes available via which specimens may be delivered to Pathology.
Please note that any specimens collected out of hours will need to be delivered directly to the laboratory.

3.4.1 Within Russells Hall Hospital

Porters collect specimens from wards and deliver them to the laboratory at Russells Hall Hospital on request to the Interserve Help Desk – extension 1234.

The **Pathology Air Tube Delivery System** links directly to the main specimen reception areas within the department, each of which has a unique 3 digit address. Use of the most appropriate address will avoid any unnecessary delays:

Biochemistry
Haematology
Immunology
Microbiology
} **074**

Specimens must be suitably bagged and placed into a carrier, taking care that the carrier is correctly closed. **Under no circumstances** must items be placed in the funnel without a carrier. The carrier is then placed into the despatch tube, and will be automatically sent as soon as the system is free – the status of the system is indicated by a series of lights:

Green	Carrier leaving your station
Yellow	Carrier arriving at your station
Red	System in use

Do not attempt to use the system without appropriate training, or if you are unsure of what to do. For training and help please contact the Interserve Helpdesk on extension 1234.
To ensure the safety of all staff, and in accordance with the DGH Infection Control Policy, the air tube delivery system **must not be used for the transport of**:

- COVID swabs
- specimens from high risk patients
- blood cultures
- CSF (cerebro spinal fluid) specimens
- Histology specimens

3.4.2 From GP surgeries

Work from GP surgeries is transported to Russells Hall Hospital via the courier services (operated by Interserve and the CCG) which calls at practices once a day at an appointed time between 9.00 am and 3.15 pm.

3.4.3 From Corbett / Guest Hospitals

During normal working hours (Monday – Friday), routine work will be transported to Russells Hall Hospital by scheduled transport:

Corbett to Russells Hall		Guest to Russells Hall	
Depart	**Arrive**	**Depart**	**Arrive**
09:30	10:00	10:10	11:15
10:45	11:15	11:55	12:20
13:20	13:40	14:00	14:20
15:15	15:45	16:30	16:45
17:10	17:45		

3.4.4 General safety precautions for transporting specimens

- All specimens must be securely closed, clearly labelled and sealed into specimen bags.
- Specimens for transport to laboratory must be sealed in a separate outer bag. They must be kept separate from mail.
- All request forms and specimens from high-risk patients **MUST** be labelled with Special Precautions or Danger of Infection labels and details of the risk stated on the request form to enable appropriate tests to be performed and precautions taken. These include:
    - HIV
    - hepatitis B/C
    - iv drug user
    - Tuberculosis
    - Salmonella typhi
    - nV CJD and CJD
- Containers for tissue in formalin must be securely closed and labelled with appropriate COSHH stickers.

Unsafe specimens which have broken or leaked will not be processed.

3.5 URGENT REQUESTS

Arrangement and contact details for urgent work will vary depending on the test required and whether the request is made within normal working hours or during a period covered by an out of hours service. Please see the relevant sections below for more details.

3.6 OUT OF HOURS SERVICE

Each night and at weekends, an out of hour's service operates from Russells Hall Hospital for Biochemistry, Haematology, and Microbiology requests. This service is designed to provide results required for the immediate management and treatment of patients outside normal laboratory hours.

The Biomedical Scientist (BMS) on duty must be contacted via the Trust Switchboard and urgent requests discussed directly, giving the reasons for the degree of urgency, so that work can be prioritised.

In life-threatening situations, such as major trauma requiring blood transfusion, requests should be classed as "Immediate". The BMS on duty will then ensure priority is given to the immediate request. When making immediate requests, please provide all available details including patient's full name, date of birth and hospital or NHS number, as this can also save time. Due to the reduced staffing levels available during out of hours periods, please double-check that any immediate request is necessary prior to request to enable us to prioritise the most urgent specimens appropriately.
Please see the relevant sections below for more details.

3.7 REPORTING OF RESULTS

All results are available as paper reports and in an electronic format, either via Keystone or available on Sunrise. In addition, users who request electronically also have access to a database of previous requests and results.

There are two main sources of uncertainty attached to the measurement of analytes. One area is uncertainty associated with pre-analytical processes and the second area is the variation (or imprecision) due to the analytical process in the laboratory and biological variation within and between individuals.

4 PHLEBOTOMY SERVICES

Please refer to The Dudley Group NHS Foundation Trust Internet for details
Blood tests - The Dudley Group NHS Foundation Trust (dgft.nhs.uk)

4.1 INPATIENTS

Russells Hall Monday – Saturday
Request forms **must** be available on the ward at 07.00 hours.

Bushey Fields Tuesday & Thursday
Request forms from Bushey Fields are sent by porter to the laboratory.

4.2 OUTPATIENTS / GP PATIENTS

Appointments can be booked Telephone number 01384 365155

Corbett Hospital Outpatient Centre
Russells Hall hospital Outpatients Centre
Guest Hospital Outpatient Centre

5 POINT OF CARE TESTING (POCT)

The Department of Pathology is responsible for the co-ordination of all POCT processes across the DGFT and certain outlying non-Trust locations, including staff training and technical support. POCT refers to a wide range of equipment and processes used outside the traditional laboratory setting to perform analytical testing, from simple urine dipstick tests to sophisticated desktop analysers.
Training sessions are designed to cover key issues such as Quality Control, External Quality Assessment, calibration and maintenance in addition to instructions for safe use.

We can also provide support to GPs in the use and management of POCT, from general advice to fully managed services.

6 CLINICAL BIOCHEMISTRY

6.1 SUMMARY OF SERVICE

The Department of Clinical Biochemistry offers an extensive range of tests, many of which are done in the department, and more that are referred to external laboratories.
The Consultant Chemical Pathologist and the Clinical Scientist (Biochemists) staff provide a clinical advisory service for both in-patients and out-patients. The medical team provide clinical advice during normal and out of hours both on the telephone and at the bedside. Facilities for 'day case' dynamic function tests for endocrine and other disorders are available and require written referral to the Consultant Chemical Pathology Team.

6.1.1 Clinical Services

The Consultant Chemical Pathologist has four out-patient clinics per week for lipid, obesity and metabolic disorders. Referral to these clinics should be in writing to the Consultants or through the Choose and Book system. Referrals for dynamic function tests, other than oral glucose tolerance tests, should be in writing.

6.2 CONTACT DETAILS

	Internal extension	External (01384)
General enquiries and results	3300	244086
Dr Helen Ashby Consultant Chemical Pathologist	2079	244079
Secretary to Dr Ashby	2078	244078
Mr Pervaz Mohammed Consultant Clinical Scientist	3375	244375
Dr Anna Sanders Principal Clinical Scientist	2081	244081
Dr Andrew Chadburn Principal Clinical Scientist	2081	244081
Mr Waqqas Usmani Head Biomedical Scientist	2080	244080

6.3 REQUESTING BIOCHEMISTRY

All requests require completion of the combined Biochemistry/Haematology request form. Please provide any details of drugs and IV therapy where appropriate. Drugs may interfere with laboratory tests and failure to appreciate this may not only affect the results obtained but also have legal consequences.

For suspected acute coronary syndromes, please refer to the Front Door Chest pain Pathway (available on The Hub). **For troponin T specimens, the date and time of specimen collection must be stated on the request form**.

For therapeutic drug monitoring the dose, date/time of last dose and date/time of specimen collection must be stated.

6.3.1 Adding on tests

When all requested tests are complete, blood samples are stored refrigerated for up to 4 days. Provided the correct specimen type was collected initially, certain tests can be added on after the initial investigations are complete. Please telephone the laboratory to discuss

your requirements. If you wish to add tests on, please telephone 2482 or bleep the on call biochemist out of hours.

6.3.2 Urgent Requests

During working hours and out of hours up until midnight, there is no need to notify the laboratory unless results are required in less than 1 hour. After midnight, the duty BMS must be contacted by bleep via the hospital switchboard.

6.4 AVAILABLE TESTS

6.4.1 Turnaround times

Please refer to the table below for turnaround times for individual tests. For tests sent tor referral laboratories, the external laboratory turnaround time has been given, and therefore allow an extra few days for postage of reports and entry onto the laboratory IT system.

The reproductive hormones, especially prolactin, and thyroid function tests may generate further tests depending on initial results. The turnaround time for these may then be slightly longer than stated.

6.4.2 Reference ranges

These are reported with each result - details can also be found in the table below. If further information is required, please contact the laboratory.

6.4.3 Patient information sheets

These are available upon request for the following:

- Glucose tolerance tests
- 24 hour urine collection
- Sweat tests
- 5HIAA dietary instructions

6.4.4 Uncertainty of measurement

There are two main sources of uncertainty attached to the measurement of analytes. One area is uncertainty associated with pre-analytical processes and the second area is the variation (or imprecision) due to the analytical process in the laboratory and biological variation within and between individuals.

Pre-analytical sources of uncertainty include posture of the patient, tourniquet application time, bleeding the right patient, labelling blood tubes correctly, using the right preservatives and anti-coagulants if required and minimising transport delays.

The contribution to the uncertainty of measurement associated with biological variation is determined by the physiology of the subjects observed and this uncertainty is caused by the inherent biological variation around the homeostatic set point. Factors contributing to biological variation include biological rhythms, puberty, menopause, age and gender. Similarly, the analytical variation will be determined by a number of factors, for example the method of analysis and calibration of the analysers. Together, biological and analytical variation determines the ‘critical difference’ which is a measure of the value by which two consecutive measurements on the same patient of the same analyte must differ to be considered a statistically significant change in the results.

Therefore, the pre-analytical processes, biological and analytical variation together all contribute to the uncertainty of measurement. Please contact the laboratory if you require further information.

6.4.5 Test/Assay Interference

Whilst assay interference is uncommon, it is important to be aware that it can occur and should be considered when results do not fit the clinical picture. This is particularly relevant for many of our immunoassay tests (e.g. hormone, peptide and tumour marker tests); where interfering antibodies, some hormone therapies, and high dose biotin (>2mg) can lead to erroneous results.

Please contact the Duty Biochemist on ext. 2081 (01384 244081) if you wish to discuss this.

6.4.6 Available Tests

The table below details the main tests provided by the laboratory.
For any other tests not listed below, or for test specific information regarding specimen requirements, please contact the department directly on extension 2081. Whilst we attempt to ensure all of our specialist referred tests are accredited, we cannot always guarantee this. Where a test is not accredited, this will be stated on the report.

Click a letter to navigate through the test list:

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

Profiles

Renal Profile	Sodium, potassium, urea, creatinine and eGFR.
Liver Profile	ALT, alkaline phosphatase, albumin and bilirubin.
Bone Profile	Calcium, adjusted calcium, phosphate, alkaline phosphatase and albumin.

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
17-Hydroxy progesterone	Serum, yellow top	Neonates (2-10 days): <8.0 Females: follicular phase: 0.4-4.0; luteal phase: 1.0-6.0 Males: 1.2-5.0 Tanner Stage 1 Males and Females: <5.0 A 9 am specimen is required for late onset congenital hyperplasia	nmol/L	Sandwell Hospital, Birmingham (7 days)		Yes
5-HIAA	Urine, 24 hour with acid	0-47	µmol/24h	8 days		Yes
ACE	Serum, yellow top	>18 years: 20-70 <18 years: 29-112	U/L	Up to 7 days		Yes
ACTH	EDTA plasma **To be received in the laboratory within 10 minutes of collection**	09:00 hours: <50 ng/L	ng/L	Up to 7 days		Yes
Acyl carnitines	Heparin plasma (green top) Blood spots made upon receipt in laboratory			(15 days) Birmingham Children's Hospital		Yes
Adalimumab	Serum, yellow top	See individual report. Anti-adalimumab antibodies added on if required.	ug/mL	City Hospital, B'ham (5 days)		Yes
AFP	Serum, yellow top	≤5.8	IU/mL	Same day		Yes

Albumin	Serum, yellow top	35-50	g/L	Same day	Yes	Yes

Albumin/creatinine ratio (ACR)	Urine, random, plain	In diabetic nephropathy: proteinuria is defined as Females: >3.5 Males: >2.5 In CKD: proteinuria is defined as a protein excretion of >30.	mg/mmol creatinine	1 day		Yes
Alcohol	Fluoride oxalate		mg/dL	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Alkaline phosphatase						
Total	Serum, yellow top	Adults: 30-130	IU/L	Same day	Yes	Yes
Bone alkaline phosphatase		Premenopausal females: 11-30 Male and postmenopausal females: 14-40	IU/L	8 days		Yes
Alpha-1 antitrypsin	Serum, yellow top Serum, red top (paediatric)	0.9-2.0	g/L	up to 7 days		Yes
Aldosterone	EDTA plasma, purple top	Upright: 100-1200 pmol/L Supine:100-860 pmol/L	pmol/L	up to 7 days		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Aldosterone:renin Ratio	EDTA plasma, purple top	<31 pmol/mlUL (cut off has a sensitivity of 99%, specificity of 79% in identifying PHA in hypertensive individuals)	pmol/mlUL	up to 7 days		Yes
ALT (alanine transaminase)	Serum, yellow top	Adult males: 0-50 Adult females: 0-35	IU/L	Same day	Yes	Yes
Amino acids	Heparin plasma (green top)	Interpretation given on each report		(15 days) Birmingham Children's Hospital		Yes
	Urine, random, plain (2 mL)					Yes
Ammonia	Heparin plasma (green top). **Take to the laboratory immediately**	Premature neonates: <150 Term neonates: <100 Infants and children: <40	µmol/L	Same day	Yes	Yes
Amylase	Serum, yellow top	28-100	U/L	Same day	Yes	Yes
	Urine, random or 4 hour with no preservative	Males 16-491; Females 21-447	U/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Androstenedione	Serum, yellow top	Adult females (pre-menopausal): 0.9-7.5 Adult females (post-menopausal): 0.4-2.9 Adult males 18-40 yr: 1.1-4.7 Adult males 40-67 yr: 0.8-3.1	nmol/L	Sandwell Hospital, Birmingham (7 days)		Yes
Antenatal screening (Down's/Trisomy screening)	Serum, yellow top	Interpretation given on each report		Referred To Birmingham Women's Hospital		Yes
AST	Serum, yellow top	Males 0-40; Females 0-32	IU/L	Same day	Yes	Yes
Beta-2 microglobulin	Serum, yellow top	0.8-2.2	mg/L	4 days		Yes
Beta-hydroxy butyrate	Fluoride oxalate	Interpreted in relation to other results	mmol/L	(3-days) Birmingham Children's Hospital		Yes
Bicarbonate	Serum, yellow top	22-29	mmol/L	Same day	Yes	Yes
Bile acids	Serum, yellow top	0-14 µmol/L in pregnancy	µmol/L	4 days		Yes
Bilirubin						Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Total	Serum, yellow top	>1 month: ≤21	µmol/L	Same day	Yes	
Conjugated bilirubin		<1 month: 0-10 >1 month ≤5				
<u>Blood Gases**</u>	Heparinised gas syringe - **brought to the laboratory immediately**			1 hour	Yes	No
Base excess		±3	mmol/L			
Bicarbonate		22-28	µmol/L			
Hydrogen ion concentration		38-45	nmol/L			
pCO2		4.5-6.1	kPa			
pH		7.35-7.42				
pO2		12-15	kPa			
BNP (NT-pro brain natriuretic peptide)	Serum, yellow top	<203 Should be interpreted in relation to appropriate NICE CG cut-offs (Acute heart failure/chronic heart failure)	ng/L	Same day		Yes
CA 15-3	Serum, yellow top	≤26.4	U/mL	4 days		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
CA 19-9	Serum, yellow top	≤26.4	U/mL	4 days		Yes
Caeruloplasmin	Serum, yellow top	Male 0.15-0.3; Female 0.16-0.45	g/L	4 days		Yes
Calcium	Serum, yellow top	2.1-2.6	mmol/L	Same day	Yes	Yes
	Urine, 24 hour with acid	2.7-7.5	mmol/24h	1 day		
Calprotectin	Faeces	<50	ug/g	7 days		Yes
Carbamazepine	Serum, yellow top	4-12 pre-dose	mg/L	4 days	Yes, must contact lab	Yes
Carnitine (free)	Heparin plasma (green top)			(15 days) Birmingham Children's Hospital		Yes
Metadrenalines (Metanephrines)	Urine, 24 hour with acid (A random urine may be appropriate for paediatrics – contact laboratory for advice)			8 days		Yes
Normetadrenaline		0.89-2.88	µmol/24h			
Metadrenaline		0.33-1.53	µmol/24h			
CEA	Serum, yellow top	≤3.8	µg/L	4 days		Yes
Chloride	Serum, yellow top	95-108	mmol/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Chloride (urine)	Urine, random, plain	Please contact the laboratory	mmol/L	Same day	Yes	Yes
Cholesterol	Serum, yellow top	Based on current National guidelines	mmol/L	Same day	Yes	Yes
Cholinesterase	Serum, yellow top	Interpretation given on individual report		Referred to North Bristol NHSFT (3 weeks)		Yes
Chromium	Sodium heparin trace element free tube (navy blue)	<40 (MHRA threshold [7ppb] = 135)	nmol/L	(5-7 days) City Hospital, Birmingham		Yes
Chromogranin A	EDTA plasma **Must be brought to laboratory immediately after collection**	Interpretation on report		Referred to Charing Cross Hospital, London		Yes
Ciclosporin	EDTA, purple top	Please contact the laboratory. Collect immediately pre-dose.	µg/L	Sandwell Hospital, Birmingham (Tuesdays and Thursdays, and **urgent by special request**)		Yes
CK (creatine kinase)	Serum, yellow top	Females: 25-200 Males: 40-320	IU/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
<u>Complement</u> C3	Serum, yellow top	0.9-1.8	g/L	1 day		Yes
C4		0.1-0.4	g/L			
Cobalt	Sodium heparin trace element free tube (navy blue)	<10 (MHRA threshold [7ppb] = 120)	nmol/L	(5-7 days) City Hospital, Birmingham		Yes
Copper	Sodium heparin trace element free tube (navy blue)	11-25 (Children older than 12 months and adults)	µmol/L	(5-7 days) City Hospital, Birmingham		Yes
	Urine, 24 hour, no preservative	0-0.9	µmol/24h	Referred to Sheffield		
Cortisol	Serum, yellow top	>16 years (9am): 133-537. >16 years (4-8pm): 68-327 30 mins post synacthen >450	nmol/L	Same day		Yes
	Urine, 24 hour, no preservative	<130	nmol/24h	(7 days) University Hospital B'ham		
Covid-19 Antibodies (see SARS-COV-2)						

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
C-peptide	Serum, yellow top	Interpretation in relation to glucose OR Random C-peptide: 370 - 1470 <200 pmol/L is associated with type 1 diabetes mellitus.	pmol/L	Up to 7 days		Yes
C-reactive protein	Serum, yellow top	0-5	mg/L	Same day	Yes	Yes
Creatinine	Serum, yellow top	Adult Males 59-104 Adult Females 45-84 Paediatric reference ranges apply	µmol/L	Same day	Yes	Yes
	Urine, random, plain	Please contact the laboratory	mmol/L	Same day	Yes	
	Urine, 24 hour with thymol	Please contact the laboratory	mmol/24 h	1 day		
CSF glucose	Fluoride oxalate	Please contact the laboratory	mmol/L	Same day	Yes	Yes
CSF protein	CSF in plain universal	0.15-0.4	g/L	Same day	Yes	Yes
DHEAS	Serum, yellow top	Gender and age specific reference ranges apply	µmol/L	Same day		Yes
Digoxin	Serum, yellow top	0.5-2.0, 6-8 hours post dose	µg/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Drugs of abuse (26 common drugs + some legal highs)	Urine, random, plain (5 mL)	Please contact the laboratory		(1-2 days) Toxicology City Hospital, Birmingam		Yes
Elastase	Faeces, random	Interpretation given on each report	µg/g	(3 days) City Hospital, Birmingham		Yes
Enhanced Liver Fibrosis screen (ELF): Fibrosis-4 Score (FIB-4)* *Calculated from AST, ALT and platelets count Procollagen III N-terminal peptide (P3NP) Hyaluronic Acid (HA) Tissue Inhibitor of Matrix Metalloproteinases (TIMP-1)	Serum, yellow top + EDTA for FIB-4	FIB4 Score: <1.29 Fibrosis Unlikely 1.3 to 3.25 Equivocal >3.25 Fibrosis Likely ELF score: <7.7 none to mild ≥7.7 to <9.8 moderate ≥9.8 Severe	ug/L	Up to 7 days		Yes
Faecal Immunochemical Testing	Faeces, random	Interpretation given on each report		2 days		Yes
Ferritin	Serum, yellow top	Female: 13-150 Male:30-400	ug/L	Same day		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Folate (request with vitamin B12)	Serum, yellow top	2.8-15	ug/L	Same day		Yes
Free fatty acids (and beta-hydroxy butyrate)	Fluoride oxalate	Interpretation given on each report		(3 days) Birmingham Children's Hospital		Yes
Fructosamine	Serum, yellow top	211-328	umol/L	(2 days) New Cross Hospital, Wolv'n		Yes
FSH	Serum, yellow top	Male: 1.5-12.4. Follicular 3.5-12.5; Ovulatory 4.7-21.5; Luteal 1.7-7.7; Post-menopausal 25.8-134.8	IU/L	Same day		Yes
Galactosaemia screen (galactose-1-phosphate)	Heparin whole blood (green top)(1mL) Blood spot made in the laboratory			(15 days) Birmingham Children's Hospital		Yes
Genetic testing (Molecular genetics as opposed to cytogenetics which is requested via Haematology Dept.)	EDTA	Full clinical details required. Requests preferred on West Midlands Regional Molecular Genetics request form		Dependent on genetic test requested (specimens sent to West Midlands Regional Genetics Lab., B'ham)		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Gentamicin	Serum, yellow top	Trough level <1.0 mg/L for once daily dosing	mg/L	1 day	Yes	Yes
GGT	Serum, yellow top	Adult males <60 Adult females <40	IU/L	Same day	Yes	Yes
<u>Glucose</u> Glucose, fasting or random	Fluoride oxalate	If fasting glucose >= 7.0 mmol/L or random >11.0 mmol/L consider diabetes. If random between 5.5 and 11.0 repeat after fasting.	mmol/L	Same day	Yes	Yes
Glucose tolerance test		If standard protocol of 75g anhydrous glucose given: 2 Hour glucose 7.8-11.0 suggests impaired glucose tolerance 2 Hour glucose >11.0 suggests diabetes mellitus.				Yes
Growth hormone	Serum, yellow top	No normal reference range. Interpretation dependent on clinical scenario. Please contact the Biochemist on ext. 2081.	ug/L	Up to 7 days		Yes
Haemochromatosis gene analysis	EDTA	Interpretation given on each report		Referred to West Midlands Regional Genetics Service		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Haptoglobin	Serum, yellow top	0.3-2.0	g/L	Same day		Yes
HbA1c Hba1c (HPLC)	Fluoride oxalate	IFCC: 20-42	mmol/mol	1 day		Yes
Homocysteine (adults)	EDTA plasma (adult) **Specimens must be taken to the laboratory IMMEDIATELY after collection**	6.7-15.2	umol/L	Birmingham Heartlands Hospital		Yes
Homocysteine (paediatrics)	Heparin plasma, green top (paediatric) **Specimens must be taken to the laboratory IMMEDIATELY after collection**	<18 (male) <16 (female)	umol/L	(10 days) Birmingham Children's Hospital		Yes
HCG	Serum, yellow top	Male: 0-1.9. Female: Pre-menopausal 0-1; Post-menopausal 0-7	IU/L	Same day	Yes	Yes
HDL	Serum, yellow top	Based on current National guidelines	mmol/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
IGF-1	Serum, yellow top	Complex age and sex specific reference ranges apply. See individual reports.	nmol/L	Up to 8 days		Yes
Insulin	Serum, yellow top	Interpreted in relation to plasma glucose	pmol/L	Up to 7 days		Yes
Infliximab	Serum, yellow top	See individual report. Anti-infliximab antibodies added if required	ug/mL	City Hospital, B'ham (5 days)		Yes
Iron	Serum, yellow top		µmol/L	1 day		Yes
Iron		5.83-34.5				Yes
Iron saturation		Females: 15-50 Males: 20-55	%			
TIBC		Females: 47-89 Males: 47-83	µmol/L			
Lactate	Fluoride oxalate	0.5-2.2	mmol/L	Same day	Yes	Yes
Lamotrigine	Serum, yellow top. Taken pre-dose	0-4	mg/L	Referred to City Hospital (Birmingham)		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
LDH	Serum, yellow top	≤250 (adults)	IU/L	Same day	Yes	Yes
Lead	EDTA, purple top	Environmental exposure <10 (<0.48) Industrial exposure <30 (<1.45)	µg/100 mL (µmol/L)	Referred to City Hospital (Birmingham)		Yes
LH	Serum, yellow top	Male: 1.7-8.6. Follicular 2.4-12.6; Ovulatory 14-95.6; Luteal 1-11.4; Post-menopausal 7.7-58.5	IU/L	Same day		Yes
Lipoprotein (a) (LPA)	Serum, yellow top	Values >75 nmol/L suggest increased risk of cardiovascular disease	nmol/L	7 days		No
Lithium	Serum, yellow top	0.4-1.0 at 12 hours post dose	mmol/L	Same day	Yes	Yes
Magnesium	Serum, yellow top	0.7-1.0	mmol/L	Same day	Yes	Yes
Manganese	Sodium heparin, dark blue top	children < 1 year: 127-328 children > 1 year: adults: 73-218	nmol/L	Referred to City Hospital (Birmingham)		Yes
Oestradiol	Serum, yellow top	Male: 95-223 Follicular 45-854; Ovulatory 151-1461; Luteal 82-1251; Post-menopausal 0-505	pmol/L	Same day		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Oligoclonal bands	CSF, plain (with serum)	Simultaneous serum specimen required. Interpretation given on each report		Immunology, University Birmingham		Yes
Oligosaccharides (mucopolysaccharidoses)	Urine, plain	Interpretation given on each report		(15 days) Birmingham Children's Hospital		No
Organic Acids	Urine, random, plain (min 5 mL)	Interpretation given on each report		(10 days) Birmingham Children's Hospital		Yes
Osmolality	Serum, yellow top	275-295	mmol/Kg	1 day		Yes
	Urine, random, plain	Please contact the laboratory for interpretation		1 day		
Ovarian tumour marker (CA 125)	Serum, yellow top	≤35	U/mL	4 days		Yes
Oxalate	Urine, 24 hour with acid	0.08-0.49	mmol/24 h	City Hospital, Birmingham (5 days)		Yes
Paracetamol	Serum, yellow top	Please refer to the BNF	mg/L	Same day	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Phenobarbitone	Serum, yellow top	15-40	mg/L	City Hospital, Birmingham (2-3 days)		Yes
Phenytoin	Serum, yellow top	10-20, pre-dose	mg/L	4 days		Yes
Phosphate	Serum, yellow top	0.8-1.5	mmol/L	Same day	Yes	Yes
	Urine, 24 hour with acid	Please contact the laboratory	mmol/24 h	1 day		
Porphyria screen	Urine, random, plain **(protect from light)** and EDTA (purple top) and faeces	**Protect from light-** give FULL clinical details. If '?' Acute Porphyria, take urine when symptomatic. Please telephone the laboratory to discuss.		Same day/referred to Porphyria Service, Cardiff	Contact lab	Yes
Potassium	Serum, yellow top Plasma, green top	3.5-5.3 3.4-4.5 (Suggest request plasma potassium if querying pseudohyperkalaemia)	mmol/L	Same day		Yes
	Urine, random, plain	Please contact the laboratory	mmol/L	Same day		
	Urine, 24 hour	Please contact the laboratory	mmol/24 h	1 day		

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Procalcitonin	Serum, yellow top	To contact Microbiology for interpretation	ng/ml	1 day	Yes	Yes
Progesterone	Serum, yellow top	Male: 0-0.5 Follicular 0.2-2.8; Luteal 5.8-76	nmol/L	Same day		Yes
Prolactin	Serum, yellow top	Male 86-324; Female 102-496	mU/L	Same day (High prolactins are subjected to further testing and may take up to 7 days)		Yes
<u>Protein</u> Total Protein	Serum, yellow top	60-80	g/L	Same day	Yes	Yes
Protein/creatinine ratio (PCRR)	Urine, random, plain	In CKD, proteinuria is defined as a ratio of ≥45, on more than one occasion	mg/mmol creatinine	1 day		Yes
Urine Protein	Urine, 24 hour with thymol	In CKD, proteinuria is defined as a protein excretion of >0.5	g/24 h	1 day		Yes
PSA	Serum, yellow top	<40years 0-1.4 40-49 years 0-2 50-59 years 0-3.1 60-69 years 0-4.1 >69 years 0-4.4	µg/L	Same day		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
PTH	Serum, yellow top	1.9-6.9	pmol/L	Same day		Yes
Reducing substances	Urine, random, plain (and faeces)	Interpretation given on each report **(not to be used as a screen for galactosaemia – please see 'galactosaemia screen')**		Birmingham Children's Hospital (2 days)		Yes
Renin (and aldosterone)	Plasma, purple top **Take to laboratory immediately after collection**	Interpretation given on each report. **Patients should be taken off beta-blockers and ACE inhibitors where possible as this affects results.**	mIU/L (Renin) pmol/L (Aldosterone)	Up to 7 days		Yes
Rheumatoid factor	Serum, yellow top					Yes
Salicylate	Serum, yellow top	Please contact the laboratory	mg/L	Same day	Yes	Yes
SARS-COV-2 Anti-nucelocapsid antibody	Serum, Yellow top	Cut Off Index (COI) <1.0 Negative for SARS Cov-2 anti-nucleocapsid antibodies		1 day	Yes	Yes
SARS-COV-2 Anti-spike antibody	Serum, Yellow top	Cut Off Index (COI) <15.0 Negative for SARS Cov-2 anti-spike antibodies		1 day	Yes	No
Selenium	Sodium heparin, trace element free tube (navy-blue top)	0-30 days: 0.4-0.7 Up to 5 years: 0.6-1.1 Up to 16 years: 0.7-1.5 Adults: 0.9-1.7	µmol/L	(5-7 days) City Hospital, Birmingham		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
sFlt-1/PlGF ratio	Serum, yellow top	sFlt-1/PlGF ratio ≤ 38		Same day	Yes	No
SHBG	Serum, yellow top	Male age 20-49, 18.3-54.1; Males age ≥50, 20.6-76.7; Females age 20-49, 32.4-128; Females age ≥50, 27.1-128	nmol/L	Same day		Yes
Sodium	Serum, yellow top	133-146	mmol/L	Same day	Yes	Yes
	Urine, random, plain	Please contact the laboratory	mmol/L			
	Urine, 24 hour	Please contact the laboratory	mmol/24 h	1 day		
Stone analysis	Calculus			City Hospital, B'ham (5 days)		YES
Sweat test	By appointment only, please contact the laboratory	A sweat chloride of less than 40 (<30 if <5 months) is normal and there is a low probability of CF. Intermediate chloride concentrations of 40-60 (30-60 if <5 months) are suggestive but not diagnostic of CF. A sweat chloride concentration of greater than 60 supports the diagnosis of CF.	mmol/L	1 day		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Tacrolimus	EDTA	Please contact the laboratory. Collect immediately pre-dose.	µg/L	Sandwell Hospital, Birmingham (Tuesdays and Thursdays, and **urgent same day by special request**)		Yes
Testosterone	Serum, yellow top **(9am specimen for males)**	Males 20-50 yr: 8.6-29.0 Males age >50 yr: 6.7-25.7 Females: ≤1.9	nmol/L	Same day (High female testosterones are sent to Sandwell Hospital, Birmingham		Yes
Theophylline	Serum, yellow top	0-5 years: 0-13 over 5 years: 10-20, pre-dose or 4 hour post- dose	mg/L	Same day	Yes, contact lab	Yes
Thioguanine nucleotides (6-TGN, 6MMPN)	EDTA, purple top			City Hospital, B'ham (2 days)		Yes
Thiopurine methyl transferase (TPMT)	EDTA, purple top	deficient: <10 low: 20-67 normal: 68-150 high: >150 NB recent blood transfusions may mask a deficient result.	mU/L	City Hospital, Birmingham (2 days)		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Thyroid (TSH front line)	Serum, yellow top		pmol/L	Same day	Yes, contact lab	Yes
FT3		3.1-6.8				
FT4		12-22	pmol/L			
TSH		0.27-4.2	mIU/L			
Thyroglobulin	Serum, yellow top		ug/L	10 days		No
Thyroglobulin Antibodies	Serum, yellow top	0-20	KU/L	10 days		No
Thyroid Microsomal (TPO) ABS	Serum, yellow top	<34	IU/mL	3 days		Yes
Toxicology	Urine, plain (5 mL)	**FULL clinical details must be provided including specific drugs of interest**		Toxicology City Hospital, Birmingham (1 day). **Contact the lab. on ext. 2081 if urgent**		Yes
Triglycerides	Serum, yellow top	<1.7	mmol/L	Same day	Yes	Yes
Troponin T	Serum, yellow top	Check Front Door Chest Pain pathway on The Hub for guidance	ng/L	1 hour (for ED/EAU)	Yes	Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
TSH Receptor Antibodies (TRAb/thyrotrophin receptor antibodies)	Serum, yellow top	0-1.75	IU/L	7 days		Yes
Urea	Serum, yellow top	2.5-7.8	mmol/L	Same day	Yes	Yes
	Urine, random, plain	Please contact the laboratory	mmol/L			
	Urine, 24 hour with thymol	Please contact the laboratory	mmol/24 h	1 day		
Uric Acid	Serum, yellow top	Male 200-430; Female 140-360	µmol/L	Same day	Yes	Yes
	Urine, 24 hour with thymol	Please contact the laboratory	µmol/24 h	1 day		
Valproate	Serum, yellow top	<100 Collect pre-dose. Routine monitoring of serum sodium valproate is not recommended. The only clinical indications are suspected toxicity and non-compliance in uncontrolled patients.	mg/L	(1 day) City Hospital, Birmingham		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Vancomycin	Serum, yellow top	pre-dose levels should be 10-15 mg/L (for deep seated infection e.g SBE,spinal abcess: pre-dose levels should be 15-20 mg/L)	mg/L	1 day	Yes	Yes
Very long chain fatty acids	Heparin plasma, green top			(15 days) Birmingham Children's Hospital		Yes
Vitamin A	Serum, yellow top	up to 7 years: 0.70-1.50 up to 13 years: 0.90-1.70 up to 20 years: 0.90-2.50 Adult females: 0.99-3.35 Adult males: 0.77-3.95	µmol/L	(2-3 days) City Hospital, Birmingham		Yes
Vitamin B12 (request with folate)	Serum, yellow top	180-650	ng/L	Same day		Yes
Vitamin D (25-hydroxy vitamin D)	Serum, yellow top	Deficient <30 May be insufficient 30-50 Sufficient >50	nmol/L	Up to 3 days		Yes

Test	Specimen type	Reference range	Units	Turnaround time (referral lab turnaround time)	Available out of hours?	Accredited
Vitamin E	Serum, yellow top	up to 2 years: 11.5-24.4 up to 7 years: 7.0-21.0 up to 13 years: 10.0-21.0 up to 20 years: 13.0-24.0 Adults: 9.5-41.5	µmol/L	(2-3 days) City Hospital, Birmingham		Yes
Xanthochromia	CSF in plain universal, **must be protected from light**	Interpretation given on each report		Same day	Yes	Yes
Zinc	Sodium heparin, trace element free tube (navy blue top) **(Serum, red top for paediatrics)**	11-24	µmol/L	(5-7 days) City Hospital, Birmingham		Yes

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****Blood Gas Analyser (BGA) use remains under the care of Point of Care testing (POCT). Blood gas analysers are situated on acute wards throughout the Trust (ITUA, ITUB, Theartres, OBS, SDEC, ED Major, ED ISO, MHDU, NNU, C5 and laboratory), and can be used by all trained personnel. An analyser is available for use in the department of Biochemistry should ones located throughout the hospital be out of use. These requests are NOT booked in through the Pathology system and no report is generated for posting to the requestor. A patient's unit number can be entered following analysis after logging onto the BGA using individual personal identification barcodes. A small till receipt type printout (with no accreditation body on the printout), is generated from the BGA with results on for clinical interpretation.**

Note: The result report is not issued by Biochemistry and is the responsibility of the trained operator of the analyser.

7 HAEMATOLOGY

7.1 SUMMARY OF SERVICE

The Department of Haematology offers a comprehensive range of tests including Coagulation and Transfusion Services.
The Consultant Haematologists provide a clinical advisory service for both in-patients and out-patients.

7.2 CONTACT DETAILS

	Internal extension	External (01384)
General enquiries & results (including antenatal results)	3300	244086
Haematology & Blood Transfusion	2487 / 2488	
Lisa Page Haematology Laboratory Manager	2091	244091
Mrs Anna Smith Blood Transfusion Manager	2091	244091
Mrs C Tuckwell Transfusion Practitioner	2758	
Anticoagulant Nursing Services	2380	
Anticoagulant Clinic Booking	2048	244048
Consultants: Clinical Haematology		
Dr S Elmoamly	3618	
Dr S Jenkins	3617	
Dr S Fernandes		
Dr O Gamage	4353	
Dr J Neilson	3700	
Dr R Hipkins	3622	
Dr C Taylor Laboratory Director; Transfusion Medicine and Clinical Haematology	3616	

7.3 CLINICAL SERVICES

The Consultant Haematologists are always willing to discuss clinical problems and offer advice. In addition, the following clinical services are provided:

Anticoagulant Services	01384 244048 (options below)
Anticoagulant Nursing Services	ext. Option 2
Anticoagulant Thrombosis Clinic	ext. Option 3
Anticoagulant Clinic Booking	ext. Option 1

Any patient admitted to hospital already receiving anticoagulant therapy should be notified to the Team on ext. 2441. Upon discharge the Anticoagulant Team MUST be contacted on ext. 2441 to ensure safe and appropriate follow up.
For anticoagulant therapy and advice contact the Anticoagulant Nursing Service on ext. 2441.

7.3.1 Out-Patient Anticoagulation services

Hospital-based warfarin maintenance clinics are held at 2 sites – appointments may be booked on 01384 244048 option 1

Day	Time	Hospital
Monday	09:00 - 12:30	Corbett
Monday	13:30 - 15:00	Russell's Hall
Tuesday*	13:30 - 15:00	Russell's Hall
Wednesday	09:00 - 12:30	Corbett
Wednesday	13:30 - 15:00	Russell's Hall
Thursday	13:30 - 15:00	Russell's Hall
Friday	09:00 - 11:00	Russell's Hall
Saturday	09:30 - 12:00	Russell's Hall

*An Anticoagulation Induction Clinic is available in the DVT suite at Russell's Hall each Tuesday & Thursday morning for patients new to Anticoagulant treatments.

Additional advice and dosage regimes for Warfarin and Heparin are available from the Anticoagulant team on ext.: 2441 or trust guidelines on the hub.
Non-ambulant patients only are catered for by a comprehensive domiciliary service, operated throughout the week.

The Anticoagulant team can be contacted 7 days a week 9am – 17.00pm for advice on warfarin dosing for inpatients.

For management of Anticoagulant Therapy please see full Anticoagulant Guidelines on The Hub.

7.4 CLINICAL HAEMATOLOGY

7.4.1 Out Patients

Patients can be referred to Haematology Consultants as above in contacts. Clinics are held twice a week at Russell's Hall:

Tuesday 13:30 – 17:30
Thursday 14:00 – 17:30

Referral is preferred through the Choose and Book system, though can also be made by referral letter.

7.4.2 In Patients

Drs Jenkins, Hipkins, Fernandes, Neilson, Taylor, Gamage and Elmoamly are available for consultation. They should be contacted to discuss individual cases where a haematological opinion is sought. There is a rota in place available from the secretaries. In the first instance, referral should be made through the electronic (Sunrise) referral system, or contact can be made with the specialist registrar or Consultant via the switchboard.

7.5 REQUESTING - HAEMATOLOGY

All requests require the completion of the combined Haematology/Biochemistry request form. Please provide relevant clinical details on all requests. These will be used to prioritise requests for testing.

Add-on tests Haematology:
Any additional test requests should be made to the laboratory within the following timescales:
Citrate samples within 4 hours of venepuncture for APTT and Special coagulation tests.
24hrs for INR, D-Dimer and Clauss fibrinogen.
EDTA samples within 24 hours venepuncture.

7.5.1 Urgent Requests

Please review Sunrise for results. There is no need to notify the laboratory unless results are required in less than one hour for urgent results and less than 4 hours for routine inpatient results. The Biomedical Scientist (BMS) on duty can be contacted via the Trust Switchboard

7.5.2 Uncertainty of measurement

There are two main sources of uncertainty attached to the measurement of analytes. One area is uncertainty associated with pre-analytical processes and the second area is the variation (or imprecision) due to the analytical process in the laboratory and biological variation within and between individuals.

Pre-analytical sources of uncertainty include posture of the patient, tourniquet application time, bleeding the right patient, labelling blood tubes correctly, using the right preservatives and anti-coagulants if required and minimising transport delays.

The contribution to the uncertainty of measurement associated with biological variation is determined by the physiology of the subjects observed and this uncertainty is caused by the inherent biological variation around the homeostatic set point. Factors contributing to biological variation include biological rhythms, puberty, menopause, age and gender. Similarly, the analytical variation will be determined by a number of factors, for example the method of analysis and calibration of the analysers. Together, biological and analytical variation determines the 'critical difference' which is a measure of the value by which two consecutive measurements on the same patient of the same analyte must differ to be considered a statistically significant change in the results.

Therefore, the pre-analytical processes, biological and analytical variation together all contribute to the uncertainty of measurement. Please contact the laboratory if you require further information.

Specific values for measurement of uncertainty can be obtained by contacting the Haematology/Blood Bank Department directly.

7.5.3 Blood Bank

A separate form is required for blood-bank requests. This must be completed in full; the patient information **MUST** include full name, hospital/NHS number, date of birth and address. Even in emergency or lack of formal identification, an emergency registration number is available. Pre-printed labels are now acceptable on the request form providing the patient's full name is also **handwritten** on the label to confirm the patient identity. The same details **MUST** be completed **BY HAND** on the patient's specimen including date and time of collection and signed by the collector, after confirming both the details with the patient and the wristband. Without this information, blood or blood products cannot be provided. Both the sample requestor and the sample collector must clearly fill in their details on the form.

Add-on tests Blood Bank:

If you have already made a Blood Bank request but wish to add on additional tests or request additional products please contact the Blood Bank for advice on extension 2488 or bleep via switchboard.

7.5.4 Antenatal blood grouping and serology requests

These specimens must be clearly labelled by hand – patient labels are NOT acceptable. The details MUST include full name, hospital/NHS number, date of birth, address, date of collection and initials of the person collecting the specimen. Without this information the blood group or any serology request cannot be provided. Pre-printed labels are now acceptable on the request form providing the patient's full name is also **handwritten** on the label to confirm the patient identity.

7.5.5 Thrombophilia Screen

When requesting thrombophilia screens, please give details of:

- reason for request
- patient's history including All thrombotic episodes, miscarriages, etc. and age at events
- family history including thrombotic history of close family members and dates at which thromboses occurred

BSH Clinical Guidelines for testing for Heritable Thrombophilia are followed.
https://b-s-h.org.uk/guidelines/

7.6 AVAILABLE TESTS

The table below details the main tests provided by the laboratory. For any other tests not listed below, please contact the department to discuss availability. ***Please note the following quoted reference ranges relate to adult requests. Paediatric reference ranges vary with age and are reported with the results.***

Click a heading to navigate through the test list:

Please note:

* Urgent requests for these tests available within 4 hours from receipt of specimen

◆ Urgent requests for these tests may be available within 1 hour from receipt of specimen – please discuss with the laboratory.

▫ Some tests have restricted availability

Critical Results are telephoned to the requestor where deemed appropriate with view of history, if new or unexpected and in line with RCPath suggested critical limits Microsoft Word - Comm Crit Results Final version.docx (rcpath.org) . **DDimers** are a negative indicator and therefore NOT telephoned as a critical results.
Note: The decision to rapidly communicate results is based solely on the numerical value and it is the requestor's responsibility for assessment and clinical decisions.

7.6.1 Factors Affecting Performance of Haematology Results

Test	**Factor affecting result** (Samples below will most likely be rejected as the result is not assured)
All Tests	Failed sample labelling acceptance criteria section 10.3 of Pathology Guide including: Unlabelled Poorly printed Label not straight/vertical on sample Incorrect sample type for test requested Sample received and no test requested Sample leaked in transit Storage and transportation conditions usually ambient temperature and within 24 hours unless stated otherwise in the Test information table below e.g. APTT must be tested within 4 hours. Contamination with Heparin or IV Fluids e.g. flushed from venflons etc. Clotted samples – results would be inaccurate and the clot may obstruct the analyser probes and delay processing of all other samples. Expired Sample tubes
Coagulation	Under filled – must be within the black triangular fill mark for accurate results Overfilled - must be within the black triangular fill mark for accurate results Haemolysed – D-Dimer would be inaccurate and therefore rejected Lipaemia – maybe unable to obtain a result due to the analytical method. Clotted samples – results would be inaccurate and the clot may obstruct the analyser probes and delay processing of all other samples. Please collect coagulation samples before all other sample types with a minimum of stasis or delay. Do not top up coagulation tubes from other samples. Special Haemostasis assays must be centrifuged, separated and frozen within 4 hours of collection – this process can take 30 minutes and it is therefore important to receive samples in the laboratory as soon as possible. Suggest discuss with a consultant haematologist before requesting any of the following investigations: · Investigation of a possible bleeding disorder · Investigation of a possible thrombophilia Please state any current anticoagulation therapy on the request form
FBC ESR Film	Small sample may produce inaccurate results e.g. falsely raised MCV EDTA may cause clumping of platelets – in this instance a citrated (coagulation) sample would be required for the platelet count, along with an EDTA for the other FBC parameters. Clotted samples – results would be inaccurate and the clot may obstruct the analyser probes and delay processing of all other samples. Old sample > 24 hours

	Cold Agglutinins require samples may require testing at 37ºC and results may be delayed where prolonged incubation required.
ESR	Small / insufficient sample unable to process – requires absolute minimum of 2.5 mls
Bone Marrow	Insufficient material to produce quality slides
Malaria Screen	Fresh sample required asap with travel history and Malaria reference report form completed and sent with the sample Malaria report form - GOV.UK (www.gov.uk)
Group & Save and Cross-match samples	Failure to meet hand written sample labelling; sufficient details on form and signature requirements Extreme Haemolysis Clotted sample Cold Agglutinins Insufficient Sample Expired Sample tubes
Age, gender and race may affect some indices for test parameters and may affect reference ranges.	

7.6.2 Table of Haematology Tests

The laboratory changed the internal IT system for reporting results to Sunrise (Hospital system) and ICE (for GPs) on 27th Sep 2022. There are some slight changes to reference ranges which will be available on the report both on the electronic systems (Sunrise and ICE) and on printed reports.

Test	Specimen type	Reference range	Units	Turnaround time	Available out of hours?	UKAS accredited ?
Full Blood Count*	4 ml EDTA, purple top	Male 130 - 180		4 hours	Y	Y
Haemoglobin		Female 115 - 165	g/L	4 hours	Y	Y
White Cell Count		4.0 - 11.00	x 10^9/L	4 hours	Y	Y
Red Cell Count		Male 4.5 - 6.5 Female 3.8 - 5.8	x 10^{12}/L	4 hours	Y	Y
PCV		Male 0.40 - 0.52 Female 0.37 - 0.47	L/L	4 hours	Y	Y
MCV		80 - 100	fL	4 hours	Y	Y
MCH		27 - 32	pg	4 hours	Y	Y
MCHC		320 - 360	g/L	4 hours	Y	Y
Platelets		150- 450	x 10^9/L	4 hours	Y	Y
Neutrophils		2.0 – 7.5	x 10^9/L	4 hours	Y	Y
Lymphocytes		1.5 – 4.5	x 10^9/L	4 hours	Y	Y
Monocytes		0.2 – 0.8	x 10^9/L	4 hours	Y	Y
Eosinophils		0.0 - 0.4	x 10^9/L	4 hours	Y	Y

Basophils		0.00 – 0.1	x 10^9/L	4 hours	Y	Y
Other Haematology Requests						
ESR*	4 ml EDTA, purple top	Male 1 -10 Female 1 - 12	mm/ 1st hour	4 hours	Y	Y
MicroESR ***non-accredited test***	1ml EDTA ***in addition*** *to* any other requests (minimum of 3 paed specimens filled to 500µl line)	Male 1 -10 Female 1 - 12	mm/ 1st hour	4 hours	Y	N
Plasma viscosity	6 ml EDTA, pink top	1.5 - 1.72	M Pas	48 hours *(referred to Heartlands Haematology)*	N	Y
Reticulocyte count*	4 ml EDTA, purple top	0.2 - 2.0 (20-100)	% (x 10^9/L)	4 hours	Y	Y
Malarial parasites blood film examination*	4 ml EDTA, purple top taken when pyrexial	Nil		24 hours *N.B. Positive results will be phoned to the requesting clinician.*	Y	Y
Blood Film	4 ml EDTA, purple top	Nil		48 hours	Y	Y
Coagulation Studies						
Prothrombin time INR	3.5 ml citrate, blue top	INR 0.8-1.2		4 hours	Y	Y
Partial thromboplastin time (PTTK aka APTT)	3.5 ml citrate, blue top	APTT ratio 0.8-1.2		4 hours	Y	Y

D-Dimer (for use in cases of ?PE & ?DVT)	3.5 ml citrate, blue top	Cut off for negative predictive value = 500 *Please note; the false positive rate of the D-dimer increases with age. Please interpret positive values in those aged over 50 years in the clinical context and/or Wells score.*	ng/ml FEU	4 hours	Y	Y
Clauss fibrinogen	3.5 ml citrate, blue top	1.5-4.5	g/L	4 hours	Y	Y
Factor Assays	***All paediatric special coagulation investigations are referred to Birmingham Children's Hospital; reference ranges available on report. Contact Haematology lab for specimen requirements.***					
VIII	3.5 ml citrate, blue top	50 – 150	IU/dl	28 days *(analysed at Royal Wolverhampton Hospital)*	N	Y
IX	3.5 ml citrate, blue top	50 – 150			N	Y
II	3.5 ml citrate, blue top	50-150	IU/dl		N	Y
V	3.5 ml citrate, blue top	50-150	IU/dl		N	Y
VII	3.5 ml citrate, blue top	50-150	IU/dl		N	Y
X	3.5 ml citrate, blue top	50-150	IU/dl		N	Y
XI	3.5 ml citrate, blue top	50-150	IU/dl		N	Y
XII	3.5 ml citrate, blue top	50-150	IU/dl		N	Y

Von Willebrand Screen	4 x 3.5 ml citrate, blue top	Von Willebrand factor antigen = 52-177.9 Von Willebrand factor activity = 45.6-176.3 Von Willebrand factor collagen binding activity (vWF;CBA = 50.5-181.2	IU/dl	6-8 weeks *(analysed at Royal Wolverhampton Hospital)*	N	Y
Anti-Xa activity assay	3.5 ml citrate, blue top *(Assay only performed by prior arrangement with Haematology)*	*Results only valid if sample collected 3-4 hours post dose.* Therapeutic range 0.6 – 1.0 Prophylactic range 0.1 – 0.3	IU/ml	7 days *(analysed at Royal Wolverhampton Hospital)*	N	Y
<u>Thrombophilia Screen</u>						
Lupus anticoagulant (screen)	2 x 3.5 ml citrate, blue top	Ratio <1.2		14 days *(analysed at Royal Wolverhampton Hospital)*	N	Y
Antithrombin III	3.5 ml citrate, blue top	83 - 128	IU/dl	28 days *(analysed at Royal Wolverhampton Hospital)*	N	Y
Protein C	3.5 ml citrate, blue top	70 - 140	IU/dl		N	Y
Free Protein S	3.5 ml citrate, blue top	Male 74.1-146.1 Female 54.7 – 123.7	IU/dl		N	Y
Factor V Leiden	4 ml EDTA, purple top	Normal			N	Y
Prothombin 2020 Gene	4 ml EDTA, purple top	Normal			N	Y

MTHFR	4 ml EDTA, purple top	Normal		28 days *(analysed at Royal Wolverhampton Hospital)*	N	Y
ADAMTS13 activity	2 x 3.5 ml citrate, blue top	38.0-110.0 *(Must be discussed with Haematology Department before sending)*	%	Dependent on clinical urgency *(referred to Sheffield Teaching Hospitals NHS Foundation Trust)*	N	Y
ADAMTS13 inhibitor *(performed if activity low)*		Negative <12 Borderline 12-15 Positive >15	U/ml			Y
Blood Transfusion Laboratory Estimation of Feto-maternal haemorrhage (Kleihauer)	6ml EDTA, pink top for maternal blood 4ml EDTA, purple top for cord blood (both hand-written)	<2ml	mls	48 hours	N	Y
		>2ml		72 hours *(Samples referred for flow cytometry at University Hospitals Birmingham NHS Foundation Trust (Heartlands) if >4ml bleed identified)*	N	Y
Baby Group, DAT and crossmatch	EDTA pink top microtainer	NA		24 hours	Y	Y
Antenatal screening: Blood group and antibody screen, full blood count and serology	6ml EDTA, pink top x 2 6ml serum, red top x 1 - (primary bloods only) 4ml EDTA, purple top x 1	NA		7 working days	N	Y

Blood Group, antibody screen	6ml EDTA, pink top	N/A		24 hours	Y	Y
Red cell immunohaematology investigations•	2x 6ml EDTA, pink top will be requested by RHH Blood Bank	N/A		5 days *(referred to NHSBT, Vincent Drive, Edgbaston)*	Y	Y
Cross Match•	6ml EDTA, pink top	N/A		24 hours	Y	Y
Direct Coombs Test•	6ml EDTA, pink top or 4 ml EDTA, purple top	N/A		24 hours	Y	Y
Haemoglobinopathy Studies Sickle haemoglobin screen (solubility test)	4 ml EDTA, purple top	Negative		4 hours	Y	Y
Hb electrophoresis		A+A		72 hours	N	Y
HbA_2 measurement		-	%	72 hours	N	Y
HbF measurement		-	%	72 hours	N	Y
Confirmation of HbC/D/E by gel electrophoresis		NA		7 days	N	Y
Unknown haemoglobin variants (except HbS/C/D/E)	2x4ml EDTA, purple top *(only by prior arrangement with Haematology Consultants)*	NA		Case dependent *(referred to UK National Haemoglobinopathy Reference Laboratory, Oxford University Hospitals)*	N	Y

Other Investigations˚						
Glandular Fever Screening Test	Preferably 4 ml EDTA, purple top but able to use 4 ml Serum, yellow top	Negative		24 hours	N	Y
Cold Agglutinins Screen (includes FBC, retics, DCT and Blood Film)	4 ml EDTA, purple top	(if approved by Haematology Consultant sent for titre if appropriate – further specimens will be required)		72 hours	N	N
Cerebrospinal fluid (CSF) cytospin *(for Haematology patients only)*	CSF	To d/w Consultant Haematologist		24 hours	N	N
Glucose-6-phosphate dehydrogenase screen	4 ml EDTA, purple top	Screen: normal activity		24 hours	N	Y
Glucose-6-phosphate dehydrogenase assay	4 ml EDTA, purple top	Assay: 4.6 – 13.5	µg/Hb	7 days *(referred to University Hospitals Birmingham NHS Foundation Trust (Heartlands))*	N	Y
Pyruvate Kinase Assay	4 ml EDTA, purple top	11-19	IU/g Hb	21 days *(referred to The Red Cell Centre, King's College Hospital, London)*	N	Y
PNH screen	4 ml EDTA, purple top	Negative	NA	5 days *(referred to University Hospitals Birmingham NHS Foundation Trust (Heartlands))*	N	Y
Erythropoietin	4 ml Serum, yellow top	5-25	IU/L	28 days *(referred to Sandwell Hospital, BCPS Laboratory)*	N	Y

JAK2 mutation	4 ml EDTA, purple top **Separate sample to FBC.**	Negative		2 months *(referred to Regional Genetics Laboratory, Birmingham Women's and Children's NHS Foundation Trust)*	N	Y
Cell Markers	4 ml EDTA, purple top **Separate sample to FBC**	Interpretation given on each report		14 days *(referred to Clinical Immunology Service, Birmingham Medical School)*	N	Y
Cytogenetics	4ml Lithium Heparin, Green top	Interpretation given on each report		Complex up to 3 months *(referred to Regional Genetics Laboratory, Birmingham Women's and Children's NHS Foundation Trust)*	N	Y
Urine Haemosiderin	Universal, plain white top	Negative		48 hours	N	Y
Investigation of possible non-accidental injury (?NAI)	**Requirements MUST be discussed on individual case basis with Haematology team at Birmingham Women's and Children's NHS Foundation Trust (0121 333 9867)**			Dependent on investigations *(referred to Birmingham Women's and Children's NHS Foundation Trust)*	N	Y
Bone Marrow Studies	Bone marrow aspirate/trephine biopsy is only performed where indicated following assessment by a Consultant Haematologist.			Non-Haematology patients: *Provisional report available within 2 weeks; final report available within 12 weeks* Haematology patients: *Full report available within 12 weeks (to include cell marker studies & cytogenetics)*	N	Y

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8 CELLULAR PATHOLOGY & MORTUARY

Cellular Pathology has relocated services to the BCPS Hub at C37 New Cross Hospital, The Royal Wolverhampton NHS Trust (RWT):
Pathology Services (royalwolverhampton.nhs.uk)

8.1 CONTACT DETAILS

BCPS Cellular Pathology	
Cellular Pathology Results and General Enquiries	01902 307999 ext 88277
Andrology results and General Enquiries	01902 695287
Consumables orders	01902 307999 ext. 88781
General Laboratory Enquiries	01902 307999 ext 88277
Cellular Pathology Consultants BCPS: (Please contact for clinical advice)	01902 695287
BCPS Discipline Lead Cellular Pathology Mrs Rita Mistry	01902 69529
Cervical Cytology (New Cross Hospital)	01902 695288
Retained Pathology Services (DGFT)	
Mortuary Services Manager: Retained Services Manager	01384 456111 ext 3314 07876 503078
Mortuary / Post-Mortem Enquiries	01384 456111 ext 2387 / 2199
Bereavement Services	01384 456111 ext 2198
HTA Designated Individual PM License: Retained Services Manager	01384 456111 ext 3314 07876 503078

8.2 CYTOLOGY

Cytology specimens are split into Diagnostic specimens (Non-Gynaecological) and Cervical Cytology specimens.

PLEASE NOTE: All cervical cytology samples are collected, processed and reported by The Royal Wolverhampton Hospitals NHS Trust.

All enquiries, result requests and requests for stock must be made to The Royal Wolverhampton Hospital NHS Trust by calling 01902 695288.

Transport of Non Gynae Cytology samples to C37 New Cross Hospital, The Royal Wolverhampton NHS Trust from The Dudley Group NHS Foundation Trust.

The procedure for sample transportation is described below:

- All sample packaging must conform to UN3373 regulations
- Diagnostic cytology specimens must be submitted to the laboratory by service users in a tightly closed leak proof container. This should be sealed in a leak proof plastic Green Non Gynae specimen bag; accompanied by a fully completed request form placed separately in the clear pocket of the bag.

- Green specimen bags must be placed into a clear outer transport bag together with a completed tracking form (see below) The tracking form must be scanned and sent to rwh-tr.cytology-non-gynae@nhs.net
- Transport bags containing the individual sample bags should be taken to RHH Pathology reception and placed in to a Versapak Insulated Pathology Bag fitted with Thinsulate insulation (C5150) which maintains the temperature of the contents for up to 6 hours. The Versapak bag should be labelled with the laboratory address and exact site location. (Cytology, A18 New Cross Hospital)
- The transport drivers must deliver the samples to New Cross Hospital, A18 Cytology Non Gynae reception, which is located directly inside the West entrance. A telephone is situated in the left hand corner outside the doors to the department to be used for admittance.
- RWT staff must sign to confirm delivery of the samples and the forms will be date/time stamped upon receipt.
- Non gynae prep room staff must check the tracking form sent with the samples against the scanned sheet which has been sent to rwh-tr.cytology-non-gynae@nhs.net to ensure every sample which has been sent by the service user has arrived at the department. If there are any discrepancies the service user will be contacted immediately.
- Opening times for receipt of samples at New Cross cytology reception is 8.30am – 5.30pm (last transport from Dudley RHH is 4pm).
- Samples that are taken too late for the last transport from RHH and before closure of Path lab reception at RHH at 5pm are to be placed in the fridge situated in Path lab reception at RHH and can be sent on the next available transport
- Last transport from Corbett hospital is no different from current practice (2.30pm). All samples that meet this time will be sent to RWT the same day.

Urgent Samples

- If the sample is Urgent please write this clearly on the request form and ideally phone the laboratory on extension 88723 or 88722 to discuss your requirements
- Please also add a contact number to the request form in order that the laboratory can make contact if there are going to be any delays. Urgent samples are prioritised and results may be available within a short time frame. Where results are not available quickly, you may be able to obtain an indication of the result by discussion with the reporting Consultant Pathologist.

Consumables

- Specimen request forms, sample containers, sample bags, transport media, LBC vials and FNA kits are supplied by the Cytology laboratory and can be requested by emailing the NG email address:
  rwh-tr.cytology-non-gynae@nhs.net or calling 01902 307999 ext.88722/88723

Contact numbers

Contact Name	Telephone Number	Email
Pathology Stores	01902 307999 ext. 88781	
Non Gynae Staff	01902 307999 ext. 88722	rwh-tr.cytology-non-gynae@nhs.net
Cytology Service Manager	01902 307999 ext. 85858	karen.kendall5@nhs.net
Senior BMS Non Gynae – Karen Taylor	01902 307999 ext.88723	k.taylor5@nhs.net
Specialist BMS Non gynae – Ann Marie Jervis	01902 307999 ext.88723	ann-mariejervis@nhs.net
Office manager – Karen Wiley	01902 695939	karen.wiley@nhs.net

Cytology Department, Royal Wolverhampton Trust

Non -Gynaecological Specimen Tracking Form

SCAN FORM AND EMAIL TO: rwh-tr.cytology-non-gynae@nhs.net
Place form in Clear Non-Gynae transport bag with samples.

Sample source: (GP Practice/Clinic/Theatre etc)	Date Sent:

PATIENT NAME/DOB/NHS NUMBER (Or patients ID label including the above)	Sample Type	Green sample bag placed in clear transport bag in clinic Name and Signature	Clear transport bag containing samples received at RWT Cytology Laboratory Name and Signature

Diagnostic Cytology (Non-Gynaecological)

The New Cross Cytology laboratory processes a wide variety of specimens, details of the requirements for individual specimen types can be found below.

Cytology **WILL NOT** accept specimens, slides or request forms which are inadequately labelled and will return these to the sender. This will result in deterioration of the quality of the specimen and will inevitably lead to a delay in reporting.

High Risk Non-Gynaecological specimens **MUST NOT** be sent in formalin.

Diagnostic cytology specimens are in the main unfixed and need to be processed as soon as possible. Cytology specimens can be susceptible to rapid deterioration of the cells and so it is crucial that they are transported to the laboratory promptly. Any samples unable to be transported to the lab immediately, for example if the specimen is collected after hours, should be stored in a refrigerator at 4°C overnight and delivered to the laboratory at the earliest opportunity the following morning.

Further advice on any aspect of specimen collection, transport or suitability for examination can be obtained from the Histology laboratory on ext. 2469

Specimen type	Guidance for submission
FNA (Fine Needle Aspiration)	See below for further details
Sputum	Specimens of early morning 'deep cough' sputum should be submitted on 3 consecutive days. The specimens should be placed in a sterile plastic specimen container. Early morning specimens before eating are preferable to avoid contamination of specimen by food particles. Induced specimens are valuable.
Body fluids including: Pleural, Peritoneal (Ascites) and pericardial fluid.	Collect fluids in sterile white topped universal containers. ***Do not send full drain bottles / bags, decant a sample of the fluid into a sterile white topped universal container***
Urine	Collect the specimen in a sterile container. Ideally, collect the specimen after the first morning specimen has been discarded. A representative specimen of **up to** 50mL of urine should be sent to the Cytology laboratory.
CSF	Collect CSF specimens for cytology in a plastic sterile white topped universal container. **DO NOT** collect in a glass container as cells adhere to glass and can be lost in preparation. The specimen must reach the laboratory as soon as possible, preferably within 2 hours.
Other Cytology Specimens: Cyst Fluids, Synovial Aspirates and Hydrocele Fluids	Collect fluid in sterile white topped universal containers.

Brush Samples	The brush should be cut off and placed directly into a Thinprep vial (available from Cytology ext2469)

FNA kit boxes and Procedures

FNA kit boxes dispatched to RHH clinics will contain the following:
X1 10ml syringe X1 safety needle X1 universal tube containing 10ml Shandon cytospin collection fluid (Shanfix) X1 plastic slide carrier containing 5 slides X1 request form X1 Non Gynae specimen bag

Procedures

Sample takers should use one slide to spread x4 slides (x2 slides should be spray fixed and x2 slides air-dried) and the needle rinsed in the Shanfix.

The Shanfix needle rinse is only processed if the reporting consultant requests a cell block to further aid diagnosis.

Fixed slides should be marked ‘F’ and air-dried slides should be marked as ‘A’ for ease of identifying for correct staining. Fixed slides are PAP stained and air-dries slides are DQ (MGG) stained.

Slides should be labelled in pencil (pen dissolves during staining process and printed labels disintegrate during staining process).

The Shanfix needle rinse universal tube and each slide should be labelled with patient’s name and NHS number, hospital number or date of birth.

Once dry the slides should be placed in the plastic slide carrier and placed in the Non Gynae specimen bag together with the Shanfix needle rinse.

The form should be completed with all relevant details – patient name/DOB/NHS No./ Hospital No./sample taker name/location (ward or clinic etc)/sample type/clinical data/contact number.

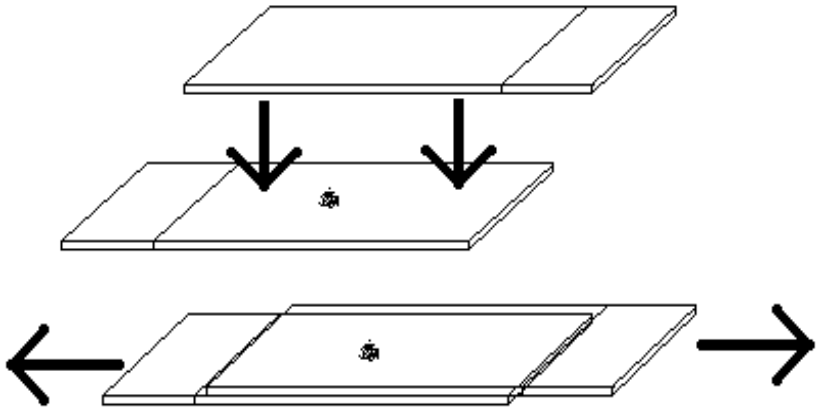
The form should be placed in the clear pocket of Non -Gynae specimen bag (separate to specimen) and all should be placed into the FNA kit box and returned to RWT New Cross (return address on front of box).

Sample takers should not put any labels on the FNA kit box.

RHH clinics can request new supplies of FNA kits by emailing the NG email address - rwh-tr.cytology-non-gynae@nhs.net or calling 01902 307999 ext.88722/88723.

FINE NEEDLE ASPIRATION- RECOMMENDED METHOD

1 Following aspiration deposit a small amount/blob (no more than 1 - 2 drops) of aspirate onto a microscope slide labelled with the patients' name and date of birth in pencil. (PLEASE ENSURE NOT TO WRITE IN INK OR USE LABELS) Sandwich the droplet between another glass slide and draw the two slides apart, smearing the aspirate thinly over both slides. If sufficient material has been collected repeat this procedure so that up to 4 preparations are made.



2 Prepare 2 air dried slides and 2 fixed slides (Spray the 2 slides to be fixed with the Cytofixx spray provided immediately after spreading) Fixed slides should be marked 'F' and air-dried slides should be marked as 'A' for ease of identifying for correct staining.

3 Rinse the needle and syringe out in the green Shandon fixative supplied. Discard the needle and syringe.

4 Place the prepared slides into the slide carrier and place into the biohazard bag together with the needle rinse. Put the completed form into the side pocket of the sample bag. Place the biohazard sample bag in the FNA kit box and return the box to the Non Gynae Cytology Department situated in A18 at New Cross Hospital.

5 Please ensure that all slides and needle rinse are clearly labelled and that the aspirate is spread on the same side of the microscope slide as the label.

8.3 MORTUARY

8.3.1 Hospital Post Mortems

A hospital post mortem should only be requested where the cause of death is essentially known and is not in a category reportable to HM Coroner. To arrange for a hospital post mortem, the following are required:

- Medical Certificate of Cause of Death
- Signed Hospital Post Mortem Examination consent form.
- Completed autopsy request form/clinical summary.
- Case notes with cause of death as on death certificate

Consent for a hospital post mortem examination must be obtained in advance from the next of kin or nominated individual and by someone trained to take consent, usually the bereavement officer or a member of the mortuary team. For further information see the Trust Policy 'Consent for hospital Post Mortem Examination and Retention of Tissue and Use of Organs.

8.3.2 Foetal, Perinatal & Neonatal Autopsies

Abortuses up to 23 weeks

Send fresh to Russells Hall Hospital Mortuary with questionnaire/clinical summary form (available in Delivery Suite).

Stillbirths (from 24 weeks onwards)

Obtain consent for autopsy. Complete consent forms (available in Delivery Suite). Send the completed forms and the foetus with placenta, where available to the mortuary at Russells Hall Hospital for collection (even if the family are arranging the funeral with their own Funeral Director). Certification of cremation of stillbirth remains will also be required.

Perinatal & Neonatal Deaths

Obtain consent and complete questionnaire. Follow above procedure. A certificate of Cremation will be required if the baby is to be cremated after post mortem.

8.3.3 Medical Certificate of Cause of Death

It is important that the Medical Certificate of Cause of Death is completed correctly otherwise problems are created when the family attempt to register the death.
The correct format is:

1. (a) the condition directly leading to the death (not mere mode of dying).

   (b) the condition(s) that caused 1 (a)

   (c) the condition (if anything) caused 1 (b).

2. Other significant condition actually contributing to death, but not part of 1 (a).

You cannot sign a certificate unless you have seen the patient within the last 14 days or have seen the deceased outside this period **AND** seen after death. It may still be possible to issue a certificate but only after consultation with HM Coroner's Office.

You can only issue death certificate if you were in attendance during the last illness (monitoring or treating). Before you issue a certificate, ask yourself the following questions:

- Do I know the cause of death?
- Was I in attendance on last illness?
- Have I seen the patient 14 days before, or after death?
- Is the death NATURAL CAUSES? (Refer to list)
- Has the death occurred MORE than 24hours after admission?

If the answer is YES to ALL of the questions, issue the certificate.

If the answer is NO to ANY of the questions, refer the death to the Coroner's Office (see below).

8.3.4 Reporting deaths to the HM Coroner's office

The following deaths **MUST** be reported to HM Coroner's Office:

- All deaths where no doctor has been in attendance within 14 days or during the last illness
- Where the cause of death is unknown.
- Deaths within 24 hours of admission to hospital, even if the cause of death is known or suspected.
- Death following accident or injury. This includes all deaths following fracture of the femur, cases of septicaemia if originating from injury, and hypothermia (cold injury).
- Deaths during or within 24 hours of operation (anaesthetic).
- Deaths related to drugs including therapeutic mishap, drugs of addiction. Also suspected transfusion reactions.
- Poisoning including self-poisoning, food poisoning, and acute alcoholic poisoning (but **not** chronic alcoholism).
- Industrial diseases including pneumoconioses, asbestosis with or without malignant mesothelioma, Weil's disease*****.
- Deaths in legal custody e.g. prisoners transferred from H.M. Prison, Bedford for treatment. Also patients **compulsorily detained** in psychiatric units under the provisions of the Mental Health Act.
- Stillbirths **only** if there are suspicious features.
- Sudden infant deaths and infant deaths, which are in any way obscure (to include suspected non-accidental injury).
- Ill-treatment (starvation, neglect).
- War pensioners if death connected to the pensionable disability.
- Crime or suspected crime, including suspected **criminal** abortion.
- Where it is known that the body is to be moved from England or Wales for burial or disposal abroad.

*****_Weil's disease (Leptospirosis) is also a notifiable disease_

The Coroner for the Black Country is Mr Zafar Siddique and he can be contacted as follows:

Telephone 0121 569 7200

Email sandwell_coroners@sandwell.gov.uk

The coroner is based at Jack Judge House in Oldbury, where inquests also take place. The address is:
H.M. Coroner's Office Black Country Coroner's Court
Jack Judge House
Halesowen Street
Oldbury
West Midlands
B69 2AJ

The opening hours of the Coroner's Office are:
Monday to Wednesday 8am to 4pm
Thursday 9am to 4pm
Friday 8am to 3.30pm.
If you have any doubt as to whether or not to issue a death certificate, then contact the pathologist, coroner's office, the bereavement officer, or mortuary technicians for advice.

8.7 Andrology

8.7.1 Completion of request forms

All sections of the request form must be completed.

This must include:
- Full surname
- Full first name
- Date of Birth
- Registration Number
- Location
- Consultant/GP
  (*Please note: that the Consultant responsible for the patients care must be included and where additional reports are to go to other relevant clinicians then these names must be included in the Additional Reports box on the request form*).
- Address & Post code
- NHS Number

Test required must be completed for semen analysis (fertility/post vasectomy).

Andrology provide an appointment booking system for ALL samples this is based at the BCPS hub (01902 695287). Please advise patients when requesting semen analysis that an appointment must be made. Toxicity tested semen pots and information leaflets are sent directly to the patient after booking their appointment.

8.7.2 Rejection Criteria

- **No request form**
- **Sample not received within 1 hour of production.**
- **Abstinence under 48 hours or over 7 days.**

- **Complete sample not collected.**
- **Not received in a toxicity tested pot.**

Patients will be asked to rebook an appointment if the sample is rejected.

9 IMMUNOLOGY

9.1 CONTACT DETAILS

	Internal	External (01384)
General enquiries / results	2447	456111 ext 2447
BCPS Discipline Lead Helen Sandy		244802
Dr M Bhole **Consultant Immunologist and BCPS Clinical Lead Immunology**	3070	
Dr C Tsakona **Locum Consultant**	1869	
Secretary	2755	244855

9.2 CLINICAL SERVICES

Both consultants are available for clinical consultations and advice on investigations and interpretation of laboratory results.

General Immunology & Allergy clinics for both adult and paediatric patients are held at the New Guest Hospital and at Russells Hall Hospital and attendance is by referral from General Practitioners or Hospital Specialists.

9.3 AVAILABLE ASSAYS AND SPECIMEN REQUIREMENTS

Daily assays

The majority of Immunology tests are performed daily and results are usually available the day following sample receipt. Some assays are used as screening tests and positive results may generate further testing which may take a few additional days.

Batched assays

Specific assays that are labour intensive, expensive or non-urgent, are batched for analysis and include C1 inhibitor quantification by radial immunodiffusion and functional antibodies to *Haemophilus influenza B* and *Pneumococcus.*

Referred tests

A relatively small number of tests are referred to reference laboratories and may take up to four weeks for results to be returned.

Requesting Additional tests

The Immunology department keeps serum samples for approximately four weeks from the date of collection. To add tests to existing samples please contact the lab on ext 2447 for advice.

9.3.1 Requests for Urgent Results

All urgent requests must be discussed with laboratory staff. Some assays can be performed within a few hours while others are performed in batches. The department will endeavour to perform the assay as soon as possible, if clinically relevant and indicated.

Special Services

Specialised assays such as lymphocyte subset markers and neutrophil function tests require specific specimens to be collected and to reach the laboratory within a certain period after

collection for the results to be valid. These assays are expensive in terms of reagents and laboratory staff time and must be discussed with laboratory staff prior to sample collection.

9.3.2 Uncertainty of measurement

There are two main sources of uncertainty attached to the measurement of analytes. One area is uncertainty associated with pre-analytical processes and the second area is the variation (or imprecision) due to the analytical process in the laboratory and biological variation within and between individuals.

Pre-analytical sources of uncertainty include posture of the patient, tourniquet application time, bleeding the right patient, labelling blood tubes correctly, using the right preservatives and anti-coagulants if required and minimising transport delays.

The contribution to the uncertainty of measurement associated with biological variation is determined by the physiology of the subjects observed and this uncertainty is caused by the inherent biological variation around the homeostatic set point. Factors contributing to biological variation include biological rhythms, puberty, menopause, age and gender. Similarly, the analytical variation will be determined by a number of factors, for example the method of analysis and calibration of the analysers. Together, biological and analytical variation determines the 'critical difference' which is a measure of the value by which two consecutive measurements on the same patient of the same analyte must differ to be considered a statistically significant change in the results.

Therefore, the pre-analytical processes, biological and analytical variation together all contribute to the uncertainty of measurement. Please contact the laboratory if you require further information.

9.3.3 Specimen Collection

Unless otherwise stated below, please use 1 full 4ml YELLOW (Ochre) with white ring top tube for all Immunology requests.

No specific clinical patient preparation is needed for sample collection for Immunology testing. All materials used in sample collection should be disposed of safely following local sharps and clinical waste procedures.

Table 1

Request	Specimen required
Allergy (*paediatric specimens only*)	If using paediatric tubes, please use a red top tube and allow at least 1 full tube for every 4 allergens requested.
Cryoglobulins	Venous blood to be taken directly into a pre-warmed (37ºC) yellow with white ring top tube and kept at 37ºC until clotted and separated in a warm centrifuge.
Functional complement CH50	1 yellow with white ring top tube to reach the Immunology Department within 3 hours of collection
Functional C1 inhibitor	2mL blood in an EDTA tube to reach the Immunology department within 3-4 hours of collection.

Table 1	
Request	**Specimen required**
Urine free light chain analysis	3mL random urine in preservative free container. **Specimens taken into boric or hydrochloric acid are <u>not</u> suitable.**
HLA-B27 Typing	3mL venous blood in EDTA to reach Immunology Department within 3-4 hours of collection
CD 4 counts / Lymphocyte subsets	3mL venous blood in EDTA, to reach the Immunology Department within 3 hours of collection. **By prior arrangement with the Department only**
NBT Test (Neutrophil function)	3mL venous blood in EDTA, to reach the Immunology Department within 3 hours collection. **By prior arrangement with the Department only**
Tryptase & Specific IgE to drugs	2 yellow with white ring top tubes; one taken at 1-2 hours post-reaction and a further sample at 24 hours.
Serum electrophoresis	If myeloma is suspected, urine should be submitted as well

9.3.4 Request Forms

- All Immunology requests must be submitted on BLUE IMMUNOLOGY forms with integral specimen bags
- Requests must include all details specified on the form, legibly completed

The points of identification provided on the request form must match the information provided on the sample:-

- The **name, date of birth** and **hospital number**
- Gender and location of patient
- Identification of the requesting clinician and destination for the report
- Exact description of specimen type and site of origin
- Examinations requested
- Date and time of primary sample collection
- Clinically relevant information about the patient. Clinical information is essential for providing the most appropriate testing and advice. The quality of clinical advice will also depend on provision of adequate clinical information. Absence of clinical information may lead to a delay in the processing of the sample while the requester is contacted to clarify or ascertain the type of investigations required.

- Patient identification labels should be applied to both forms.

Remember to include the ward or destination for the report.

The laboratory may not accept samples with inadequately completed request forms or incomplete sample labelling or where sample and request details do not match.

9.3.5 Tests Available / Assay Frequency

The table below details the main tests provided by the laboratory. Assay frequency is denoted as follows:

Table 2 Assay frequency							
D	Daily	W	Weekly			TW	Twice a week
TRW	Three time a week	FW	Fortnightly	M	Monthly	S	Sent away (usually 2-3 weeks for result)

Click a heading to navigate through the assay list:

Autoantibodies Immunoproteins Complement Assays Cellular Studies

9.3.6 Key Factors that May Affect Testing

Sample storage time: In general, samples should be sent to the laboratory with minimum delay and to arrive within 24 hours of sample collection.

Sample storage and transportation temperature: In general, samples should be stored and transported at ambient temperature unless otherwise specified.

It is important to collect samples into the correct tubes. Please ensure the correct anticoagulant (usually EDTA) or no anticoagulant (clot) is used. It is also important to supply adequate volumes of blood to allow completion of testing (sample types and volumes are listed in Table 3)

9.3.6 Patient Consent

Where patient consent is required it is the responsibility of the requester to ensure the subjects of any tests have given informed consent. Unless written notice is received to the contrary, consent for investigations and the use of any surplus sample in scheduled purposes (quality control or sample exchange schemes) will be assumed.

There is a requirement to disclose clinical information and family history to third parties when a sample is referred to another laboratory for testing. By requesting a test that requires referral, consent to disclose this information shall be automatically accepted.

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**

Antinuclear antibody (ANA, ANF)	4 ml Serum, yellow top with white ring	Positive results from the screen are titred the following day	Titre <1:80	D	4	✓
Centromere	4 ml Serum, yellow top with white ring		Negative	D	4	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Myositis extended panel	4 ml Serum, yellow top with white ring	Immunoblot includes:- Mi-2α Mi-2β TIF1γ MDA5 NXP2 SAE1 Ku PM-Scl-100 PM-Scl-75 Jo-1 SRP PL-7 PL-12 EJ OJ Ro-52	Negative	TW	7	✓
Systemic sclerosis antigens by Immunoblot	4 ml Serum, yellow top with white ring	Immunoblot includes:- Scl-70 CENP A CENP B RP11 RP155 Fibrillarin NOR90 Th/To PM-Scl100 PM-Scl75 Ku PDGFR Ro-52	Negative	TW	7	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Histone antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	<40 U/ml	S	10	✓
Smooth muscle antibody	4 ml Serum, yellow top with white ring		Negative	TW	5	✓
Mitochondrial antibody	4 ml Serum, yellow top with white ring		Negative	TW	5	✓
Gastric parietal cell antibody (GPC)	4 ml Serum, yellow top with white ring	Intrinsic factor antibodies added to positive GPC	Negative	TW	5	✓
Liver Kidney Microsomal	4 ml Serum, yellow top with white ring		Negative	TW	5	✓
Autoimmune Liver Diseases immunoblot	4 ml Serum, yellow top with white ring	Immunoblot includes:- AMA-M2 M2-3E Sp100 PML Gp210 LKM-1 LC-1 SLA/LP SS-A Ro-52 Scl-70 CENP A CENP B PGDH	Negative	TW	7	✘

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Antineutrophil Cytoplasmic Antibody (ANCA)	4 ml Serum, yellow top with white ring	All ANCA requests will be tested for PR3 and MPO antibodies. Urgent requests for ANCA antibodies must be arranged with the laboratory.	PR3 IU/ml Negative: <2 Equivocal: 2-3 Positive: >3 MPO IU/ml Negative: <3.5 Equivocal: 3.5-5 Positive >5	D	4	✓
Antibody to ds-DNA	4 ml Serum, yellow top with white ring	All new Positive ds-DNA sera are tested on Crithidia which may take a further day or two	Negative: <10 IU/ml = <10 IU/ml Equivocal: 10-15 IU/ml = 10-15 IU/ml Positive: >15 IU/ml = >15 IU/ml	D	4	✓
Crithidia Luciliae	4 ml Serum, yellow top with white ring	Follow on test for a positive ds-DNA result	Negative	TW	5	✓
Antibodies to Extractable Nuclear Antigens (ENA)	4 ml Serum, yellow top with white ring	Positive results from the screen require an additional test to confirm identity.	Screen only reported if negative. If positive, see individual identities	D	5	✓
Anti Sm	4 ml Serum, yellow top with white ring		Negative			✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Anti RNP	4 ml Serum, yellow top with white ring		Negative			✓
Anti Jo-1	4 ml Serum, yellow top with white ring		Negative			✓
Anti Ro/SSA	4 ml Serum, yellow top with white ring		Negative			✓
Anti La/SSB	4 ml Serum, yellow top with white ring		Negative			✓
Anti Scl-70	4 ml Serum, yellow top with white ring		Negative			✓
Anti Cardiolipin IgG Antibodies (ACA)	4 ml Serum, yellow top with white ring	Positive results should be repeated in 12 weeks' time for confirmation.	Negative: <10 U/ml Weak Pos: 10-40 U/ml Positive >40 U/ml	D	4	✓
Anti Cardiolipin IgM Antibodies (ACA)	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative: <10 MPLU/ml Equivocal: 10-40 MPLU/ml Positive: >40 MPLU/ml	S	5	✓
Anti β2 glycoprotein 1 IgG Antibodies (B2GP1)	4 ml Serum, yellow top with white ring	Positive results should be repeated in 12 weeks' time for confirmation.	Negative: <7 GP/L Weak Pos: 7-10 GP/L Positive: >10 GP/L	D	4	✓
Anti β2 glycoprotein 1 IgM Antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative: <10 U/ml	S	5	✓
Aspergillus Fumigates IgG Abs	4 ml Serum, yellow top with white ring	Allergic bronchopulmonary aspergillosis (ABPA)	Normal: <40 mgA/L	FW	12	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Micropolyspora faenii IgG Abs and Thermoactinomyces vulgaris Abs	4 ml Serum, yellow top with white ring	Farmers Lung	Normal: <60 mgA/L	FW	12	✓
Avian IgG Abs – Pigeon Serum Protein	4 ml Serum, yellow top with white ring	Bird Fanciers lung	Normal: <10 mgA/L	FW	12	✓
Otoblot (Hearing Loss antibodies)	4 ml Serum, yellow top with white ring	Autoimmune Inner Ear Disease Referred to Cambridge Life Sciences (ISO13485:2003)	Negative	S	10	✓
Tissue Transglutaminase IgA Abs (tTG)	4 ml Serum, yellow top with white ring	Screening test for Coeliac Disease	Negative: <7 U/ml Equivocal: 7-10 U/ml Positive: >10 U/ml	D	4	✓
Tissue Transglutaminase IgG Abs (tTG)	4 ml Serum, yellow top with white ring	Performed if the patient is IgA deficient	Negative: <7 U/ml Equivocal: 7-10 U/ml Positive: >10 U/ml	D	4	✓
Endomysial abs	4 ml Serum, yellow top with white ring	Performed to confirm positive tTG abs.	Negative	TW	5	✓
HLA DQ2, HLA DQ8	4 ml **EDTA**	Referred to H&I Blood transfusion Service, Birmingham	Negative	S	5	✓
Acetylcholine Receptor (ACR)	4 ml Serum, yellow top with white ring	Referred to Sheffield (UKAS 8494)	0.0-0.2 nmol/L	S	5	✓
MUSK abs (Muscle Specific Kinase)	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Not applicable	S	21	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Adrenal Cortex	4 ml Serum, yellow top with white ring		Negative	W	7	✓
Epithelial (skin) abs:- Epidermal Basement Membrane / Epidermal Intercellular Substance	4 ml Serum, yellow top with white ring		Negative	W	7	✓
Myocardial antibodies (Skeletal muscle done at the same time.)	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative	S	20	✓
Ovary antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative	S	20	✓
Pituitary Gland antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative	S	20	✓
Salivary Gland antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	Negative	S	20	✓
Glomerular Basement Membrane (GBM)	4 ml Serum, yellow top with white ring	Urgent requests for GBM antibodies must be arranged with the laboratory.	Negative: <7 U/ml Equivocal: 7-10 U/ml Positive: >10 U/ml	D	4	✓
Intrinsic Factor	4 ml Serum, yellow top with white ring		Negative: <7 U/ml Equivocal: 7-10 U/ml Positive: >10 U/ml	D	4	✓
Pancreatic Islet Cell	4 ml Serum, yellow top with white ring		Negative	D	7	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Insulin antibodies	4 ml Serum, yellow top with white ring	Referred to Immunology St Peters Hospital (CPA:1167)	Negative	S	20	✓
IA-2 (INSULINOMA ANTIGEN 2) antibodies	4 ml Serum, yellow top with white ring	Referred to Royal Devon & Exeter Immunology (CPA:56,57,58,59,2080,2645)	Negative	S	10	✓
PLA-2 antibodies (Phospholipase A2 Receptor)	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	<14 RU/ml	S	20	✓
Cerebellum antibodies	4 ml Serum, yellow top with white ring	Used as a screening test by indirect immunofluorescence.	Negative	W	7	✓
Cerebellum antibodies	CSF	Referred to Churchill Hospital, Immunology (UKAS 8782)	Negative	S	20	✓
Paraneoplastic antibodies by Immunoblot	4 ml Serum, yellow top with white ring	Used as a confirmatory test following the cerebellum screen Immunoblot includes:- Amphiphysin CV2/CRMP5 PNMA2 (ma2/Ta) Ri Yo Hu	Negative	TW	7	✓
Paraneoplastic extended brain blot	4 ml Serum, yellow top with white ring	Referred to Medical School, University Hospital Birmingham (UKAS 9556)	Negative	S	14	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
GAD antibodies (Glutamic Acid Decarboxylase)	4 ml Serum, yellow top with white ring Plasma unsuitable CSF also available	Referred to Sandwell Hospital Immunology (UKAS 8407)	0-5 U/ml	S	5	✓
Aquaporin 4 abs (NMO)	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Not applicable	S	20	✘
Autoimmune/Limbic Encephalopathy screen.	4 ml Serum, yellow top with white ring For CSF samples a minimum volume of 250 microliters is required	Includes GABA receptor, AMPA 1, AMPA 2, LIGL, CASP and NMDA. Referred to Medical School, University Hospital Birmingham (UKAS 9556)	Negative	S	14	✓
Ganglionic Acetylcholine Receptor abs	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Not applicable	S	42	✘
Basal Ganglia Antibodies	4 ml Serum, yellow top with white ring	Referred to Queen Square, London (UCLH) (UKAS 8045)	Negative	S	10	✓
Glycine Receptor antibodies	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Not applicable	S	28	✘

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
MOG (Myelin Oligodendrocyte Glycoprotein) antibodies	4 ml Serum, yellow top with white ring. Plasma is acceptable CSF also available	Referred to Churchill Hospital, Oxford (UKAS 8782)	Not applicable	S	20	✘
Myelin Associated Glycoprotein (MAG) antibodies	4 ml Serum, yellow top with white ring	Referred to Medical School, University Hospital Birmingham (UKAS 9556)	Negative	S	14	✓
Motorneurone antibodies (GM1, GD1a +b)	4 ml Serum, yellow top with white ring	Referred to Glasgow Neuroimmunology (UKAS 9713)	Normal result is a titre of <1/500	S	14	✓
Voltage Gated Calcium Channel antibodies	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Negative = <45pM Low Positive = 45-100pM	S	20	✘
Anti-CCP Antibodies	4 ml Serum, yellow top with white ring		Negative: <7 U/ml Equivocal: 7-10 U/ml Positive: >10 U/ml U/ml	D	4	✓
Allergy	4 ml Serum, yellow top with white ring	Total & Specific IgE (Allergy Testing). Please specify which allergens are required. A small number of less common allergens are sent away to Sheffield Immunology	0 – 0.35 kU/l	D S	4 20	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
ISAC test for component allergens	4 ml Serum, yellow top with white ring	Referred to Sandwell Hospital Immunology (UKAS 8407)	See report	S	7	✓
Mast Cell Tryptase	4 ml Serum, yellow top with white ring	Required specimens taken at 1-2 hour & 24 hours post reaction	Normal: <14 µg/L Positive: >14 µg/L	W	8	✓
Immunoglobulins IgG, IgA, IgM, Serum Protein Electrophoresis	4 ml Serum, yellow top with white ring	Age related reference ranges. Electrophoresis is performed on every request for immunoglobulins	**15-45 yrs g/l** IgG 5.4-16.0 IgA 0.8-2.8 IgM 0.5-1.9 **≥45 yrs g/l** IgG 6.0-16.0 IgA 0.8-4.0 IgM 0.5-2.0	D	5	✓
Capillary Immuno-electrophoresis / Gel Immunofixation.	4 ml Serum, yellow top with white ring		No paraprotein band	TRW	5	✓
Urine Free Light chains (Bence-Jones Protein)	25 ml random urine in universal container (without preservatives) Early morning if possible		Negative	FW	15	✘

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
IgD levels	4 ml Serum, yellow top with white ring	Referred to Medical School, University Hospital Birmingham (UKAS 9556)	2 – 100 mg/l	S	14	✓
Functional antibodies (IgG) to :- Pneumococcus Haemophilus Tetanus	4 ml Serum, yellow top with white ring	Referred to Sandwell & West Birmingham Hospital (UKAS 8407)	<u>Pneumococcal:-</u> Inadequate Ab levels: <10 mg/L Adequate Ab levels: >10 mg/L <u>Haemophilus:-</u> Inadequate levels; <0.15 mg/L Minimum protective: 0.15 mg/L Optimum protective: >1.00 mg/L <u>Tetanus:-</u> Basal protective: >0.1IU/ml	M M S	30 30 7	✓ ✓ ✓
Pneumococcal Serotypes	4 ml Serum, yellow top with white ring	Referred to Churchill Hospital, Oxford (UKAS 8782)	Protective level: ≥0.35 µg/ml	S	20	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
IgG Subclasses IgG4 subclass	4 ml Serum, yellow top with white ring	IgG subs will only be done after discussion with Immunology Consultant - functional IgG abs to *Pneumococcus*, *Haemophilus B* and *Tetanus* are more clinically relevant than IgG Subclasses to assess immune-competency. Referred to Churchill Hospital, Oxford (UKAS 8782) IgG4 requested on its own is useful in the diagnosis of autoimmune pancreatitis and other IgG 4 related diseases.	Adult reference range: •IgG1 = 3.80 - 9.30g/L •IgG2 = 2.40 - 7.00g/L •IgG3 = 0.20 - 1.80g/L •IgG4 = 0.04 - 0.86g/L	S	7	✓
Meningococcal C abs levels	4 ml Serum, yellow top with white ring	Referred to Manchester Medical Vaccine Evaluation Unit (UKAS 8393)	Protective >1:8 Titre	S	28	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Cryoglobulins	4 ml Serum, yellow top with white ring	Clotted specimen must be taken into a pre-warmed container not less than 37°C (and up to 40°C). The assay requires an initial 7 days at 4ºC to allow any cryoprecipitate to form. Presence of cryoprecipitate will require further work for identification.	Negative	W	14	✓
C1 Esterase Inhibitor	4 ml Serum, yellow top with white ring	Referred to Royal Wolverhampton (UKAS 8663)	0.21-0.39 g/l	FW	14	✓
Functional C1 Inhibitor	4 ml Serum yellow top with white ring must be frozen within 1 hour of collection. Must be sent to the referral laboratory frozen and arrive frozen.	FC1 inhibitor will only be done after discussion with Immunology Consultant Referred to Medical School, University Hospital Birmingham (UKAS 9556)	70 – 130%	S	28	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Functional CH50 Classical Complement Pathway	4 ml Serum, yellow top with white ring. Frozen within 2 hours of collection	Functional Complement assays will only be done after discussion with Immunology Consultant. Referred to UHB, Heartlands Immunology (UKAS 8217)	Normal 42-95 U/mL Borderline 29-42 U/mL Low <29 U/mL	S	20	✘
C3 Nephritic Factor (C3NeF)	4 ml Serum, yellow top with white ring. Frozen within 2 hours of collection	C3NeF will only be done after discussion with Immunology Consultant Referred to Sheffield Immunology (UKAS 8494)	Negative	S	20	✓
C1q	4 ml Serum, yellow top with white ring. Frozen within 2 hours of collection	Referred to Sheffield Immunology (UKAS 8494)	50-250 Mg/L	S	20	✓
C1q antibodies	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)	0-15 U/ml	S	20	✓
Mannose Binding Lectin (MBL)	4 ml Serum, yellow top with white ring	Referred to Sheffield Immunology (UKAS 8494)		S	20	✓

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
Angioedema Screening Panel: ANA Total IgE C3,C4 (performed by Biochemistry) Igs	4 ml Serum, yellow top with white ring		See individual tests	See individual tests	See individual tests	✓
Lymphocyte Surface Markers HIV Monitoring (CD3,CD4,CD8,CD45) TBNK (CD3, CD56.CD16, CD19, CD45)	4 ml **EDTA** sample to be kept at room temperature	HIV positive samples must be labelled as high risk	Age related reference ranges adapted from Commans-Bitter WM *et al*, J Pediatr.1997;130:388-393	D	2	✓
HLA-B27 Typing	4 ml **EDTA** sample to be kept at room temperature	Histocompatobility & Immunogenetics, Blood Transfusion Service Birmingham B12 2SG	Negative	D	3	✓
Class-switched memory B cells (EUROClass)	4 ml **EDTA** sample to be kept at room temperature		Not applicable	D	3	✓
Nitroblue Tetrazolium Test (NBT)	4 ml **EDTA** sample to be kept at room temperature	For Phagocytic Respiratory Burst	Unstimulated: <10 % Stimulated: >30 %	Same Day	3	✘

Table 3: Sample type, volume, reference ranges, assay frequency and turnaround times						
Investigation	**Sample Type**	**Comments**	**Reference Range**	**Assay Frequency**	**Turnaround time in days (excludes week ends)**	**Accredited Test**
T cell Proliferation Assay (PHA)	2 **Lithium Heparin** paediatric tubes or 1 adult **Lithium Heparin** plus control tube (usually from parent) Kept at room temperature	Referred to Heartlands Hospital, Immunology. Test only performed Monday, Tuesday and Wednesday. To be arranged with the lab before sending.	Not applicable	S	4-10	✓
Skin Prick Tests		Will be performed by Consultant Immunologist as part of Immunology Outpatients Consultation.				

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9.3.7 Guide to the appropriate use of immunological assays

Diagnosis of SLE	ANA, dsDNA, ENA, Igs and C3/C4 *(please request C3/C4 from Biochemistry)* dsDNA and C34 are useful for monitoring disease progression.
SLE in pregnancy	include anti-Cardiolipin abs in above panels
Diagnosis of Myeloma	Igs and electrophoresis (immunofixation will be performed if indicated) Send both blood and urine
Autoimmune screen	ANA, Smooth Muscle, Igs and C3/C4 *(please request C3/C4 from Biochemistry)*
Vasculitis screen	ANA, ANCA, Igs and C3/C4 *(please request C3/C4 from Biochemistry)* Secondary testing for anti- Cardiolipin and Cryoglobulin may be useful
Renal Screen	ANA, Smooth Muscle, ANCA, Igs and C3/C4 *(please request C3/C4 from Biochemistry)* Secondary testing for Cryoglobulin and GBM may be useful
Angioedema screen	Total IgE, ANA, Igs and C3/C4 *(please request C3/C4 from Biochemistry)*

9.3.8 Description of available assays

Assay	Description / Comments
Acetylcholine receptor abs	Test for Myasthenia Gravis.
Adrenal abs	Test for autoimmune adrenal disease.
Antinuclear abs	This is used as a screening test for Lupus (SLE) and certain other connective tissue diseases. Strong positive results (titres of 1:320 and above) may be clinically significant, particularly with some staining patterns. For example: *Speckled pattern* – connective tissue disease, SLE; *Homogenous pattern* – SLE, and drug induced lupus; *Nucleolar pattern* – scleroderma or sicca syndrome. However, positive ANA (particularly at low titre) may also be seen after infection or even in asymptomatic individuals (especially older people and females).
Aspergillus Fumigates (IgG)	Hypersensitivity pneumonitis, also known as Extrinsic Allergic Alveolitis (EAA), is an inflammatory lung disease resulting from an exaggerated immune response (hypersensitivity) to certain inhaled allergens, including moulds (aspergillus species)
Avian IgG abs – Pigeon Serum Protein	Hypersensitivity pneumonitis, also known as Extrinsic Allergic Alveolitis (EAA), is an inflammatory lung disease resulting from an exaggerated immune response (hypersensitivity) to certain inhaled allergens. Bird fanciers lung is the common syndrome associated with exposure to avian antigens. A Pigeon Serum Protein assay is used to screen for this condition as antigen epitopes in pigeon serum protein are shared across most common pet avian species.
Cardiolipin/Phospholipid abs (B2GP1 abs)	Persistent high levels of anti-cardiolipin antibodies are associated with anti-phospholipid syndrome, characterised by a risk of arterial or venous thrombosis. Please check lupus anticoagulant (Haematology) at the same time. Positive results should be repeated in 12 weeks' time for confirmation.
CCP abs	Specific for and suggestive of RA in patients with early un-differentiated arthritis.
Centromere abs	Strongly associated with the limited cutaneous form and the CREST variant of systemic sclerosis. In cases with Raynaud's, the presence of centromere antibody indicates an increased chance of developing connective tissue disease in the future.
Complement C3 and C4	Measurements of both are of value in monitoring the activity of SLE and immune complex disease. C4 is of particular value in both SLE and angioedema when levels are well below normal. C4 levels are used as a screening test for patients with suspected angioedema due to C1 INH deficiency (See below). Please note that C3 and C4 are performed in the Clinical Chemistry department.
C1 esterase inhibitor	Antigenic and functional levels. Typically C1 INH deficiency, both hereditary and acquired, is associated with low C4 levels during acute episodes, which is therefore used as a screening test for suspected HAE or AAE – see below.
Hereditary Angioedema (HAE)	Autosomal dominant disorder commonly due to C1INH deficiency. Most cases have reduced serum C1 INH levels (Type 1). One in ten cases may have normal C1 INH levels, but reduced function (Type 2).
Acquired angioedema (AAE)	Reduced C1 INH levels, most commonly associated with B-cell lymphoproliferative disorders.

Assay	Description / Comments
Cryoglobulins	These are immunoglobulins that precipitate on cooling of serum or plasma and are classified into three categories: Type 1: Typically monoclonal (commonly IgM) with rheumatoid factor activity. Clinical associations include Waldenströms macroglobulinaemia, myeloma or lymphoma. Type 2 and 3: These are mixed or polyclonal cryoglobulins resulting in the formation of immune complexes that can clinically present as vasculitis, synovitis or glomerulonephritis. (Sample must be collected into a pre-warmed tube and kept at 37ºC till clotted).
ds DNA abs	High levels are associated with active SLE. Low positive levels may be seen in quiescent SLE, RA, and other autoimmune conditions and must be correlated clinically. Assay of antibodies to native, double stranded DNA (dsDNA antibodies), is performed by EIA and followed up with qualitative test by IIF on the kinetoplast of crithidia lucillae.
Endomysial abs	A positive result is strongly associated with coeliac disease. This assay is done by IIF and is used as a confirmatory laboratory test following a positive tTG antibody by ELISA. The gold standard for diagnosis of coeliac disease still remains a tissue diagnosis whilst on a gluten diet. Endomysial antibodies may be falsely negative in very mild gluten induced enteropathy or in patients on a gluten free diet.
ENA abs	the department currently identifies six specificities:-
RNP	Highly specific for MCTD, also 25% of SLE and 15% of Myositis.
Sm.	Highly specific for SLE, with renal involvement and poor prognosis.
Ro (SS-A)	In 75% of Primary Sicca syndrome, 75% of annular LE, 25% of SLE, 20% of MCTD, 5% of Myositis and PBC.
La (SS-B)	In 50% of Primary Sjögrens syndrome, 10% of SLE and <5% in other CTD.
Jo1	In 20-40% of patients with aggressive Polymyositis, usually in association with interstitial lung disease and arthralgia.
Scl70	Positive in 20-40% of patients with progressive systemic sclerosis (PSS). These antibodies are considered to be specific for PSS, but may be also seen in some patients with MCTD or overlap syndromes.
Functional Antibodies	These tests are to be used to check immune competency and not as surrogate markers of protection against infection.
Gliadin abs	This assay is not currently recommended and not routinely offered for the diagnosis of coeliac disease. Serum tTG and Endomysial antibodies are more specific screening assays for coeliac disease than Gliadin (NICE guidelines) and should be used in preference. **All requests for Gliadin antibodies will be referred to the Immunology Consultant to establish the clinical relevance.**
Glomerular basement membrane abs	Associated with rapidly progressive glomerulonephritis with or without lung involvement (Goodpastures or pulmonary renal syndrome). Immunosuppression or plasmapheresis may be indicated.

Assay	Description / Comments
Immunoglobulins (IgG,A,M)	Immunoglobulin levels and electrophoresis are useful screening tests in patients with severe, persistent, recurrent or unusual infections. Reduced Immunoglobulin levels may be seen in primary or secondary immunodeficiency disorders. Secondary causes for low Immunoglobulin levels commonly include:- Haematological malignancies (CLL, Myeloma) Nephrotic syndrome Other protein losing states (enteropathy, lymphangectasia) Drugs (anti convulsants, immunosuppressant's, biologics etc) All patients with persistent low Immunoglobulins should preferably be referred to and evaluated by an Immunology Consultant. Polyclonal increase of IgG can occur in chronic infection and inflammation, chronic liver disease and connective tissue disease. Monoclonal bands are significant in the diagnosis and monitoring of patients with myeloma. Monoclonal gammopathy of uncertain significance (MGUS) is found in 1% of the general population over the age of 50 years.
IgG Subclasses	IgG1 and IgG2 subclass deficiencies are the most clinically important in individuals who suffer recurrent infections. However, functional antibodies to tetanus (requiring the presence of IgG1) and pneumococcus (requiring the presence of IgG2) give a much clearer picture of the patient's ability to mount an appropriate antibody response and should be used in preference. **All requests for IgG Subclasses will be referred to an Immunology Consultant to establish the clinical relevance.**

Assay	Description / Comments
IgE – Total and Specific	**Total IgE:** This assay is commonly requested in patients with atopy or suspected allergies. 'Atopy' is defined as the genetic predisposition to produce greater amounts of IGE. These individuals are more likely to have childhood eczema, asthma or hay fever. The results of total IgE must be interpreted in relation to the clinical history. High levels of total IgE may be seen in patients with personal or family history of atopy particularly atopic dermatitis (eczema), hay fever or asthma. **Allergen specific IgE:** A wide range of allergens are available to test for allergen specific IgE and it is **essential** that as much clinical information as possible is supplied by the clinician so the most appropriate testing can be performed. Allergen specific IgE testing **is not to be used** as a screening test for allergy. Raised allergen specific IgE (> 0.35KuA/L) can be found without any clinical history of allergic reactions, particularly in atopic individuals (See above). Positive or raised specific IgE is not a 100% proof of allergy and must be interpreted in the light of individual atopic status and clinical history. It is recommended that patients with strong clinical history **should to be referred** to the Allergy clinic for further evaluation irrespective of total and/or specific IgE levels.
Intrinsic factor abs	Detected in 70% of patients with pernicious anaemia and are more disease-specific than antibodies to gastric parietal cells.
Liver kidney microsomal abs (LKM)	Positive in autoimmune chronic active hepatitis.
Lymphocyte surface markers	Must be discussed with a senior member of the laboratory staff prior to blood collection.
Mast cell tryptase	Rapid mast cell degranulation during an anaphylactic reaction results in an immediate rise of serum tryptase levels within 1-2 hours. This reaches a peak at around 6 hours and returns to baseline by 24 hours. In order to reflect this please take 1 clotted blood sample as soon as possible after the onset of symptoms, and a second sample within 4 hours. A baseline sample should ideally be taken 24 hours after the reaction.
Mitochondrial abs	M2 type is present in >95% of cases of primary biliary cirrhosis. Other types are associated with a wide range of conditions.

Assay	Description / Comments
Neutrophil cytoplasmic abs (ANCA)	Anti-neutrophil cytoplasmic antibodies (ANCAs), such as those directed towards proteinase 3 (PR3) and myeloperoxidase (MPO), are associated with a distinct form of small-vessel vasculitis known as ANCA-associated vasculitis (AAV); a term that includes granulomatosis with polyangiitis (GPA), Eosinophilic Granulomatosis with polyangiitis (EGPA) and microscopic polyangiitis (MPA). Screening for the presence of ANCAs is a commonly used diagnostic test for AAV. The Immunology department recently adopted the recommendations proposed by the Revised 2017 international consensus on testing of ANCAs in granulomatosis with polyangiitis and microscopic polyangiitis. Bossuyt X *et al.* Nature Reviews Rheumatology 2017: 13; 683–692 • ANCA testing only to be offered for patients with a **high pre-test probability of AAV** • Move to first line testing with MPO and PR3 by fluoroenzyme immunoassays • ANCA IIF will be done if MPO and PR3 are negative and there is still a high clinical suspicion of AAV All serum will be saved in Immunology lab for 4 weeks. Please contact the lab (01384 456111 ext. 2447) within 4 weeks of collection to discuss any further tests if required.
Neutrophil function test (NBT)	Must be discussed with a senior member of the laboratory staff prior to blood collection.
Pancreatic islet cell abs	Have a prevalence of 75% in IDDM at diagnosis and antibody levels will decrease and eventually disappear with the duration of the disease.
Serum electrophoresis	Serum electrophoresis is performed in all requests for immunoglobulin quantification (Serum IgG/A/M levels). Polyclonal increase in the gammaglobulin region can be seen in chronic infection and inflammation, chronic liver disease or connective tissue disease. Monoclonal bands, particularly in this region, are suggestive of possible lymphoproliferative process and require further confirmatory tests. All sera with monoclonal bands on serum electrophoresis will be followed up by immunofixation to type the paraprotein and quantify it wherever possible. In patients where myeloma is clinically suspected, it is strongly recommended that paired serum and urine samples (see below for urine electrophoresis) are sent together. Oligoclonal bands may sometimes be seen in severe infections, post bone marrow transplant patients and rarely in certain primary immunodeficiencies.
Skin abs	Antibodies to the intercellular substance of the epidermis (desmosome) are seen in patients with pemphigus. Antibodies to the dermal-epidermal basement membrane are highly specific for bullous pemphigoid and seen in 80% of cases, where the titre correlates with disease activity.
Smooth muscle abs	These are present in high titres in 50-70% of patients with type 1 autoimmune hepatitis. They may also be seen in other types of autoimmune hepatitis, primary biliary cirrhosis and chronic viral hepatitis.
Striated muscle abs	These antibodies are seen in almost all patients with Myasthenia gravis with thymoma; however, in patients without thymoma the antibodies are only present in a small proportion of cases.

Assay	Description / Comments
Urinary Electrophoresis	This test is performed in the investigation of patients with suspected multiple myeloma (either intact immunoglobulin or light chain myeloma), light chain deposition disease and primary AL amyloidosis. In all patients, particularly initial requests for diagnosis, it is recommended that a simultaneous paired serum sample is sent along with complete clinical details in order to facilitate accurate interpretation of the results. Free urinary light chains (Bence Jones protein) may be seen in all the above mentioned conditions. Subsequent monitoring of light chain only diseases (light chain myeloma, light chain deposition disease or primary AL amyloidosis) may be done with only urine electrophoresis (or serum free light chains if requested).

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10 MICROBIOLOGY

10.1 SUMMARY OF SERVICE

Microbiology has relocated services to the BCPS Hub at C37 New Cross Hospital, The Royal Wolverhampton NHS Trust (RWT):
Pathology Services (royalwolverhampton.nhs.uk)

Contact Details

	Internal	External
BCPS Microbiology		
Microbiology Enquiries		01902 307999 ext. 88775
Main laboratory		01902 307999 ext. 88257
Serology		01902 307999 ext. 88255
Mrs S Lovegrove **Service Lead**		01902 307999 ext. 88254
Consultants:		
Dr E Rees **Head of Department**	2473	01384 456111 ext. 2473
Locum Consultant	2817	01384 456111 ext. 2817
Secretaries:		
Mrs L White **Consultant's Secretary**	2697	01384 456111 ext. 2697
Mrs C.Homer/ Ms S Harper **Department Secretary**	2056	01384 244056
Contact email for clinical enquiries	dgoh.microbiology@nhs.net	

Infection Control Department
Infection Control Team/Secretary ext: 2174

10.1.1 Urgent Microbiology investigations

Urgent investigations such as CSF and sterile body fluids should be taken to Pathology reception as soon as possible. Contact the DGFT biochemistry laboratory to inform them that an urgent sample has been taken via:

- 09:00-17:30 on extension 2482
- 17:30-09:00 bleep biochemistry lab via switchboard.

Advice from the **Medical Microbiologists** is available via switchboard. Please avoid requesting results outside laboratory opening hours. All authorised results are available 24 hrs on the Soarian system. All essential results (e.g., significant blood culture isolates) are notified to clinical staff immediately.

10.1.2 Specimen Containers and Swabs

Hospital wards and departments obtain these from NHS logistics with the exception of blood culture vials and liquid COPAN swabs (general swab and MRSA) which are available for collection from Pathology Reception. Pathology reception supply GPs with containers and swabs.

For COVID PCR tests the following swabs will be accepted

MWE Virocult

COBAS Uniswab

Red-topped Remel (M4RT) tube

1. Complete a request for COVID-19 on Sunrise
   Enter date and time of collection.
2. Apply the SUNRISE patient detail label to the viral transport media tube.
3. Collect a throat and nose swab using the same swab (throat first then nose).
4. Please note, the viral transport tube then need to be wiped over after the sample has been collected, with green Clinel wipes
5. Place the viral transport tube into a sample bag and seal. Place this sealed bag into a second sample bag and seal. Run fingers across the seal to ensure this is closed. This is called 'double bagging' the sample.
6. Place the Sunrise request form in the pocket of the outer, second sample bag with the details showing. This is so the details can be read without opening the sealed bag.
7. Place all of this inside a COVID carrier bag,
8. Place the Yellow Infection Control "Special Precaution" stickers on the exterior of the second bag being careful to not cover any of the details on the request form.
9. Deliver samples directly to Pathology Reception as soon as possible. Avoid delay. **Do not send with routine samples or via the Pod System**. In the absence of Reception staff, use the black phone on the wall outside the laboratory entrance to call direct to the laboratory on ext 2482.

10. Outside Pathology Reception opening hours, ie. before 9am and after 8pm, leave containers in the dedicated COVID swab collection box in Pathology Reception. These are regularly checked by laboratory staff out of hours.

10.1.3 Reports

- Telephone to request urgent or preliminary results. Cultures are reviewed daily by Medical Microbiologists and preliminary results are telephoned to clinical staff when appropriate. Notify the medical staff about patients with serious infections - it may be possible to expedite preliminary results.
- Reports are issued to comply with specified turnaround times as far as possible.
- Organisms interpreted as ‘of doubtful significance’ may be reported without antibiotic sensitivities. Following clinical discussion, it may be possible to provide this information.

For any queries about microbiological investigations please do not hesitate to contact the laboratory.

11 KEY CONTACTS

Chief Medical Officer Black Country Pathology Service Dr Branko Perunovic branko.perunovic@nhs.net	**Operational Manager Black Country Pathology Service** Mr Graham Danks graham.danks@nhs.net ☎01902 695297	**Chief of Clinical Support Services** Dr E Rees elizabethrees@nhs.net ☎01384 244056

Biochemistry		
Head of Department Dr H Ashby Consultant Biochemist Helen.ashby@nhs.net ☎01384244078	**Head BMS** Mr Waqqas Usmani waqqas.usmani@nhs.net ☎01384244081	**Consultant Clinical Scientist** Dr Pervaz Mohammed Pervaz.mohammed@nhs.net ☎01384 244081 / internal ext 2081
Haematology		
Head of Department Dr Craig Taylor Consultant Haematologist Craig.Taylor@nhs.net ☎01384 456111 ext 2492	**Head BMS** Ms Lisa Page lisa.page9@nhs.net ☎01384 244091	**Blood Transfusion Manager** Mrs Anna Smith annadobson@nhs.net ☎01384 244091
Immunology		
Head of Department Dr M Bhole Consultant Immunologist malini.bhole@nhs.net ☎01384 244755	**BCPS Discipline Lead Immunology** Helen Sandy Helen.sandy@nhs.net ☎01384 244802	

Cellular Pathology	
Cellular Pathology Consultants BCPS (Please contact for clinical advice) 01902 69529	**BCPS Discipline Lead Cellular Pathology** Mrs Rita Mistry 01902 695287

Microbiology	
Head of Department Dr E Rees Consultant Microbiologist elizabethrees@nhs.net ☎01384 244056	**BCPS Discipline Lead Microbiology** Susan Lovegrove Susan.lovegrove@nhs.net ☎01902 307999 ext 88254

BCPS Quality Manager Katy New katy.new@nhs.net ☎ 01902 307999 ext. 88247	**BCPS Deputy Quality Manager** Vikki Banton victoria.banton@nhs.net ☎ 01902 307999 ext. 88247
Out-Patient Phlebotomy / In-Patient Phlebotomy Blood tests - The Dudley Group NHS Foundation Trust (dgft.nhs.uk)	
Point of Care Testing Carole Payne carole.payne1@nhs.net ☎01384 244299 ext.2299	
Andrology Natalie Worton BCPS Andrology Lead Natalie.worton@nhs.net ☎01902 695287	
Pathology IT issues ☎ 01384 456111 ext 2376	
Retained Services (mortuary, phlebotomy) ☎ 01384 456111 ext 3314 07876 503078	