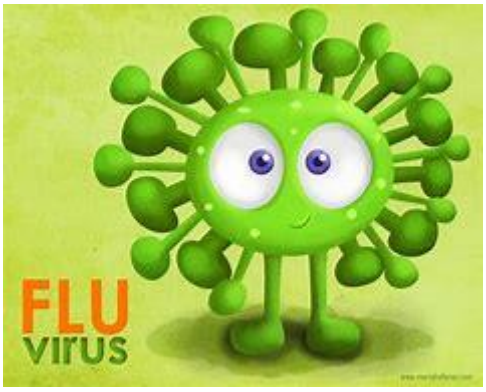
South Tees Hospitals NHS
NHS Foundation Trust

Pathology department

Virology laboratory

User Handbook

Revision 1, June 2019



https://www.toonpool.com/cartoons/The%20Flu%20Virus_166757

Virology Laboratory

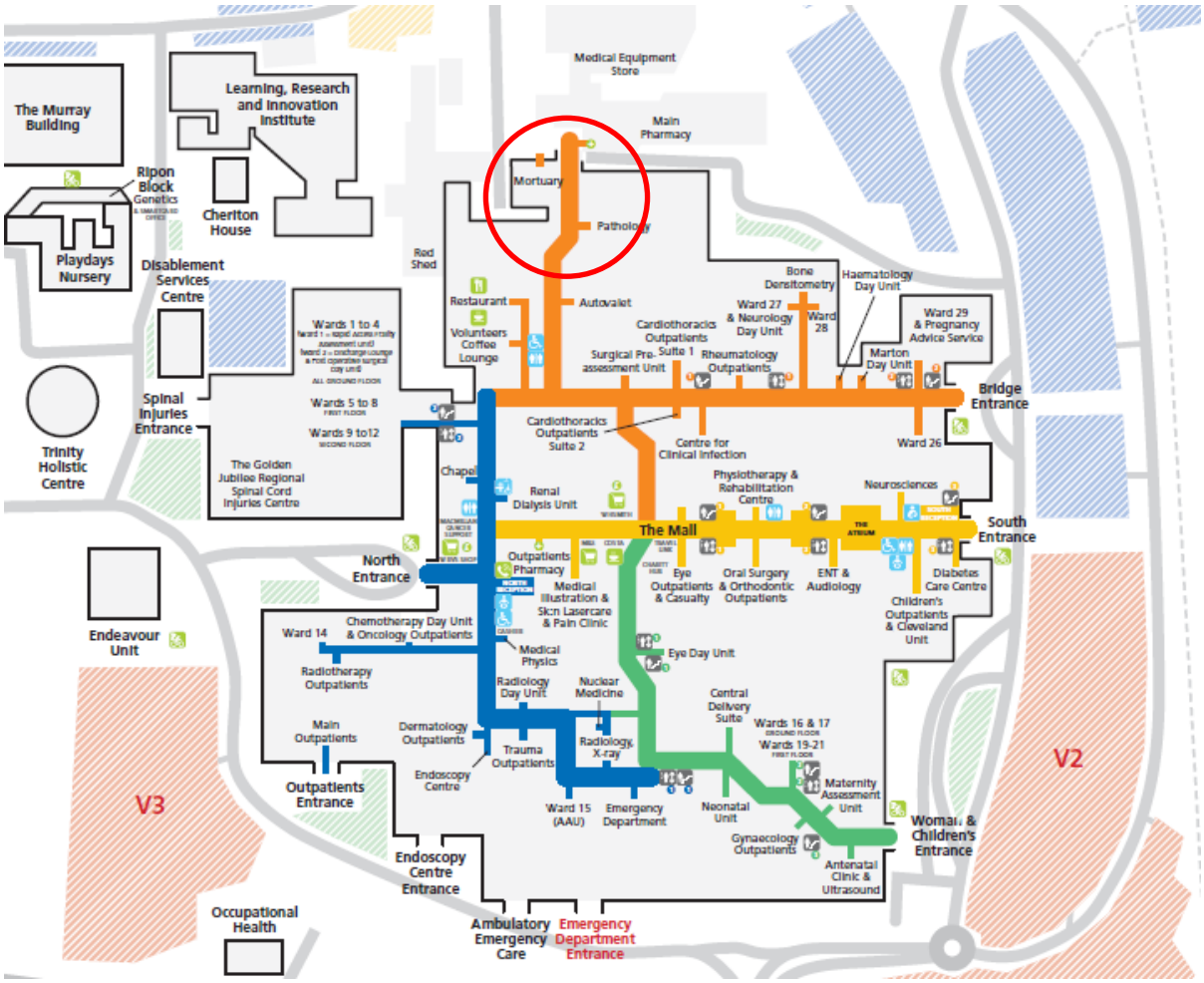
The James Cook University Hospital

Marton Road

Middlesbrough

TS4 3BW

Tel: 01642 835932



https://www.southtees.nhs.uk/content/uploads/James-Cook-campus-map-landscape.pdf

Prepared by: Sandra Gittins

For queries relating to this document, please contact: sandra.gittins1@nhs.net

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We provide a full range of virology tests to our users and are continuously updating and introducing new assays. Our user guide is aimed at providing useful information that is required to provide an effective service. We will send samples to reference laboratories in other parts of the UK if testing cannot be done locally.

The laboratory also undertakes the testing of specimens for other disciplines, please check the list below, which gives details of sample requirements for the diagnosis of adult and paediatric patients.

Virology deals with the detection of viral infections, immunity investigations, and outbreak monitoring. Serological and molecular techniques are used to perform screening assays and confirmation testing on a range of clinical samples. Most investigations are performed on site by automated or manual methods within 5 working days, with more specialized investigations referred to reference laboratories. The laboratory also undertakes the testing of specimens for other disciplines.

During 2018-2019, the Virology laboratory reported 143,566 results on specimens received.

Clinical authorisation of Virology results during core hours is provided by the Consultant Virologist team at the Freeman Hospital, Newcastle.

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Key personnel and contact details

Name	Designation	e-mail	Telephone
Mrs Sandra Gittins	Lead BMS (Virology)	sandra.gittins1@nhs.net	01642 835932
Dr. Igor Kubelka	Consultant Microbiologist	igor.kubelka@nhs.net	
Dr. Monika Kalra	Consultant Microbiologist	monika.kalra@nhs.net	
Dr. Csaba Marodi	Consultant Microbiologist	csaba.marodi@nhs.net	
Victoria McCune	Consultant Clinical Scientist	victoria.mccune@nhs.net	

Microbiology office: 01642 282604

Virology laboratory: 01642 854289

24 hour switchboard: 01642 850850

Out of hours clinical advice via switchboard (24 hours)

Clinical advice and enquiries

During working hours, the duty clinician can be contacted for advice on patient management, diagnosis and treatment on ext 52604 (external 01642 282604)

DX address

Middlesbrough Microbiology Laboratory

DX 6350100

Hours of Service

The core hours of the laboratory are 9am – 5pm Monday to Friday. Telephone enquiries are available from 8:30am – 6pm Monday to Friday. A restricted service is available on Saturday, Sunday and Bank Holidays.

The Virology laboratory does not offer diagnostic services to members of the public except via a registered medical practitioner. Results can only be issued to the requesting physician or medical unit and will not be given to patients directly under any circumstance. We reserve the right to check the authenticity of callers in order to protect the confidentiality of patients' personal data.
There are no clinical facilities at the laboratory and we are unable to see patients or give telephone medical advice directly to members of the public.

Specimen submission guidelines

Consent

It is assumed from the receipt of a completed request form together with a suitable specimen that the diagnostic samples received in Virology are arriving with implicit consent for all assays relevant to the best interest of the patient. Samples received directly from patients cannot be processed without consent from an appropriate medical professional.
Requests for further testing on samples received by Virology can be made within the specified storage times for samples (see page 13).
In all instances, the laboratory may perform additional assays to confirm or clarify earlier assay results.

Specimens

All specimens must be labelled with the following:

- surname/forename or other unique patient identifier

- NHS number
- date of birth
- sender's sample number
- date of collection of specimen

Printed specimen labels should be used wherever possible. Please note that unlabelled specimens cannot be processed and may be discarded.

Request forms

Forms must match the information on the sample. Any specimens where there is a mismatch between data on the sample and on the request form may be rejected.

Forms must include the following information:

- tests required
- specimen type and site where appropriate
- date of collection
- contact information of requester (vital for urgent requests)

Request Forms should also have:

- date of dispatch
- sex
- relevant clinical information including details of any antiviral therapy
- date of onset
- vaccination history

For investigations of maternal transmission, please identify the linked mother or child.

Failure to comply with our specimen submission guidelines may lead to specimen rejection and/or delay of reports.

Samples which are dispatched at ambient temperature (10°C – 25°C) must have a transit time of no more than 72 hours. If the date of receipt is greater than 72 hours from the date of dispatch, the specimens may not be processed.

Specimen rejection criteria

Samples may be rejected if:

- there is insufficient patient identifiable information on either the sample or request form. Some specimens are difficult to repeat (CSF, biopsies etc) and, in exceptional circumstances, may still be processed
- the sample type is inappropriate for the investigation requested
- the sample has leaked during transportation to the laboratory with no fluid remaining in the original container
- during transportation of a number of samples, multiple liquid samples have leaked within a larger container leading to potential cross-contamination of samples
- the sample container is inappropriate for safe processing (e.g. broken glass, syringe needles etc)

Key factors affecting tests

Serology tests:

Samples that have previously been tested by another discipline will not be acceptable for virology testing due to the possibility of cross-contamination. Please send a separate sample for Virology tests.

Samples which are highly haemolysed, hyperlipaemic or which contain microbial contamination will not be processed.

If sending samples at ambient temperature, transit time must be less than 72 hours.

Please note that while post-mortem samples may be accepted, the laboratory has not evaluated tests for use with samples from cadavers.

Certain assays require serum only – plasma samples are not suitable. Specific requirements are listed from page 10 onwards.

When sending blood specimens please send a single 9ml tube. We store serum for up to 2 years, so retrospective testing can be arranged after discussion.

Molecular tests:

EDTA plasma is preferable to serum, as degradation of nucleic acid can occur in serum/ clotted samples, which may result in under-reporting of viral load. Samples which are highly haemolysed, hyperlipaemic or which contain gross microbial contamination may not be processed; where this is unavoidable (e.g. haemolysed samples from post-mortem specimens) the laboratory should be contacted in advance for advice. Do not send dry swabs, charcoal swabs, swabs in bacterial transport gel or swabs with wooden shafts, as all are unsuitable for molecular testing. Heparinised samples, or samples from patients who have received heparin, may give erroneous results – please contact laboratory for advice.

Whole (unseparated) blood samples:

Certain tests (e.g. CMV DNA) require whole unseparated blood collected on EDTA. Samples should be sent to the laboratory as soon as possible after collection. Where possible, whole blood samples should not be sent over a weekend. Samples over three days old may not be suitable for testing.

CSF, urine and other samples:

CSF samples must be received as soon as possible after collection. If viral tests are required, it is advisable to send a separate container for virology to ensure that the sample will be received by the laboratory.

Urine for viral PCR must be sent in a plain universal container without any additives. If this is not the case, the sample will not be processed.

Only if viral PCR sample solution (VPSS) is unavailable:

When viral PCR sample solution is not available, swabs can be cut off and sent dry in a sterile container. **This should be avoided whenever possible as the sensitivity of the test is reduced and a false negative result may be issued.**

Nasopharyngeal aspirates: collected and sent in a mucus trap preferably without the suction catheter. Please attempt to take this sample without obvious signs of blood.

Biopsies: in sterile universal containers. Tissue should be submitted fresh in normal saline if possible. We can test formalin fixed tissue but sensitivity is reduced.

Dried blood spots (DBS) for blood borne virus testing: useful for difficult to bleed patients. Please contact virology in advance as this testing is arranged with the virology laboratory in Newcastle. Following a finger prick, drops of blood are collected onto filter paper cards.

For *Chlamydia trachomatis* PCR ONLY

First catch female urine specimens are acceptable, but they may detect up to 10% fewer CT infections when compared with vaginal and endocervical swab specimens. To ensure collection of cells infected with CT, columnar epithelial cells lining the endocervix should be sampled. If excess mucus is not removed, sampling of these cells is not ensured and a false negative result may be obtained.

Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.

Therapeutic failure or success cannot be determined with the CTPCR Assay since nucleic acid may persist following appropriate antimicrobial therapy.

A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection.

Patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain procedures and precautions.

The performance of the assay has not been evaluated in adolescents less than 14 years of age.

Key factors which affect the performance of our tests and interpretation of results:

- Optimal performance of our tests requires appropriate specimen collection, handling and storage.
- Specimens should arrive with the minimum of delay.
- Once the specimen has been taken, storage and transport prior to analysis have an effect on sample quality and the likelihood of obtaining the true result.
- Factors that are under the control of the laboratory staff include: test method, calibration of equipment, reagent handling and staff training.
- All assays have been validated for the relevant clinical samples; for example, respiratory PCR tests are validated for respiratory samples alone.
- A negative result does not exclude the possibility of infection because one or more of the above is breached and biological inhibitors in the sample adversely affect the result.

Services available

The department undertakes tests for the infections listed on the following pages. Key factors affecting individual tests are noted against the relevant test, including minimum sample volumes where relevant.

Turnaround times are from day of receipt in the laboratory to issue of reports in working days. The times shown are the typical turnaround times achieved by the laboratory, but may be longer or shorter depending on the availability of staff and the complexity of the investigation. Virology staff are committed to the fastest possible issue of reports, consistent with accuracy, on the specimens they examine. Turnaround times may vary during seasonal outbreaks; testing may be conducted more frequently during epidemic seasons.

Requests for additional tests: time limits and specimen retention

If additional laboratory testing is required on a sample previously submitted to Virology, please contact the laboratory in the first instance. Original specimens are normally retained for at least two years (up to several years in the case of certain specimens) but further testing may not be possible due to sample volume constraints, specimen viability or other factors. The laboratory will be able to advise on the feasibility of using the original specimen for analysis. All requests for additional testing should be accompanied by a written request form.

A to Z list of tests available

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Adenovirus - enteric		Faeces <5days post onset	3 days	Mon, Wed, Fri
Adenovirus		Conjunctival swab or 5ml whole blood in EDTA	*3 days*	Tue, Fri
Astrovirus RT-PCR		Faeces <5days post onset	3 days	Mon, Wed, Fri
Antenatal serology (Hepatitis B, HIV, Syphilis)		5ml clotted blood in a serum separator tube (SST)	8 days	Mon – Fri
Borrelia burgdorferi serology (Lyme serology)	Requests must include clinical information: symptoms, date of symptom onset, history of tick bite, and UK location or country of exposure. Test not indicated in asymptomatic patients following tick bite. Positives are referred to another laboratory for further investigation	5ml clotted blood in a serum separator tube (SST)	2 days	Mon – Fri

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Chlamydia trachomatis PCR		Endocervical swab using the swab provided, or 5ml urine in a plain universal tube	3 days	1 – 2 times per week
Cytomegalovirus Avidity	To determine timing of recent infection in pregnant patients.	5ml clotted blood in a serum separator tube (SST)	3 days	As requested
Cytomegalovirus IgG	To determine timing of recent infection in pregnant patients who are CMV IgM positive, or to determine CMV status for pre-transplant patients	5ml clotted blood in a serum separator tube (SST)	3 days	Mon, Thu
Cytomegalovirus IgM	To check for recent infection	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri
Cytomegalovirus PCR		5ml whole blood in EDTA, or 2ml urine in a plain universal tube.	3 days	Tue, Fri
CSF virology		A minimum of 200µl CSF in a plain universal tube	2 days for CSF tested at JCUH up to 2 weeks for CSF samples referred to other laboratories	Mon - Sat

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Epstein Barr Virus antibodies		5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Enterovirus/Parechovirus RT-PCR		A minimum of 200µl CSF in a plain universal tube or green topped virol swab	3 days	Mon - Sat
Hepatitis A IgM	Check for recent infection	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Hepatitis A total antibody	Check for immunity (previous infection or vaccination)	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Hepatitis B surface antibody	Check for response to vaccine	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Hepatitis B surface antigen	**First line test to check for infection** Positives will receive further investigations.	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Hepatitis B core total	All new HBs Ag positive samples will be tested for anti-core Ab. Other viable requests for this test: vaccine non-responders, before some biologicals, or after discussion with microbiologist	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Other hepatitis B markers	All new HBs Ag positive samples will be tested for other markers e Ag and e Ab, anti-core IgM.	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Hepatitis B PCR		5ml whole blood in EDTA, or 1ml serum	7-14 days	1 run per fortnight
Hepatitis C antibody	To check for infection. Positives will be investigated further.	5ml clotted blood in a serum separator tube (SST)	3-5 days	Mon - Fri
Hepatitis C PCR	Indications are - For HCV positive patients to determine whether antiviral treatment is required - Needlestick follow-up by Occupational Health Other requests should be discussed with Microbiologist	5ml whole blood EDTA, or 1ml serum	3 – 5 days	2 runs per week
Hepatitis E serology	Acute hepatitis where standard markers (HAV IgM, HBSAg and HCV Ab) are negative.	5ml clotted blood in a serum separator tube (SST)	7 days	Thu
Helicobacter pylori stool antigen		Faeces	7 days	Tue, Fri

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Herpes Simplex Virus 1 & 2 PCR		A minimum of 200µl CSF in a plain universal tube, or green topped virol swab	2 days	Mon - Sat
HIV serology	To check for infection. Positives will be investigated further.	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri
HIV-1 RT-PCR (Viral load)	For treatment monitoring/compliance	5ml whole blood in EDTA	3 – 5 days	2 runs per week
Influenza A & B RT-PCR		Nose/throat swab, NPA	2 days (24 hours in peak season)	Mon, Wed, Fri (Mon – Sat in peak season)
Legionella antigen (Urine)		5ml urine in a plain universal container or boric acid container	1 day	Mon – Sun
Measles IgM	To check for recent infection	5ml clotted blood in a serum separator tube (SST)	5 days	Mon
Measles IgG	To check immunity	5ml clotted blood in a serum separator tube (SST)	3-5 days	Tue, Fri
Mumps IgG	To check immunity	5ml clotted blood in a serum separator tube (SST)	2 days	Mon – Fri
Mumps IgM	To check for recent infection	5ml clotted blood in a serum separator tube	5 days	Wed

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Mycoplasma IgM	To check for recent infection. Patients must be ≤ 16 years of age.	5ml clotted blood in a serum separator tube (SST)	5 days	Wed
Norovirus PCR		Faeces <5 days post onset	3 days	Mon, Wed, Fri
Parainfluenza 1-4 RT-PCR		Nose/throat swab, Nasopharyngeal aspirate	2 days (24 hours in peak season)	Mon, Wed, Fri (Mon – Sat in peak season)
Parvovirus antibodies	IgG – previous infection / immunity IgM – recent infection	5ml clotted blood in a serum separator tube (SST)	3 days	Tue, Fri
Pneumococcal antigen in urine		5ml urine in a plain universal or boric acid container	1 day	Mon - Sun
Quantiferon Gold TB serology		1ml blood in dedicated Quantiferon tubes supplied by the laboratory on request	7 days	Thu
Rotavirus RT-PCR		Faeces <5days post onset	3 days	Mon, Wed, Fri

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Respiratory Syncytial Virus A & B RT-PCR	Acute RSV infection	Nose/throat swab, Nasopharyngeal aspirate	2 days (24 hours in peak season)	Mon, Wed, Fri (Mon – Sat in peak season)
Rubella antibodies	IgG - Check for Immunity. For IgM, if clinically suspicious, discuss testing with Microbiologist	5ml clotted blood in a serum separator tube (SST)	5 days	Mon - Fri
Sapovirus RT-PCR		Faeces <5days post onset	3 days	Mon, Wed, Fri
SARS-CoV-2		Nose and throat swab	Rapid – 2 hours Routine patients – 6 hours Routine staff – 24 hours	Mon – Sun 24h
Toxoplasma antibodies	IgG – previous infection / immunity IgM – recent infection	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri
Treponema pallidum (Syphilis) serology	Initial screen. Positives referred for further investigation – turnaround 3 weeks	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri

Varicella zoster PCR		A minimum of 200µl CSF in a plain universal tube, or green topped virol swab for other sites	2 days	Mon - Sat
Varicella zoster IgG	Phone laboratory if patient is a contact of chickenpox AND pregnant AND has no history of previous chickenpox.	5ml clotted blood in a serum separator tube (SST)	3 days	Tue, Fri
Investigation	**Special requirements**	**Sample required**	**Target turnaround time**	**Test schedule**
	Tests performed by Virology on behalf of Haematology, JCUH			
BCR-ABL genetic mutation analysis		9ml whole blood in EDTA	2 days	Mon – Fri
FII/V genetic mutation analysis		5ml blood in sodium citrate	1 day	Mon – Fri

Reports

Reports will be delivered electronically via Web-ICE, or will be printed and delivered by post if the requesting location does not have this facility available.

Policy on faxing and emailing reports containing patients' data

The following guidelines have been prepared having taken into account the code of practice on reporting patients' results by fax prepared by the Department of Health and Caldicott recommendations.

1. It is South Tees Hospitals NHS Foundation Trust Microbiology policy that reports containing patients' data should not be sent by fax or email.
2. Emails cannot be relied on to guarantee security of patients' data because they can be intercepted by a third party en-route.

Quality assurance in the Virology laboratory

The Virology laboratory participates in numerous EQA schemes, including those run by the UK National External Quality Assurance Scheme (NEQAS), Quality Control for Molecular Diagnostics (QCMD). Details of participation in specific schemes are available on request.

The quality of our systems is also checked by an IQA scheme, which requires selection of received samples for "blinded" testing. After processing, the results for IQA samples are unblinded and are assessed against the results originally reported to the referring clinician. Any discrepancies are fully investigated as to their root cause before remedial action is implemented.

The validity of results produced on each analysis performed is also checked by an IQC scheme. This scheme requires the use of controls independent of the controls supplied by the kit manufacturer to assess trends in the performance and to determine the uncertainty of measurement steps in the analysis.

Results of our EQA, IQA and IQC performance are discussed at Annual Management Review meetings, and also at laboratory meetings, as appropriate.

Uncertainty of Measurement

The 'Uncertainty of Measurement' of tests is available on request from senior laboratory staff.

The factors that contribute to the Uncertainty of Measurement of assays include: specimen collection, transportation and storage, the performance of equipment, staff competencies, reagent performance and method selection. Laboratory procedures are standardized and monitored to remove or minimize error and optimize reproducibility and repeatability.

The virology section's performance at JCUH is regularly measured and monitored using quality control, internal and external quality measurements. When laboratory staff are aware of factors that may have a significant impact on interpretation, these are communicated to users by a comment on the report or a further sample is requested.

Complaints

If there is a problem, or you are not satisfied with the service you have received, in the first instance contact the Lead BMS.

Our endeavour is to be responsive to the changing needs of all users of our services. We welcome comments on how we can improve the provision of these services. Please contact the department if you have any queries.

Otherwise contact:

Patient Advice and Liaison Service (PALS)

The PALS team can be contacted on freephone: 0800 0282451, or on 01642 854807/01642 282657 (internal extension numbers 54807 or 52657) JCUH.