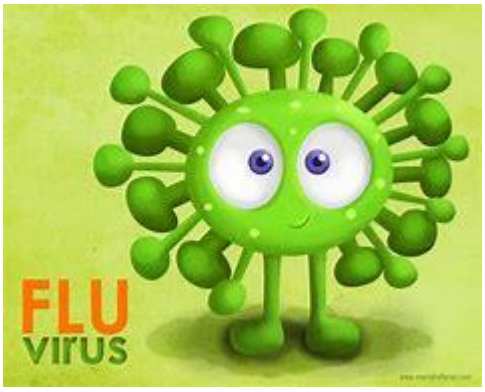
South Tees Hospitals NHS
NHS Foundation Trust

Pathology department

Virology laboratory

User Handbook

Revision 4



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Virology Laboratory

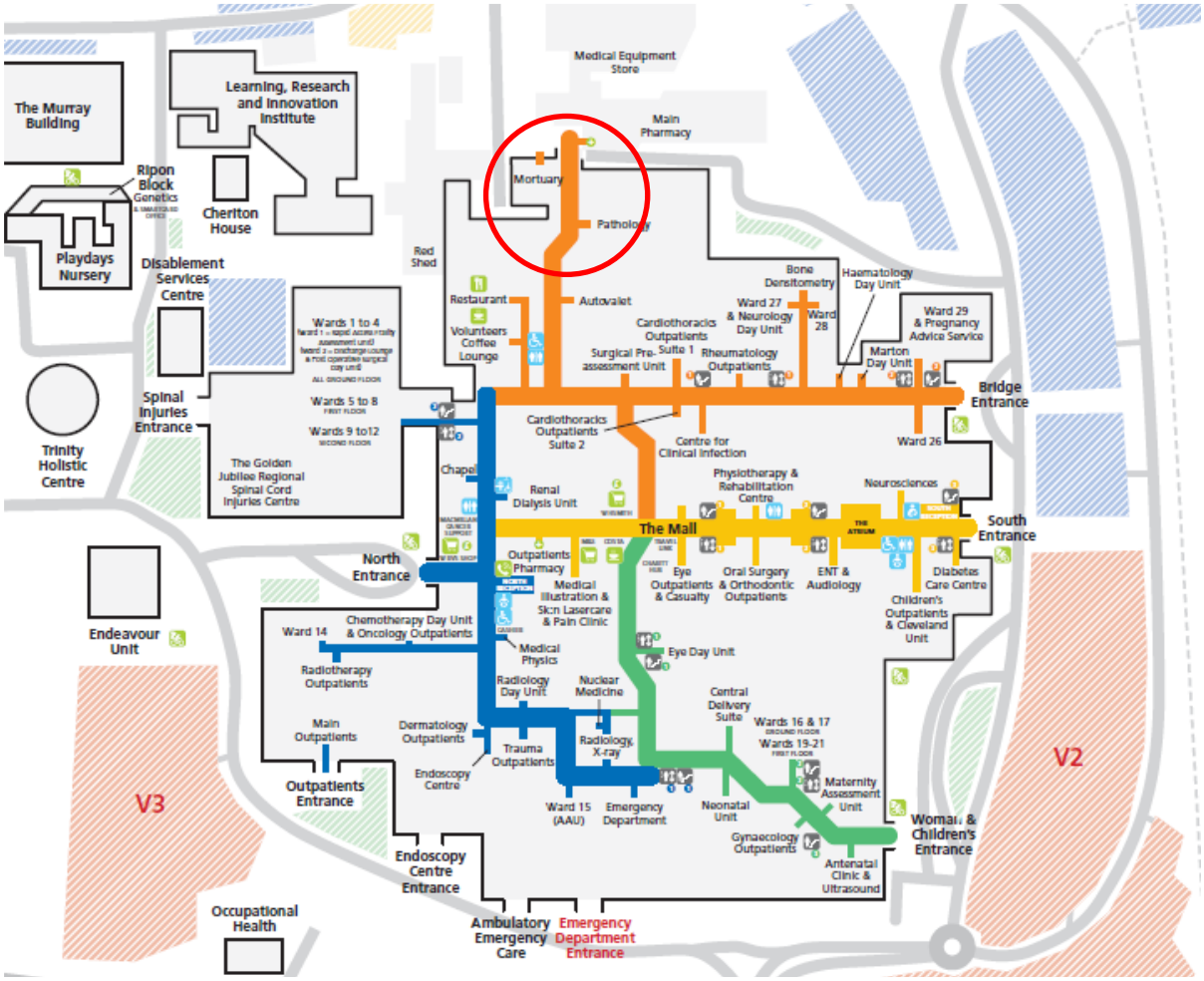
The James Cook University Hospital

Marton Road

Middlesbrough

TS4 3BW

Tel: 01642 835932



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Prepared by: Sandra Gittins

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Forward

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 2020-2021, the Virology laboratory reported 232,917 results on specimens received for viral analysis, and together with Bacteriology, reported 263,880 Covid-19 results making a total of 496,797 results reported.

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

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Microbiology office: 01642 854456

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 54456 (external 01642 854456)

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 9am – 4pm 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 and 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 3.5ml serum separator tube (gold/yellow top). We store serum for a minimum of 2 years, so retrospective testing can be arranged after discussion.

Quantiferons for TB:

Quantiferon tests require a specific set of tubes that can be sourced from the virology department. Please come to reception to collect these. Please follow the instructions provided. **1ml** of blood is required in each tube so that it is within the black range indicated on the side of the tubes. The results determined by each tube together calculate the overall result. Consequently, any over filling or under filling will lead to inaccurate results; therefore will be rejected upon receipt. Please ensure they are shaken to mix and then kept at **room temperature.** Please send the samples straight to the virology department; they have a time limit for which they must be incubated by prior to testing. Please refer to 'sample types accepted by virology' and 'Appendix 1' at the bottom of this document for Quantiferon user information.

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 due to degradation of nucleic acids.

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.

Viral PCR of rashes/ respiratory specimens: please send a green-topped virocult swab 'sample types accepted by virology'. This is essential as the media prevents any degradation of viral DNA/RNA. Please refer to 'A to Z list of tests available' for expected turn-around times.

- Please do not send other swabs such as bacteriology swabs (pink/orange e swabs) for virology testing, as these will be rejected as are unsuitable for testing.
- 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.

Only if viral transport medium (VTM) is unavailable:

Please **contact the pathology reception** for VTM swabs**.** If viral transport medium is not available either an alternative will be provided or 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 refer testing for formalin fixed tissue but sensitivity of the test 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:

Please see: 'sample types accepted by virology'

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 send a request form with the additional requests required. Please highlight on the request form that this is an add on request, and whether the test is urgent. Some 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.

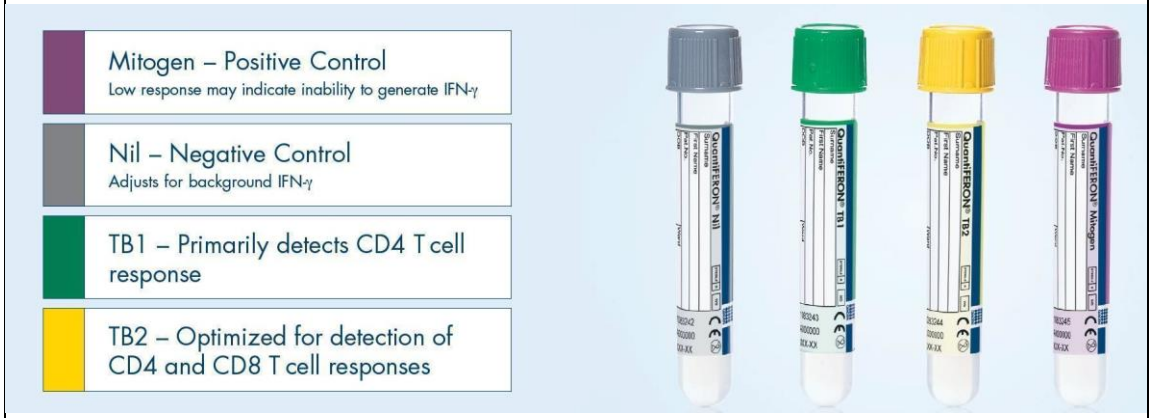
- For a request to add on a test to another department's specimen. This facility is not routinely provided, please send Virology a separate sample. Only in **exceptional** circumstances such as for non-repeatable specimens will this be possible.

Specimen types accepted by Virology

Sample Types Key:	
Sample type	**Image**
Whole blood on EDTA	
Aptima Swab for Chlamydia trachomatis (CT) PCR	
Clotted blood in a serum separator tube (SST)	
Green-topped virocult swab (VTM)	
CSF samples/ Urines/ Stool samples/Biopsies/Sputum's/ BALs/ NPA specimens	

Quantiferon tubes (x4 tubes)

- Please do NOT substitute any of these tubes for other tube types e.g. EDTA-blood instead of mitogen tube.
- Tubes are coated specifically
- Please follow instructions given
- Please fill with 1ml of blood in each tube indicated by black range on side of the tube



A to Z list of tests available

Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Adenovirus NAAT	Limited to immunocompromised patients and children <5 years old.	Faeces <5days post onset	3 days	Mon - Fri
Adenovirus NAAT - currently sent away		Conjunctival swab in VTM 5ml whole blood EDTA (immunocompromised)	3 days	
Astrovirus NAAT	Limited to immunocompromised patients and children <5 years old	Faeces <5days post onset	3 days	Mon - Fri
Antenatal serology (Hepatitis B, HIV, Syphilis)		5ml clotted blood in a serum separator tube (SST)	2 days/ 8 days if any results are positive	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 for negative results	Mon – Fri

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Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Chlamydia trachomatis NAAT		Endocervical swab using the Aptima swab provided, or 5ml urine in a plain universal tube. Other swabs may be tested but are not locally validated for this test	3 days	2 runs a week
Covid-19 RT-PCR Rapid	Samples must be transported to the laboratory without delay. For urgent use only – this test is restricted to certain wards/departments.	Nose/throat swab in VTM	1 hour from receipt of specimen in laboratory	24/7
Covid-19 RT-PCR Routine		Nose/throat swab in VTM	8 hours from receipt of specimen in laboratory	24/7
Cytomegalovirus Avidity	To determine timing of recent infection in pregnant patients.	5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
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-Fri
Cytomegalovirus IgM	To check for recent infection	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri

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Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Cytomegalovirus PCR- Currently sent away		5ml whole blood in EDTA, or 2ml urine in a plain universal.	3 days	
CSF virology		A minimum of 200µl CSF in a plain universal tube	2 days for CSFs in-house ~1-2 weeks those referred elsewhere	Mon - Sun
Epstein Barr Virus antibodies		5ml clotted blood in a serum separator tube (SST)	3 days	Mon - Fri
Enterovirus/Parechovirus RT-PCR - currently sent away		A minimum of 200µl CSF in a plain universal tube or green topped virol swab	3 days	Mon - Fri
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

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Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
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
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 NAAT (Viral Load)		5ml whole blood in EDTA, or 1ml serum	7-14 days	1 run a week
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 NAAT (Viral Load)	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	1-2 runs per week

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Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
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	Mon-Fri
Helicobacter pylori stool antigen		Faeces	3 days	Mon-Fri
Herpes Simplex Virus 1 & 2 PCR		A minimum of 200µl CSF in a plain universal tube, or green topped Virocult swab (skin, conjunctiva, genital, mouth).	4 days	Mon - Sun
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 NAAT (Viral load)	For treatment monitoring/compliance	5ml whole blood in EDTA	3 – 5 days	1-2 runs per week
Influenza A & B RT-PCR		Nose/throat swab (VTM), NPA	2 days (24 hours in peak season)	Mon-Sun
Legionella antigen (Urine)		5ml urine in a plain universal container or boric acid container	2 days	Mon-Fri

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Investigation	Special requirements	Sample required	Target turnaround time	Test schedule
Mumps IgG	To check immunity	5ml clotted blood in a serum separator tube (SST)	2 days	Mon – Fri
Norovirus NAAT	Limited to immunocompromised patients and children <5 years old. For outbreaks, please see referral test table.	Faeces <5days post onset	3 days	
Parainfluenza 1-4 RT-PCR -Currently sent away		Nose/throat swab (VTM), Nasopharyngeal aspirate	3 days	Mon-Fri
Parvovirus antibodies	IgG – previous infection / immunity IgM – recent infection	5ml clotted blood in a serum separator tube (SST).	3 days	Mon - Fri
Quantiferon Gold TB serology	For detection of latent infection	1ml blood in dedicated Quantiferon tubes supplied by the laboratory on request	7 days	Mon - Fri
Rotavirus NAAT	Limited to immunocompromised patients and children <5 years old. For outbreaks, please discuss with infection control team.	Faeces <5days post onset	3 days	
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 - Sun
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 NAAT	Limited to immunocompromised patients and children <5 years old. For outbreaks, please discuss with infection control team.	Faeces <5days post onset	3 days	
Toxoplasma antibodies	IgG – previous infection / immunity IgM – recent infection	5ml clotted blood in a serum separator tube (SST).	5 days	Mon - Fri
Treponema pallidum (Syphilis) serology	Initial screen. Positives referred for further investigation – turnaround 5 days	5ml clotted blood in a serum separator tube (SST)	2 days	Mon - Fri
Varicella zoster PCR **Currently sent away**		A minimum of 200µl CSF in a plain universal tube, or green topped Virocult swab (skin, conjunctiva, mouth).	2 days	Mon - Fri
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	Mon-Fri (Weekend testing available

				for pregnant contacts)

Tests that are referred

Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Hantavirus serology	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	5ml clotted blood in a serum separator tube (SST)	2-4 days	Containment Level 3 organism
Helicobacter pylori culture	Antimicrobial Resistance and Healthcare Associated Infections Laboratory (UKHSA Colindale)	Biopsy samples (please ensure they are not held within clip and are free floating in solution)	12-25 days	
Hepatitis C Virus Genotyping	Virology, Freeman Hospital, Newcastle	EDTA/Whole Blood (Purple Top) or Plasma	7-10 days	
Hepatitis D antibodies	Virus Reference Department (UKHSA Colindale)	Serum/Clotted Blood (SST)	7-10 days	
Herpes Simplex virus (HSV) serology (pregnant women)	Laboratory Medicine, Manchester University NHS Foundation Trust	Serum/Clotted Blood (SST)	4 days	
Herpes Simplex Virus (HSV) serology (non-pregnant)	Virology, Freeman Hospital, Newcastle	Serum/Clotted Blood (SST)	4 days	
Human Herpes Virus 6 (HHV6)	Micropathology (Coventry)	CSF	24 hours	Mon - Fri
Investigation	**Referral Laboratory**	**Sample required**	**Target turnaround time**	**Comments**

Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Human Herpes Virus 7 (HHV7)	Micropathology (Coventry)	CSF	24 hours	Mon - Fri
Human Herpes Virus 8 (HHV8)	Micropathology (Coventry)	CSF EDTA blood	24 hours	Mon - Fri
Haemophilus influenza B (HiB) antibodies	Meningococcal reference Unit (UKHSA Manchester)	Serum/Clotted Blood (SST)		
HIV Proviral DNA	Virus Reference Department (UKHSA Colindale)	EDTA/Whole Blood (Purple Top)	21 days	Limited to neonates of HIV positive mothers.
HLA-B*5701	Lab 21, Cambridge	EDTA/Whole Blood (Purple Top)	Not known	Results are sent directly to requesting clinicians from Lab 21
Human Papilloma Virus (HPV) Typing	Laboratory Medicine, Manchester University NHS Foundation Trust	Swabs, biopsies, paraffin wax sections	14-16 days	
Human T-Lymphotropic Virus (HTLV) Antibodies	Virology, Freeman Hospital, Newcastle	Serum/Clotted Blood (SST)	3-7 days	
Human T-Lymphotropic Virus PCR	Micropathology (Coventry)	EDTA/Whole Blood (Purple Top)	3 days	Mon - Fri

Hydatid ELISA	UKHSA Parasitology Lab, Hospital for Tropical Diseases, London	CSF or Serum/Clotted Blood.	10 days	
Japanese Encephalitis Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF EDTA Whole Blood	2-4 days	Containment Level 3 organism
JC or BK Polyoma viruses antibodies	Virus reference Department (UKHSA Colindale)	Serum/Clotted Blood (SST)		Containment Level 3 organism
JC or BK Polyoma viruses PCR	Micropathology (Coventry)	CSF or EDTA/Whole Blood (Purple Top)	48 hours	Mon - Fri
Lassa Fever Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	Throat swab (VTM), Urine, Serum/Clotted Blood, EDTA/Whole Blood	2-4 days	**CATEGORY A organism TELEPHONE ESSENTIAL**
Legionella Urinary Antigen Confirmation	Antimicrobial Resistance and Healthcare Associated Infections Laboratory (UKHSA Colindale)	Urine	8-10 days	Urine that has been tested at JCUH may be referred for this test for clarification of result
Investigation	**Referral Laboratory**	**Sample required**	**Target turnaround time**	**Comments**

Leptospira (IgM and/or PCR)	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	Serum/Clotted Blood (SST) or urine	3-5 days	Hanatavirus testing may also be indicated.
Malaria ELISA	UKHSA Parasitology Lab, Hospital for Tropical Diseases, London	Serum/Clotted Blood (SST)	10 days	
Marburg Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	Throat swab, Urine, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	**CATEGORY A organism TELEPHONE ESSENTIAL**
Measles IgM	Virology, Freeman Hospital, Newcastle	5ml clotted blood in a serum separator tube (SST)	5 days	
Measles or Mumps PCR	Virus Reference Department (UKHSA Colindale)	Virocult buccal swab Urine	10 days	
Mumps IgM	Virology, Freeman Hospital, Newcastle	5ml clotted blood in a serum separator tube	5 days	
Murray Valley Encephalitis	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	Containment Level 3 organism
Mycoplasmoides pneumoniae IgM	Virology, Freeman Hospital, Newcastle	5ml clotted blood in a serum separator tube (SST)	5 days	Patients must be ≤ 16 years of age.
Investigation	**Referral Laboratory**	**Sample required**	**Target turnaround time**	**Comments**

Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Mycoplasmoides pneumoniae PCR	Micropathology (Coventry)	Virocult nasal/throat swab, sputum, BAL.	48 hours	Mon - Fri
Neonatal HIV	Virus Reference Department (UKHSA Colindale)	Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	21 days	Must be accompanied by a specimen of maternal blood to ensure that virus can be detected in both samples.
Norovirus (from Outbreak Samples)	Virology, Freeman Hospital, Newcastle	Faeces	3 days	Community outbreak samples are not tested at JCUH
Parvovirus Confirmation and PCR	Virus Reference Department, (UKHSA Colindale) Or Micropathology (Coventry) for urgent samples	Serum/Clotted Blood (SST)	10 days	Serum that has been tested at JCUH may be referred for this test for clarification of result
Pneumococcal Antibodies and Immunity testing	Vaccine Evaluation Unit (UKHSA Manchester)	Serum/Clotted Blood (SST)	28 days	

Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Respiratory viruses other than Influenza A&B, Parainfluenza 1-4 and Respiratory Syncytial Virua A&B	Virology, Freeman Hospital, Newcastle	Nasopharyngeal aspirate, Bronchoalveolar lavage, Nose/throat swabs in VTM or Sputum	2 days	
Rickettsia serology	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	Serum/Clotted Blood (SST)	2-4 days	
Rift Valley Fever Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	
Ross River Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood	2-4 days	
Rubella IgM Confirmation	Virus Reference Department (UKHSA Colindale)	Serum/Clotted Blood (SST)	10 days	Serum that has been tested at JCUH may be referred for clarification of result

Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Sandfly Fever (Naples) Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	
Schistosoma ELISA	UKHSA Parasitology Laboratory, Hospital for Tropical Diseases, London	CSF or Serum/Clotted Blood (SST)	10 days	
Sindbis Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	
St. Louis Encephalitis Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	
Syphilis confirmation	Virology, Freeman Hospital, Newcastle	Serum/Clotted Blood	3-7 days	
Syphilis PCR	Micropathology (Coventry)	CSF	24 hours	Mon - Fri
Tapeworm serology	UKHSA Parasitology Laboratory, Hospital for Tropical Diseases, London	Serum/Clotted (SST)	10 days	

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Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Therapeutic Drug Monitoring for HIV	Cambridge Clinical Laboratories	EDTA/Whole Blood (Purple Top)	Not known	Results are sent directly to requesting clinicians from Lab 21
Tick-borne Encephalitis	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	
Toxoplasma confirmation	UKHSA Swansea	Serum/Clotted blood (SST)	5-10 days	Serum that has been tested at JCUH may be referred for this test for clarification of result
Trypanosome brucei IFAT	UKHSA Parasitology Laboratory, Hospital for Tropical Diseases, London	CSF or Serum/Clotted Blood (SST)	10 days	
Trypanosome cruzi serology	UKHSA Parasitology Laboratory, Hospital for Tropical Diseases, London	Serum/Clotted Blood (SST)	10 days	

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Investigation	Referral Laboratory	Sample required	Target turnaround time	Comments
Venezuelan Equine Encephalitis Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	Containment Level 3 organism
Venezuelan Haemorrhagic Fever	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	Containment Level 3 organism
West Nile Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	Containment Level 3 organism
Western Equine Encephalitis Virus	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood	2-4 days	Containment Level 3 organism
Whipples PCR	Micropathology (Coventry)	EDTA/Whole Blood (Purple Top) or CSF	24 hours	Mon - Fri

Yellow Fever	Rare and Imported Pathogens Laboratory (UKHSA Porton Down)	CSF, Serum/Clotted Blood (SST) or EDTA/Whole Blood (Purple Top)	2-4 days	Containment Level 3 organism

The above lists are not exhaustive – other test requests may be accommodated with prior arrangement with the laboratory

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. Please do NOT contact the laboratory for results; all results will be available to see when complete. In the instance of the laboratory breaching the turn-around times stated above, please telephone the laboratory.

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), Immqas, Lab quality. Details of participation in specific schemes are available on request.

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, 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 Experience

The team can be contacted on freephone: 01642 835964, or by email at stees.patient.experience@nhs.net

Appendix 1:

The QuantiFERON-TB GOLD Plus assay

New whole blood assay for the diagnosis of latent tuberculosis

The QuantiFERON-TB GOLD Plus assay measures IFN-gamma, an important marker of the cell-mediated immune response to tuberculosis in blood.

Procedure at clinical area

- The four specific Quantiferon tubes are sent to the requesting source with this instruction sheet supplied.
- Check the expiry date on the tube, do not use beyond this date.
- They MUST only be taken Monday to Friday. Specimens must be delivered to the laboratory by 7pm the same day.
- Tubes should be between 17°C to 25°C at the time of blood filling.
- Fill each tube with exactly 1ml of blood (yellow, green, grey and purple). Volume check indicated by black line on side of tube.
- Immediately after filling the tubes, shake them 10 times just firmly enough to ensure that the entire inner surface of the tube is coated with blood - **lack of shaking may result in false negative results**
- **Please note over-energetic shaking may cause gel disruption and could lead to aberrant results**
- Provide all relevant clinical information on the request form including level of exposure, skin sensitivity, BCG history and any features or treatment suggestive of immunodeficiency.
- The collection date of the blood taken must be clearly marked on the request form. Failure to do so may result in the sample being rejected
- These tests are batched with an average turnaround time of up to 1 week.
- Return to the Microbiology laboratory immediately- Samples need to be processed on the day the sample is taken and **must** arrive at microbiology before 7pm.
- Samples must be incubated by the laboratory within 16 hours of the sample being taken.