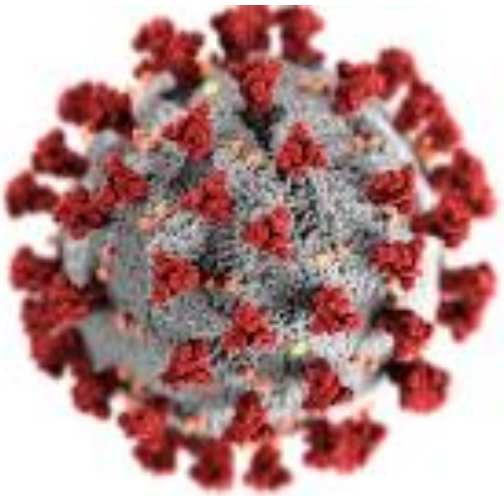
Public Health England

NHS Severn Pathology
North Bristol NHS Trust

Severn Pathology

Bristol Infection Sciences Laboratory

SARS-CoV-2 Pandemic - Laboratory User Manual



Amendment History

Any copy printed in the wards or GP surgery or other location outside the laboratories control becomes an uncontrolled document and is not managed under the Infection Sciences Document Control procedure. It is the responsibility of the copyholder to ensure that any hard copy in their possession reflects the current version available on the intranet / internet sites.

Notification will be sent to all copyholders when an updated version of this manual becomes available

Date	Old edition no	New edition no	Section/page No	Amendments
October 2020	n/a	1.0	All	First issue

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Scope

This document provides information on the specific diagnostic and advisory services related to SARS-CoV-2 and COVID-19 provided by the Infection Sciences laboratory.

Guidance of clinical care and infection control of patients with suspected or proven COVID-19 is outside the scope of this document.

This document does not replace official national or local trust guidance available to clinicians, which should always be consulted when investigating potential cases or issues associated with the management of patients and their contacts during the pandemic.

For information on other Laboratory services please see the Infection Sciences user's manual which can be accessed through the following link:

https://www.nbt.nhs.uk/severn-pathology/pathology-services/infection-sciences-microbiology-virology

Background

On 31 December 2019, the World Health Organization (WHO) was informed of a cluster of cases of pneumonia of unknown cause detected in Wuhan, Hubei Province, China. A novel coronavirus (SARS coronavirus-2 (SARS-CoV-2)) was subsequently identified from patient samples. Following this on the 12th January 2020 a novel coronavirus was announced which was suggested to be the cause of this outbreak.

Coronaviruses are a large family of viruses with some causing less severe disease, such as the common cold, and others causing more severe disease, such as Middle East respiratory syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) coronaviruses. The newly identified pathogen, now designated SARS-CoV-2 was described as the aetiological agent associated with the syndrome "COVID-19".

Introduction

The Infection Sciences Bristol Laboratory is located at the North Bristol NHS trust (NBT) hospital site and the laboratory is one of the largest Infection Sciences laboratories in the UK, providing a clinical service for the North Bristol NHS Trust, University Hospitals Bristol NHS Foundation Trust (UHBristol), the Royal United Hospital Bath NHS Trust (RUHT) and for the many GP practices in the Bristol and Bath areas.

The Virology department within Infection Sciences provides the diagnostic and clinical virology service to NBT, UHBristol, WAHT and the RUHT. The laboratory also supplies a referral service for many other pathology depts located within hospitals across the South West and some regional and national specialist tests.

Both laboratories' scopes have been accredited by UKAS (PHE Accreditation No. 8043 & NBT accreditation No. 8099). The laboratory services have been assessed against the ISO15189 standard and the schedule of accreditation can be found via the links below:

- NBT Microbiology

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8099%20Medical%20Single.pdf

- PHE Public Health Laboratory

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8043%20Medical%20Multiple.pdf

Contacting the laboratory

The laboratory has implemented specific contact numbers which should be used for CoVID-19 related enquiries.

Monday - Friday	09:00 – 17:15 (core hours)	All calls → Ext. 46222 Option 3 "Virology" then Option 1 "CoVID-19 enquiries"
	17:15 – 09:00 (out of hours)	Clinical Advice → On Call Consultant Laboratory enquiry → ext 47234/47231
Saturday – Sunday and Bank Holidays	All Hours	Laboratory Services including test results and sample queries → ext 47234/47231 Clinical Advice → On Call Consultant

Testing services for SARS-CoV-2

The structure of the testing service provided by the Virology dept within the Infection Sciences laboratory has developed rapidly since being one of the first to offer PCR testing in February 2020.

North Bristol NHS site - Routine

Diagnostic testing- detection of SARS-CoV-2 by RT-PCR (test for virus genome)

The laboratory is able to offer a routine testing service 24/7 on a high through put random access analyser. This test enables the analysis of respiratory samples (including nose and throat swabs, respiratory tract secretions, and bronchoalveolar lavage fluid but no other sample types) for the detection of SARS-CoV-2.

Sample types

Sample types which can be tested on this platform include:

- Upper respiratory tract samples
  - Viral respiratory swabs (Nose, Throat)
  - ETA plain sterile container
  - NPA

- Lower respiratory tract samples
  - BAL plain sterile container
  - Sputum plain sterile container

Turn Around Time

The laboratory turnaround time (TAT) is defined as the time from sample receipt to the availability of results electronically.

National guidelines stipulate that results should be available within 24hrs of collection and with 15hrs of receipt of sample in the laboratory. Service users should note that the responsibility for timely transport of samples is not always within the control of the laboratory.

The laboratory works with the local trusts to provide routine transports between hospital and GP sites in and around the Bristol and Bath area during the working day. Out of hours transport of samples should be discussed with the relevant clinical teams.

The laboratory aims to provide an average TAT 10 hours of receipt of routine (not urgent or prioritised following prior notification) samples and aims to provide >99% of primary test results within 12 hours of receipt. However this may change if there is a significant increase in demand for testing activity.

The laboratory testing protocols requires that all initial reactive test results are subject to a confirmation test which can extend the time until the final result is available.

The laboratory is unable to provide rapid/urgent testing on this platform without prior notification that the sample is being sent.

Urgent requests

The laboratory is able to provide urgent testing within 2 hours of sample receipt using a dedicated rapid testing pathway. Please note that there is a separate testing pathway for urgent requests for UHBW.

Urgent laboratory requests for the NBT site is provided to a limited number of patient groups:

- Organ donors
- ITU/PICU/ NICU
- Renal transplant ?potential recipients

Please note, samples from Organ donor and renal transplant potential recipients must be telephoned in advance to the Virology BMS on duty

Patients which meet one of the criteria above and that require an urgent test should have a sample sent to the laboratory by the quickest route possible. Please note it is the responsibility of the clinical team requesting the urgent testing to organise urgent transport of samples to the laboratory.

Notification to the laboratory of the sending of the sample is required so that appropriate identification of the sample can be made on receipt. Please note that it is not sufficient to just label a sample as urgent and the laboratory must be contacted to notify them of testing requirements.

Results

Test results are reported as follows:

- **Negative – Virus (genome) has not been detected in the sample.**

A negative result indicates that the sample does not contain virus however the validity of the results are dependent on several factors including:

  - Timing of sample in relation to illness onset (same as below)
  - Transport conditions may impact on sample stability
  - Quality of sample
  - Site/Sample type

- **Positive – Virus (genome) has been detected in the sample**

A positive (detected or reactive) result indicates that the sample tested contains viral particles which have been detected by the test. While this is indicative that the patient has been exposed to the virus it does not indicate that they are currently ill or showing symptoms as infections can be asymptomatic.

Virus can also be detected many weeks post infection. For all patients whose samples test positive for the virus please ensure that government guidance is followed regarding isolation and quarantine.

https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance

Serology (Antibody) testing

The Infection Sciences Laboratory provides antibody testing from the North Bristol site. This testing is performed by the blood sciences dept but is owned and managed by the Infection Sciences laboratory (PHE). Antibody testing is not offered as an urgent test and has a turnaround time of 24hours

Satellite laboratory – UHBW Pathology

The Infection Sciences laboratory has a rapid diagnostic PCR service situated within the UHBW pathology dept at the Bristol Royal Infirmary. This service is delivered for the PHE Laboratory by UHBW pathology staff.

This is a rapid service for urgent samples from within the UHBW trust and testing should be discussed with the relevant site team on a case by case basis.
Antibody testing is also provided from the Blood Sciences dept of the UHBW pathology however this is owned, managed and delivered by the trust and is not a service provided by the Infection Sciences laboratory. All enquiries regarding this service should be addressed to UHBW Pathology dept, Bristol Royal Infirmary.

Service enquiries/issues

Issues or enquiries relating to the laboratory service can be addressed to one of the following individuals as appropriate:

Name	Role	Email	Contact Number
Dr Matthew Donati	Consultant Clinical Virologist and Head of Virology	Matthew.Donati@nbt.nhs.uk	
Mr Richard Hopes	Interim Infection Sciences Service Manager	Rich.Hopes@nbt.nhs.uk	0117 4146276
Mrs Elisabeth North	Infection Sciences Quality Manager	Elisabeth.North@nbt.nhs.uk	0117 414 6265 07810 630240

Alternatively the following email can also be used to contact the laboratory:

ISQuality@nbt.nhs.uk

Appendix : General laboratory information

Contacting the laboratory

Southmead Hospital switchboard: **Telephone: 0117 950 5050**

General Infection Sciences Enquiries **Telephone: 0117 4146222**

This is our main automated switchboard number. Use this and then select the appropriate option.

Finalised results should be accessed in ICE, or Open ICE - please use these whenever possible. Incomplete results which still require clinical review cannot be given.

Stores/Supplies
If you wish to order laboratory consumables (specimen containers, forms swabs etc) please call

BRI site	0117 342 2573
RUH Site	01225 82 4724
NBT Site	0117 414 8406

Normal hours of service

Outside of the COVID testing service the Laboratory operates a 24/7 service on the following basis:

North Bristol Site		
Monday to Friday	09:00h – 17:15h	Routine laboratory hours
	17:15h – 09:00h	Late shift/On call
Saturday, Sunday & Public Holidays	08.00h – 17.00h	Routine laboratory hours
	17:00h – 08:00	On call suggest change this to the switchboard text
	17:00h – 09:00	On call

Out-of-Hours Services

The dept. offers a 24 hour 7 days a week on-call service for clinical advice and urgent specimen processing covering all times outside of normal hours as follows:

Virology

A qualified, state registered Biomedical Scientist (BMS) is always ‘on-call’ to process urgent specimens and is contactable via switchboard to arrange testing in relation to urgent organ donations. For clinical advice the consultant clinical virologist on call should be contacted via the NBT Switchboard on 0117 950 5050.

Duty Incident management

The laboratory provides an out of hours rota so that a member of the Infection Sciences management team can be contacted in the event of a significant service delivery issue not relating to urgent testing requirements. This may include but not be limited to issues with estates, accommodation, national outbreaks or incidents that require local management coordination.

Contact the on-call duty incident manager via the NBT switchboard on 0117 950 5050.

Specimen collection – general guidelines

Consent for testing

The laboratory does not seek to confirm that informed consent has been obtained for any specimen that is sent for analysis. It is the responsibility of referring clinicians to ensure appropriate consent has been obtained. Requesting a specific test implies patient consent has been obtained. Where this is impossible, testing should only take place when it is in the best interests of the patient. The General Medical Council provides guidance which should be consulted on this issue.

Sample integrity

Specimens should be transported to the laboratory as promptly as possible. Specimens, particularly blood, should be obtained in strict accordance with guidelines to prevent needlestick injuries.

Sample containers are labelled with “expiry” dates and care should be taken not to use containers which have exceeded this. The laboratory is unable to guarantee the validity of the results if an expired container is used and if found will review whether it is appropriate to continue with testing or reject the sample and request a repeat.

Reference and adherence to the following guidelines on the control of clinical material is complied with:

1) The Retention and Storage of Pathological Records and Archives, a Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science 2015.
2) The Human Tissue April 2017.

Protecting Personal Information.

North Bristol Trust and Public Health England has a legal obligation to comply with all appropriate legislation in respect of data, information and IT Security. Both organisations also have a duty to comply with guidance issued by the Department of Health and Social Care, the NHS Executive, other advisory groups to the NHS guidance issued by professional bodies.

Requesting of laboratory tests

Electronic Requesting

Where this is available please use whenever possible as it enables more rapid receipt and processing within the laboratories. Please answer all questions and include RELEVANT clinical details. If there is a history of a particular risk e,g. recent travel to a area of risk this must be included. Please ensure that details of risk is included on all requests irrespective of test requested as this information is essential to ensure that the correct laboratory precautions are taken when processing all samples, e.g. risk of a particular viral pathogen associated with travel should also be included in bacteriology requests details (see section on High risk samples).

It is important to ensure that the correct system (barcoded) number is attached to the correct specimen before placing inside the specimen bag.

Please ensure that you order the correct test(s) and select the correct specimen type as failure to do this may lead to incorrect testing or a delay in result. The electronic requesting systems currently available in the local trusts have been created to enable rapid selection of appropriate tests.

It is extremely important to include clinical details when sending specimens for Infection Sciences to ensure correct processing and interpretation of results. This information is the same as that currently required on handwritten request forms and should include clinical details and symptoms as well as information on antibiotic use (dosage information e.g. pre/post), foreign travel, outbreaks, date of onset etc.

Request forms

The majority of requests from the Bristol and Bath area will be made through the local electronic ordering system. These requests are then activated once the specimen has been received in the laboratory. If electronic requesting is not possible then a request can be made by completing the relevant request form available from your local trust. Please see below for minimum data required for these types of requests.

Completion of Request Forms

Poor or illegible handwriting may be misinterpreted and result in report delay or incorrect test selection. Please help to minimise this by completing all sections of the appropriate request form using a ballpoint pen. It is important to fill in the relevant request box by placing the 'X' accurately within the box. This will facilitate the requesting process and improve speed of booking the patient onto the laboratory system.

Printed patient addressograph labels are preferable to minimise error. Where addressograph labels are used, please ensure that the current Consultant and Location of the patient are added if these details are not on the label attached. Failure to do so may result in a delay of results as details are required for the delivery of hard copy reports.

It is **essential** that a a minimum data set is available to ensure that results are assigned to the correct patient and returned to the correct clinician. Please provide the name and contact details of the requesting healthcare worker or telephoning of important results may be significantly delayed or impossible.

Please include the following information on the request form:

PLEASE NOTE: One other unique parameter i.e. NHS or Hospital No or date of birth is required in addition to patient first name and surname to ensure that the request is matched to the correct patient record on the laboratory database. For requests from patients submitted under unique coded identifiers e.g. GUM Numbers, the number and date of birth is required.

Failure to provide sufficient patient identifiers on the request form may result in the rejection of the request or a delay in processing of the sample.

NHS Number (preferred where available)
Hospital number (if available).
Date of birth

One of these is essential (to match sample)

Surname (or unique coded identifier) (please PRINT) (Essential)
First name(s): (Essential)

Gender:
First line of patient address & postcode:
Ward or location: (Essential)
GP code/Consultant in charge:
Bleep or contact number of the staff requesting the test:
Specimen type: (Essential)
Test(s) requested: (Essential)
Date and time of sampling: (Date Essential, Time not essential but may help)
Additional information in clinical details should include (Essential):

- Details of foreign travel, occupation (where relevant), contact with infectious diseases
- Additional details of sampling sites if relevant
- Details of recent, current and intended antimicrobial therapy

Please ensure that details of risk is included on all requests irrespective of test requested as this information is essential to ensure that the correct laboratory precautions are taken when processing all samples.

Labelling of Specimens

It is essential that all specimens are carefully labelled and dated to ensure that the correct analysis is attributed to the correct patient. Specimens requested electronically **MUST** be labelled with the system generated label. Non - electronically requested specimens should be labelled with the following information:

NHS number or Hospital Number (if available) **or Date of birth (One Essential)**
Surname (please PRINT) **or unique coded identifier (Essential)**
Full Forename (Essential)
Date of specimen
Site of sampling / specimen type
If unsure about the availability or value of any test, please contact the laboratory prior to taking a specimen.

Failure to comply with these guidelines may lead to the rejection of the sample. Specimens should be placed in appropriate containers and it is especially important that those containing pus, fluids or blood should be shut tight as leakage in transit may result in the sample being discarded or may make analysis difficult or invalid and pose an obvious hazard to others

Rejection Policy

Incorrectly/Unlabelled specimens

The laboratory regularly receives specimens that are unlabelled or incorrectly labelled (e.g. patient name/dob on specimen differs from that on form or electronic request). We are unable to process these specimens and they will generally be rejected. Any such specimens which are difficult or cannot be repeated will be discussed with requesting healthcare professional. However, these specimens will only be processed in exceptional circumstances and a comment will be added to the report to alert the requestor to the laboratory concerns relating to the identity of sample and thus the reliability of the results in relation to patient management. In addition clinical teams may be asked to provide assurance of sample origin or to correctly label the specimen.

Inappropriate sample type

Where inappropriate specimens are submitted for tests requested a report will be issued requesting submission of the correct sample.

These specimens will not normally be processed and will generally be rejected. Any such specimen that is difficult to repeat (as above) will be stored for a period of time. Other specimens may be rejected see section on relevant specimen types.

Other specimens that are unsuitable for microbiological examination and thus rejected include the following:

- unlabelled or improperly labelled specimens
- specimens received in leaking, cracked or broken containers
- specimens received in containers, the external aspects of which are contaminated
- unpreserved specimens received more than 12 hours after being collected

Specimens should be transported in sterile containers. If transport is to be significantly delayed, a suitable transport medium/device should be used or the specimen refrigerated in order to optimise testing.