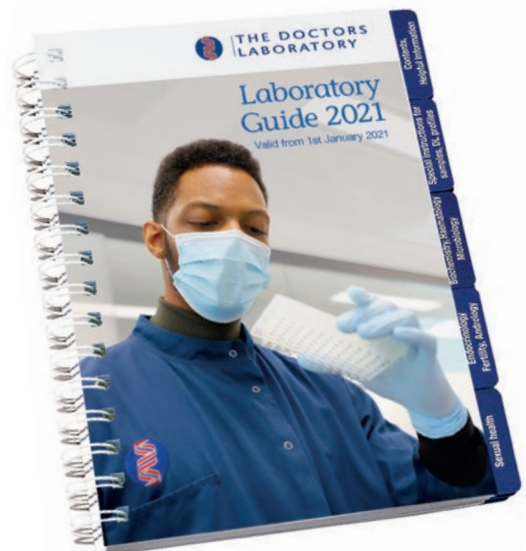


TDL Laboratory Guide 2021

At the end of every normal year we review requesting patterns, frequency of use, new best practice, new methods, and include new and relevant assays into the test menu. We also try to incorporate the changes that have originated from feedback received over the past year. This helps us to keep profiles and test menus as up to date and relevant as possible. The Laboratory Guide 2021 has been updated; there are about 1500 test listed through the departments, by speciality, and through the **A–Z test** index in the last section of the guide. For advice or information about any of the tests that are listed – and particularly if you cannot find the test you are looking for – please contact the laboratory on **020 7307 7373**. If you need information and advice about Genetic Tests please call **020 7307 7409**.

The symbol **NEW** shows new entries with reference to new tests, changes and updates effective from 1st January 2021.

The **Tab**s will help you navigate to the various disciplines, and for sample takers, the inside back cover of the laboratory guide gives details of sample requirements, with coloured dots to match the number of tubes, and colour of the BD vacutainer top (**A B C F G H K**).



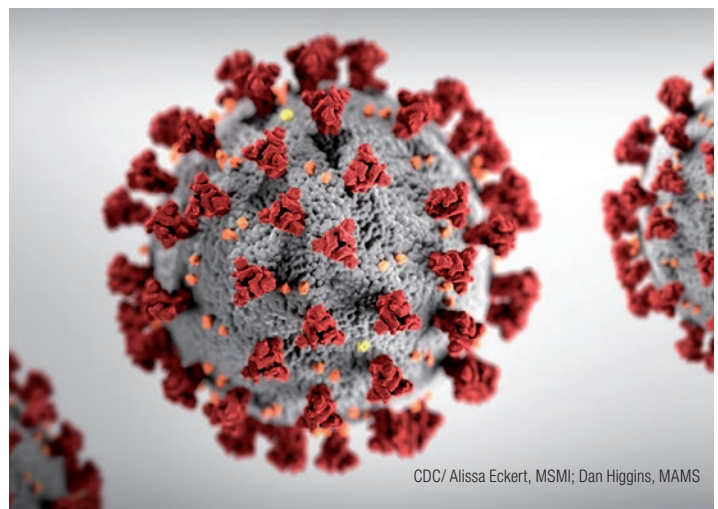
But this hasn't been a normal year. Nearly everything has had a COVID-19 signature, and everyone has had to change their ways of living and working. Apart from the significant changes to laboratory process, the testing and identification of one virus might sound either limiting, or limited, but because of the enormity of its impact, nothing could be further from the fact. Our vocabulary this year has increased with new words, phrases and meanings: lock down, the R-number, self-isolating, shielding, social distancing, spreader and spreading, flattening the curve – all derived from an illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that has been termed 'COVID-19'.

The focus given to the development of COVID-19 tests sits around five key areas:

- Performance of assay: sensitivity, specificity, accuracy
- Speed of processing – how quickly can results be reported
- Sample type and ease of specimen collection
- Choice of tests: which test to use, and when?
- Price: dependant on method and manufacturer: PCR, Antigen and Antibody

There are two kinds of tests currently available for COVID19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection at the time of testing.
- An antibody test tells you if you had a previous infection and that an antibody response has developed.



CDC/ Alissa Eckert, MSMI; Dan Higgins, MAMS

An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies. It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is also not known whether having antibodies to SARS-CoV-2 will provide protection from getting infected again or help reduce the severity or duration of a future COVID-19 infection. **Results from antibody tests must not be taken as an indication or degree of immunity or protection from reinfection.** Regardless of a test result, guidelines to reduce the risk of infection should be followed, including social distancing and wearing masks.

Details of breakthroughs for COVID-19 pre and post vaccine testing will continue. TDL will update on test developments throughout this coming year.

TDL's current COVID-19 testing options

TEST	CODE	SAMPLE REQUIREMENTS
COVID-19 PCR Swab test	NCOV	PCR Swab
Roche Total IgM/IgG Antibody	TCOV	Venous/ SST B
Roche Total IgM/IgG Antibody	TCOV	Capillary sample from CE marked self-collection kit
Abbott IgG Antibody	GCOV	Venous/ SST B
Abbott IgM Antibody	MCOV	Venous/ SST B

COVID-19 PCR Swab test

Test code	NCOV
Sample Type	PCR swab (COVID-19 Royal Mail Priority Tracked 24 kits provided)
Performance	Sensitivity 98.0%, Specificity 100%, Accuracy 98.8%
Analysers	Hologic Panther SARS-CoV-2 Assay UKAS Accredited Hologic Panther Fusion UKAS Accredited QuantStudio/Reagents ThermoFisher UKAS Accredited
Turnaround time	Within 48 hours of receipt of sample

Roche Total (IgG/IgM) Antibody: CE marked, UKAS accredited NEW

Test code	TCOV
Sample Type	SST/Serum B Venous (>14 days after onset of symptoms)
Performance	Specificity 100%, Sensitivity 97.4%
Analyser	Roche e801
Turnaround time	24 hours from receipt of sample

Roche Total (IgG/IgM) Antibody: Self-Collection CE marked IVD for COVID-19, UKAS accredited NEW

Test code	TCOV
Sample Type	SST/Serum B Capillary (>14 days after onset of symptoms)
Performance	Specificity 100%, Sensitivity 97.4%
Analyser	Roche e801
Turnaround time	24 hours from receipt of sample

Self-collection CE marked IVD for COVID Postal kits include a Royal Mail Tracked 24 return label.

Abbott IgG Antibody: CE marked, UKAS accredited

Test code	GCOV
Sample Type	SST/Serum B Venous only (>14 days after onset of symptoms)
Performance	Specificity 99.1%, Sensitivity 97.5%
Analyser	Abbott Architect
Turnaround time	24 hours from receipt of sample

Abbott IgM Antibody: CE marked NEW

Test code	MCOV
Sample Type	SST/Serum B Venous only (>14 days after onset of symptoms)
Analyser	Abbott Architect
Turnaround time	24 hours from receipt of sample

The presence of IgM antibodies allows for the identification of recent infection and evaluation of disease course. Specific IgM antibodies to SARS-CoV-2 may be detectable in COVID-19 patients during the symptomatic phase of the disease. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The IgM Antibody assay should not be used to diagnose acute SARS-CoV-2 infection. **It does not replace PCR testing.**

SENDING COVID-19 SAMPLES TO THE LABORATORY

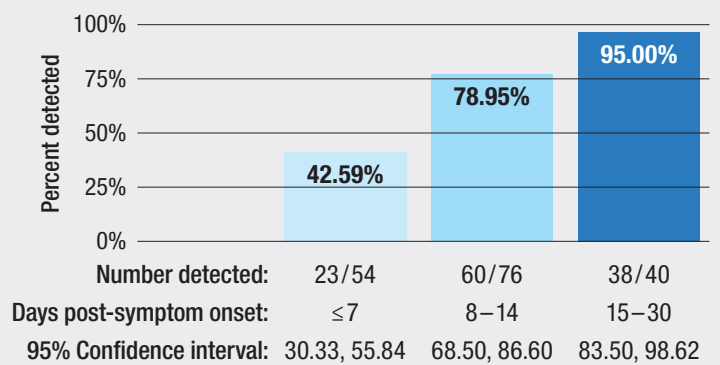
Samples for Covid-19 (PCR swabs or Blood antibody samples) can be sent to the laboratory:

- with your practice's courier collection
- delivered to Patient Reception at 76 Wimpole Street W1G 9RT
- delivered to the HALO Laboratory (WC1H 9AX)
- delivered to TDL Manchester (M50 2GY)
- posted to the Halo Laboratory, using next day delivery **Royal Mail COVID Tracked 24** for all postal samples. Tracked 24 labels are enclosed in all pathology postal packs. A PRIORITY postal service for COVID-19 swabs is provided by Royal Mail – user friendly instructions are given in each pack.

TDL report all Antibody and PCR activity on a twice daily basis to Public Health England (PHE). It is a requirement that laboratories notify this information and it is therefore essential that the patient's address and postcode are provided with the request for testing, so that positive results can be followed quickly by Test and Trace.

Percentage of positive patients detected by time post-symptom onset

Excluding immunocompromised specimens. Instrument: Architect i2000SR



<https://www.corelaboratory.abbott/us/en/offerings/segments/infectious-disease/sars-cov-2>

NEW Respiratory PCR testing – symptomatic

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TDL has introduced multiplex realtime RT-PCR testing for the rapid and qualitative detection from upper and lower respiratory tract specimens obtained from individuals who show signs and symptoms of respiratory tract infection. Specimen types include nasopharyngeal swab specimens, bronchoalveolar lavages and bronchial washes.

- Respiratory syncytial virus A & B
- COVID-19
- Influenza A virus
- Influenza B virus

RESPIRATORY VIRAL RNA SCREEN BY PCR	
Flu A	
Flu B	
Respiratory Syncytial Virus (RSV)	
COVID-19	NEW 2021 TAT 48 HOURS
FLU4	

PCR nasopharyngeal

TDL TINIES™ & SELF-COLLECTION SAMPLES (tinies@tdlpathology.com)

Self-collection testing services that provide a range that can be offered to patients, using TDL TINIES™ and Royal Mail Tracked 24 postal packs. Orders for TDL TINIES™ (packs with instructions) can be provided to the practice to be sent out individually to patients, or supplied directly to doctors or healthcare companies.

This is not a patient self-referral service and it is not point of care testing. All testing is undertaken in the laboratory and results are always returned directly to the healthcare company or doctor, not to the patient. TDL TINY™ samples can be combined with other self-collected samples types (urine, stool, swabs, HPV).

The sample volume from one TINY™ sample, when filled to the upper fill line, is **600 microlitres**. These, on receipt in the laboratory, are centrifuged and provide a volume of 300 microlitres of serum/plasma (depending on the tube type used). Different tests require varying amounts of sample, and this, together with analyser dead volumes, means that although certain tests can be carried out from TINY™ tubes, many tests simply cannot be achieved from these smaller sample volumes. To discuss test suitability for this service, please email or phone for advice.

Recommendation: most people are not experienced with collecting their own blood. Whilst it is possible to collect a blood drops sample for two or three microtainers, the most successful outcomes are collected by patients who read the instructions that are given in each pack, and who collect enough sample for one microtainer. Instructions for sample collection are enclosed in each pack. A completed **request form** must be enclosed with the returned sample. Results will always be sent to the requesting doctor/healthcare organisation.

There is a TDL TINY™ video to assist patients with sample collection.


Visit <http://www.tdlpathology.com/test-information/test-service-updates/tdl-tinies>

For information and packs, please contact Annette Wilkinson on 020 7307 7343 or email tinies@tdlpathology.com.

Roche Total (IgG/IgM) Antibody: Self-Collection CE marked IVD for COVID-19, UKAS accredited

NEW

Self-collection kits include a Royal Mail Tracked 24 return label.

Test code	TCOV
Sample Type	SST Tiny™  Capillary (>14 days after onset of symptoms)
Performance	Specificity 100%, Sensitivity 97.4%
Analyser	Roche e801
Turnaround time	24 hours from receipt of sample

Results of this test must not be taken as an indication or degree of immunity or protection from reinfection.

SELF-COLLECTION HPV SAMPLES

The **Self-Collection HPV Test** provides women with the option to self-collect a vaginal specimen that is then sent to the laboratory for testing. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens.

A **NEGATIVE HPV** result means that these high-risk subtypes HPV have not been detected and the patient is at extremely low risk of developing high-grade cervical disease/CIN2+ before their next routine visit.

A **POSITIVE HPV** result might indicate an increased risk of developing CIN/cervical cancer, and the report from the laboratory will provide a clear recommendation for follow-up/colposcopy.

Self-collection of specimens for HPV testing is not intended to replace existing patient management pathways but allows for:

- Those who wish to test following a change of sexual partner
- Option for identifying individual high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears
- Self-collection for HPV increases acceptability and coverage rate of cervical cancer prevention

Results will always be sent directly to the requesting clinician, clinic or healthcare organisation.

HPVY Self-Collected HPV DNA with reporting of high risk subtypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)

HPVZ Self-Collected HPV DNA with **individual** reporting of all subtypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

For more information, or to order Self-Collection HPV Test Packs, please contact Annette Wilkinson on 020 7307 7373 or annette.wilkinson@tdlpathology.com

POSTAL PATHOLOGY

Postal pathology services should be considered by all practices and healthcare organisations in the UK who need a rapid delivery service to the laboratory. Changes with Royal Mail means that ALL pathology postal packs are now made up with **Tracked 24 returns**.

Postal pathology with **Tracked 24 returns** provides:

- Simple and convenient sample handling throughout the UK for most tests. It is not suitable for microbiology or coagulation samples
- Offers scope for large or small numbers of samples
- Next morning delivery to the laboratory
- Allows patients and practices to track samples through the Royal Mail system
- Samples can be posted from any Royal Mail post box, including COVID-19 antibodies
- Designated **Priority Boxes** for COVID-19 PCR (swab) kits
- From 1st January there will be a charge of £2.26 for each Royal Mail Tracked 24 pack. This will be charged with the pathology to the patient if requested, or itemised in monthly invoices to the practice. The option to send postal pathology using Tracked 48 at a lower rate is also available.

DX SYSTEM: DX 340201, St Pancras 90 WC

DX is a well known next-day courier of Category B specimens – transporting biological samples in compliance with the industry's highest regulations. DX is compliant to IATA regulations, is audited independently by Dangerous Goods Safety Advisors. They work with a combination of large health organisations and smaller, independent laboratories to ensure the safe delivery of specimens every year.

TDL's DX Address is **DX 340201, St Pancras 90 WC**.

Discontinued service

The manufacture of Abbott Hep C Core Antigen (HCV Ag) has been discontinued worldwide. This test has been removed from the Sexual Health Profiles. HCV Ag testing has been used by TDL as the confirmatory test for reactive HCV Antibodies. The confirmation reflex protocol has therefore changed as follows:

- Using the same sample positive HCV Antibody will now reflex to HCV RNA (QPCR) instead of HCV Ag on the same sample.
- If a test battery is requested on a sample which includes HCV Ag, this is closed and an HCV Antibody is requested. If the HCV Antibody is reported as positive, then a reflex HCV RNA is added to the sample.

TDL advised of this change (01/11/2020) at the time the HCV Ag assay was discontinued. The communication could not indicate expected return of reagents.

Service email addresses, who to contact to make arrangements

addons@tdlpathology.com	Request ADDITIONAL TESTS from a sample already in the laboratory	see page 8
andrology@tdlpathology.com	Arrange an APPOINTMENT FOR SEMEN ANALYSIS (Tel: 020 7025 7940)	see page 7
couriers@tdlpathology.com	Contact couriers as an alternative to ONLINE BOOKING	see page 8
eview@tdlpathology.com	To arrange a secure Login/Password for RESULTS LOOK-UP	see page 10
finance@tdlpathology.com	Contact credit control for INVOICE RELATED QUERIES	see page 11
homevisits@tdlpathology.com	ARRANGE A HOME VISIT for your London based patients	see page 8
logo@tdlpathology.com	Include your LOGO (GIF format) for all emailed results	see page 11
patientreception@tdlpathology.com	Email ahead for SPECIAL ARRANGEMENTS for your patients	see page 6
phlebotomy@tdlpathology.com	Email for SPECIAL ARRANGEMENTS for patients when needed	see page 6
supplies@tdlpathology.com	ORDER PATHOLOGY SUPPLIES/POSTAL PACKS for TDL samples (Supplies Reorder Form – see Laboratory Guide inside back cover)	see page 10
tdl@tdlpathology.com	GENERAL ENQUIRIES	

TDL's Laboratory Guide 2021 is designed to give you an easy to use reference, for the most regularly requested tests and profiles. If you need help or advice in finding information about tests or services, please contact the laboratory on 020 7307 7373 or email tdl@tdlpathology.com. We will continue to develop clinically relevant diagnostic services and our aim is to offer commitment to customer service, strong working relationships and help and support to doctors and their practises.