TEST UPDATE

THE DOCTORS LABORATORY

Coronavirus COVID-19 (SARS-CoV-2) testing options by PCR and IgG Antibody

COVID-19 (SARS-CoV-2) testing by PCR assay

Specimen

- Nasal/Throat swabs collected using BD dry swabs/ Remel M4RT/Copan 321C UTM or Copan 147C.
- Samples should be taken from symptomatic patients between days 1-5 from onset of symptoms.
- Specimens should be sent to the laboratory at ambient temperature in Category B packaging and labelled as containing HIGH RISK specimen.
- Please send samples on the day they are taken for best results, however samples are stable at ambient temperature for 3 days for wet swabs and up to 6 days for dry swabs.
- Test code NCOV

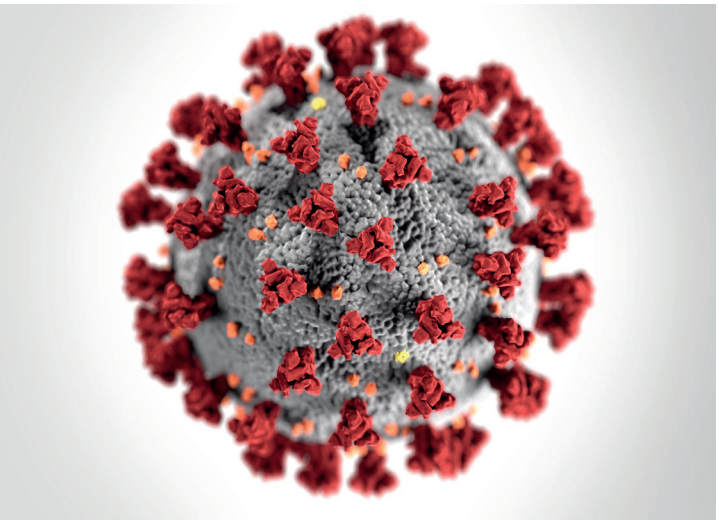

Image: CDC/ Alissa Eckert, MS; Dan Higgins, MAMS

Clinical background and biology

Coronavirus disease 2019 (COVID-19) is a respiratory tract infection caused by a newly emergent coronavirus – Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2) – which was first recognised in Wuhan, Hubei Province, China, in December 2019. Genetic sequencing of the virus suggests that SARS-CoV-2 is a betacoronavirus closely linked to SARS coronavirus 1.

The outbreak was declared a Public Health Emergency of International Concern on 30 January 2020, and has since spread globally, resulting in the 2019–20 coronavirus pandemic. Current measures are in place globally to reduce the spread of the virus, most commonly from droplets (person-to-person) but also from infected surfaces. The target is to reduce the reproduction number (R0) to <1.0 – i.e. < one person infected by one affected individual.

Infectivity is now recognized to occur before the onset of symptoms and yet high titres of virus can be detected on upper airway surfaces in people who do not develop symptoms.

Infection with SARS-CoV-2, an RNA virus, is diagnosed using reverse-transcriptase PCR. The assays used at TDL show a minimum sensitivity of 98% and a specificity of 100%, with no cross-reactivity with other viruses.

Indications

The majority of people with COVID-19 have uncomplicated or mild illness (81%), with non-specific symptoms such as fever, fatigue, cough (with or without sputum production), anorexia, malaise, muscle pain, sore throat, dyspnea, nasal congestion, or headache. Rarely, patients may also present with diarrhoea, nausea and vomiting. Loss of taste and smell has been reported early in the infection.

A relatively small proportion of people, particularly but by no means exclusively in those aged >70 years, will develop severe illness requiring oxygen therapy (14%) and approximately 5% will require intensive care unit treatment. Time from the onset of the infection to hospitalisation can be up to ~13 days. Of those critically ill, most will require mechanical ventilation. The most common diagnosis in severe COVID-19 patients is severe pneumonia; this can progress to acute respiratory distress syndrome, and life-threatening multi-organ dysfunction and death. Mortality has been estimated at between 1 and 2% of those infected, the higher figure in men.

Current testing for COVID-19 (SARS-CoV-2) is rapidly evolving. **Laboratory review of new assays as they become available is essential.**

Limitations and clinical interpretation

As with all viral PCR assays, patients with very low viral loads are less likely to be detected. 'Not detected' results do not preclude infection with the SARS-CoV-2 virus and should not be the sole basis of a patient treatment/management or public health decision. Where there is a strong clinical suspicion of an early COVID-19 infection repeat sampling should be considered 24-48 hours later.

Patients with COVID-19 symptoms in intensive care have been shown to no longer carry the virus in the upper respiratory tract. Viral detection tests should assist in the decision on when to discontinue additional precautions for hospitalised patients.

Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.

References

Department of Health (DoH), Coronavirus (COVID-19) Guidance: what you need to do. Available at: https://www.gov.uk/guidance/coronavirus-covid-19-information-for-the-public. Updated daily.

The Lancet, Covid-19 Resource Centre. Available at: https://www.thelancet.com/coronavirus-19/dgcid=kr_pop-up_tlcoronavirus20.

National Institute for Health and Care Excellence (NICE), NICE Guideline (NG) 159. COVID-19 rapid guideline: critical care. March 2020. Available at: https://www.nice.org.uk/covid-19.

Fauci, AS *et al*, Editorial – Covid-19 – Navigating the unchartered. NEJM 2020; 382:1268-1269

WHO: Coronavirus disease (COVID-19) Pandemic. https://www.who.int/emergencies/diseases/novel-coronavirus-2019.

WHO: Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. 13 March 2020. https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected.

Coronavirus – COVID-19 (SARS-CoV-2) Abbott IgG Antibody

Molecular testing (PCR Swab) will identify people with the virus. Antibody testing can tell whether a person has been previously infected. Most patients who recover from coronavirus have been found to produce antibodies, but it is not yet known if an individual with a positive result showing presence of IgG levels following being infected with SARS-CoV-2 will be protected, either fully or partially from future infection, or for how long protective immunity may last.

Testing should be undertaken 14 days or more following exposure or onset of symptoms. The incubation period of COVID-19 ranges from between 1 to 14 days, with the majority of cases manifesting with symptoms at 3–5 days. The most common symptoms of COVID-19 are fever, tiredness, dry cough and difficulty breathing. These symptoms have the potential to develop into a very severe acute respiratory illness. Evidence shows that fatality rates increase with age, gender, body weight, ethnicity and comorbidities.

The host immune system reacts to the infection by SARS-CoV-2 by producing antibodies from a few days to 2 weeks after the onset of symptoms. Specific IgG antibodies are produced in the later stages of infection to SARS-CoV-2, and are detectable after RNA is no longer detectable.

The persistence of IgG antibodies allows identification of people who have been infected by SARS-CoV-2. Test development relating to SARS-CoV-2 is rapidly evolving. **Laboratory review of new assays as they become available is essential.**

Interpretation of Results

COV-2 IgG	< 1.4	Not Detected	(Negative)
COV-2 IgG	>=1.4	Detected	(Positive)

Specificity	100%
Sensitivity	97.5%

Results should be used in conjunction with information available from clinical evaluation and other diagnostic procedures. It has been recognised that there can be delayed responses in immunocompromised patients.

Test information

TEST	CODE	SAMPLE TYPE	TURNAROUND TIME
PCR Swab Coronavirus – COVID-19	NCOV	**PCR swab** (nasal/pharyngeal)	2 days
Abbot IgG Antibody Coronavirus – COVID-19	GCOV	**SST/Serum** B*	24 hours

* Contact the laboratory for patient self-collection sample kits.

For further information, please contact:

Annette Wilkinson, The Doctors Laboratory, The Halo Building, 1 Mabledon Place, London WC1H 9AX
Tel: +44 (0)20 7307 7373 **E-mail:** tdl@tdlpathology.com **Website:** www.tdlpathology.com

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