



SARS-CoV-2 Antibody Test

Information for GPs



The information in this booklet is provided for health professionals. When using this information, please follow all advice on COVID-19 management and testing provided by the Australian Commonwealth Government and by the Department of Health in your state or territory.

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Wondfo SARS-CoV-2 Antibody Test (lateral flow method) is manufactured by Guangzhou Wondfo Biotech Co Ltd, China.

It is registered by the Australian Therapeutic Goods Administration (ARTG number 333902), sponsored by Tayler Dental Consulting Pty Ltd. Little Whales Pty Ltd is the authorised distributor in Australia and New Zealand.

In Australia, this test kit may only be supplied to accredited pathology laboratories, registered medical practitioners, healthcare professionals in residential aged care facilities, or Commonwealth, state or territory department of health or their agencies.



Key points

The Wondfo SARS-CoV-2 Antibody Test (lateral flow method) is a rapid point-of-care test.

- **Convenient** – performed on a blood sample (e.g. finger prick)
- **Rapid** – test results available in 15 minutes
- **Easy to interpret** – result indicated by coloured bands
- **Can be performed in general practice** – allows GPs to provide testing services without the need to refer patients to a pathology collection point.

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What is the clinical role of SARS-CoV-2 antibody testing?

In unvaccinated patients, the Wondfo SARS-CoV-2 Antibody Test is validated for the detection of past COVID-19 infection.¹

It is suitable for rapid point-of-care testing in clinical practice.

Rapid serology testing might also be useful in testing the antibody response in vaccinated patients who request this test from their doctor.

Notes:

Serology testing performs best 14 days or more after the onset of COVID-19 symptoms.¹ It is not recommended in the diagnosis of acute COVID-19 infection.^{2,3}

The results of rapid point-of-care tests should be interpreted along with other clinical findings.²

Types of COVID-19 tests in use³

- **Nucleic acid testing** – also called PCR testing (respiratory tract samples) – used in the diagnosis of acute COVID-19 infection
- **SARS-CoV-2 serology (blood samples)** – used the detection of past infection or SARS-CoV-2-specific antibody response, including to detect patterns of previous infection in the population
- **Whole genome sequencing** – used in public health investigations, including contact tracing
- **Virus isolation** – used in special investigations

Technical information

What the test measures

The Wondfo SARS-CoV-2 Antibody Test detects the presence of IgM and IgG against SARS-CoV-2.

A positive test indicates an immune response to the virus.

Type of test

The Wondfo SARS-CoV-2 Antibody Test is a lateral flow immunochromatographic assay.

Ig: immunoglobulin; PCR: polymerase chain reaction



Benefits of rapid antibody testing



Benefits to patients

- **For unvaccinated patients** – a second chance to test if infection has occurred, after viral particles are no longer detectable^(a)
- **For travellers** – potential proof of seronegative status as required for travel to some countries^(b)
- **For vaccinated patients** – an opportunity to check for the presence of neutralising antibodies^(c)



Benefits to GPs

Choice of venous blood or fingertip capillary sampling offers flexibility across a range of clinical settings

The ability to offer opportunistic testing as a private service

Notes

(a) Even if positive, the presence of SARS-CoV-2-specific antibodies is not a reason to avoid vaccination.

(b) Antibody testing does not replace direct viral testing with swabs, which is required by some countries. Patients should obtain information from authorities in each destination country.

(c) The absence of antibodies or low antibody titres do not necessarily indicate lack of immunity, as T cells are responsible for long-term immunity.

How is the test performed?

Blood sampling

Three types of blood samples can be used:

- **fingertip capillary blood** – the test is performed immediately on-the spot test (remaining sample should be discarded after the test)
- **venous whole blood** – the test can be performed immediately, or the sample refrigerated and tested within 7 days of collection
- **serum and plasma** – the sample should be centrifuged immediately for plasma collection.

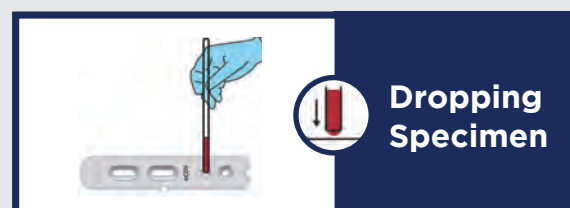
Test kit contents



The kit contains:

- 20 Individual sealed pouches, each containing one test cassette and one desiccant pouch
- 20 disposable droppers
- detection buffer
- instruction sheet.

Simple 4-step method



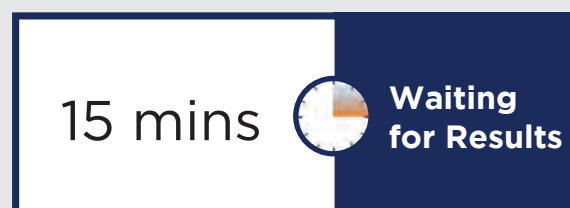
Dropping Specimen

1. Use micropipette to transfer 10 microlitres of serum, plasma or whole blood to the sample well (small well).



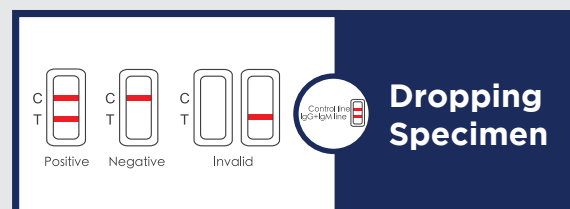
Dropping Buffer

2. Add 2-3 drops (80 microlitres) of buffer solution to the buffer well (large well).



Waiting for Results

3. Wait 15 minutes. Read results. (Do not read results after 20 minutes.)



Dropping Specimen

4. Interpret the result based on the coloured bands of test line (T). The result is invalid if no visible coloured band appears at the control line (C).

Is the test reliable?

The Wondfo SARS-CoV-2 Antibody Test has a good sensitivity and specificity for samples collected two weeks or more after the onset of symptoms (Table 1).

In an Australian TGA-commissioned validation study of commercial serological assays,¹ the Wondfo test showed good comparative performance in patients with confirmed COVID-19 infection (Table 2).

There is strong concordance (95%) between serum and plasma samples among patients with COVID-19 infection confirmed by RT-PCR testing.¹

Table 1. Sensitivity and specificity of Wondfo SARS-CoV-2 Antibody Test

Source	Sensitivity	Specificity
Manufacturer's data ¹	86%	100%*
Valdivia, et al. (2020) ^{†4}	Overall: 91% Sample collected >14 days post symptom onset: 94%	95%
TGA-commissioned validation study ¹	Overall: 69% Sample collected >14 days post symptom onset: 94%	98%

*Rounded from 99.57% †Independent Spanish study in hospitalised patients with moderate-severe COVID-19

Table 2. Comparative performance of point-of-care antibody tests in patients with RT-PCR-confirmed COVID-19 infection¹

Test (ranked in order of performance)	Positive test result % (95% CI)
Wondfo (Combined IgM/IgG)	68.6 (60.1–76.3)
Hangzhou Unlabelled IgG	60.6 (51.9–68.8)
Hangzhou AllTest IgG	59.9 (51.1–68.1)
Hightop IgG	58.8 (50.1–67.2)
EUROIMMUNEIA IgG	56.2 (47.5–64.7)
VivaDiag IgG	51.8 (43.1–60.4)
Onsite IgG	46.7 (38.2–55.4)

CI: Confidence interval (Clopper-Pearson)

The table shows the percentage of positive test results for 137 samples from 91 patients with confirmed COVID-19 infection valuated in the Australian validation study (combined results for samples taken at days 0–30 post onset of symptoms). The methods and comparator tests are described in the report.¹

RT-PCR: reverse transcription polymerase chain reaction; Ig: immunoglobulin; TGA: Therapeutic Goods Administration



References

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