



A/Prof Tom Dodd

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Updated information on COVID-19 serology testing

SA Pathology provides serology testing for SARS-CoV-2, the causative agent of COVID-19 infection. The Laboratory uses the Roche Elecsys® Anti-SARS-CoV-2 serology tests which detect high-affinity antibodies (IgM, IgA, or IgG) to the nucleocapsid (N) and spike (S) proteins. Serum is the preferred specimen type (10 ml gold-top tubes).

SA Pathology automatically performs both anti-N and -S tests on SARS-CoV-2 antibody requests. Confirmed detection of only anti-S antibodies is consistent with immunisation with Pfizer, AstraZeneca or another S sub-unit vaccine. Presence of both N and S antibodies may reflect past infection or immunisation with an inactivated whole-virus vaccine (eg CoronaVax/Sinovax used in China, Indonesia and elsewhere)

Most importantly seropositivity does not indicate immunity to SARS-CoV-2. The Australian Technical Advisory Group on Immunisation (ATAGI) therefore does not recommend post-vaccination antibody testing. ATAGI also does not recommend serological testing or other testing to detect current or previous infection with SARS-CoV-2 before vaccination.

The Laboratory's verification reflects the published data by the manufacturer. In healthy subjects, the test sensitivity is low from days 0-6 post symptom onset but increases to 98.8% (95% CI, 98.1-99.3%) for anti-S antibodies and 100% for anti-N antibodies (88.1%-100%) ≥ 14 days. Antibody development may be delayed or not detectable in the elderly and immunocompromised. Specificity is 99.8% or better for both tests, as confirmed on blood donor specimens collected in 2019 before the COVID-19 pandemic.

Requestors must remember that the incidence of COVID-19 infection in South Australia is negligible. In this low-incident population, most positive serology results will unavoidably represent false-positive cross-reactions despite the excellent specificity of the test.

These performance characteristics and recommendations have important implications for clinicians.

- SARS-CoV-2 serology plays no role in diagnosis of acute COVID-19 disease.
- Patients with symptoms consistent with COVID-19 should undergo PCR (not antibody) testing.
- **SARS-CoV-2 serology should not be used for immunity testing.**

- There are limited indications for ordering SARS-CoV-2 serology testing that target patients with a high pre-test probability of COVID-19 infection:
 - Testing patients who have had symptoms of COVID-19 but are PCR negative on repeat testing or were not tested by PCR during their acute illness;
 - Testing patients who have an unexpected positive or equivocal PCR result;
 - Testing of contacts as part of a public health investigation.

In view of these limited indications and the implications of a positive result, the Communicable Diseases Control Branch (CDCB) request that all SARS-CoV-2 serology requests be approved by a CDCB medical officer (1300 232 272) prior to the collection of blood.

Any questions about SARS-CoV-2 serology testing should be directed to the SA Pathology on-call clinical microbiologist on 8222 3000.

Regards,

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