

Fact Sheet for Healthcare Providers

November 2022

This Fact Sheet informs you of the known and potential risks of the Rako Science SARS-CoV-2 IgG Antibody Test

What is the test?

COVID-19 is caused by the coronavirus, SARS-CoV-2, a spherical virus comprising four main proteins, nucleocapsid protein (NP), spike protein (SP), membrane protein (MP), and the envelope protein (EP).



Diagram of SARS-CoV-2 depicting the virus antigens, (SP and NP) used in the RAKO SCIENCE SARS-CoV-2 Antibody Test.

The RAKO SCIENCE SARS-CoV-2 Antibody Test is a high performance, all-in-one, SP and NP SARS-CoV-2 antibody test with serological differentiation.

The RAKO SCIENCE SARS-CoV-2 IgG Antibody Test is a duplex immunoassay that detects the presence or absence of antibodies to SARS-CoV-2 NP and SP protein. The assay can detect the immune response from individuals who have been infected by SARS-CoV-2 (NP & SP) and those vaccinated with mRNA vaccines (SP).

What are the risks and benefits of the test?

Immune responses are individual and variable. Variation in response has been linked to age, sex and ethnicity, as well as prior SARS-CoV-2 infection and vaccination history.

Importantly the clinically vulnerable are reported to generate lower levels of antibodies compared with healthier people following vaccination.

The advantages of this antibody test are:

- It has the ability to detect two biomarkers in one test. i.e. Spike protein (SP) and Nucleocapsid protein (NP).
- It detects antibodies from vaccination, from a recent infection or both.
- Clinically proven sensitivity and specificity in one test has improved accuracy and reliability.
- The test will help identify at-risk patients who have failed to mount a detectable antibody response despite having been previously vaccinated or infected.
- It conforms to NZ Gov guidance on interpretation of SP and NP antibodies results. <https://covid19.govt.nz/>

Patients may experience minor discomfort or other complications that can happen during blood sample collection.

When should the test be collected?

Testing for antibodies induced by vaccination should be performed at least 14 days after the second vaccine dose.

Testing for antibodies induced by infection should be performed at least 14 days after symptom onset. Likewise, an antibody response may no longer be measurable >125 days after exposure.

Due to the kinetics of seroconversion, some patients may not have measurable antibody until more than 21 days after symptom onset.

What do the results mean?

A "Present" test result indicates IgG antibodies have been detected.

A "Absent" test result means no serological evidence of vaccination/infection has been detected.

An "Equivocal" test result means a repeat test in 14 days may be

NP Antibody	SP Antibody	Interpretation*
Present	Present	Antibodies to Nucleocapsid and Spike proteins were detected. This indicates an antibody response to recent SARS-CoV-2 infection (with or without previous vaccination).
Absent	Present	The absence of antibodies to Nucleocapsid indicates no serological evidence for recent SARS-CoV-2 infection. The presence of Spike protein antibodies however indicates a serological response to SARS-CoV-2 infection or vaccination.**
Absent	Absent	No antibodies to Nucleocapsid or Spike protein were detected. This indicates no serological evidence for recent SARS-CoV-2 infection or vaccination.***

* These results should be interpreted alongside vaccination history and the clinical and epidemiological findings.

** If recent illness or exposure consider retesting after 14 days

*** Client may have been infected or vaccinated and either has not produced an antibody response or the antibody level has become undetectable.

Is a quantitative result available?

No. The clinical interpretation of a quantitative result is currently in development.