COVID 19 Antibodies

General information

Elecsys Anti-SARS-CoV-2 is intended for the detection of total antibodies to SARS-CoV-2. There are two tests produced by Roche as detailed in table 1 below.

ASSAY	ANTIGENIC TARGETS
Roche COVID Antibody Assay **COVID NC Antibody**	Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2. This assay uses a recombinant protein representing the NUCLEOCAPSID (NC) ANTIGEN for the determination of antibodies against SARS-CoV-2. Provides qualitative Pos/Neg result
Roche COVID Spike Antibody Assay **COVID S Antibody**	Immunoassay for the in vitro quantitative determination of antibodies (including IgG) to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) SPIKE (S) PROTEIN receptor binding domain (RBD) in human serum and plasma. The test is intended as an aid to assess the adaptive humoral immune response to the SARS-CoV-2 S protein. Provides quantitative Antibody concentration result with a cut off for positive.

Table 1 – current Roche COVID 19 Antibody tests

Currently the GMIS laboratory offers both the **COVID NC and S Antibody** tests as a composite report.

Specimen transport: At room temperature

Repeat frequency: Not currently defined/indicated

Special precautions: None

Laboratory information

Specimen type: 4ml serum

Turnaround time: 24 hours

Method: Electrochemiluminescent immunoassay

Interferences: Potential endogenous interferences e.g. haemolysis, bilirubin, rheumatoid factors and pharmaceutical compounds such as biotin.

Participation in EQA Scheme: Pilot NEQAS for COVID-19/SARS CoV-2-Ab

Clinical information

Indications for the test:

• The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results from different manufacturers should not be used interchangeably.

• For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

• A negative test result does not completely rule out the possibility of an infection with SARS-CoV-2 or prior vaccination. Serum or plasma samples from the very early (pre-seroconversion) phase can yield negative findings. Therefore, this test cannot be used to diagnose an acute infection. Also, over time, titres may decline and eventually become negative.

• A positive test result implies previous exposure / infection or vaccination, but does not mean immunity, or inability to pass on the virus to others. It also does not mean that social distancing measures can be ignored

• Please see table 2 for current vaccines in the UK

VACCINES	ANTIGENIC TARGETS
Pfizer-BioNTech	mRNA vaccine composed of nucleoside-modified mRNA encoding a mutated form of the SPIKE protein for SARS-CoV-2.
Oxford University-AstraZeneca	Genetic material has been added to the ChAdOx1 virus construct, which used to make the SPIKE proteins.
Moderna	mRNA vaccine (similar to Pfizer-BioNTech). Immune system cells take up mRNA code and present with SARS-CoV-2 SPIKE proteins. The immune system recognises the foreign spike proteins and initiates an immune response including production of antibodies to the spike protein.

Table 2 – current vaccines in UK vaccine roll out

Interpretation of results:

Interpretation of results will be based on the test used and vaccine exposure. If prior exposure to one of the current vaccines, which all present the Spike protein to the immune system, then you would expect a positive response on the COVID S Antibody test. Natural infection would expose the immune system to all of

COVID-19 meaning an antibody response would be expected on both the NC and S tests. We will make the report clear as to which test has been used to help with interpretation.

Test	Result	Interpretation of results
COVID NC Antibody	**Positive**	Consistent with exposure to SARS-CoV-2 at some time. Currently this result should not be taken as evidence of immunity to SARS-CoV-2.
	Negative	No serological evidence of SARS-CoV-2 infection
COVID S Antibody	**Positive**	Consistent with exposure to SARS-CoV-2, or vaccination at some time. Currently this result should not be taken as evidence of immunity to SARS-CoV-2.
	Negative	No serological evidence of SARS-CoV-2 infection or vaccination

Table 3 – interpretation and comments based on results provided

When both results are available consider the below interpretation:

Test / result	Interpretation of results
Negative N & negative S	No serological evidence of SARS-CoV-2 infection or vaccination
Positive N & negative S	Consistent with exposure to SARS-CoV-2 **infection** at some time. Currently this result should not be taken as evidence of immunity to SARS-CoV-2.
Negative N & positive S	Consistent with exposure to SARS-CoV-2 **vaccination** at some time. Currently this result should not be taken as evidence of immunity to SARS-CoV-2.
Positive N & positive S	Consistent with exposure to SARS-CoV-2 **infection** at some time. Currently this result should not be taken as evidence of immunity to SARS-CoV-2.

Table 4 – composite interpretation and comments

Reference range:
NC assay not applicable (qualitative)
S assay < 0.80 U/mL negative and ≥ 0.80 U/mL positive

(Last updated July 2023)