



SsmarTest

COVID-19 Spike Protein Ab(IgM/IgG) Test

Catalogue number : SLS-007

Panel : Immunology

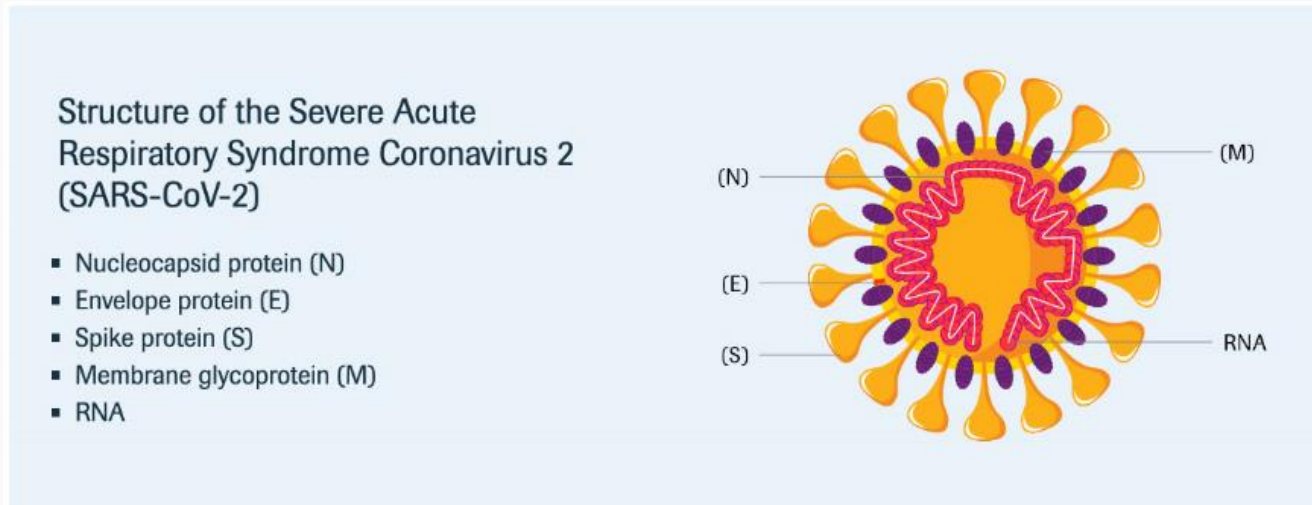
1. About SsmarTest COVID-19 Spike Protein Ab(IgM/IgG) Test

1 What is SsmarTest COVID-19 Spike Protein Ab(IgM/IgG) Test?

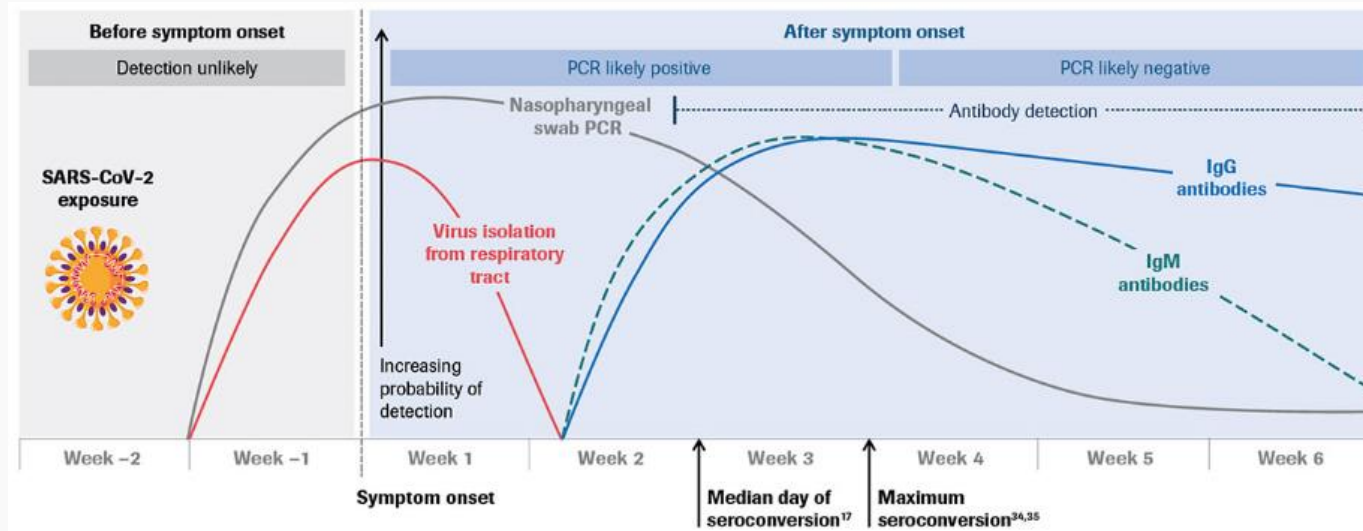
Spike Protein Ab(IgM/IgG) Test can detect whether a person has been infected previously(person to person)or has a Vaccine-induced immune response.

The Spike Protein Ab(IgM/IgG) Test enables the determination of the presence of antibodies to the SARS-CoV-2 Spike Protein, which is the target of many COVID-19 vaccines.

It can be a signal whether a person has already been infected and has potentially developed immunity to the virus, and plays an important part in characterizing a vaccine-induced immune response.



Testing should be undertaken 14 days or more following exposure, onset of symptoms or post-vaccination. The incubation period of COVID-19 ranges from between 1 to 14 days, with the majority of cases manifesting with symptoms at 3-5days.



2 Specification

Detection Target	Antibodies to SARS-CoV-2 Spike Protein
Detection Technology	Antibody test with immunochromatography assay (ICA)
Specimen Type	Human blood (Serum, Plasma or Whole blood)
Test Time	10 to 15 minutes

3 Highlights

- Can detect the presence of antibodies to SARS-CoV-2 Spike Protein, the target of COVID-19 vaccines
- Simple and easy test procedure
- Test result within 10 to 15 minutes

4 Kit Contents

- [1] Test Device
- [2] Spuit
- [3] Running Solution
- [4] Information for Use



5 Clinical and analytical performance

	SsmarTest COVID19 Spike Protein Ab (IgM/IgG) Test	Roche Elecsys Anti-SARS-CoV-2 S(Spike) Total antibody NEW	Abbott Architect SARS-CoV-2IgM
Platform	POCT	Roche e801	Abbott Architect
Assay type	Immunochromatographic Assay(ICA)	Electrochemiluminescence immunoassay (ECLIA)	Chemiluminescent Microparticle Immunoassay (CMIA)
Reporting format	Qualitative	Quantitative	Qualitative
Reporting ranges	Positive/Negative	Positive with value reported in U/ml / Negative	Positive/Negative
Antigen used	Spike Protein receptor binding domain (RBD)	Spike Protein receptor binding domain (RBD)	Spike Protein
Analyte target	SARS-CoV-2 Antibodies (IgG/IgM) Total antibodies	SARS-CoV-2 Antibodies (IgG/IgM) Total antibodies	SARS-CoV-2 Antibodies (IgM)
Sample type verified	Serum, Plasma and Whole blood (finger stick)	Serum – venous or capillary self-collection	Serum – venous
Sensitivity	100% (95%CI, 90.0-100.0%)	99.8%	96.67% in samples taken more than 14 days post symptoms onset
Specificity	97.50% (95% CI, 91.26-99.70%)	98.8% in samples taken 14 days or later after positive PCR	99.0%
Seasonal Corona Virus Panel	8/8 Negative	24/24 Negative	N/A

Cross reactivity

As a result of testing with serum and plasma samples containing the pathogens (HIV, HBV, HCV, RSV, influenza A/B, enterovirus 71), no false negative or false positive results were found.

Interference

There were no false-negative or false-positive results in the tests using the following substances: hemoglobin, EDTA, HAMA, human IgG, human IgM, HSA)

2. Specimen collection Procedure

Sample Collection

- [Blood collection]
- Must use sterile vacutainer or syringe needle.
 - Place blood immediately in blood collection tube and invert for the anticoagulants mixing

Transport

- If specimens cannot be shipped within 72 hrs of collection, separate serum or plasma and store at 4 °C or below.

Analysis

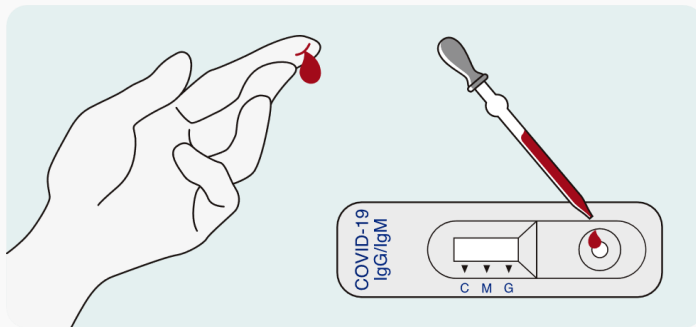
- Use by doctor, nurse or medical laboratory technician.
- Test with the user manual.

Interpretation

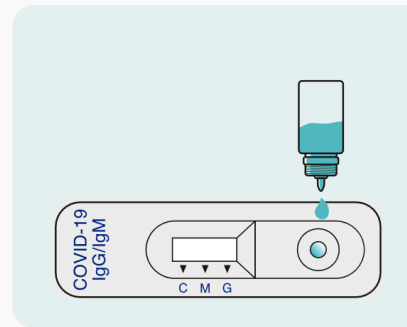
- The test results must be interpreted with the user manual.
- The test results are used in conjunction with other laboratory tests.

3. Test Method

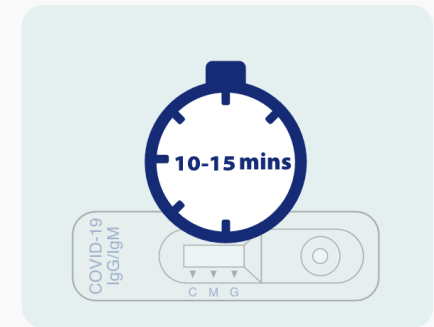
1) Add 1 drops of specimen(whole blood, serum or plasma)



2) Add 2 drops of running solution



3) Read results in 15 minutes

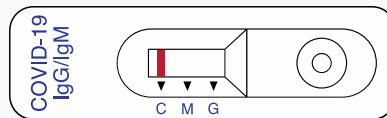


4. Result Interpretation

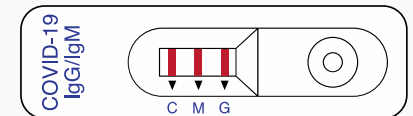
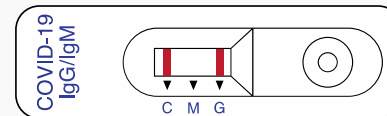
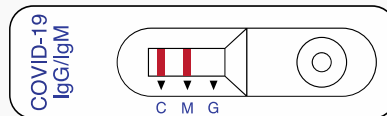
IgM	IgG		Interpretation
-	-	X	Not infected or vaccinated
+	+	O	Infected or vaccinated (8 ~ 15 D)
+	-	X	Early stage
-	+	O	Infected or vaccinated (15 D<)

* Abbr. -, negative; +, positive; D, day

Negative



Positive



Re-Test

