PRODUCT

RAPID TEST 2019 –nCoV Total Ig (V1210/V1230)

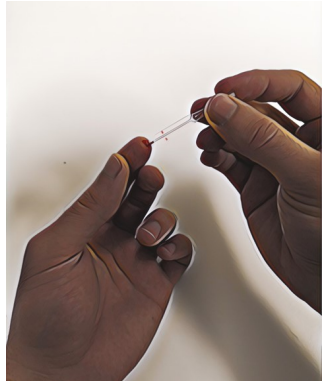
PROGNOSIS BIOTECH

	Time	Sample	Shelf life	Storage	Format
Lateral Flow Test for the determination of Total Immunoglobulins (IgA, IgG and IgM) against SARS-CoV-2	10 min	Whole blood or serum	12 months	4-30 °C	10/30 tests

PROCEDURE

Add 4 drops of the dilution buffer into the test tube

Twist the cap of the lancet device, place it on the fingertip and then press the green button



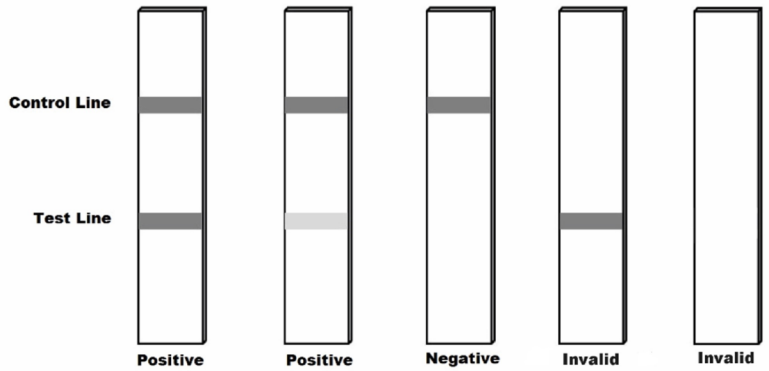
Apply the capillary tube to the blood sample and slightly press it against the area. It will automatically collect the specimen

Load the sample (5 µl or 2µl with serum) into the test tube and mix thoroughly

Insert the test strip into the test tube and incubate for 10 mins

Remove the strip and interpret the results visually according to the table below

ANALYSIS



RESULT INTERPRETATION TABLE

Control line & Test line	Positive result for SARS-CoV-2 antibodies in the specimen
Control Line & Weak Test line	Positive result for SARS-CoV-2 antibodies in the specimen
Control line only	Negative result for SARS-CoV-2 antibodies in the specimen
Test line only	Indicates an invalid result
No lines	Indicates an invalid result

Clinical Performance Study

On June 12, 2020, at the 2nd department of Microbiology, School of Medicine, of the Aristotle University of Thessaloniki, which serves as one of the official Reference Laboratories for SARS-CoV-2 in Greece, took place the latest performance study for the **RAPID TEST 2019 –nCoV Total Ig.** The study aimed to evaluate the sensitivity and the specificity of the lateral flow test kit, which determines the IgA, IgM, IgG antibodies against SARS-CoV-2. For the evaluation, 80 positive and 114 negative samples were examined (194 in total). The positive samples had been priorly confirmed by RT-PCR in several reference laboratories of Northern Greece, while the negative ones had been collected prior to the pandemic.

Clinical Performance Results

The **RAPID TEST 2019 –nCoV Total Ig** demonstrated excellent results in terms of *sensitivity* and *specificity* (98,75% and 100% respectively), for the total number of antibodies against the SARS-CoV-2. Additionally, for samples that were collected after the first 7 days from the onset of the symptoms, both their sensitivity and specificity reached 100%.

Rapid Test 2019 –nCoV Total Ig	Positive Specimens	Negative Specimens
Positive	79	0
Negative	1	114
Total	**80**	**114**

Sensitivity (%): 98,75%

Specificity (%): 100%