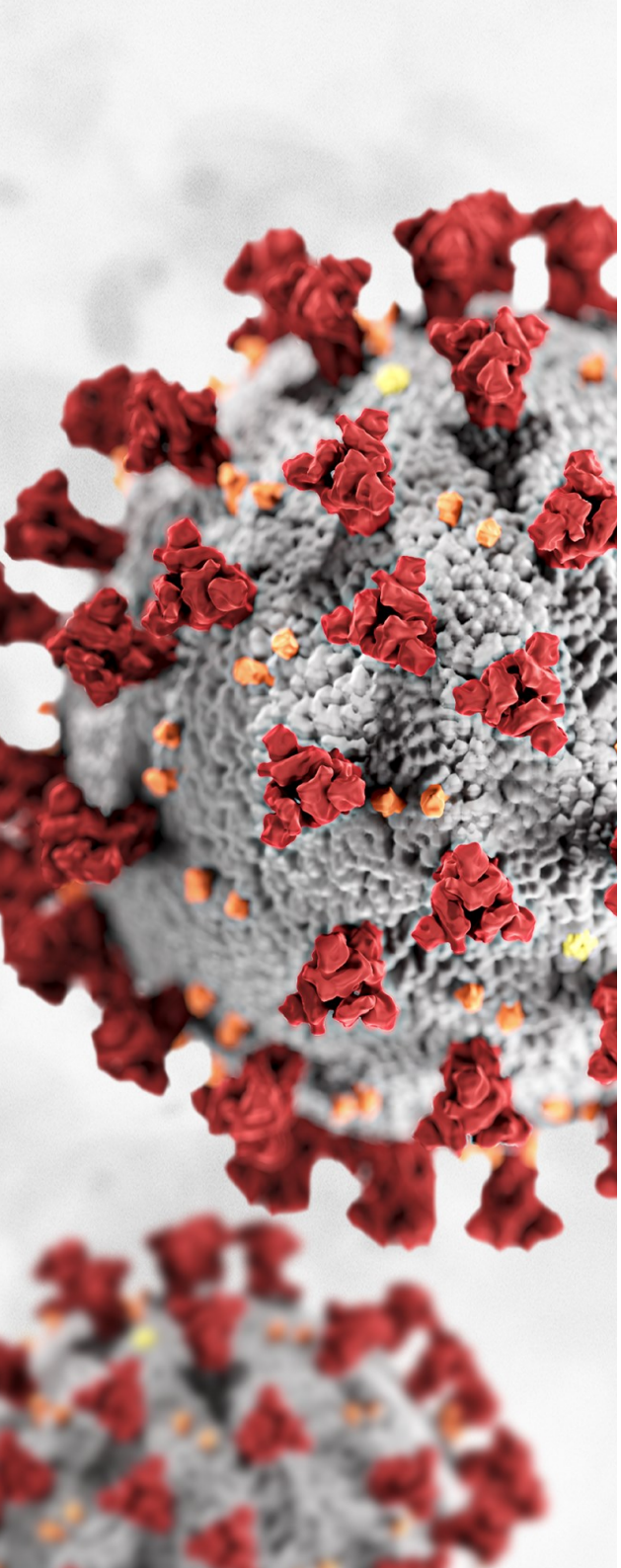


REF H1301 H1302 H1305 H1320

HOME TEST COVID-19 AG

PROGNOSIS BIOTECH

For private use/home use/self-testing

Lateral Flow Test | IVD

for the detection of SARS-CoV-2 antigen in human nasal specimen.

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A. and conforms with Directive 98/79/EC requirements.

Use only the current version of Product Data Sheet enclosed with the kit.

Home Test COVID-19 Ag, H1301, H1302, H1305, H1320 is a qualitative Lateral Flow test for the detection of SARS-CoV-2 antigen in nasal specimen.

The Lateral flow kit contains all reagents required for the immunoassay method.

Specimen: Nasal swab.

- For *in vitro diagnostic* use only
- Home Test COVID-19 Ag, is a sensitive screening assay for the detection of SARS-CoV-2. Results should not be used as the only source to diagnose or to determine infection status.
- Negative results do not rule out SARS-CoV-2 infection
- Test time (incubation time after specimen preparation): 15 min
- Shelf life: 24 months
- Storage: 4-30°C

1. Intended use

Home Test COVID-19 Ag, is a fast qualitative, lateral flow immunoassay designed to detect the presence or absence of nucleocapsid protein of SARS-CoV-2 in nasal swab specimens directly collected, in the first seven days from the onset of the symptoms.

2. Introduction

A novel coronavirus (identified as 2019-nCoV) emerged in the Chinese province of Hubei (Wuhan) in December 2019, which has resulted in hundreds of thousands of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2. The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection. The most common symptoms of COVID-19 (according to WHO), are similar to other viral respiratory diseases and include fever, dry cough and tiredness. The virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes. Molecular and antigen testing are the only techniques capable of detecting the SARS-CoV-2 virus.

3. Kit content

	H1301	H1302	H1305	H1320
Reaction device Rapid Test Ag 2019-nCoV in sealed foil	1	2	5	20
Extraction tube prefill with running buffer	1	2	5	20
Sterile swab	1	2	5	20
Instructions For use	1	1	1	1
Carton case	-	-	-	1

4. Warnings

- Read the instructions carefully.
- Kit remain stable till the expiry date. DO NOT USE after the expiration date.
- Do not use the kit if the packaging of components is damaged, if there is an expired reagent or if the desiccant bag is absent inside the foil containing the reaction device.
- Store kit components between 4 and 30°C (39.2 - 96°F). Do not freeze any components provided. Avoid direct sunlight.
- After opening the pouch with the desiccant, use the device as soon as possible. Do not use if the device is open for more than 2 hours.
- All reagents should be warmed in room temperature before use.
- Treat all specimens as though they contain an infectious agent.
- Failure to follow the guidelines for proper specimen collection, test procedure and interpretation of test results may adversely affect test performance and/or produce invalid result.
- After the extraction specimens should be tested as soon as possible.
- Add three drops in the circular window of the reaction device.
- Children under the age of 18 should be helped by an adult.
- Blow your nose before the specimen collection.
- Do not use nasal care products (such as nasal sprays) at least 30min before testing.
- Use a clean surface when perform the test.
- Do not re-use any of the kit components as they are single-use only
- Sterile swabs must be used only for nasal specimen. Avoid to touch the tip of the swab.
- All positive results should be processed following local news and regulations.
- WASTE MANAGEMENT: Discard the used device and the rest of the kit components sealed in a plastic bag.

5. Limitations

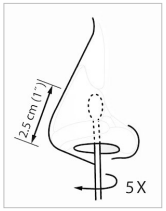
- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen ONLY in nasal swab specimens.
- Failure to follow the guidelines for proper specimen collection, test procedure and interpretation of test results may adversely affect test performance and/or produce invalid result.
- USE ONLY the sterile swabs that are provided in the kit for the specimen collection.
- During specimen collection avoid contact with bleeding areas and excess of mucus as both of them may give a false positive result due to interference with the test performance.
- Positive results indicate the presence of SARS-CoV-2 antigens but a diagnosis of an infection should only be made by a physician evaluating all clinical and laboratory findings and must be based in the correlation of the results with further clinical observations.
- Any medical decision should not be made before contact with doctor.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
- In case there is eyes, skin or mouth contact with the extraction/running buffer, rinse with clear water. If any irritation persists, consult a medical professional.

6. Specimen collection

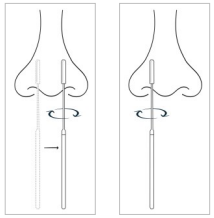
6.1 Remove a sterile swab from the pouch without touching the tip.

6.2 While gently rotating it, insert the swab less than one inch (about 2-2.5 cm) into your nostril

6.3 Rotate the swab five times against the nasal wall then slowly remove from the nostril.



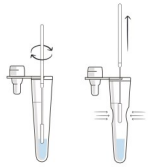
6.4 Using the same swab repeat the collection procedure with the second nostril.



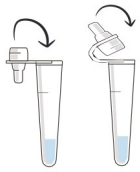
7. Method procedure

7.1 After the specimen collection (see Chapter 6), open the prefilled extraction tube and place the swab in it, rotate the swab forcefully against the side of the tube for 1min.

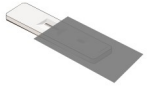
7.2 Remove the swab, **squeezing the sides of the tube to extract as much liquid as possible**



7.3 Close the extraction tube with the dropper cup.



7.4 Open the foil containing the reaction device.



7.5 Add 3 drops in the circular window of the reaction device.

7.6 After 15 minutes, the test can be visually read and interpreted according to the corresponding figure. (see next page)

NOTE: The test result should not be read and interpreted after 30 minutes.

8. Interpretation of results

Note*: For internal procedure purposes two colored lines (blue & green) are present on the result window of the Home Test COVID-19 Ag. The colored lines (Blue& Green*) have no effect on the product's performance since they are washed away during the experiment.

Positive: Two visible colored bands appear at both Test (T) and Control (C) line. It indicates a positive result for the SARS-CoV-2 Nucleocapsid Protein in the specimen.

Negative: One visible colored band appears at Control line. It indicates that the concentration of the SARS-CoV-2 NP is zero or below the detection limit of the test.

Invalid: No colored band appears at Control line no matter whether it appears at Test line or not.

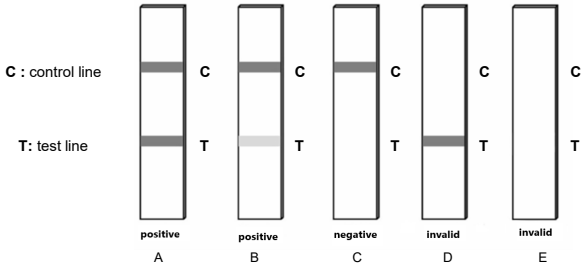


Figure : Interpretation of results

RESULT INTERPRETATION TABLE	
A. Control line & Test line	Positive results for SARS-CoV-2
B. Control line & Test line	Positive results for SARS-CoV-2
C. Control line only	Negative results for SARS-CoV-2
D. Test line only	Indicates invalid result
E. No lines	Indicates invalid result

9. Cross-reactivity

In order to determine the cross reactivity of Home Test COVID-19 Ag, an evaluation was performed; no cross reactivity against organism, pathogens that could cause infections was observed.

Home Test COVID-19 Ag could have some cross reaction with SARS and very low with MERS.

Microorganism	Concentration	Result
Adenovirus	$1x10^6$ PFU/ml	Negative
Astrovirus	$1x10^5$ PFU/ml	Negative
Alpha coronavirus 229E	$1x10^5$ PFU/ml	Negative
Alpha coronavirus NL63	$1x10^6$ PFU/ml	Negative
Beta coronavirus OC43	$1x10^5$ PFU/ml	Negative
Beta coronavirus HKU1	$1x10^6$ PFU/ml	Negative
Escherichia Coli O157	$6.4x10^6$ CFU/ml	Negative
Influenza A virus	$1x10^6$ PFU/ml	Negative
Influenza B virus	$1x10^5$ PFU/ml	Negative
Listeria monocytogenes	$2.5x10^6$ CFU/ml	Negative
Salmonella enteritidis	$3.6x10^6$ CFU/ml	Negative
Streptococcus pneumo-coccal	$4.2x10^6$ CFU/ml	Negative
Streptococcus pyogenes	$3.6x10^6$ CFU/ml	Negative

10 Interference Data

The following substances showed no significant interference on the test results of Home Test COVID-19 Ag.

No	Interfering Substances	Final Test
1	Azithromycin	84 mg/ml
2	Amoxicillin	54 mg/L
3	Albuterol	0.05 mg/L
4	Acarbose	0.3 mg/L
5	Chlorpheniramine	0.8 mg/L
6	Chlorothiazide	27 mg/L
7	Rheumatoid factor	200 IU/ml
8	Triglycerides	1.5 mg/L
9	Hemoglobin	100 mg/L
10	Human Chorionic Gonadotropin Hormone (pregnancy)	10-fold dilution
11	Ibuprofen	219 mg/L
12	Xylometazoline (Otriven)	10%
13	Acetylsalicylic Acid	3 mg/ml
14	Mucin	0.5%

11. Limit of detection

The lowest detectable concentration of an analyte in a method is known as LOD. In this case, we check the concentration of heat inactivated SARS-CoV-2 isolate USA-WA1/2020 in Home Test COVID-19 Ag. The LOD is the level at which 95% of the replicates are characterized as positive.

LOD : 358.75 TCID50/mL

12. High Dose Hook Effect

No high dose hook effect was observed up to 1.15 x 107 TCID50/mL of inactivated SARS-CoV-2 with Home Test COVID-19 Ag.

13. Clinical performance characteristics

In order to determine the clinical performance of the Home Test COVID-19 AG, 2 clinical trials took place, one in random cases included 386 negative and 142 positive nasal specimens confirmed with RT-PCR assay LightCycler Multiplex RNA Virus Master (ROCHE). The results are presented at the table below.

Home Test COVID-19 Ag	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	140	1	141
Negative	2	385	387
Total	142	386	528

Clinical Diagnostic Specificity: 99.74%

Clinical Diagnostic Sensitivity: 98.59%

One more trial took place at the Clinical Laboratory of Biohellenika S.A., Greece, over a period of one month. The trial included 246 suspected COVID-19 cases, with at least one symptom consistent with possible COVID-19 infection. The results were confirmed with LightCycler Multiplex RNA Virus Master (ROCHE) and are presented below.

Home Test COVID-19 Ag	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	45	3	48
Negative	4	194	198
Total	49	197	246

Clinical Diagnostic Specificity: 98.48%

Clinical Diagnostic Sensitivity: 91.84%

After the two different trials all the results were summarized in order to determine the overall sensitivity and specificity of Home Test COVID-19 Ag. The results are presented below.

Home Test COVID-19 Ag	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	185	4	189
Negative	6	579	585
Total	191	583	774

Clinical Diagnostic Specificity: 99.31%

Clinical Diagnostic Sensitivity: 96.85%

14. FAQs

14.1 How does the detection work?

In this test, antibodies specific to the virus antigen/Nucleocapsid Protein (NP) are coated on the test line region of the reaction device. During testing, and while the mixture moves through the device antigens of SARS-CoV-2 in the specimen react with the antibodies and generate one colored line in the test region. The presence of this colored line indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has been performed properly.

14.2 When should/can I test myself?

You can test yourself whether you have symptoms or not and if you came in close contact with a confirmed case.

14.3 What can affect my test result? What should I pay attention to?

Follow the instructions for use carefully. Perform the test as soon as possible after the specimen collection. Add 3 drops in the circular window of the reaction device.

14.4 After 15 minutes there is no obvious line in the reaction device. What can I do?

If there is no visible line in the reaction device the test is invalid. Make sure you followed the instructions correctly and repeat the test.

14.5 I am not sure I read and evaluate the results correctly. What can I do?

For the test to be positive two straight lines must be clearly visible (Test line/ Control line). If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.

14.6 The result is positive. What can I do?

If your result is positive (there is Test and Control line in the reaction device), you should contact the nearest medical facility as recommended by your local authorities. Your test result may be double-checked and the authority or facility will explain the appropriate next steps.

14.7 The result is negative. What can I do?

If the result is negative (there is ONLY CONTROL line), this may mean that you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician, or the nearest health care facility as recommended by your local authorities. If you are not sure, you can repeat the test.

14.8 How can I dispose of the product?

The test kit may be disposed of with normal household waste in accordance with the applicable local regulations.

15. References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

2. BioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 30, 2020.

3. https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm.

4. Wu F, et al. A new coronavirus associated with human respiratory disease in China. Nature 2020;579:265-269.

5. https://www.who.int/health-topics/coronavirus#tab=tab_1

6. https://www.acpjournals.org/doi/10.7326/M20-0504

IVD In Vitro Diagnostics Medical Device

Instructions for use

Content sufficient for <n> tests

Expiration Date

REF Catalog number

Do not reuse

Manufacturer

Do not use if package is damaged

Keep dry

Do not freeze

Keep away from sunlight

30°C
4°C Storage Conditions

CE
2854

Edition 2023-12-05/rev.03

REF H1301 H1302 H1305 H1320

HOME TEST COVID-19 AG

PROGNOSIS BIOTECH

For private use/home use/self-testing

Lateral Flow Test | IVD

for the detection of SARS-CoV-2 antigen in human nasal specimen.

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A. and conforms with Directive 98/79/EC requirements.

Use only the current version of Product Data Sheet enclosed with the kit.

Home Test COVID-19 Ag, H1301, H1302, H1305, H1320 is a qualitative Lateral Flow test for the detection of SARS-CoV-2 antigen in nasal specimen.

The Lateral flow kit contains all reagents required for the immunoassay method.

Specimen: Nasal swab.

- For *in vitro diagnostic* use only
- Home Test COVID-19 Ag, is a sensitive screening assay for the detection of SARS-CoV-2. Results should not be used as the only source to diagnose or to determine infection status.
- Negative results do not rule out SARS-CoV-2 infection

- Test time (incubation time after specimen preparation): 15 min
- Shelf life: 24 months
- Storage: 4-30°C

www.prognosis-biotech.com
e: info@prognosis-biotech.com
t: +30 2410 623922
f: +30 700 700 6262
Farsalon 153 | 41335 Larissa, Greece

PROGNOSIS BIOTECH