INSTRUCTIONS FOR USE

Please read all the instructions before performing this test.

1. Product Name:
ImmuTrak ™ COVID-19 Urine Antibody Test

2. Intended Use:
This is a urine test for the rapid and qualitative detection by immunochromatography (Lateral Flow Method) of IgG (Immunoglobulin G) SARS -CoV-2 antibodies.

For in vitro diagnostic use only.

It helps you to know the state of your immunity (antibodies IgG) to this new virus.

3. Kit Components:
1 test device in sealed bag
1 Instructions for Use

Equipment needed but not provided: timer, cup to collect urine and gloves (as desired)

4. Storage Conditions and Validity:

- Store between 2 and 30°C, away from light and humidity. Perform test at room temperature.
- Freezing or use after expiration is prohibited.
- The expiry date is indicated on the packaging label.
- After opening the foil pouch, the test device should be used as soon as possible within 30 minutes.

5. Usage specifications:

This in vitro kit is used for the qualitative detection of Novel Coronavirus IgG antibodies (SARS-CoV-2) **in the first morning urine collected after wake-up.**

Novel Coronavirus 2019, abbreviated to SARS-CoV-2, is a new strain of β coronavirus discovered in the human body. The human-to-human transmission capacity of the virus has been confirmed: currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source.

The shortest incubation period of the virus is only one day, while the longest incubation period is 14 days, mostly 3 to 7 days. Incubating patients are contagious.

The main manifestations include fatigue, fever, and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. In severe cases, symptoms include acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction that cannot be reversed.

Once infected with this new virus, the body's immune system begins to defend itself and, after a certain period of time, to produce antibodies. In general, IgM antibodies appear within 1-2 weeks and IgG antibodies within 4 weeks.

6. Principle of the test:
This kit is based on the principle of capture immunoassay for determination of SARS-CoV-2 antibodies (IgG) in human Urine.

When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-colloidal conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 antibodies level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To monitor the effectiveness of the Test Card, a quality control line (Line C) is set up. For the test to be validated, the C line must show the appearance of a band. Otherwise, the test result will be considered invalid.

7. Requirements:

- **Urine must be taken from the first morning sample when getting up because the production of antibodies is highest at this time of day.**
- The sample should be tested as soon as possible, within a maximum of 2 hours at room temperature.
- The use of heat-inactivated samples is not recommended as this may distort the antibody conformation.
- Ensure the test device and sample are at room temperature when performing the test.

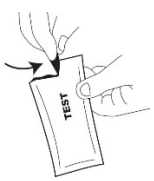
8. Materials:
The test card consists of a device and a plastic box in PVC. The test device consists of a nitrocellulose membrane, this nitrocellulose membrane is coated with anti-μ chain antibody, anti-human IgG antibody and anti-rabbit IgG polyclonal antibody, and the binding pad contains SARS-Co-V-2 recombinant antigen and rabbit IgG.

9. Test Procedure:

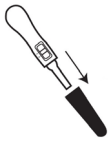
a. Read the instructions for use carefully before testing.

b. Collect first morning urine into a clean container.

c. Tear open the foil bag.



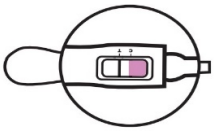
d. Remove the protective cover at the bottom of the test device.



e. Dip the device in the urine.

Note: Never let the urine level go above the "MAX" line seen above the slots at the bottom of the test device.

f.



When a traveling purple liquid appears halfway up the white strip showing in the window, remove the test device from the urine.

g. Place device down on a flat surface.
h. Wait 15-20 minutes and read the results. Do not read the results after 30 minutes

10. Interpretation of test results:

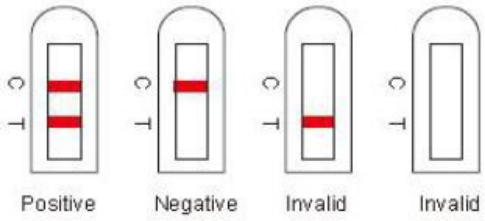


Fig. 1

a. Valid results (fig. 1):
Positive results:
- A line appears at both the C (control) and the T (test) areas of the test device.

A positive result indicates the presence of antibodies to SARS-CoV-2.

Negative results:
- A line appears only at the C (control) area of the test device.
- If a very weak or perceptible but not clear line appears at the T (test) area, consider the test negative and re-test in two weeks.

A negative result indicates the absence of detectable antibodies to SARS-CoV-2.

b. Invalid results (fig. 1):
- Only one line appeared at the T (test) area, but **NO line** appeared at the C (control) area.
- No line appears at the T (test) area or the C (control) area of the device.

11. Limitations of the test:

a. This test does not detect the new coronavirus SARS-COV-2 (antigen). It is an antibody detection test.
b. This test is only used for the qualitative detection of IgG antibodies to SARS-CoV-2 in **human urine samples collected in the morning upon waking** and cannot accurately determine the antibody content in samples collected after the first morning urine.
c. Improper sample collection, diluted urine, improper sample storage and improperly performed test procedures can produce erroneous results.
d. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay.
e. This kit is intended to be used for in vitro diagnostic purposes only.
f. This device is for testing human urine specimens only.
g. The test results of this device are provided for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment.

12. Precautions:

- This test is for professional use only.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- Do not reuse test. Do not use expired tests.
- Do not open the test pouch until ready to use.
- Do not use if foil bag containing test is damaged.
- Avoid excessively high temperatures when testing.
- After testing, discard the test device, urine cup, etc. as medical biological waste.
- There is a desiccant in the foil packaging bag, which should not be taken orally.
- As with all diagnostic reagents, the final definitive diagnosis should be made by the physician after synthesizing various test indicators and clinical symptoms.

13. Performance and Characteristics of the Test:

<u>Test performance:</u>
The clinical study was registered with the French National Clinical Research Ethics Board under number 2020-A01494-35 and approved on May 20, 2020.

The study was conducted at the public hospital Center of Beauvais; the public hospital was among the first to be impacted by the Covid-19 pandemic in France and in Europe. Two other clinics were included in this study. The study focused on health workers to be able to establish with certainty their state of their immunity. The test was performed at least 6 weeks after suspected infection of the patient.

152 patients tested	Infected with SARS-CoV- 2	Not infected	Total
RDT IgG positive	74	0	74
RDT IgG negative	2	76	78
Specificity 100 % Sensitivity after 6 weeks 97.37%			

The overall sensitivity and specificity of the new coronavirus IgG antibody test is 97.37% and 100%, respectively.

Assay Cross Reactivity:

Cross-reactivity was evaluated using urine samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following:

Human coronavirus panel (collected before Oct 2019)

Influenza A virus (H1N1, H3N2)	Rhinovirus
Influenza B virus (Yamagata, Victoria)	Human Metapneumovirus (hMPV)
Parainfluenza virus 1-4	Chlamydia pneumoniae
Endemic human coronavirus (OC43, 229E)	Mycoplasma pneumoniae
CMV	Mycobacterium tuberculosis
Rubella	Coxsackie virus type A16
Toxo	Varicella zoster virus
HSV	Mumps Virus
HBV	Hepatitis C
HCV	Respiratory syncytial virus
HIV-1 / 2	Adenovirus
Coxsackie virus group B Ig	Measles virus
Epstein-Barr virus	Enterovirus 71

Potentially Endogenous Interfering Substances:

SARS-CoV-2 antibody negative urine samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity was found with the following:

Substance	
Rheumatoid factor	Meropenem
Antinuclear antibody (ANA)	Levofloxacin
Anti-mitochondrial antibody (AMA)	Oseltamivir
Bilirubin	Mupirocin
Hemoglobin	Benzocaine
Triglycerides	Tobramycin
α-interferon	Peramivir
Zanamivir	Epinephrine
Ritonavir	Menthol
Tramadol	Ribavirin
Azithromycin	Lopinavir
Azithromycin	

Hook effect:

Within the titer range of clinical positive samples of SARS-CoV-2 antibodies, there is no hook effect in the test results.

Symbols:

	Consult Instructions for use	LOT	Batch Code
IVD	*In Vitro* Diagnostic Medical device	REF	Catalogue number
30°C 2°C	Temperature limits 2°C to 30°C	Σ	Number of tests per kit
	Keep dry		Do Not re-use
	Use-by-date		Manufacturer
CE	CE Mark	EC REP	Authorized Representative

REF UACOV19 PN130005 R2 2/22

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