

INSTRUCTIONS FOR USE

ImmuTrak™ SARS-CoV-2 Urine Antibody Rapid Test

Please read all instructions before performing this test.

1. Intended Use:

ImmuTrak™ is a urine test for the detection of IgG antibodies to SARS-CoV-2 **in the first morning urine collected after wake-up.**

ImmuTrak™ is a wellness self-test for use at home. By using the ImmuTrak™ urine antibody test, an individual will know if they currently have SARS-CoV-2 antibodies. This knowledge will help to guide lifestyle choices of the individual as well as minimize the stressful effects of living during a pandemic.

Note: General wellness products do not require FDA clearance. The intended use statements have not been evaluated by the Food and Drug Administration. ImmuTrak™ is not intended to diagnose, treat, cure or prevent any disease

2. 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)

3. Background:

SARS-CoV-2 is a new strain of coronavirus discovered in the human body. The human-to-human transmission of the virus has been confirmed. The usual incubation period of the virus is 3 to 7 days but can vary from 1-14 days. Incubating patients are contagious.

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

4. Important Pre-Test Information:

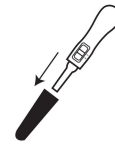
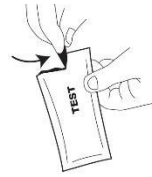
- Store test device between 2 and 30°C, away from light and humidity. Perform test at room temperature.
- The expiry date is indicated on the packaging label. Do not use expired tests.
- Do not use if test has been frozen.
- After opening the foil pouch, the test strip should be used as soon as possible within 30 minutes.
- **Collect urine 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.
- Have a clock ready to time the test results.

5. Test Procedure:

- a. Read the instructions for use carefully before testing.
- b. Collect first morning urine into a clean container.

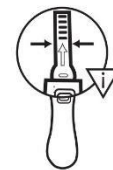


- c. Tear open the foil bag.
- d. Remove the protective cover at the bottom of the test device.

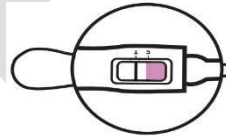


- e. Dip the device in the urine.

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



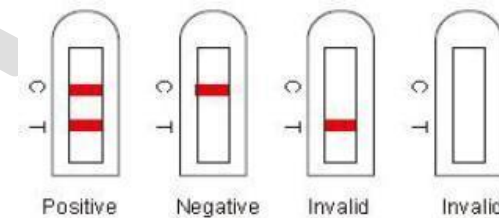
- f.



When a traveling purple liquid appears halfway up the white strip showing in the window, remove the test strip 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
- i. After testing, discard the test device, urine cup, etc. as normal household waste following applicable local regulations.

6. Interpretation of test results:



- a. Valid results

Positive results:

- A line appears at both the C (control) and the T (test) areas of the test strip.

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 strip.
- 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.

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- b. Invalid results:
- 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 strip.

7. Be Careful of the Following:

- 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.
- There is a desiccant in the foil packaging bag, which should not be taken orally.
- Keep test kit out of the reach of children.

8. Limitations of the test:

- General wellness products do not require FDA clearance. The intended use statements have not been evaluated by the FDA. ImmuTrak™ is a general wellness product and is not intended to diagnose, treat, cure or prevent any disease
- This test does not detect the new coronavirus SARS-COV-2.
- 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.
- Improper sample collection, improper sample storage and improperly performed test procedures can produce erroneous results.
- 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.
- This reagent is for testing human urine specimens only.
- These test results are provided for reference only.

9. Frequently Asked Questions











- a. What happens if I get an invalid test result?
*You should repeat the test using a new device and a new **first morning urine sample**.*
- b. What should I do if the test pouch is opened or punctured?
Save the device and lot information and contact your distributor for a replacement.
- c. I forgot to run the test this morning, can I use a urine sample from later in the day?
NO! The number of antibodies is highest in a first morning urine and this is critical for the accurate performance of the test.
- d. What should I do if I test Negative?
Take rigorous precautions to prevent possible exposure to SARS-CoV-2. This includes the use of masks and maintaining at least 6 ft between individuals. You may want to consider lifestyle


- changes.*
- e. What does it mean if my test is Positive?
It means your body contains antibodies to SARS-CoV-2. Antibodies are proteins created by your body's immune system soon after you have been infected or vaccinated. These antibodies will help prevent you from getting sick or severely ill. It is important to be a good citizen and help protect your fellow man, no matter your antibody status!

FOR INQUIRIES AND GENERAL INFORMATION

Please visit website www.akers.biz or contact us via email at info@akers.biz

Symbols:

	Consult Instructions for use		Use-by-date
	Batch Code		Catalogue number
	Temperature limits 2°C to 30°C		Do not use if package is damaged
	Keep dry		Do Not re-use
	Number of tests per kit		Manufacturer

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