

Dear User ;

Please read the instructions carefully :

**Foaming Test COVID-19 Scanning Test Kit Working Principle :**

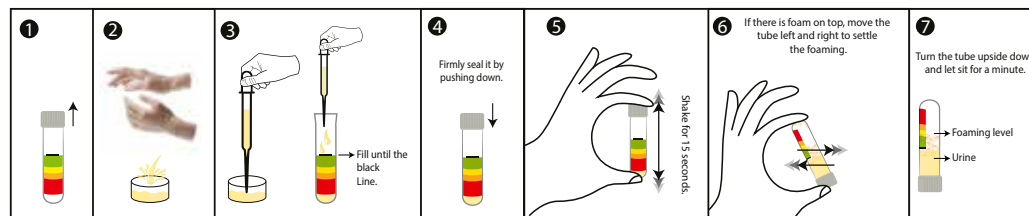
The virus (SARS COV-2) that causes COVID-19, rapidly multiplies as soon as it enters the body. During this period, even before clinical symptoms like findings in the lungs or some metabolic and chemical changes occur in the body. Some of these changes can be traced with blood or urine tests. In the meantime the body starts throwing out the virus by urinating. The speed of this process is directly related to the infectivity of the virus, the number of pathogens infected the patient and the immune system of the person. As the virus load multiplies in the body, both virus and some other substances it produced are thrown out increasingly. Foaming test, via the reactant (MSK) that is particularly prepared in the laboratory, reacts with substances on the virus surface as well as other substances that are thrown out by urination and creates foam inside the test tube. Foaming is directly proportional to virus load in the body. Less virus load less foaming, more virus load more foaming. A color scale has been generated as a result of laboratory studies carried out between patients diagnosed with COVID-19 and healthy people. Evaluation of the result is done using this color scale.

**Foaming Test COVID-19 Scanning Test Kit Indications :**

- 1- It helps to detect patients that are in the incubation period with some clinical symptoms but have not confirmed to have COVID-19.
- 2- Aids with the monitoring of clinical conditions and prognosis of the COVID-19 patients.
- 3- Helps to distinguish the patients with similar symptoms to COVID-19.
- 4- Assists the doctor to quickly decide for patients who are COVID-19 negative but in the medical hold, for the people that are in the quarantine and for the patients whose treatment is completed by practically indicating their clinic conditions to the patients, letting them share the results with their doctor easily.
- 5- Supports the people who are uncertain about COVID-19, who have to be in a suspicious environment and feel uncomfortable about it to check themselves for COVID-19 and with its result, they can consult a healthcare organization quickly.
- 6- Apart from COVID-19, it helps the people who have abnormal substances in their urine to do a self-check-up and consult to a healthcare organization in an early period.
- 7- It facilitates the pre-diagnosis, final diagnosis and the clinical follow-up periods for health care personnel.

**Foaming Test COVID-19 Scanning Test Kit Usage and How to Take Urine Sample:**

- 1- Foaming Test tube opens from the locked seal on top. Be careful not to spill the reactant inside.
- 2- Testers should wear gloves, provided inside the box, in order not to spread the urine to their hands and pour some urine to the collection container
- 3- Because SARS Cov-2 is affected by the person's metabolism and the infection strength, people with lighter infection rates can have different virus concentrations in their urine that may change every hour. Therefore, the ideal sample would be to take the urine that has been waiting in the patient's bladder for at least 1 hour. People with physically heavy jobs should take their sample after resting at least 6 hours and it shouldn't be taken from the first urine after the resting period. While testing pregnant women, the abnormal substances should be excluded from the process of evaluation.
- 4- To take a sample from patients with a urinary catheter, the urine in the catheter should be completely emptied and the sample should be taken from the first urine after that. With the samples taken after urinating, avoid taking it from the part that has water in the catheter. If changing the catheter is not possible, then the current urine bag can be mixed to take a sample.
- 5- With the help of a straw that comes in the box, draw 2.5ml urine and slowly pour it inside the test tube until the black line.
- 6- Seal the tube firmly.
- 7- Shake the tube up and down for 15 seconds.
- 8- Lightly move the tube left and right and tap lightly from the top to settle the foaming inside.
- 9- Place the tube on a straight surface and wait for 1 minute. The result can be interpreted from the alignment of the foaming's top level with the color scale.



**Foaming Test COVID-19 Scanning Test Kit Result Evaluation:**

The test results are only for briefing, to get a final diagnosis consult to a healthcare organization.

**Green Zone :** No virus load in the urine. Healthy clinical picture.

For diagnosed Covid 19 positive patients, after receiving treatment in a hospital and getting this result can be interpreted as "Cured".

**For a person who gets a positive from PCR test but hits the green zone in the Foaming Test one of the following can be said:**

- 1- Virulence of the person is low or contracted very small amount of pathogens but due to a strong immune system, the disease stays in the upper respiratory tract. For this reason it will not show any symptoms and decrease.
- 2- Immune system is strong and able to kill the virus while it's in the upper respiratory tract yet the remains of it causes a false positivity for the PCR test.
- 3- False positivity for the PCR due to other reasons like contamination, cross-reactivity.

**Yellow Zone :** Slight amount of virus load in the urine (and/or some abnormal substances), suspicious clinical picture. Follow-up required.

**\* Follow-up required Individuals:**

- 1- People with no COVID-19 diagnosis but may have contracted the virus and people who are in the incubation period.
- 2- Diagnosed COVID-19 patients and individuals that are receiving a treatment.
- 3- People who have abnormal substances in their urine other than COVID-19.

In this case, the level of the foaming inside Yellow Zone and Covid-19 symptoms, if there are any, should be considered. If one shows the symptoms and has high foaming inside Yellow Zone should isolate themselves from family and friends, follow the social protection rules and regulations, must wear a mask and they should consult to a healthcare organization as an early precaution. Even without any symptoms, people in this zone should isolate themselves from family and friends, follow the social protection rules and regulations, must wear a mask, and in the meantime should be examined for abnormal substances thrown out with urine and consecutively tested. If the foaming stays in the Yellow Zone or increases, they should consult to a healthcare organization. It would be best to consult for a urinary disorders in case there are abnormal substances in the urine without any Covid-19 symptom.

**Orange Zone :** Increased virus load in the urine (and/or some abnormal substances), unhealthy clinical picture.

People who hit Orange Zone as the result and who have Covid-19 symptoms should isolate themselves from family and friends, follow the social protection rules and regulations, must wear a mask and they should consult to a healthcare organization.

People who have hit Orange Zone as the result and yet show no Covid-19 symptoms, should isolate themselves from family and friends, follow the social protection rules and regulations, must wear a mask and they should consult to a healthcare organization just in case. These patients should be examined for both Covid-19 and urinary disorders.

**Red Zone :** Intense virus load in the urine (and/or some abnormal substances), severe clinical picture.

Common result among intensive care patient under normal conditions. However, people with Red Zone result should immediately isolated, follow the social protection rules and regulations, must wear a mask, and hospitalised in the nearest full-fledged hospital while taking these precautions at the highest level. All the people who had contact with the patient should be contained under the same conditions. Even if they do not show any symptoms, they should be examined in depth for Covid-19 and urinary disorders.

**What other clinical conditions Foaming Test COVID-19 Scanning Kit can be applied?**

In addition to detecting Covid-19 virus load in the urine, it can identify some abnormal pathologies in the urine through a %3.7 particular condition in its specificity. Thus, if interpreted correctly the test results can be used for early diagnosis and clinical follow-up. Several macro and micro sized clinical pictures like heavy renal insufficiency, diabetic nephropathy, eclampsia, some types of nephrolithiasis can be given as examples of these situations. That's why people with Orange and Red Zone despite not having Covid-19 symptoms should definitely examined for urinary system pathologies.

**WARNINGS:**

Foaming Test only shows the virus load at the time of the test. It is known how contagious SARS Cov-2 is. A person with Green Zone in the Foaming Test should not forget that the risk continues, so it is highly important to adhere to the rules and regulations of social distancing and other hygienic, protection precautions. The test results are only for briefing, to get a final diagnosis consult to a healthcare organization. Foaming Test COVID-19 Scanning Test Kit should be applied as told in the "Usage" section, otherwise it can be misleading. In case the test is not applied correctly, the responsibility of the results to be obtained belongs to the user. Do not touch the reactant in the test tube with bare hands, do not breathe it in or let it touch the eye, do not eat or drink it. Keep it away from the children. Dispose the tube after usage according to the hygien rules and throw it to the medical waste container.

