Analysis of the Urine Foaming Test for the SARS-CoV-2 Virus

by the Istanbul-based company PHARMANONA

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Introduction

Laboratory tests play an important role in the detection and treatment of COVID-19. Most of the tests are based on real-time polymerase chain reaction (RT-PCR). Indeed, this testing method has a very high rate of accuracy in the laboratory—over 99%. However, there is a problem with the sample collection. Experience has shown that swab specimens are often taken incorrectly. With swab specimen collection, it should be noted that the local viral load moves over time from the nasopharynx to the trachea. This fact is not taken into account during routine swabs because the swab always takes a sample from the nasopharynx through the nose. Another problem is that the endpoint of the RT-PCR is not clearly defined. This endpoint can be at 30 cycles or at 45 cycles, i.e. the viral load detected at 45 reproduction cycles is 32,768 times more accurate than at 30 cycles. Thus, the probability of detecting a SARS-CoV-2-positive patient is generally less than 50%.

Therefore, RT-PCR testing is not well-suited for large-scale mass testing of the population, and it makes sense to look for alternatives. Rapid antigen test systems also have the swab specimen collection problem and will likewise have an error rate of over 50%. Throat tests are not yet ready for use and are considered unreliable by the Robert Koch Institute due to potential diluting effects (www.rki.de).

The innovative urine foaming test is a promising approach that is semi-automated and provides results very quickly. Therefore, this test is suitable for use by laypersons, which means that a test system for mass screening is available. This test system is shown in Figure 1. According to Serhan (2021), the sensitivity is 92% (95% CI: 87-95%) and specifity is 89% (95% CI: 80-98%). Approximately 10 mL of a patient's urine is collected in a cup provided in the package, then a test tube is inserted into a hole on the lid of the closed cup, the vacuum inside the test tube sucks the urine out of the cup. The test tube is then removed from the

cup and shaken for 15 seconds (1), thus creating a foam. The foam level corresponds with the patient's current viral load. Individual errors are ruled out by this semi-automated test system.

Biochemical Basis of the Urine Foaming Test

The cornerstone of the protein structure consists of the amino acids serine and arginine. These two amino acids and their metabolites are excreted through the kidneys when there is a SARS-CoV-2 infection (COVID-19) and can then be detected in the urine. The reaction with the reactants in the tube and the shaking create a foam. The amount of foam is directly proportional to the amount of serine and arginine, and therefore the SARS-CoV-2 viral load.

Study Design

Twenty urine samples were collected from patients with a SARS-Cov-2 infection confirmed by an RT-PCR test and 20 urine samples from patients with no SARS-CoV-2 infection (infection ruled out by an RT-PCR test). The urine samples were collected from anonymized patients at the Bundeswehrkrankenhaus Hamburg military hospital.

The test was performed exactly according to manufacturer instructions. 10 mL of urine was collected in the provided cup, then the lid was screwed onto the cup and the test tube was inserted in the hole in the lid. The suction of the vacuum inside the tube then sucked in the necessary amount of urine automatically. Next, the tube was removed from the cup and shaken in the longitudinal direction (!) for 15 seconds. Immediately after these 15 seconds, the foam level was read off the color scale affixed to the tube (Figures 1 and 2).
All of the tests were performed by the same person.

The study group of 20 samples each was appropriate for answering the study question (Andrew, Pedersen, McEvoy 2011).

The statistical analysis was performed using the Mann-Whitney U test. Due to the small size of the group, a probability level of $p>0.98$ was established.

Results

The results are presented in Table 1.

In the test group, increased foaming was detected in all 20 samples. In 16 of the samples, the foam level was in the orange and red zones (Figure 4), and in 4 of the samples, it was at the green/yellow line (Figure 3) These four samples were from patients with only mild symptoms.

All 20 samples in the control group were correctly identified. There was little to no foam (Figure 5). In all of the samples, the foam that formed was in the lower half of the green zone. One of these samples was from a patient suffering from gout.

A correlation between the amount of foam formed and the severity of the existing viral load could not be determined.

	Test Group (RT-PCR: SARS-CoV-2 positive) Number of Samples	**Control Group** (SARS-CoV-2 negative) Number of Samples
Foam level From yellow up	16	0
Foam level Green/yellow line	4	2
Foam level Only in green	0	18

Table 1: Presentation of the findings

For the statistical analysis, the findings in the test group and the control group were considered correct. This supports the initial hypothesis that the urine foaming test examined here can verify that a patient has been exposed to SARS-CoV-2 virus with a probability of > 98%.

Evaluation of the results

The claim made by Serhan (2021) that the urine foaming test is suitable for detecting a SARS-CoV-2 infection can be confirmed by this study.
Due to the study‘s design, only qualitative evidence can be provided for the urine foaming test. Therefore, the results from the 40 samples prove that the urine foaming test is suitable for detecting and indicating a SARS-CoV-2 infection.

It is recommended that a test be considered positive if the foam has reached the green/yellow line on the color scale. At that point, a doctor must be consulted to clarify whether the patient has kidney disease or any metabolic disorders, such as gout. An RT-PCR is then necessary to determine a probable SARS-CoV-2 viral load.

This test is very easy to perform, delivers a result within 15 seconds and is semi-automated. Therefore, this testing method has a very low susceptibility of error and is suitable for use in mass testing. This test can also definitely be performed by laypersons.

References

Andrew, D.P.S., Pedersen, P.M., McEvoy, C.D. (2011)
Research methods and design in sport management. Champaign, IL: Human Kinetics

Serhan (2021)
The Urine Foaming Test in COVID-19 as a useful tool in diagnosis, prognosis and follow-up: preliminary results
htttps://mc4.manuscriptcentral.com/nclinist

www.rki.de

Figures

Figure 1: Testing system

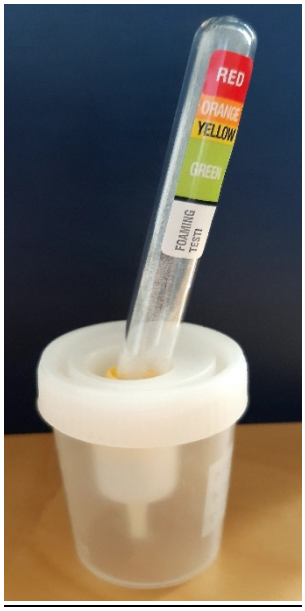

Figure 2: Test tube with phenols in the cup

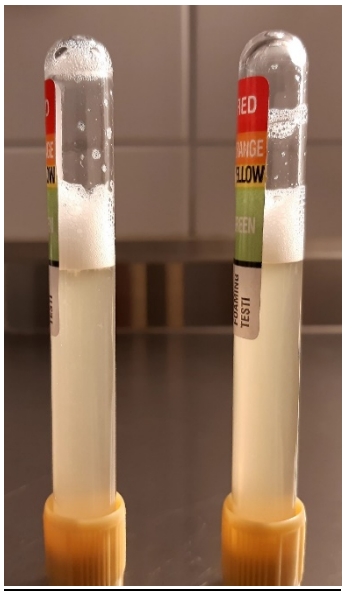

Figure 3: Result at the green/yellow line (test group)

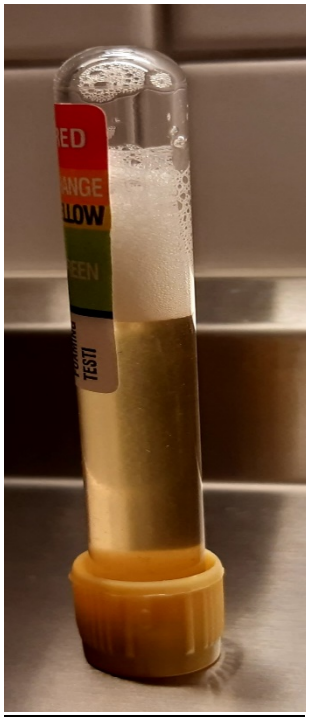

Figure 4: Result in the orange range (test group)

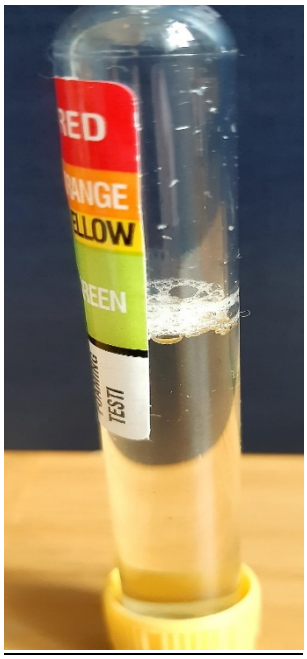

Figure 5: Negative result (control group)

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