MyMagiCon®

(Acibadem University Incubation Center R&D company with a branch in Technopark Istanbul)

Bio-T Biotechnology Solutions and Production Inc.
(GigaBiomol investor company)

Patent applications:
Turkish Patent Application No: 2020/08937 PCT: PCT/TR2020/000003
European Patent Application No: 20775152.0
US Patent Application No: 17048829

What is MyMagiCon®?

✓ MyMagiCon® concentrates antigens and RNA of SARS-CoV2 (Covid-19) in mouthwash samples 20-40 times within 5 minutes and thus increases the sensitivity of PCR and antigen tests.

✓ Eliminates the risk of infection of the healthcare worker who is obtaining the sample.

✓ Allows painless sampling.

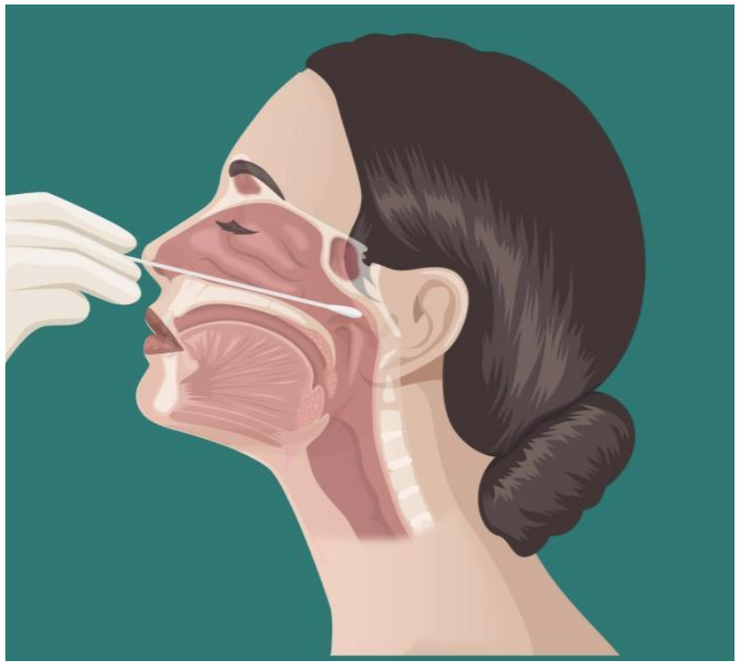
✓ European and US patent applications have been filed

✓ High volume can be produced with ISO13485 standards.

✓ Has CE-IVD certificate.

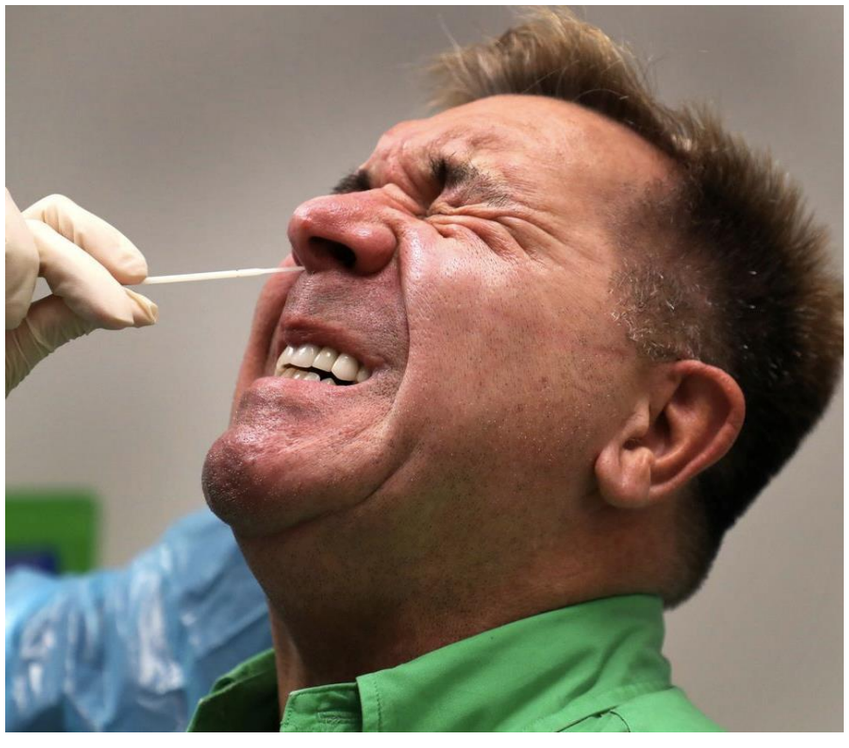
Currently, nasopharyngeal swab sample is taken for the diagnosis of Covid19 by "PCR" or antigen tests, all over the world. This is a very painful method. It can cause nose bleeding from time to time. Since it is difficult to implement, it is often not possible to take an appropriate sample. This method carries a significant risk of infection for healthcare personnel taking the samples.

Taking a Nasopharyngeal Swab Sample



Theoretical

Real life



Receiving mouthwash and gargle

Since mouthwash and gargle can be concentrated with MyMagiCon, this sample can be used in the diagnosis of Covid19 instead of a nasopharyngeal swab sample. Mouthwash sample can be easily given by people including children. Since a healthcare personnel is not required for taking the sample, the risk of infection during sampling, is significantly reduced.

A few sips of water are taken into the mouth. It is first gargled, then the mouth is rinsed with water vigorously for at least 10 seconds. Young children can rinse their mouth without gargling.

Mouthwash concentration method with MyMagiCon®

Put 20 ml of mouthwash into the tube.

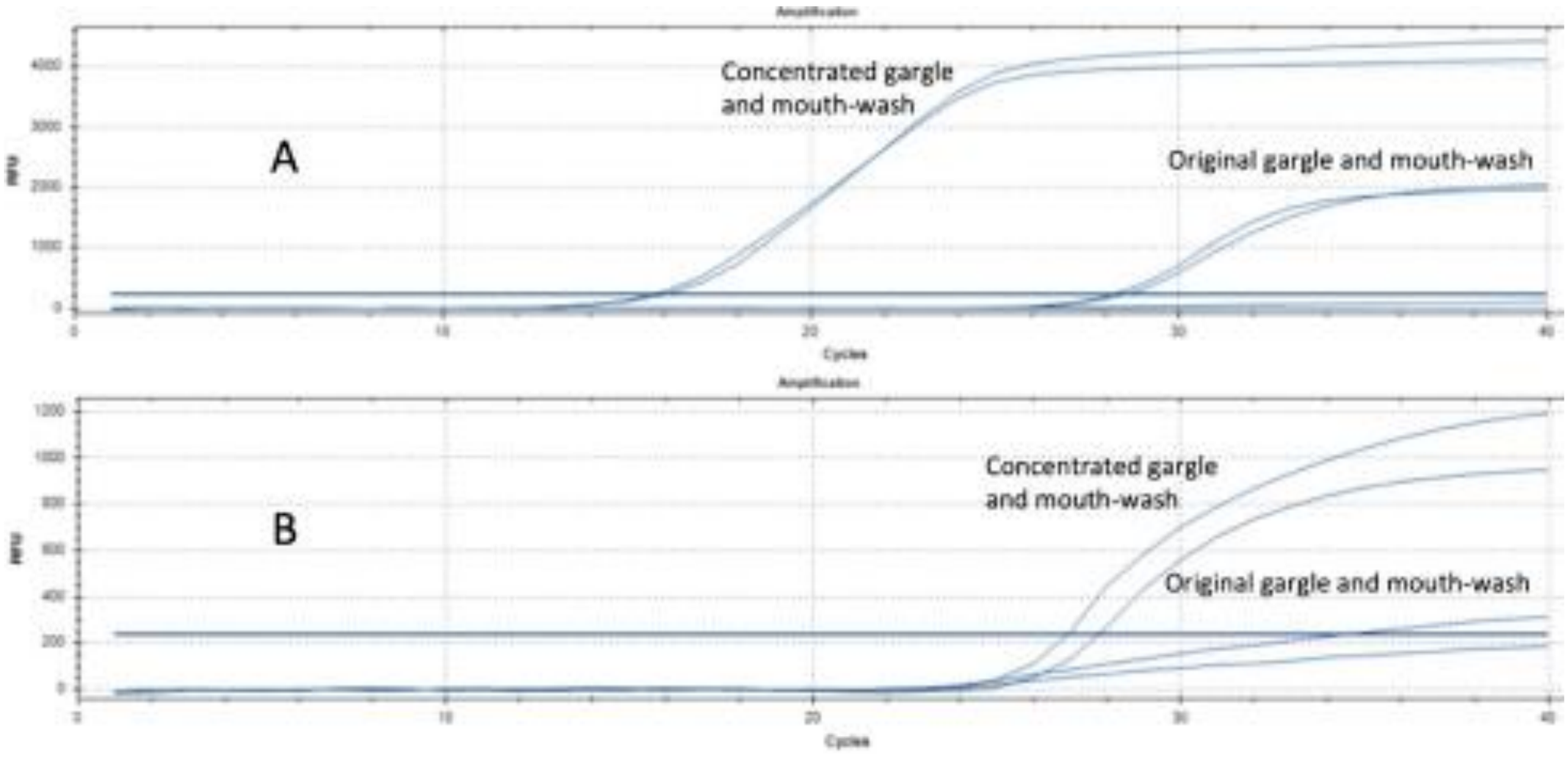
Pour the powder of MyMagiCon into the tube.

Wait for 5 minutes.

Take the concentrated sample with the help of a pipette.

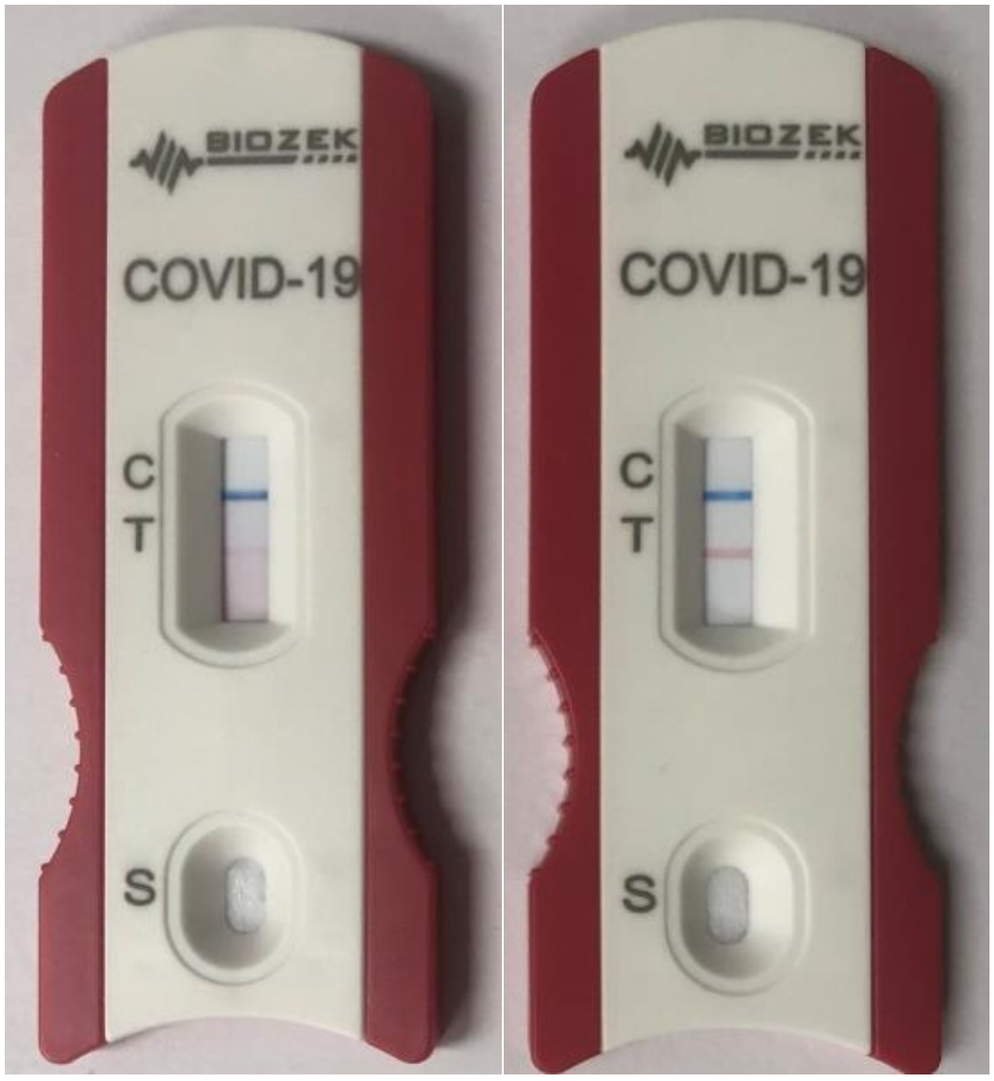
Transfer the concentrated sample into a clean tube for PCR testing. The sample can be applied directly into the rapid antigen test cassette.

The effect of concentration of gargle and mouthwash samples on the detection limit of SARS-CoV-2 by PCR



Sample A: SARS-CoV-2 is detected 10 cycles earlier in PCR which means the sample is concentrated very efficiently.
Sample B: Contains very low amount of virus which is on the limit of detection of PCR, however it is detected easily when the sample is concentrated.

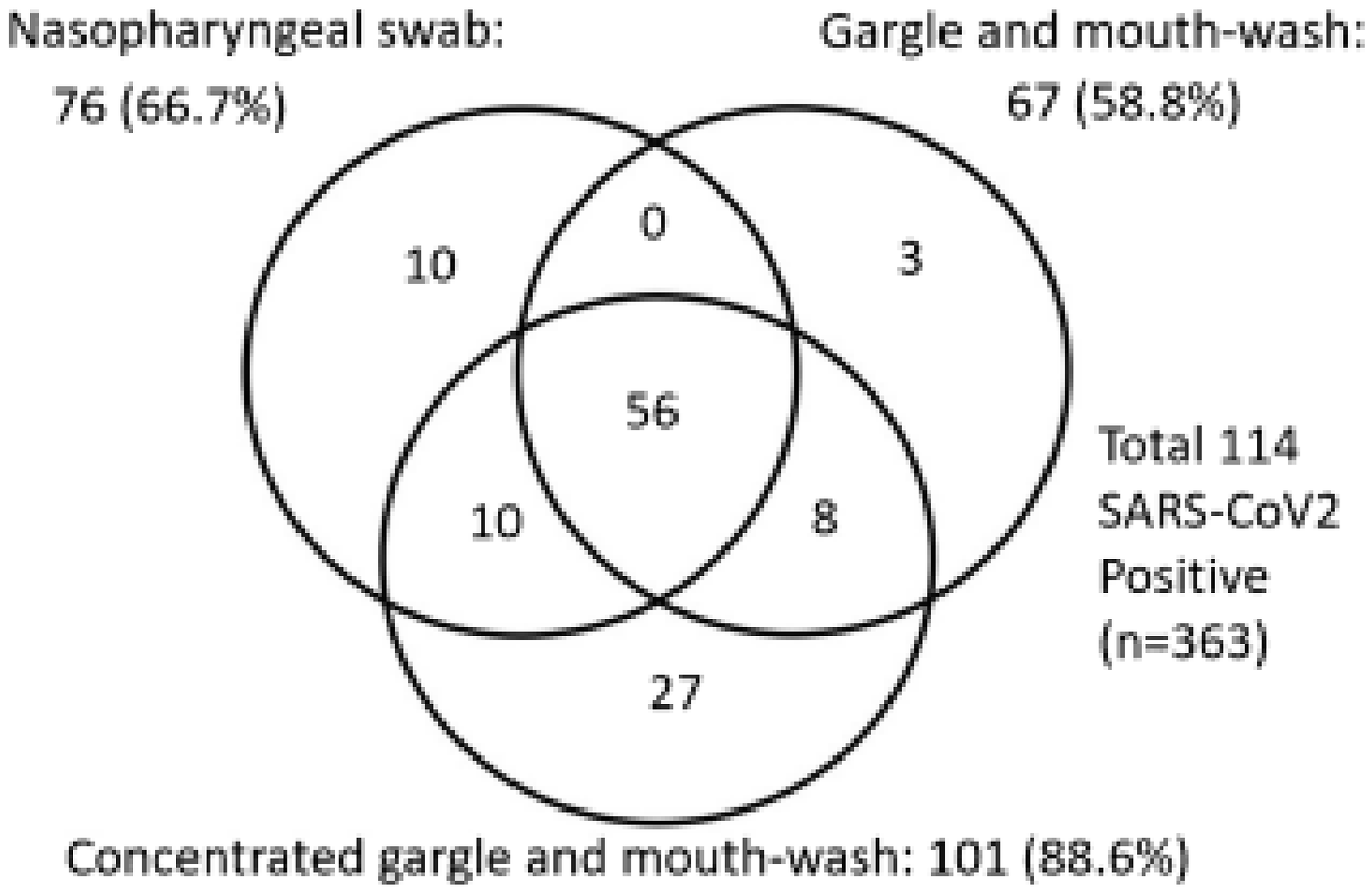
Concentration by *MyMagiCon®* increases the sensitivity of antigen tests

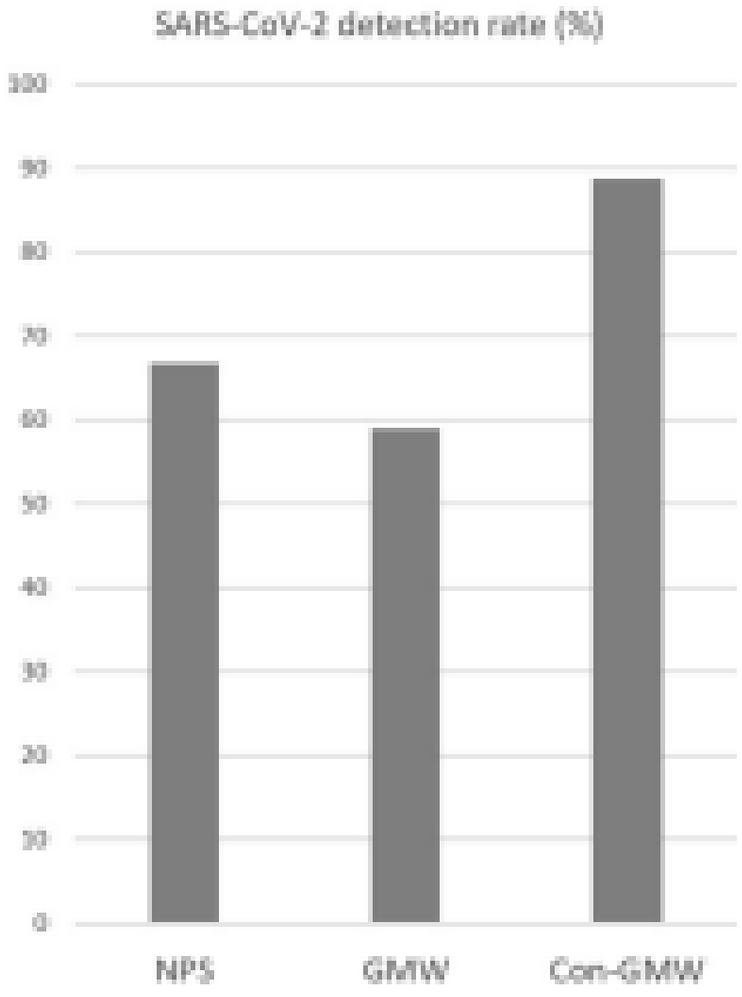


A **B**

✓ Detection of SARS-CoV2 in a patient's mouthwash sample pre-concentration with rapid antigen testing (A) and post-concentration with MyMagiCon® (B).

Clinical Study Results Comparing Detection of SARS-CoV-2 in Nasopharyngeal Swab and Mouthwash Samples Before and After Concentration by MyMagiCon





✓Clinical study results showed that compared to nasopharyngeal swab samples, equal or more virus can be detected in gargle and mouthwash samples when concentrated with MyMagiCon®.
✓These results show that MyMagiCon® has successfully concentrated the Covid-19 agent in the samples.
✓In RT-PCR tests, detection of virus in concentrated samples is earlier by an average of 4-5 cycles, indicating that the sample is concentrated approximately 16-32 times.
✓ In many mouthwash samples where the virus can not be demonstrated by rapid antigen tests, the virus becomes detectable after concentration with MyMagiCon®.

Clinical Study Results Published in the European Journal of Clinical Microbiology & Infectious Diseases

European Journal of Clinical Microbiology & Infectious Diseases
https://doi.org/10.1007/s10096-021-04326-y

ORIGINAL ARTICLE

Check for updates

Simple concentration method enables the use of gargle and mouthwash instead of nasopharyngeal swab sampling for the diagnosis of COVID-19 by PCR

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Abstract

Since its emergence in December 2019, SARS-CoV-2 is causing one of the most devastating pandemics in human history. Currently, the most important method for definitive diagnosis of COVID-19 is identification of SARS-CoV-2 RNA in nasopharyngeal swab samples by RT-PCR. Nasopharyngeal swab sampling is a discomforting procedure sometimes with adverse effects, which also poses a risk for infection for the personnel performing the sampling. We have developed a new method for concentrating biological samples, which enabled us to use gargle and mouthwash samples to be used in RT-PCR, for the diagnosis of COVID-19, as an alternative to nasopharyngeal swab samples. We have analyzed nasopharyngeal and gargle and mouthwash samples, before and after concentration, of 363 patients by RT-PCR for the presence of SARS-CoV-2. Among 114 patients in which SARS-CoV-2 was identified in at least one of their samples, the virus was identified in 76 (66.7%), 67 (58.8%), and 101 (88.6%) of nasopharyngeal swab, gargle, and mouthwash samples before and after concentration, respectively. When concentrated by our new method, gargle and mouthwash samples can be used instead of nasopharyngeal samples in identification of SARS-CoV-2 by RT-PCR, with the same or better sensitivity. Eliminating the need for nasopharyngeal sampling will save the patients from an invasive and painful procedure and will lower the risk of infection for the healthcare personnel taking the sample. This easy sampling procedure may decrease the workload of hospitals, shorten the turnaround time of obtaining test results, and thus enable rapid isolation of infected patients.

Benefits MyMagiCon® can provide

✓For the diagnosis of Covid19, instead of taking a painful nasopharyngeal swab, it enables the use of mouthwash that can be easily given by everyone, including children.

✓Increases patient compliance by enabling people, who are afraid of painful nasopharyngeal swab sampling, to give samples without fear.

✓Prevents long lines of people waiting to give a sample in hospitals, by reducing the need for experienced healthcare personnel, by enabling everyone to give their own example.

✓ Provides easy and fast collection of samples in places where fast testing is required such as airports, restaurants, shopping malls, factories.

✓Allows young children to easily give samples in schools, enabling the collection of samples by school officials, eliminating the need for experienced healthcare personnel.

✓ MyMagiCon® replaces the swab and nucleic acid transport fluid required for nasopharyngeal sampling, resulting in no increase in total testing cost.

Video explaining the use of MyMagiCon®

Prof. Dr. Ozge Can
explains:

https://www.youtube.com/watch?v=DUzpmFj5b-M

DOCUMENTS

GBM

CE

Gigabiomol Biyoteknoloji San. ve Tic. Ltd. Şti.

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AT UYGUNLUK BEYANI
DECLARATION OF CONFORMITY

In Vitro Medikal Diyagnostik Cihazlar IVD Direktifi, 98/79/EC
In Vitro Medical Diagnostic Devices IVD Directive, 98/79/EC

Gigabiomol Biyoteknoloji San. Ve Tic. Ltd. Şti 'ye ait bu deklarasyon, IVD Direktifi 98/79 EC Ek III ile uyumlu olarak hazırlanmıştır.

CERTIFICATE

kiwa

BİO-T BİYOTEKNOLOJİ ÇÖZÜMLERİ VE ÜRETİM A.Ş.

LEVAZIM MAHALLESİ KORU SOKAK ZORLU CENTER BLOK NO: 2 İÇ KAPI NO: 157
BEŞİKTAŞ - İSTANBUL - TÜRKİYE

TANI CİHAZLARI İLE BİRLİKTE KULLANILAN NUMUNE YOĞUNLAŞTIRICI POLİMER KİTİ ÜRETTİRME VE SATIŞI

kapsamında

EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim sistemi kurmuştur.

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.3" "7.5.4" "7.5.5" "7.5.7" "7.5.9.2" "7.5.10"

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