International Journal of
Virology & Infectious Diseases

Research Article

# Optimization of Olfactory Dysfunction Test for Mass Screening of COVID-19 Subjects -

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**Submitted:** 25 July 2021; **Approved:** 27 August 2021; **Published:** 03 September 2021

**Cite this article:** Lall T, Sharma YK, Sandhu D, Mathur R, Mohan N. Optimization of Olfactory Dysfunction Test for Mass Screening of COVID-19 Subjects. Int J Virol Infect Dis. 2021 Sep 03;6(1): 047-053.



ISSN: 2766-5070

## ABSTRACT

**Background**: COVID-19 infection is a result of SARS-CoV-2, and it is a major global catastrophe with significant toll on lives and economy. To control the spread of coronavirus, mass and frequent testing is essential for both symptomatic and asymptomatic persons. Evidence has suggested that sudden loss of smell or olfactory dysfunction causing anosmia or hyposmia may function as a key marker of COVID-19. Virocule's ANOSMIC COVID-19 Smell Tester is a novel COVID-19 olfactory screening device that is simple and practical for mass screening and early detection of COVID-19 as it is fast (< 30 secs), accurate (> 90%), low cost (< 30 cents / test), non-invasive and easy to use for everyone. It uses a special formulation of all-natural ingredients and has been authorized for sale by Health Canada.

**Objective:** Evaluate the sensitivity and specificity of Virocule ANOSMIC COVID-19 Smell Tester for screening COVID-19 subjects, and to evaluate its effectiveness for early detection of COVID-19 infection and enhancing its accuracy by adding other symptomatic tests.

**Method**: Four pilot studies have been conducted consisting of 826 ($n$ = 826) symptomatic and asymptomatic subjects. First three studies were conducted at Rajasthan University of Health Sciences (RUHS), Jaipur, India consisting of 626 ($n$ = 626) random symptomatic and asymptomatic subjects, and the fourth study was conducted at Toronto, Canada consisting of 200 ($n$ = 200) random asymptomatic subjects. Symptomatic subjects were first tested by ANOSMIC test and later by RT-PCR and digital X-ray for confirmation. Asymptomatic subjects were first tested by ANOSMIC test, and RT-PCR and digital X-ray confirmatory tests were conducted only for those that were COVID positive by ANOSMIC test. Any subjects that were COVID-19 negative by ANOSMIC test were observed for COVID symptoms in the future.

**Result**: The first study of 156 ($n$ = 156) symptomatic subjects showed that 98% of COVID-19 patients had some olfactory dysfunction and ANOSMIC test achieved sensitivity of 91% and specificity of 96%. The second study of 50 ($n$ = 50) asymptomatic subjects showed that 90% COVID-19 subjects had some olfactory dysfunction, and ANOSMIC test achieved sensitivity of 90% and specificity of 100%. The third study of 120 ($n$ = 120) symptomatic subjects and 300 ($n$ = 300) asymptomatic subjects showed that 90% of COVID-19 subjects had some olfactory dysfunction resulting in either anosmia or hyposmia, and ANOSMIC test achieved sensitivity of 87%, specificity of 96% and accuracy of 92%. By complementing this test with symptomatic tests for temperature, cough, and shortness of breath, the sensitivity was enhanced to 100%, specificity to 96% and accuracy to 97%. In the third study we found that 11% asymptomatic subjects had COVID-19 in India while in fourth study we found that 1.5% asymptomatic subjects had COVID-19 in Canada, and they were isolated and medically treated at an early stage. We also found that 4.3% COVID-19 subjects were detected earlier by ANOSMIC test than by RT-PCR test.

**Conclusions**: These Pilot Clinical Studies successfully demonstrated the ability of ANOSMIC COVID-19 smell tester to detect COVID-19 patients with 92% accuracy, which can be increased by complementing with other screening methods. It can prove to be an early detector and great benefactor for effectively mass screening for COVID-19 symptomatic and asymptomatic subjects to control the spread of coronavirus with high confidence.


**Keywords:** COVID-19 screening; SARS-CoV-2; Olfactory dysfunction; Anosmia; Hyposmia; Medical device; Smell tester; Swiss cheese model; Mass COVID-19 screening

## INTRODUCTION

COVID-19 pandemic is a global catastrophe with over 217.5 million patients and 4.5 million deaths in 192 countries [1] (World Health Organization; Worldometer, August 30, 2021), despite preventive measures impacting millions of people and jobs, education, businesses, sports, and industries. Many businesses have shut down, others are operating with limited capability with fear of legal liabilities in case of infection at the workplace.

According to Centers for Disease Control and Prevention (CDC), USA, it is estimated that about 40% COVID-19 patients are asymptomatic, but they are infectious [2,3]. It takes 3-5 days for symptoms to manifest themselves. To control the spread of coronavirus, mass and frequent testing is essential [4]. However, today's RT-PCR test methods are not practical for mass testing as they are costly (> $200 / test), take many days for results and require medical professionals.

Anosmia is total loss of smell and hyposmia is partial loss of smell owing to olfactory dysfunction that may be caused by coronavirus. It is usually severe and sudden in onset but transient in most COVID-19 patients [5,6]. Sudden loss of smell is one of the key symptoms of coronavirus as recognized by WHO, CDC and Canadian Government [7]. SARS-CoV-2 generally enters through the nasal cavities and attacks the olfactory respiratory epithelium that are covered with ACE-2 receptors that allow the virus to enter the cells. Therefore, loss of smell is one of the earliest symptoms of COVID-19 infection, preceding fever, and hence more sensitive screening method for asymptomatic patients [8,9]. In fact, the loss of smell has been found to be ten times more accurate than fever when screening for coronavirus infection [10] and should be treated as diagnostic test [8].

American scientific studies using smell quantitative assessment demonstrated that 98% of COVID-19 patients exhibited at least some smell dysfunction [2]. A large retrospective cohort of European centers ($n$ = 417) found that 86% of patients lost their sense of smell [11]. A Spanish case-control study (case $n$ = 79, control $n$ = 40) showed that among COVID-19 patients with new-onset smell/taste disorders, 81% exhibited with smell disorders [12]. A Monell analysis of 47 studies found that about 80% of COVID-19 patients have lost their sense of smell [13,14]. It was found that only about 44% of people self-reported loss of smell as symptom, and most did not realize that they lost partial or complete sense of smell owing to COVID-19 [15].

Currently, RT-PCR tests for detecting the virus take too long to give results, are expensive and inaccurate in initial stages of infection and cannot be effectively used for mass testing.

ANOSMIC COVID-19 smell tester is the only device authorized for sale by Health Canada, which works effectively in mass screening for COVID-19. ANOSMIC COVID-19 smell tester can be routinely

used as a first line of defense in evaluating COVID-19 patients on a mass scale followed by more robust clinical assays. This test can help in prioritizing and segregating possible COVID-19 positive cases from general population. ANOSMIC COVID-19 smell tester is a simple medical device that is made with all natural ingredients to evaluate a wide range of smell to detect olfactory dysfunction. It is a practical mass screening tool for early detection of COVID-19 that is fast, accurate, low cost, non-invasive and easy to use. These studies have a goal to evaluate ANOSMIC COVID-19 Smell Tester's sensitivity and specificity both for symptomatic and asymptomatic subjects.

## MATERIAL AND METHODS

Multiple cross-sectional studies have demonstrated that the incidence rate of olfactory dysfunction in COVID-19 patients varies from 33.9-68% with female dominance. Anosmia and dysgeusia are often comorbid in COVID-19 patients [16]. WHO continues to emphasize the utmost importance of frequent hand hygiene, respiratory etiquette, and environmental cleaning and disinfection, as well as the importance of maintaining physical distances and avoidance of close, unprotected contact with people with fever or respiratory symptoms [17]. For treatment and fast recovery in such a highly contingencious disease like COVID-19, it is an obvious need to screen the suspected cases of Covid-19 rapidly. This study aims at exploring all possibilities of the effectiveness, sensitivity and specificity of the ANOSMIC test that works perfectly.

ANOSMIC COVID-19 smell tester is a screening tool authorized for sale by Health Canada for early detection of COVID-19 infection for symptomatic and asymptomatic patients. The device gives off a particular odor derived from a specially engineered combination of all-natural organic ingredients. This product is 100 % plant based and does not contain any animal, poultry, dairy, nuts, chemicals, or CBD. To test for the loss of smell, spray a small amount on to wrist or a tissue and inhale vapor. If a distinct smell is not evident, then there is a good possibility of COVID-19 infection, and one is advised to isolate and obtain more robust confirmatory tests such as RT-PCR or Antibody tests. The ANOSMIC test product was supplied by the Canadian inventor and manufacturer, Virocule Inc. (Figure 1).

The first study was conducted on 156 ($n$ = 156) randomly selected subjects at the Rajasthan University of Health Sciences and SMS Hospital, Jaipur, India, in September 2020 to evaluate sensitivity and specificity of ANOSMIC COVID-19 Smell Tester for screening COVID-19 patients. In this study, 56 subjects ($n$ = 56) had been previously tested as COVID-19 positive, 50 subjects ($n$ = 50) had been previously tested as COVID-19 negative with RT-PCR and digital X-Rays, and another 50 subjects ($n$ = 50) were healthy and not previously tested. The odorant from ANOSMIC tester was sprayed on the back of the wrist of the subjects. The test method included verifying the intensity of smell from 0-10 (where 0 is no smell and 10 is maximum smell), reaction of the subjects to smell, and odorant identification. We also conducted a placebo test on these patients, where one hand was sprayed with ANOSMIC odorant and the other hand with water.

The second study was prospective with 50 randomly selected subjects ($n$ = 50) with various COVID-19 symptoms such as fever, cough, diarrhea, and were not previously tested by the RT-PCR/ Antibody based assay nor by the CT Scan/X-Ray. The odorant from ANOSMIC tester was sprayed on the back of the wrist of the subjects. Test method included verifying of the intensity of smell on a range of 0-10, the reaction of subjects to smell, and odorant identification. These patients were tested with the RT-PCR based assay and X-Rays after four days. The placebo test was not used in this study.

The third study consisted of three groups of randomly selected 420 ($n$ = 420) subjects divided into three groups and it was conducted in December 2020 in Jaipur, India. Group A consisted of 120 ($n$ = 120) symptomatic subjects with typical COVID-19 symptoms, such as fever, shortness of breath and cough, who came to Rajasthan University of Health Sciences, Jaipur, India. Group B consisted of asymptomatic 150 ($n$ = 150) subjects that were located at a construction site at Vivekanand Marg, Jaipur. Group C consisted of asymptomatic 150 ($n$ = 150) subjects that were located at a construction site at Pratap Nagar, Jaipur.

All the Group A symptomatic subjects were initially tested with ANOSMIC Tester and then tested for confirmation with RT-PCR and digital X-ray methods. If the patient tested COVID-19 positive with ANOSMIC tester but negative with RT-PCR and digital X-ray, then the RT-PCR and digital X-ray tests were repeated after four days for confirmation. All the Groups B and C asymptomatic subjects were tested with ANOSMIC tester, and then with RT-PCR and digital X-ray if they were COVID-19 positive. If there was discrepancy, then these tests were repeated after four days. If any of these Group B and C asymptomatic subjects had COVID-19 symptoms, they were also tested with RT-PCR and Digital X-rays.

This study was conducted with adults and children over 12 years old consisting of male and female subjects with their written consent. Those that did not have a sense of smell for reasons other than COVID-19, such as blocked nose or neurological disease, were excluded from this study.

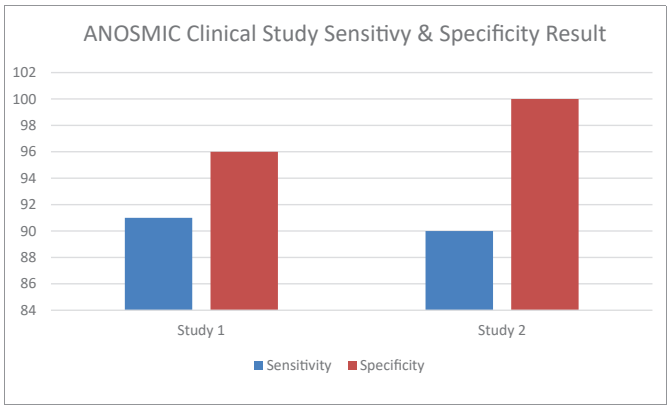
A Virocule recommended questionnaire was used for this Pilot Clinical Study. The subject was sprayed with the ANOSMIC odorant supplied by Virocule Inc., and the subject was questioned on the sense of smell which was recorded for the following: a) intensity of smell rating from 0-10, where 0 is no smell and 10 is maximum smell, b) odor identification amongst menu of 10 odors, and c) physical reaction of the subject to the smell. We classified anosmia as score 0-1, severe hyposmia as score 2-4 and mild hyposmia as score 5-7, and no olfactory dysfunction symptom as score 8-10. Items b) and c) were used for confirmation.

The fourth study consisted of randomly selected 200 asymptomatic subjects ($n$ = 200). It was conducted over 8-week period on television and movie production sets in Toronto, Canada. A screening questionnaire was used for symptom check, recent travel history and exposure history. Then the ANOSMIC smell test was conducted. If the subject was negative, then they were allowed to enter the movie set, and if they were positive, they were advised to obtain confirmatory RT-PCR test at a hospital and isolate themselves.

## RESULTS

### Studies I and 2

The result of the first trial in India demonstrated that 98% of COVID-19 patients had either anosmia or hyposmia, and the ANOSMIC test achieved sensitivity of 91% and specificity of 96%. The result of the second study demonstrated that 90% of COVID-19 patients has anosmia or hyposmia, and the ANOSMIC test achieved




sensitivity of 90% and specificity of 100% with 95% confidence level. The accuracy of ANOSMIC COVID-19 Smell Tester in both cases was greater than 90%. The second trial demonstrated that our ANOSMIC COVID-19 Smell Tester was able to identify asymptomatic patients as well as those with early infection that RT-PCR test was not able to identify initially, after four days it identified them as COVID-19 positive. These trials proved very useful in resolving the optimum thresholds for identifying COVID-19 positive and negative subjects, and those that necessitate isolation and further monitoring and testing with 95% confidence level. The product was found to be of low risk with no allergic or adverse reaction in any subject tested in these studies.

## Study 3

The mean age of the study population was 54.98 ± 16.21 years. The COVID positive mean age was 54.82 ± 16.37 and the COVID negative mean age was 55.08 ± 16.15. Both the groups were statistically not significant. There were total of 118 (28%) females and 302 (72%) males that participated in this study. Group A consisted of 120 symptomatic subjects and Groups B and C consisted of 300 asymptomatic subjects.

Following is a table of symptoms for all three Groups (Tables 1-6):

Following is a table of following tests: a) Ability to detect ANOSMIC smell, b) Intensity of smell, and c) Reaction.

**Table 1:** COVID-19 symptom classification.

| | Cases (*N* = 120) Group A | | Control (*N* = 300) Groups B & C | | Grand Total (*N* = 420) | | *p*-values LS |
|---|---|---|---|---|---|---|---|
| **Symptoms** | **No** | **%** | **No** | **%** | **No** | **%** | |
| Fever with Chills | 62 | 52 | 5 | 2% | 67 | 16 | <0.001S |
| Shortness with breath | 52 | 43 | 0 | 0.00 | 52 | 12 | <0.001S |
| Body aches | 22 | 18 | 0 | 0.00 | 22 | 5 | <0.001S |
| Sore throat | 17 | 14 | 0 | 0.00 | 17 | 4 | <0.001S |
| Loss of taste and smell | 5 | 4 | 0 | 0.00 | 5 | 1 | <0.001S |
| Cough | 45 | 38 | 5 | 2% | 50 | 12 | <0.001S |
| Congestion with Runny Nose | 2 | 2 | 0 | 0.00 | 2 | 0 | 0.004S |
| Headache | 11 | 9 | 0 | 0.00 | 11 | 3 | <0.001S |
| Diarrhea | 1 | 1 | 0 | 0.00 | 1 | 0 | <0.001S |
| Fatigue | 5 | 4 | 0 | 0.00 | 5 | 1 | <0.001S |

Following is a table of odor identification. Here 96.4% subjects identified the ingredients of the odorant correctly.

Following table classifies the grade of smell or smell intensity for Anosmia, Hyposmia – Mild and Hyposmia - Severe.

**Table 2:** ANOSMIC test-smell and reaction.

| | Cases (*N* = 120) Group A | | Control (*N* = 300) Groups B & C | | Grand Total (*N* = 420) | | *p*-values LS |
|---|---|---|---|---|---|---|---|
| Smell | No | % | No | % | No | % | |
| Yes | 12 | 10 | 264 | 88.00 | 276 | 66 | <0.001S |
| No | 108 | 90 | 36 | 12.00 | 144 | 34 | |
| Smell Intensity | | | | | | | |
| 0 | 27 | 22.5 | 17 | 5.67 | 44 | 10.5 | < 0.001S |
| 1 | 26 | 21.7 | 4 | 1.33 | 30 | 7.1 | |
| 2 | 24 | 20 | 1 | 0.33 | 25 | 6.0 | |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4 | 16 | 13.3 | 0 | 0.00 | 16 | 3.8 | |
| 5 | 14 | 11.7 | 15 | 5.00 | 29 | 6.9 | |
| 6 | 1 | 0.8 | 0 | 0.00 | 1 | 0.2 | |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 8 | 0 | 0 | 13 | 4.33 | 13 | 3.1 | |
| 9 | 0 | 0 | 90 | 30.00 | 90 | 21.4 | |
| 10 | 12 | 10 | 160 | 53.33 | 172 | 41 | |
| Reaction | | | | | | | |
| No | 107 | 89 | 37 | 12.33 | 144 | 34.29 | |
| Yes | 13 | 11 | 263 | 87.67 | 276 | 65.71 | < 0.001S |

Following is a table of the RT-PCR and Digital X-ray results for the first and second test for the subjects that tested COVID positive by ANOSMIC but negative by RT-PCR initially. There were 7 cases (4.3%) where ANOSMIC test detected COVID-19 subjects earlier than RT-PCR and Digital X-ray tests. There was 100% correlation between test results of RT-PCR and Digital X-ray tests.

**Table 3:** ANOSMIC test-odor identification.

| Odor (Out of 279) | No | % |
|---|---|---|
| Y (Lemon) | 131 | 46.95 |
| Y (Vinegar) | 129 | 46.24 |
| Y(Apple) | 6 | 2.15 |
| Y(Cardamom) | 1 | 0.36 |
| Y(Clove ) | 3 | 1.07 |
| Y(Ginger) | 1 | 0.36 |
| Y(Rose) | 1 | 0.36 |
| Y(Guava) | 1 | 0.36 |
| Y(Cinnamon) | 0 | 0 |
| Y(Pineapple) | 6 | 2.15 |
| Grand Total | 279 | 100.00 |

Following table summarizes the results of the a) Stand-alone ANOSMIC test, b) ANOSMIC test plus temperature test, and c) ANOSMIC test plus symptoms of temperature, cough, and shortness of breath. Note there were no False Positives for ANOSMIC test for anosmia and severe hyposmia (0-4).

The result of this clinical study in India demonstrated that 90%

**Table 4:** RT-PCR and digital X-ray test results.

| | Cases (Group A) | | Control (Group B & C) | | Grand Total | | |
|---|---|---|---|---|---|---|---|
| **SMELL Grade** | **number** | **Percentage %** | **number** | **Percentage %** | **number** | **Percentage %** | *p*-values LS |
| Anosmia (0 -1) | 53 | 44 | 21 | 7.33 | 74 | 17.62 | < 0.001S |
| Hyposmia-Severe (2-4) | 40 | 33 | 1 | 0.00 | 41 | 9.76 | |
| Hyposmia-Mild (2-4) | 15 | 13 | 15 | 5.00 | 30 | 7.14 | |
| Normal (8-10) | 12 | 10 | 263 | 87.67 | 275 | 65.48 | |
| Grand Total | 120 | 100 | 300 | 100.00 | 420 | 100 | |

**Table 5:** RT-PCR and digital X-ray test results.\

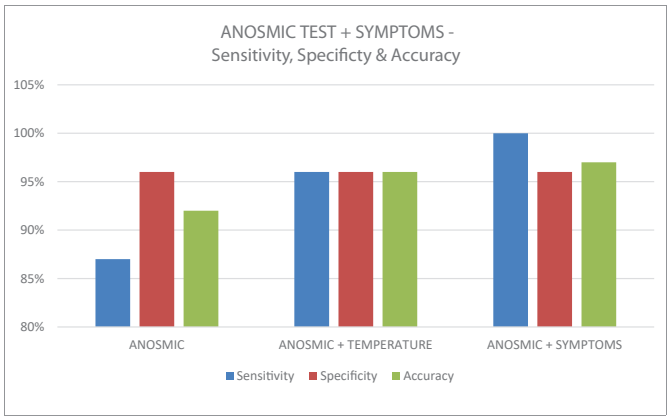
| **1 PCR** | **Cases (Group A)** | | **Control (Group B & C)** | | **Grand Total** | | |
|---|---|---|---|---|---|---|---|
| | **number** | **percentage%** | **number** | **percentage%** | **number** | **percentage%** | *p*-values LS |
| Yes | 105 | 87.5 | 30 | 10.00 | 135 | 32.14 | <0.001S |
| No | 15 | 12.5 | 15 | 5.00 | 30 | 7.14 | |
| NOT DONE | 0 | 0 | 255 | 85.00 | 255 | 60.72 | |
| **1 x ray** | **number** | **percentage%** | **number** | **percentage%** | **number** | **percentage%** | *p*-values LS |
| Yes | 105 | 87.5 | 30 | 10.00 | 135 | 32.14 | <0.001S |
| No | 15 | 12.5 | 15 | 5.00 | 30 | 7.14 | |
| NOT DONE | 0 | 0 | 255 | 85.00 | 255 | 60.72 | |
| **2 PCR** | **number** | **percentage%** | **number** | **percentage%** | **number** | **percentage%** | *p*-values LS |
| Yes | 7 | 5.8 | 11 | 3.67 | 18 | 4.3 | 0.200NS |
| No | 8 | 6.7 | 4 | 1.33 | 12 | 2.9 | |
| **2 XRAY** | **Cases** | | **control** | | **Grand Total** | | |
| | **number** | **percentage%** | **number** | **percentage%** | **number** | **percentage%** | *p*-values LS |
| Yes | 7 | 5.8 | 11 | 3.67 | 18 | 4.3 | 0.200NS |
| No | 8 | 6.7 | 4 | 1.33 | 12 | 2.9 | |

**Table 6:** ANOSMIC + symptomatic screen test.

| | **ANOSMIC Test Anosmia (0-1)** | **ANOSMIC Test Anosmia + Hyposmia (0-4)** | **ANOSMIC Test Anosmia + Hyposmia (0-7)** | **ANOSMIC + TEMPERATURE Anosmia + Hyposmia (0-7)** | **ANOSMIC + SYMPTOMS Anosmia + Hyposmia (0-7** |
|---|---|---|---|---|---|
| True Positive | 74 | 115 | 133 | 147 | 153 |
| False Positive | 0 | 0 | 12 | 12 | 12 |
| True Negative | 267 | 267 | 255 | 255 | 255 |
| False Negative | 79 | 38 | 20 | 6 | 0 |
| Sensitivity | 48% | 75% | 87% | 96% | 100% |
| Specificity | 100% | 100% | 96% | 96% | 96% |
| Accuracy | 81% | 91% | 92% | 96% | 97% |

of COVID-19 patients had either anosmia or hyposmia. We analyzed the test results by a) stand-alone ANOSMIC test, b) ANOSMIC and temperature test, and c) ANOSMIC test and symptomatic test including temperature, cough, and shortness of breath. The stand-alone ANOSMIC test achieved sensitivity of 87%, specificity of 96% and accuracy of 92%. The ANOSMIC and temperature test achieved sensitivity of 96%, specificity of 96% and accuracy of 96%. The ANOSMIC and symptomatic test achieved sensitivity of 100%, specificity of 96% and accuracy of 97% with 95% confidence level. Here the assumption is that amongst Groups B and C of asymptomatic subjects that tested negative by ANOSMIC test and did not have any further COVID symptoms were actually COVID-19 negative. Our study showed that amongst COVID-19 positive subjects the most prominent symptoms were fever and chills (52%), shortness of breath (43%) and cough (38%).

In this study about 12% asymptomatic subjects from Groups B and C were tested as COVID positive, and after performing confirmatory tests with RT-PCR and digital X-rays at RUHS, 11% were confirmed to be COVID positive. It is interesting to note that all persons with anosmia (0-1) and severe hyposmia (2-4) were confirmed to be COVID positive by RT-PCR test. Further, this study identified that about 4.3% COVID positive subjects were identified sooner by




ANOSMIC test than RT-PCR test after four days of retest. This trial proved very useful in optimizing the ANOSMIC test in conjunction with other symptomatic tests, and successfully identifying COVID positive subjects at early stage to isolate and treat them to prevent the spread of coronavirus. Further, the ANOSMIC product was found to be low risk with no allergic or adverse reaction in any subject tested.

### Study 4

The fourth study of 200 asymptomatic subjects who were tested on television and movie production was successful as there were 0 cases reported on set. 3 subjects failed the ANOSMIC COVID-19 Smell Test and were prohibited from entering the set. These 3 COVID-19 positive cases were then tested by RT-PCR at a lab and were confirmed to be COVID-19 positive. The subjects that were tested COVID-19 negative by ANOSMIC test did not show any COVID symptoms in the future were presumed to be COVID-19 negative. Therefore, the ANOSMIC COVID-19 Smell Tester found 1.5% asymptomatic subjects in Canada to be COVID-19 positive, and this tester demonstrated 100% accuracy in identifying COVID-19 positive subjects.

## DISCUSSION

Rapid and mass screening of viral infection is critical for preventing the spread of the coronavirus. Our studies showed that 90% of COVID-19 patients had olfactory dysfunction, by which they lost some sense of smell. Olfactory dysfunction is a key indicator for COVID-19 infection and generally happens before other symptoms such as fever and cough etc. Early detection and prevention of COVID-19 is key to preventing the spread of coronavirus, and current methods of screening are not practical for mass testing as they are expensive, take too long and require medically trained personnel.

The objective of this study was to test a unique ANOSMIC tester that provides fast, low-cost, accurate, non-invasive, and easy to use diagnostic tool for screening for COVID-19 using olfactory dysfunction test which uses an odorant developed using all-natural products. This test when coupled with other screening methods, such as temperature, cough and shortness of breath could provide an excellent tool for fast, cost-effective, and highly accurate test method that can be comparable in accuracy to RT-PCR method for screening symptomatic and asymptomatic persons effectively. ANOSMIC test has been proven to be effective for identifying COVID positive subjects before RT-PCR tests and it could be used as an early screening device to prevent the spread of COVID-19. Our study indicated that an objective olfactory dysfunction test, such as ANOSMIC test is much more accurate than subjective olfactory dysfunction test. The accuracy of this device is enhanced when coupled with other screening tests such as temperature, cough, and shortness of breath.

ANOSMIC COVID-19 Smell Tester could be used potentially by any person as self-test or to gain admittance safely to public places, such as businesses, airports, public transport, industries, parks, schools, restaurants, shopping malls, religious or social gatherings etc. If a person tests positive, they are advised to isolate themselves and obtain a further confirmatory test for COVID-19 by RT-PCR / Antibody. As a result, ANOSMIC has immense potential for mass testing which can further significantly reduce community acquired transmission, save lives, and reopen schools and businesses safely.

## CONCLUSIONS

These pilot clinical studies were immensely effective in successfully demonstrating the ability of ANOSMIC COVID-19 Smell Tester to detect COVID-19 patients for both symptomatic and asymptomatic subjects with about 92% accuracy in stand-alone test mode. This accuracy increased to 97% if ANOSMIC test was complemented with other symptomatic tests such as temperature, cough, and shortness of breath. We were able to detect 11% COVID-19 positive subjects amongst the asymptomatic population in India and 1.5% COVID positive subjects amongst population in Canada, who were isolated and treated at an early stage. In addition, we found that the ANOSMIC test was able to detect 4.3% COVID-19 early infected persons before the RT-PCR test could detect them. We found that by using the ANOSMIC test in conjunction with other screening methods, such as temperature, cough, and shortness of breath, we were able to detect 100% COVID-19 positive patients, similar to RT-PCR in much less time and cost. ANOSMIC device would be a wonderful mass screening tool for earlier detection of COVID-19 symptomatic and asymptomatic patients with high confidence levels, and to prevent the spread of COVID-19 infection.

This patent pending screening device is accurate (> 90%), fast (< 30 sec), low-cost (< $0.30/test), non-intrusive and easy-to-use for everyone for daily test to prevent the spread of coronavirus. This effective and economical technology was prepared with a specially engineered combination of 100% natural ingredients and manufactured in an aseptic facility that is Health Canada and FDA approved in Ontario, Canada. It can be used as a triage tool in identifying and segregating COVID-19 positive subjects. Furthermore, if any subject exhibits loss of smell, it is recommended to follow country-specific quarantine practices, get tested by diagnostic confirmatory tests such as RT-PCR/Antibody based tests, and get appropriate medical treatment. This early detection device can be used by schools, colleges, businesses, industries, airports, restaurants, subways, train and bus stations, medical clinics, churches, and social gatherings to not only help in saving lives, jobs, and reduce health care costs but also facilitate safe opening of schools and the economic business sectors in accordance with safety regulatory guidelines.

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