MY SAFE PASS™

Olfactory Test Kit

Earliest Symptom Screening Test for
Concussion - Covid 19 - Alzheimer's – Parkinson's
And other viral and Neurological Diseases

www.patriotconnectionsppe.com 843-457-0595 email - Jeffrey@patriotconnectionsppe.com

Used to detect Olfaction dysfunctions caused by underlying medical conditions

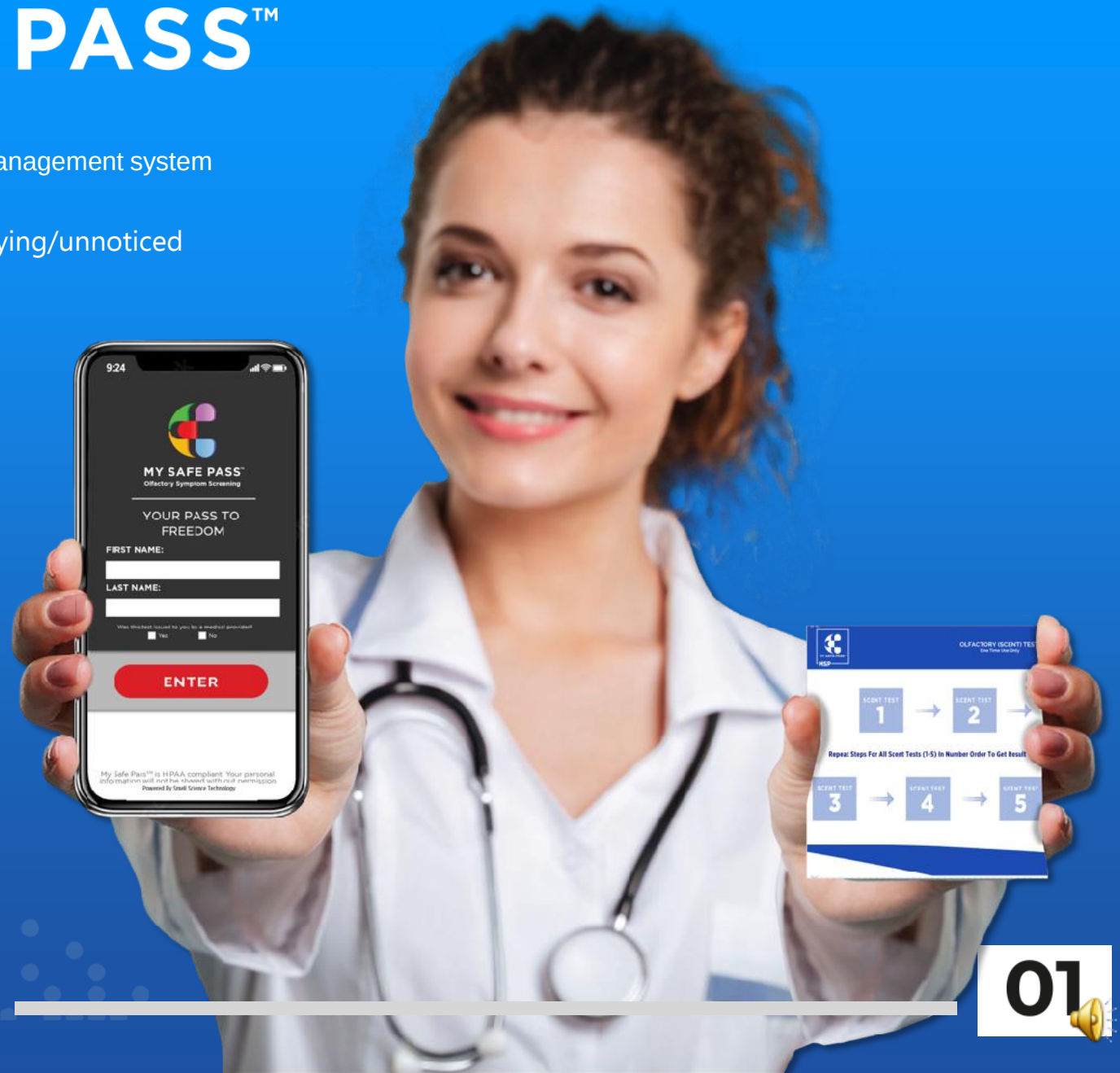
MY SAFE PASS™

Olfactory Test Kit

with monitoring and preventive care management system

Earliest symptom indicator associated with underlying/unnoticed medical conditions including:

- Covid-19 and viral infections
- Concussion
- Parkinson's
- Alzheimer's
- Neurological disorders



ACCESS THE APP

SMELL SCENTS ON TEST CARD

GET RESULTS IN MINUTES!

Overview

MY SAFE PASS™ is a powerful 1-minute test that screens for olfactory dysfunction. Olfactory bulbs located in the nasal cavity are responsible for scent understanding and scent recognition.

Our objective and sensitivity scent level test identifies scent disorders including slight and unnoticed changes such as sensitivity loss, decreased sense of smell, change of smell and loss of smell.

Scent disorders are common early symptoms of many neurological disorders, concussion and viruses including Covid-19. These symptoms often go unnoticed, preventing early diagnostic testing.

Our multi-odorant 5-point scent card screens for a range of olfactory dysfunction and helps catch the powerful hidden signs. Early symptom screening allows for early diagnostic testing and detection, which allows preventative measures and sooner response treatment.

Viral and Disease Symptoms Screening

Uses your device, or office tablet along with our 5 odorant detection test card to quickly screen for olfactory disorders.

Covid-19 – Viruses - Concussion – Alzheimer's – Parkinson's
and other neurological disorders are measured by receptors damage which can be measured in scent loss testing.


Scan Card


Rub Card


Smell


Select

Pass/Fail

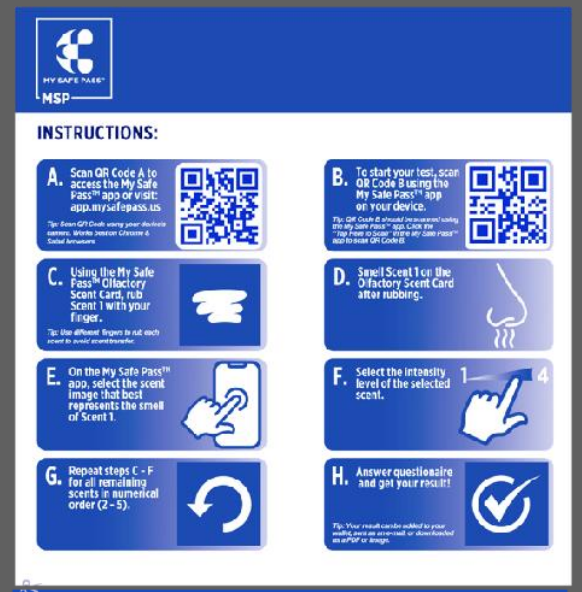
Highlights

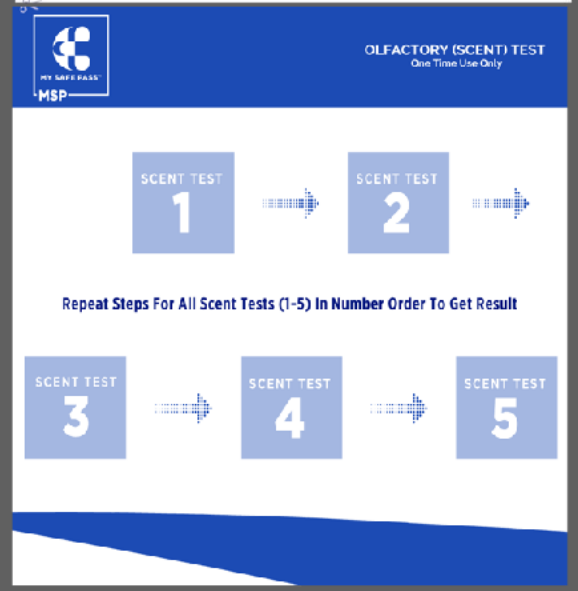
Our test includes 5 separate scents and sensitivity tests that cover a wide range of olfactory dysfunction including Hyposmia, Dysosmia and Anosmia. It is necessary to have at least 5 scents in the test to maintain accuracy.

My Safe Pass Includes:

- One multi-odorant scent card (5-Points)
- Downloadable Application
- Optional Health Screening Questionnaire – Based on WHO, CDC & OSHA Criteria
- Home RT-PCR Test with no cost option
- Daily monitoring data gathering app
- Back end reporting for employee and patient monitoring
- Low cost per use
- Insurance billing coverage

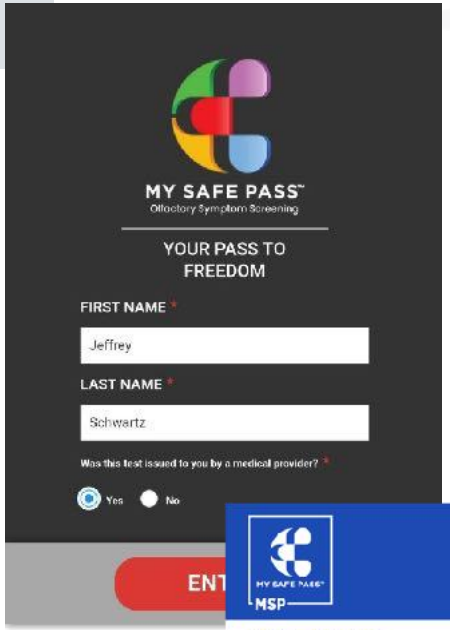
SAVE THE TEST RESULTS TO YOUR WALLET FOR VERIFICATION

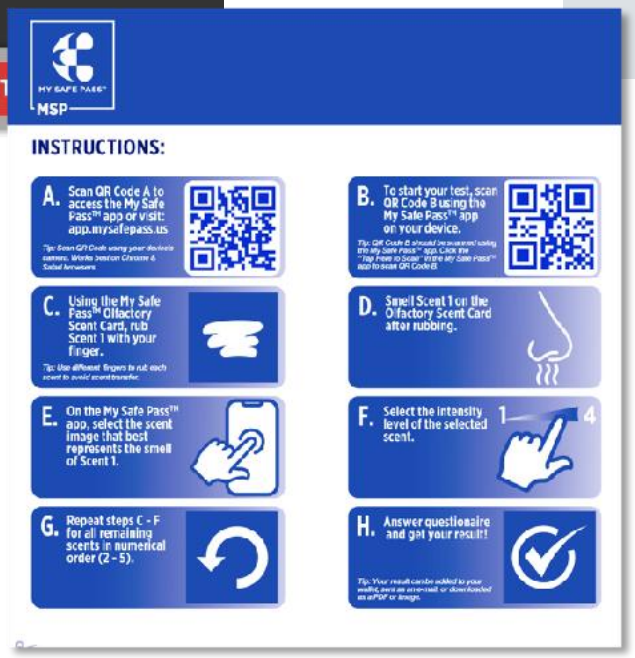




Key Benefits

- Screens for unnoticed earliest symptoms caused by viruses and neurological disorders known to cause olfaction dysfunctions. Detects concussions as well.
- Stop the spread of Covid-19 by identifying olfactory dysfunction, a strong early and often hidden indicator symptom that is highly associated with Covid infection.
- Fast, affordable, simple & non-invasive – user friendly!
- Use for Covid screening and doctor's office health monitoring.
- Free software data management and data monitoring for personal and medical patient preventative care
- Identify viral outbreak locations with back-end reporting and Google map location monitoring.
- Personal and doctor's office daily progress monitoring for users.
- HIPPA Compliant. FDA Registered Class 2 Medical Device
- Safe & affordable for everyday use.
- Visual, fast & easy to use.
- Results in 60 Seconds.
- Use for Covid screening for office-events-arenas-business hotels-cruise ships-factories.
- Covid screening -Saves test results to your device for verification and entry to public areas and events.
- Doctors use for checkups-preventative care- elderly monitoring- retirement home Covid screening and early neurological screening.





Key Features

- Highly Accurate
- Clinically Validated
- FDA Registered
- Award Winning
- Back End Reporting

HIGH ACCURACY	97% Specificity, 87% Accuracy, 3% False Positives *
CLINICALLY VALIDATED	Validated in Multiple High Caliber Peer Reviewed Clinical Trials (Yale, Gates /GHL)
USA REGISTRATIONS	FDA Registered Class II (510 K Exempt) Medical Device
EU REGISTRATIONS	CE Registered Class I Medical Device
LANGUAGES	Available in Multiple Languages
AWARD WINNING	Winner Of Covid Testing FX Competition
IMPROVES TESTING ACCURACY	Improves Antigen Test Performance – Gates Peer Reviewed Study
BACK END REPORTING	Yes
SELF PROGRESS MONITORING	Yes
HEALTH SCREENING QUESTIONER	Optional WHO Recommended Symptom Screening Test
DIAGNOSTIC VERIFICATION	FREE RT-PCR Home Kit Voucher provided for Infection verification
SHELF LIFE	3 Years
ORIGIN	MADE IN USA - Asian & European manufacturing available
NUMBER OF SCENTS	5 Per Test
RESULT TIME	60 Seconds

*Disclaimer: *Olfactory dysfunction can be due to other causes including neurodegredation disease, head trauma or other viral infections and this is not to screen or diagnose a specific disease or condition.*

* 87% Accuracy (82-87), 3% False Positives (3-11), *Specificity (87-97%)*

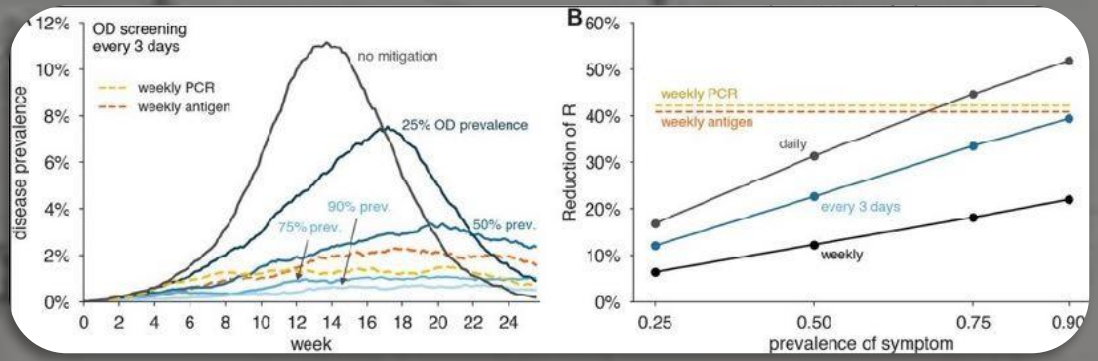
Stop the Spread of Viral infections

MY SAFE PASS™ can detect unnoticed Covid -19 symptoms earlier than other tests. With over 6 million deaths globally, current Covid-19 antigen tests only work in identifying Covid infections in later stages. New studies show antigen and RT-PCR Tests have low accuracy rates in these early stages when the viral load is too low to detect.

MY SAFE PASS™ is used to detect symptoms in days 1-5 before noticeable symptoms from Covid-19 infection. Exposed, healthy people are also unlikely to test at this stage The most critical time when infections spread is before noticeable symptoms occur. To help stop the spread of Covid-19, our screening test is used to identify symptoms sooner, protecting others from infection and allowing for early treatment.

"We observed that screening for olfactory dysfunction daily or every third day limited viral spread in simulations..." [1]

Source: Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission



*"There is a high prevalence of OGDs (*olfactory and gustatory dysfunctions) *among patients infected with COVID-19. Routine screening for these conditions could contribute to improved case detection in the ongoing COVID-19 pandemic."*

Mayo Clinic [1]

1. Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission | medRxiv

Olfactory Disorder & Neurologic Disease Alzheimer's/Parkinson's

In the 1970s, researchers learned that smell is compromised in neurodegenerative conditions like Alzheimer's Disease, Parkinson's Disease, Huntington's Disease, and Multiple Sclerosis (MS).

Loss of smell is a hallmark symptom in the earliest stages of many diseases. Recent studies of brains from Alzheimer's and Parkinson's Disease patients reveal structural and biochemical alterations in regions associated with the sense of smell.

Loss of smell occurs 90 percent of the time in Parkinson's Disease. This is greater than the prevalence of tremor, a cardinal sign of the disorder. Yet in one study of Parkinson's patients, 72 percent were unaware they had a smell disorder before undergoing standardized testing. Only two out of 34 Alzheimer's Disease patients reported suffering from smell and/or taste problems-even though 90 percent of the patients scored lower on standardized smell tests than healthy subjects.

Key Points: Parkinson's Disease

•Olfactory dysfunction is an early and sensitive marker of the preclinical phase of Parkinson's Disease (PD)

•Analogous olfactory dysfunction occurs in other—but not all—neurodegenerative diseases, suggesting the involvement of a common neuropathological substrate

•PD is a multi-system disorder in which brain neuropathology seems to begin in the olfactory bulb and the dorsal motor nucleus complex of the glossopharyngeal and vagus nerves

•Damage to largely non-dopaminergic neurotransmitter systems may contribute to, or possibly even cause, the olfactory loss observed in PD and some other neurodegenerative diseases

•Many environmental risk factors for PD, including older age, head trauma, and exposure to metal ions, viruses and pesticides, are also risk factors for smell loss that is independent of PD

Nature Neurology

1. Elevated ACE2 expression in the olfactory neuroepithelium: implications for anosmia and upper respiratory SARS-CoV-2 entry and replication

Olfactory Disorder Testing & Concussion

It has been previously known that major Traumatic Brain Injury (TBI) may cause a broad range of side effects including loss of the sense of smell. Now researchers reveal that it's true even for minor concussions. In fact, approximately 65 percent of the patients with mild concussions reported these symptoms. "**In the acute phase of mild TBI, a majority of patients have impaired olfactory function**.

MY SAFE PASS™ can be used as an additional screening tool for contact sport protocols helping to insure player safety protection from further injury. If concussions are not treated carefully, symptoms can continue for a longer duration of time. Further, if left untreated, concussion patients are at a greater risk of repeat concussions, which can significantly exacerbate the intensity and duration of symptoms.

Surprisingly, a test of olfactory function is not currently a part of the concussion protocol even though smell loss has been a common unnoticed occurrence following head injuries. Our test of olfactory function and CTE in real time is a "game-changer". Our 60 second smell test, given by a single technician, can objectively detect this common occurrence caused by head trauma. MY SAFE PASS™ is here to help.

https://www.hss.edu/condition-list_concussion.asp
https://www.news-medical.net/news/20190724/

Key Features and Benefits

- Use MY SAFE PASS™ on the field for quick concussion symptom assessment.
- Use for contact sports leagues before, during and after practice and games as safety protocol and player tracking.
- Use by EMS for immediate, on-site concussion assessment.

Olfactory Disorder & Covid-19

“The Secret Behind the Science”...

Cells by the olfactory neurons are up to 600x enriched in the ACE2 receptor and it’s where the virus goes first. SARS-Co-V2 enters through your nasal cavity which causes olfactory disorders. 1

Smell disorders in the early stages are sometimes the only symptom in Covid-19. Most infected people do not notice this symptom unless a test is used that can identify a partial loss of smell (hyposmia). This is important, for while some people can notice total smell loss, many will not notice hyposmia without an objective and quantitative olfactory test.

“Up to 83% of people infected with the Coronavirus experience loss of smell when a standardize olfactory test is used vs the infected person self-reporting a loss of taste of smell (15-44%).” [1]

Yale University School of Medicine

1. Elevated ACE2 expression in the olfactory neuroepithelium: implications for anosmia and upper respiratory SARS-CoV-2 entry and replication

Loss of Smell - Key Differentiator

Loss of smell is the differentiator symptom and is not present in flu or allergy.

Olfactory disruption is a prevalent and one of the first indications of Covid-19 infections (day 1-3). This happens before noticeable symptoms including fever, headache, and diarrhea. 1 A unique feature of Covid-19 is a loss of smell and the ability to understand scents even without a stuffy or runny nose caused by a normal cold or flu. 2, 3

Fever is not a good indicator of Covid-19 infection. A recent study *"found that Covid-19 patients were 27 times more likely than others to have lost their sense of smell. But they were only 2.6 times more likely to have fever or chills..."* 4

SYMPTOM	FLU	ALLERGY	COVID-19
ANOSMIA / HYPOSMIA	✗	✗	✓
FEVER	✓	✓	✓
COUGH	✓	✓	✓
VOMITING OR DIARRHEA	✓	✓	✓
MUSCLE ACHES	✓	✓	✓

1. Smell and Taste Dysfunction in Patients With COVID-19: A Systematic Review and Meta-analysis
2. https://www.newsobserver.com/news/coronavirus/article243567982.html
3. Fever checks are a flawed way to flag Covid-19 cases. Experts say smell tests might help
4. Augmented Curation of Clinical Notes from a Massive EHR System Reveals Symptoms of Impending COVID-19 Diagnosis

Make Your Life Safe Again

MY SAFE PASS™ is an easy-to-use tool for quick screening of symptoms related to Covid infection. Use MY SAFE PASS™ before visiting and after gatherings.

- Visiting Grandma & Grandpa
- Family & Friend Gatherings
- Dining Out
- Travel
- School
- Events
- Workplace

**This is one tool and should be used with other mitigations including diagnostic testing as appropriate.*

Make Your Workforce Safe Again

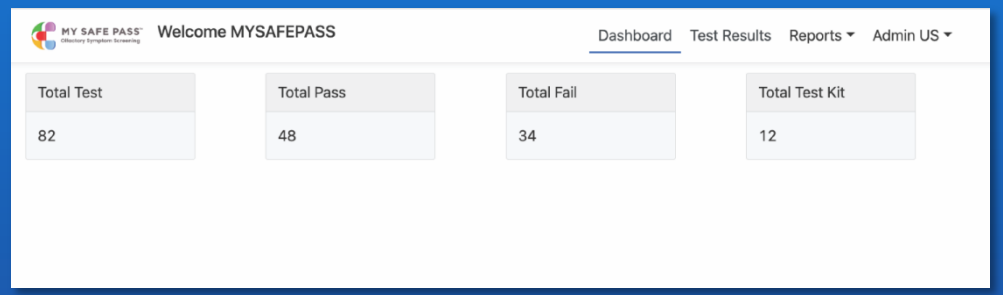
An easy-to-use, cost-effective method for Covid-19 symptom screening that can be easily implemented in seconds with high reliability.

1. Screen upon workplace entry.
2. Identify unnoticed symptoms sooner.
3. Use for employee monitoring and Covid-19 containment mitigation.
4. Meets OSHA Covid-19 compliance mandate by providing symptom screening, monitoring, management and reporting.
5. Use our backend monitoring application for employee monitoring.
6. Use daily to stop the spread.

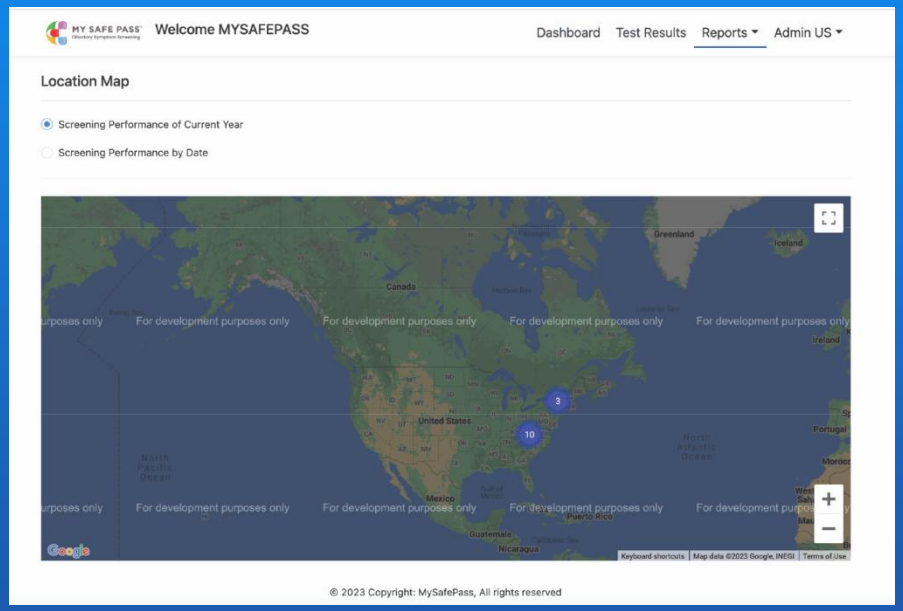
**This is one tool and should be used with other mitigations including diagnostic testing as appropriate.*

Backend Data & Reporting

Use our app which gathers date, time, approximate location and results from each user while remaining HIPAA compliant. The app also allows employers to manage its employees. Employers can obtain real time data of its employees and company overview.
Also, as an added benefit, employers can obtain full use of our software for real time monitoring and compliance.
MY SAFE PASS™ testing system covers these requirements.

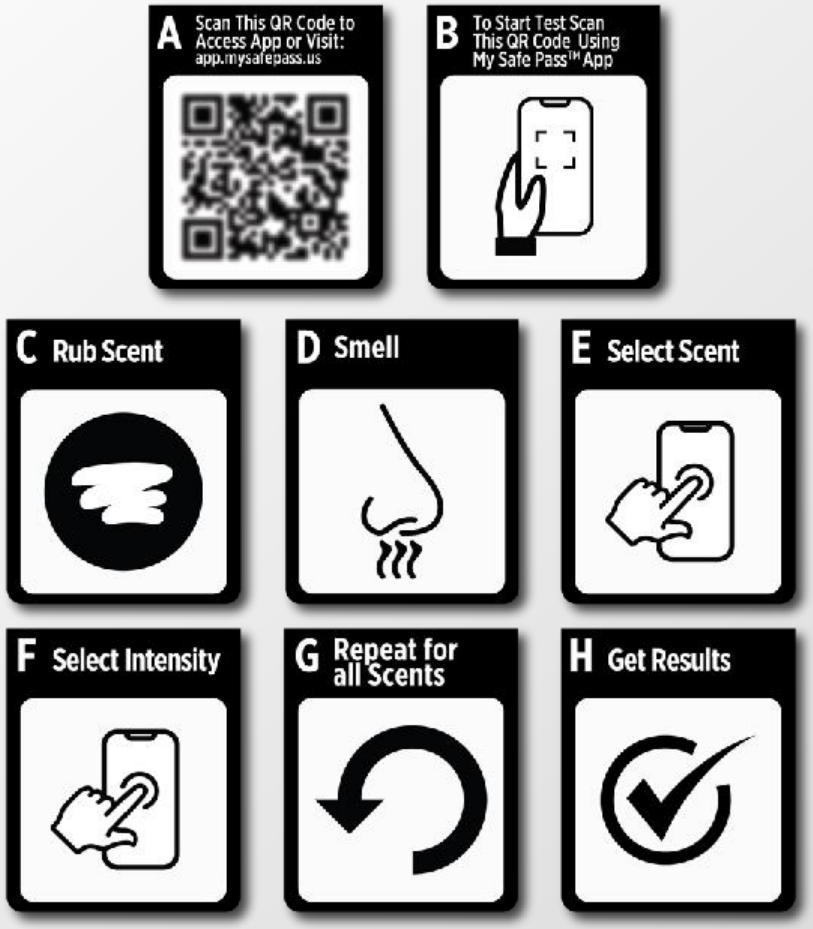


Employee Management Dashboard



Real Time-Date & Precise Location Masking

App Walkthrough



PASSED vs. FAILED

Once your test is completed you will receive a PASSED or FAILED result on your app. A PASSED result indicates that you have normal olfactory function, while a FAILED result indicates that symptoms were detected.

- Save your PASSED result to wallet.
- Scannable QR Code can be used to validate results.
- Show PASSED or FAILED for validation of results with participating partners.
- Proceed to take the optional Covid-19 Health Screening Questionnaire.
- A FAILED result will prompt you to seek additional attention from a health care provider.
- A FAILED result will give you an option to receive Home RT-PCR Test with no cost option
- Allows for instant patient diagnosis from the Medical Provider along with immediate results for billing.

**Olfactory dysfunction can be due to other causes including neurodegredation disease, head trauma or other viral infections and this is not to screen or diagnose a specific disease or condition.*

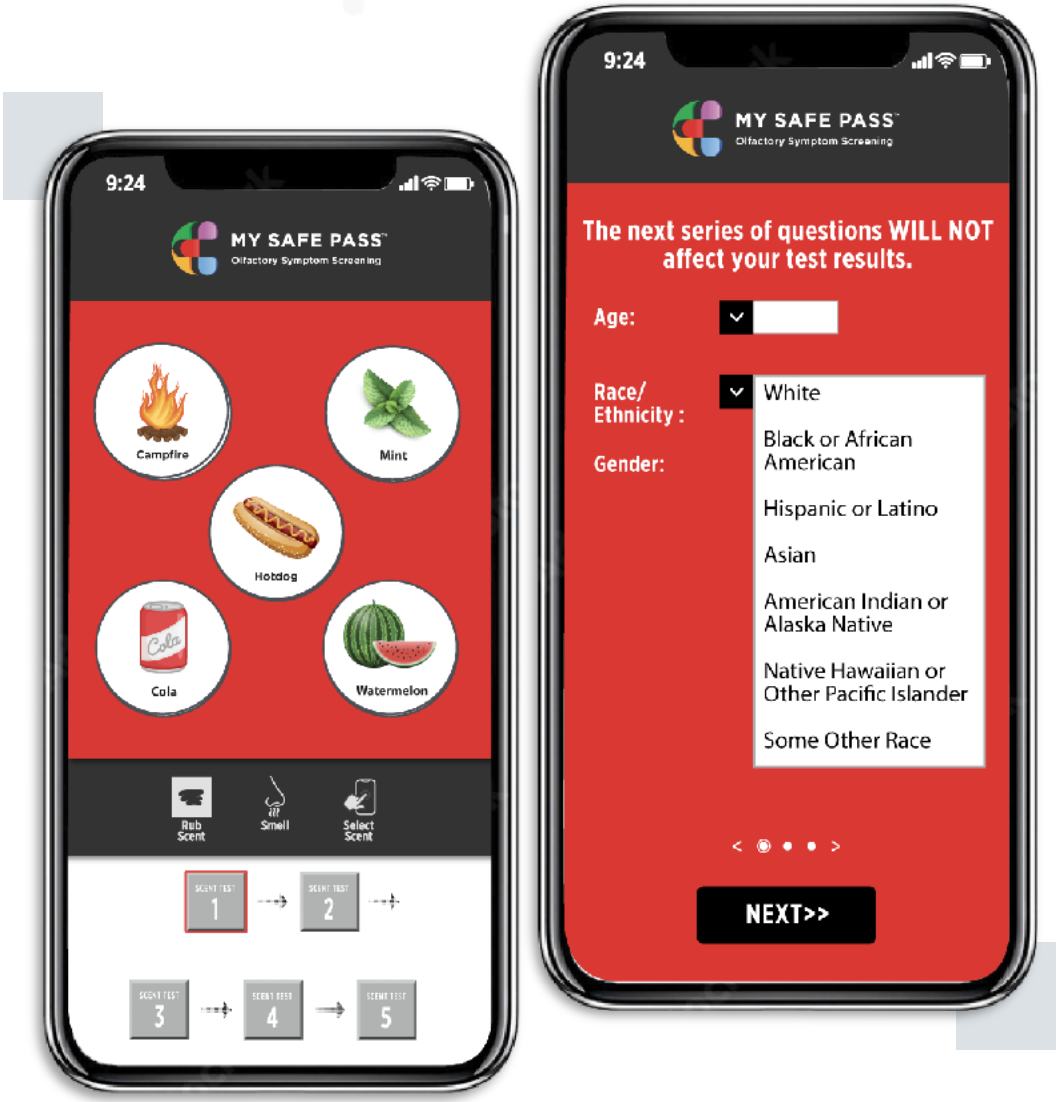
With Added Bonus

- 5-point scent check that tests a wide range of olfactory disorders, using a specially designed scent card along with a downloadable app and verification pass.

- App includes Optional Covid-19 Health Screening Questionnaire – Recommended by the WHO, CDC & OSHA. Typically used in workforce settings.

- The added Covid-19 Health Screening Questionnaire is for business entry protocol. It is a separate test independent from our olfactory test.

- If you receive a FAILED result, clients have the option to order a Home RT-PCR Test with a no-cost choice within the app.



Validations and Clinical Studies Concussion/TBI –Neurological Alzheimer's Parkinson's 140 other Neurodegenerative).

5 Scent odorant olfactory testing was validated in multiple clinical studies including:

- *FDA Medical Device Registration validation.*
- *MSP exceeds minima odorant detection requirements.*
  1 Institute of Clinical Pharmacology, Goethe –Oxford
- *Odorant Testing Requirements protocol. St Croix Sensory Inc.*

Olfaction Disorder and Neurodegenerative Disorders

- *Smell loss may precede a Parkinson's diagnosis by up to 10 years. Lasting smell loss can be a risk factor for brain disease. PPMI Clinical Study*
- *644 associated clinical studies-Olfactory disorder Parkinson's Disease NIH NLOM Clinical PMC*

Olfaction Disorder and Alzheimer's Disease Studies

- Olfaction as an early marker of Parkinson's Disease and Alzheimer's */pubmed.ncbi.nlm.nih.gov/34266602/*
- Loss of smell linked to Alzheimer's cognitive impairment and biomarkers. *NIH Link to Clinical Studies*

Olfaction Disorder and Viral Infection

- *The overwhelming majority—approximately 86% of people—who have Covid-19 report either partial or total loss of their ability to smell.*

Olfaction Disorder and Concussion

- *"It's long been known that people who suffer a major concussion can lose their sense of smell temporarily" Sciencedaily.com*
- *Olfactory, cognitive and affective dysfunction assessed 24 hours and one year after a mild Traumatic Brain Injury (mTBI)*

Clinical Studies Direct Links

National Library of Medicine- National Center for biotechnology Information J Alzheimer's Dis.2022;86(3):1275-1285. doi: 10.3233/JAD-210636.

1. *Olfactory Dysfunction in Neurodegenerative Diseases.Marin C, Vilas D, Langdon C, Alobid I, López-Chacón M, Haehner A, Hummel T, Mullol J.*
2. *Olfaction as an early marker of Parkinson's disease and Alzheimer's disease.Walker IM, Fullard ME, Morley JF, Duda JE.Handb Clin Neurol. 2021;182:317-329. doi: 10.1016/B978-0-12-819973-2.00030-7.PMID: 34266602*
3. *Olfactory,Concussion, cognitive and affective dysfunction assessed 24 hours and one year after a mild Traumatic Brain Injury (mTBI)*
4. *Traumatic brain injury and olfaction: a systematic review*
5. *Increases of phospho-Tau (Ser202/Thr205) in the olfactory regions are associated with impaired EEG and olfactory behavior in traumatic brain injury mice*
6. *The usefulness of a quantitative olfactory test for the detection of Covid-19.*
   - *World's leading institutes in Studies of Infections Disease and Public Health)*
7. *Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission*

*Disclaimer: *Olfactory dysfunction can be due to other causes including neurodegeneration disease, head trauma or other viral infections and this is not to screen or diagnose a specific disease or condition.*

Validations and Clinical Studies of 5 Scent Odorant Detection Test Viral/Covid-19

5 Scent Odorant Olfactory Testing was validated in multiple clinical studies including:

- Gates Foundation/Global Health Labs Study (170 subjects)
- Yale University School of Medicine – ENT specialists (1320 subjects*)
- FIOCRUZ, Brazil (World Renown for Infectious Disease) (165 subjects)
- USA K-12 School System (800 tests)

The modeling paper (4) that was published in Nature Communications showed that an olfactory screening every one or two days could outperform weekly PCR tests to mitigate Covid-19 transmission.

Key Summary Statistics and Takeaways:

- **Accuracy 82-87%**
- **Specificity 89-97%** (>**97**% after training card or repeated testing)
- High testing frequency (every 1-2 days) is much more important than modest sensitivity (~55%), (this is similar to the sensitivity of antigen tests in asymptomatic people)

These studies show the benefits of implementing FREQUENT olfactory testing to stop the spread of Covid-19 transmission.

* Largest objective olfactory test in Covid-19 subjects to date.

Clinical Studies Direct Links

1. *Clinical validation of an open-access SARSCOV-2 antigen detection lateral flow assay, compared to commercially available assays*
   - Organization: Global Heath Labs (nonprofit organization created in 2020 by Gates Ventures and the Bill & Melinda Gates Foundation)

2. *The usefulness of a quantitative olfactory test for the detection of Covid-19.*
   - Organization: FIOCRUZ, Brazil (One of the *World's leading institutes in Studies of Infections Disease and Public Health*)

3. *Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission*

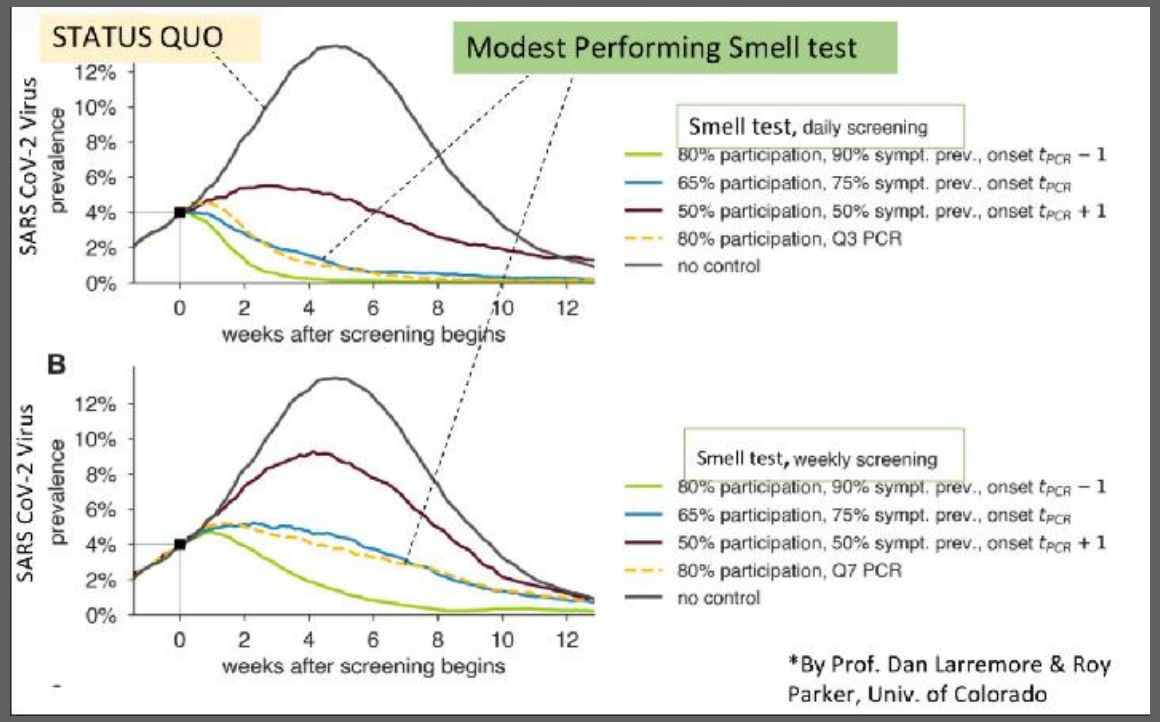
   Organizations:
   - Department of Computer Science, University of Colorado, Boulder, CO, USA
   - USA BioFrontiers Institute, University of Colorado, Boulder, CO, USA
   - Yale University School of Medicine

Viral – Covid-19

The Clinical Studies - Stop the Spread

This graph from Natures Communications paper (2021) shows that testing frequency is more important than sensitivity in mitigation of Covid transmission. Specifically, a daily olfactory test outperformed weekly PCR testing in reducing transmission at a fraction of the cost.

Clinical and real-world modeling studies show that implementing an olfactory test to screen frequently would greatly help to reduce the spread of Covid-19 in its early stages.



Modeling: Daily or Weekly Olfactory Test Can Greatly Suppress Current Covid-19 Outbreaks
Natures Communication (2021)

1. Clinical validation of an open-access SARS-COV-2 antigen detection lateral flow assay, compared to commercially available assays

Testing Issues & Low Viral Loads

Our 5-Point Scent Screen is More Accurate in Detecting Covid-19 at Low Viral Loads vs. Antigen & PCR Tests

Here is a quote in our newly published peer review clinical study by Global Health Labs (Melinda and Bill Gates Foundation), *"In the lower viral load cases detected by NP PCR, all rapid tests demonstrated low sensitivity. Amongst the antigen rapid tests, sensitivity among lower viral load cases was greatest for BinaxNOW™, but was still only 53%."* 1, 2

Implementing an olfactory test can help detect low viral loads of SARS-Co-V-2 that are missed in an antigen test.

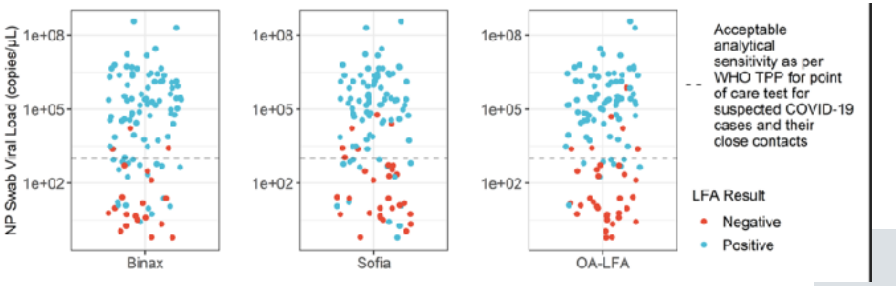
Clinical validation of an open-access SARS-COV-2 antigen detection lateral flow assay, compared to commercially available assays (plos.org)

Assay	NP Swab PCR		AN Swab PCR	
	Sensitivity < = 1000 copies/µL (95% CI)	Sensitivity >1000 copies/µL (95% CI)	Sensitivity < = 1000 copies/µL (95% CI)	Sensitivity >1000 copies/µL (95% CI)
OA-LFA	25% (12%-42%), 9/36	92% (83%-97%), 66/72	55% (36%-73%), 17/31	98% (91%-100%), 58/59
Sofia®	38% (22%-55%), 14/37	92% (83%-97%), 67/73	64% (45%-80%), 21/33	98% (91%-100%), 58/59
BinaxNOW™	53% (35%-70%), 19/36	96% (88%-99%), 70/73	79% (61%-91%), 26/33	98% (91%-100%), 58/59
MSD Ag ELISA	46% (29%-63%), 17/37	96% (88%-99%), 70/73	76% (58%-89%), 25/33	100% (94%-100%), 59/59
AN Swab PCR	57% (39%-73%), 21/37	97% (90%-100%), 71/73	NA	NA

Results are binned into two groups based on if the reference method measured less than or equal or above 1000 copies per microliter.

https://doi.org/10.1371/journal.pone.0256352.t002

Clinical validation of an open-access SARS-COV-2 antigen detection lateral flow assay, compared to commercially available assays



1. Covid-19 Target product profiles for priority diagnostics to support response to the Covid-19 pandemic v.1.0 (who.int)
2. Clinical validation of an open-access SARSCOV-2 antigen detection lateral flow assay, compared to commercially available assays

The PCR Test Strengths & Weaknesses

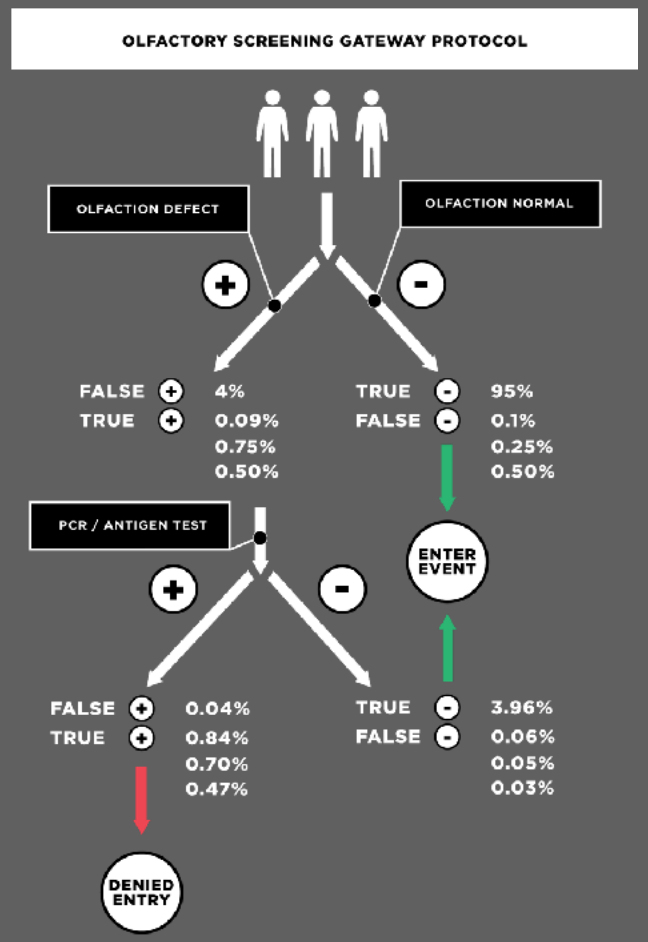
- Nasopharyngeal (NP) SARS CoV-2 RT-PCR tests are highly accurate
- Extremely Invasive
- Not Child Friendly
- Slow Reporting (2-3 days)
- Expensive
- Require a special healthcare professional to administer
- Infectivity Lasts About 10 Days While An Individual Can Be PCR Positive for ~30 Days [1]

1 Five-Item Odorant Test As An Indicator Of Covid-19 Infection In General Population and Routine Healthcare Worker Testing

Real World Modeling Airport Entry Example

Implementing MY SAFE PASS™ at gateway entry points is an effective tool to stop the spread of Covid-19 quickly, easily and cost effectively.

- Screening only those that fail the scent test with an antigen reflux (secondary test) will save tremendous cost.
- People will not mind doing a smell test vs. sticking something up their nose. It can be very uncomfortable and scary for children as well.
- Save time by screening for symptoms using a 1-minute hyposmia test that can be done on site, versus a 15-minute antigen test.
- The availability, time and cost factors associated with antigen screening for large crowds makes it impractical.
- MY SAFE PASS ™ as the first line of screening to enter facilities allows for a reduction of time to screen, cost savings and greater availability of tests.



SYMPTOM PREVELANCE	INFECTION REMOVED	FALSE POSITIVES DENIED ENTRY
90%	84%	0.06%
75%	70%	0.05%
50%	47%	0.03%

Manufacturing

- Production Capacity: 100 Million per 7 days, scalable to 500 Million per week (USA). Global manufacturing also available upon request.
- Factory Locations: 14 sites in USA
- Scent Technology: Microencapsulated scents
- Scents: Lemon, Cinnamon, Peppermint, Licorice, and Coffee (USA MARKET).
- Up to 30 additional scents available upon request.

MY SAFE PASS™

Olfactory Test Kit

Earliest Symptom Screening Test for
Concussion - Covid 19 - Alzheimer's – Parkinson's
And other viral and Neurological Diseases

Contact us at 843-457-0595 www.mysafepass.us or www.patriotconnectionsppe.com