MY SAFE PASS™

Olfactory Symptom Screening

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ACCESS
THE APP

SMELL SCENTS
ON TEST CARD

GET RESULTS
IN MINUTES!

Olfactory Disorder is an Early Symptom Indicator associated with underlying or unnoticed medical conditions, including COVID-19, Viral Infections, Concussion, Parkinson's, Alzheimer's, and Neurological Disorders.

MY SAFE PASS™ is a powerful 1-minute test that screens for olfactory dysfunction. Now available with monitoring and preventive care management system.

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 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 quicker response for treatment.

How it Works

MSP uses advanced technologies to identify unnoticed changes in your ability to accurately smell. Normal ability can change without you ever noticing these slight changes. Sensitivity degradation occurs due to viral infections, they also are early symptoms of Neurological disease. Concussion and TBI also temporarily cause Olfactory disorders. Use MSP to rapidly screen for these unnoticed and undiagnosed disorders. Safe, Effective, 60-second, affordable, insurance covered screening tool.

STEP 1
Scan the QR code on the Scent Card to start the test.

STEP 2
Rub the first scent on the scent card.

STEP 3
Select the proper answer on the MY SAFE PASS™ app. What do you smell?

STEP 4
Repeat for all scents.

STEP 5
Answer questions.

STEP 6
Get Results.

STEP 7
Save your results on your phone or send by email.

Highlights

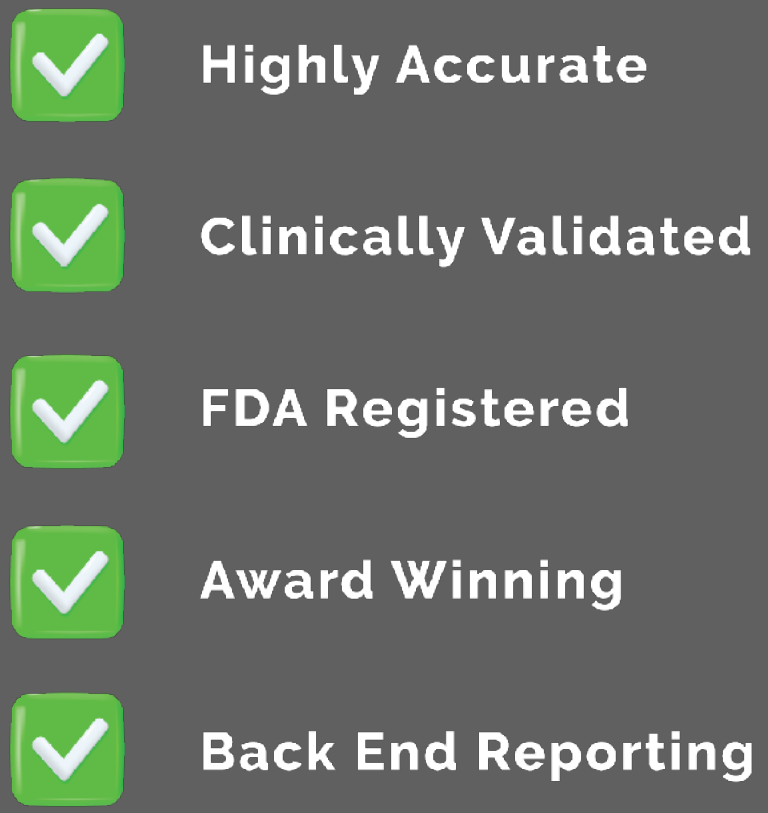
Our test includes 5 separate odorants and sensitivity tests that cover a wide range of olfactory dysfunction including Hyposmia, Dysosmia and Anosmia. It is necessary to have at least 5 scents in the test to maintain accuracy.

MY SAFE PASS™ Includes:

- One multi-odorant scent card (5-Points).
- Downloadable Application.
- Back-end reporting for employers and health care practitioners.
- Insurance billing coverage.

Key Highlights:

- Easy to Use.
- Fast Results – 60 Seconds.
- FDA Registered Class II Medical Device (510k Exempt).
- CE Registered Class I Medical Device.
- Clinically Validated.
- Back End Reporting.
- Shelf Life – 3 Years.
- Origin – Made in USA, and Asia.
- Available in Multiple Languages.



Billing

Insurance Covered Billing/Specific CPT Codes. This easy-to-use test can be performed by either the patient at check-in or staff administered during normal patient assessment. Billing for the MSP™ tests can be added to your normal office patient assessment checkup cost structure or can be billed more specifically using CPT 92700 Billing Code R.43. Olfactory Test (Smell & Taste Disorders).

The Product

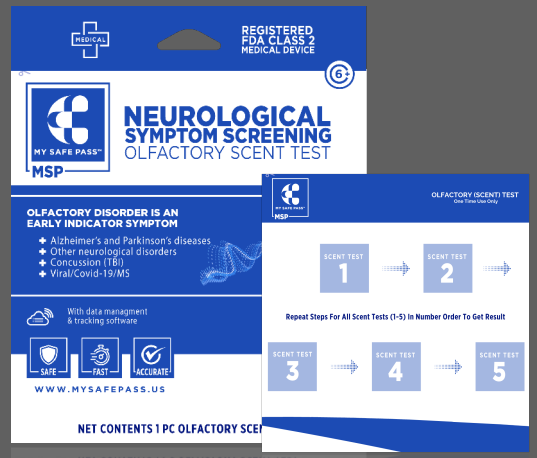
Discover the power of MY SAFE PASS™ with our three specialized products: the MSP Neurological Symptom Screening Test Kit, MSP Concussion Symptom Screening Test Kit, and MSP Covid-19 Symptom Screening Test Kit. Each kit is meticulously designed to assess and screen for symptoms associated with neurological disorders, concussions, and COVID-19, respectively. A key focus of these tests is the evaluation of olfactory loss, a prominent symptom found across these conditions. By incorporating olfactory testing into each kit, MY SAFE PASS™ equips users with an effective tool to identify and address potential issues, enabling proactive management and personalized care.

MY SAFE PASS™ Neurological Symptom Screening
Master SKU: 2023-020714
Master UPC: 00850048978225
Product SKU: 020722-01
Product UPC: 850048978232

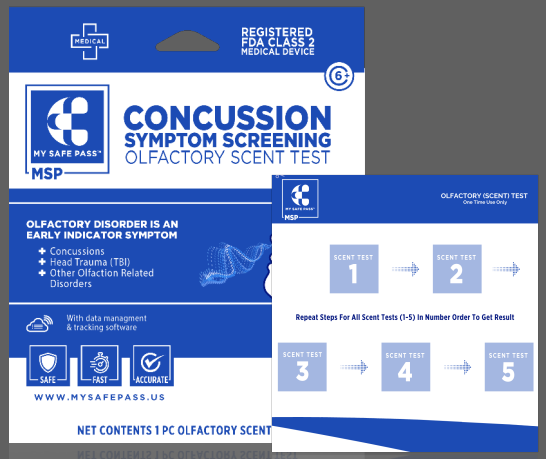
MY SAFE PASS™ Concussion Symptom Screening
Master SKU: 2023-020715
Master UPC: 00850048978249
Product SKU: 020722-02
Product UPC: 850048978256

MY SAFE PASS™ Screen for Covid-19 Symptoms
Master SKU: 2022-022408
Master UPC: 00858990004313
Product SKU: 022422-01
Product UPC: 858990004467

MY SAFE PASS™
Neurological Symptom Screening



MY SAFE PASS™
Concussion Symptom Screening



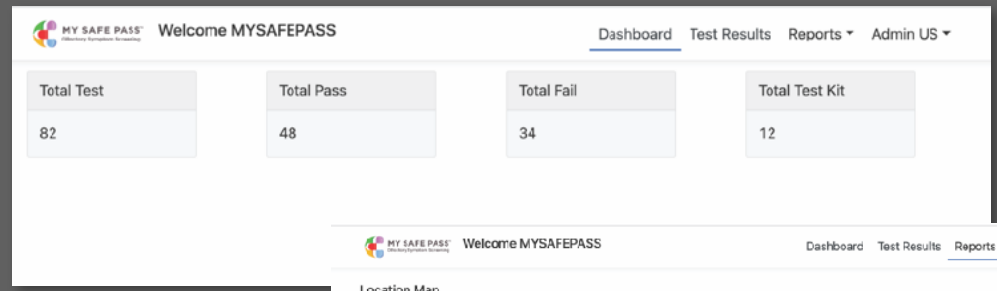
MY SAFE PASS™ Screen
for Covid-19 Symptoms

Backend Data & Reporting

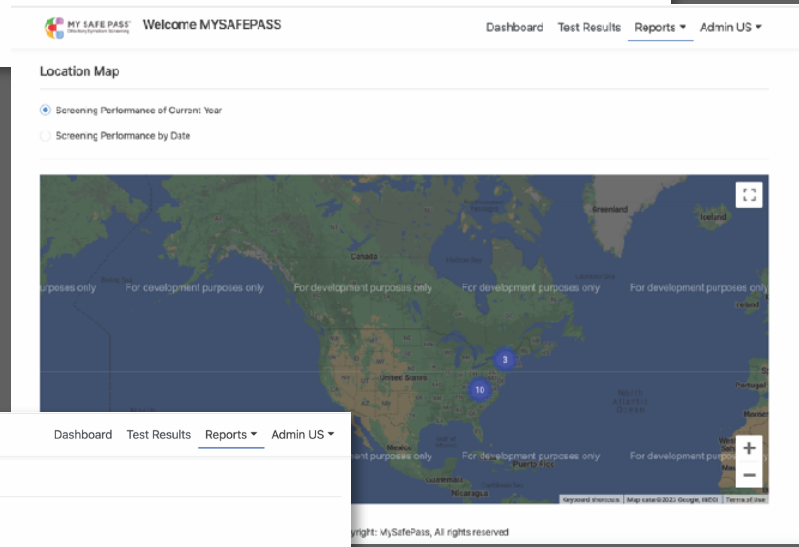
The robust back-end reporting system of My Safe Pass™ offers real-time data reporting, including age, gender, approximate location, time, and pass/fail data. This comprehensive suite of information provides practitioners and employers with a powerful tool for swift symptom detection. By analyzing aggregated data in real-time, practitioners can gain valuable insights into symptom patterns and trends, facilitating the prompt identification of potential issues.

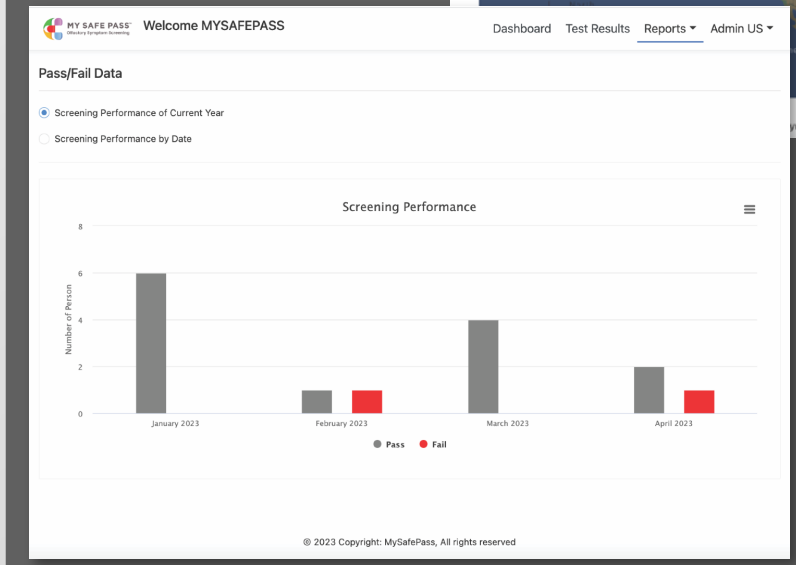
The reporting functionality allows practitioners to monitor the prevalence and severity of symptoms, particularly focusing on olfactory disorders, a key indicator for neurological issues, concussions, and COVID-19 infections. With this data-driven approach, practitioners can proactively intervene, seek timely medical attention, and make informed decisions about their patients' health. The advanced back-end reporting of My Safe Pass™ empowers practitioners and users to collaboratively work towards better health outcomes by enabling early symptom detection and intervention.

Practitioner Management Dashboard



Real Time-Date & Precise Location Masking





Access pass, fail and screening data.

App Walkthrough

Step 1: Scan QR code to gain access to app.

Step 2: Sign in.

Step 3: Scan QR code to gain access to test.

Step 4: Rub Scent 1 and press correct scent.

Step 5: Select intensity of scent.

Step 6: Repeat for remaining scents.

Step 7: Answer questions.

Step 8: Receive results.

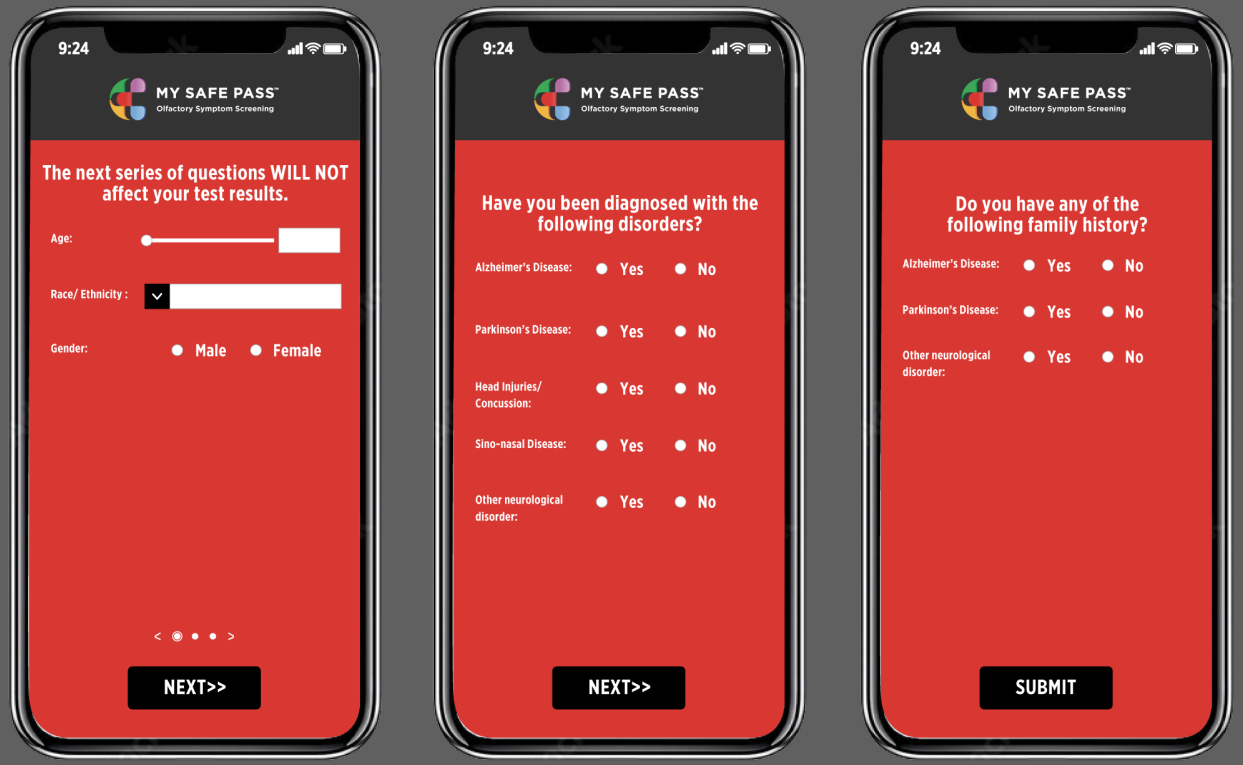
Step 9: Email results.

App Walkthrough: Health Questions

Screen 1
The next series of questions Will Not affect your test results.
- Age:
- Race/ Ethnicity:
- Gender:

Screen 2
Have you been diagnosed with the following disorders?
- Alzheimer's Disease
- Head Injuries/Concussion
- Sino-Nasal Disease
- Other Neurological Disorder

Screen 3
Do you have any of the following family history?
- Alzheimer's Disease
- Parkinson's Disease
- Other Neurological Disorders

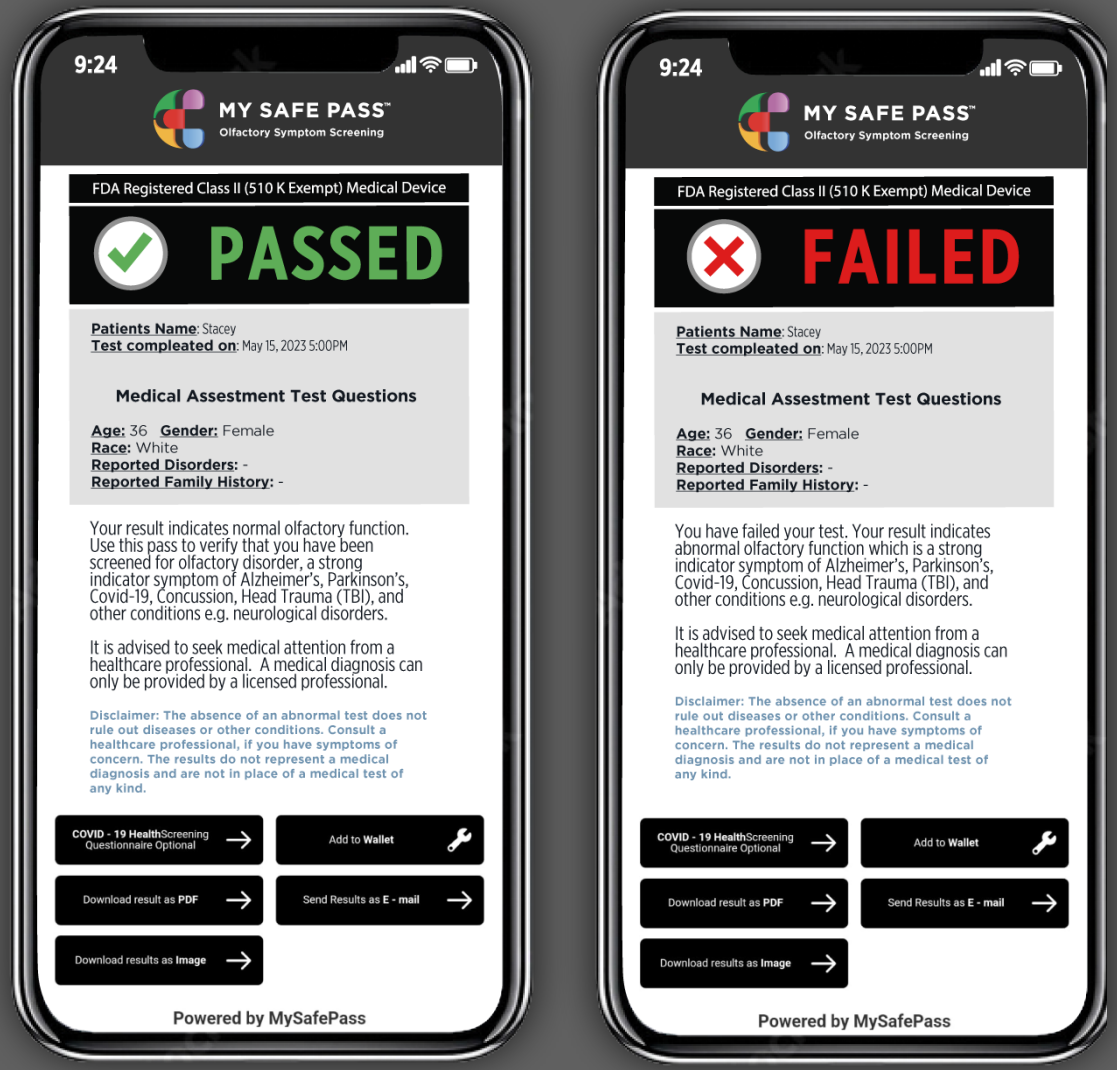


App Walkthrough: PASSED vs. FAILED

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.

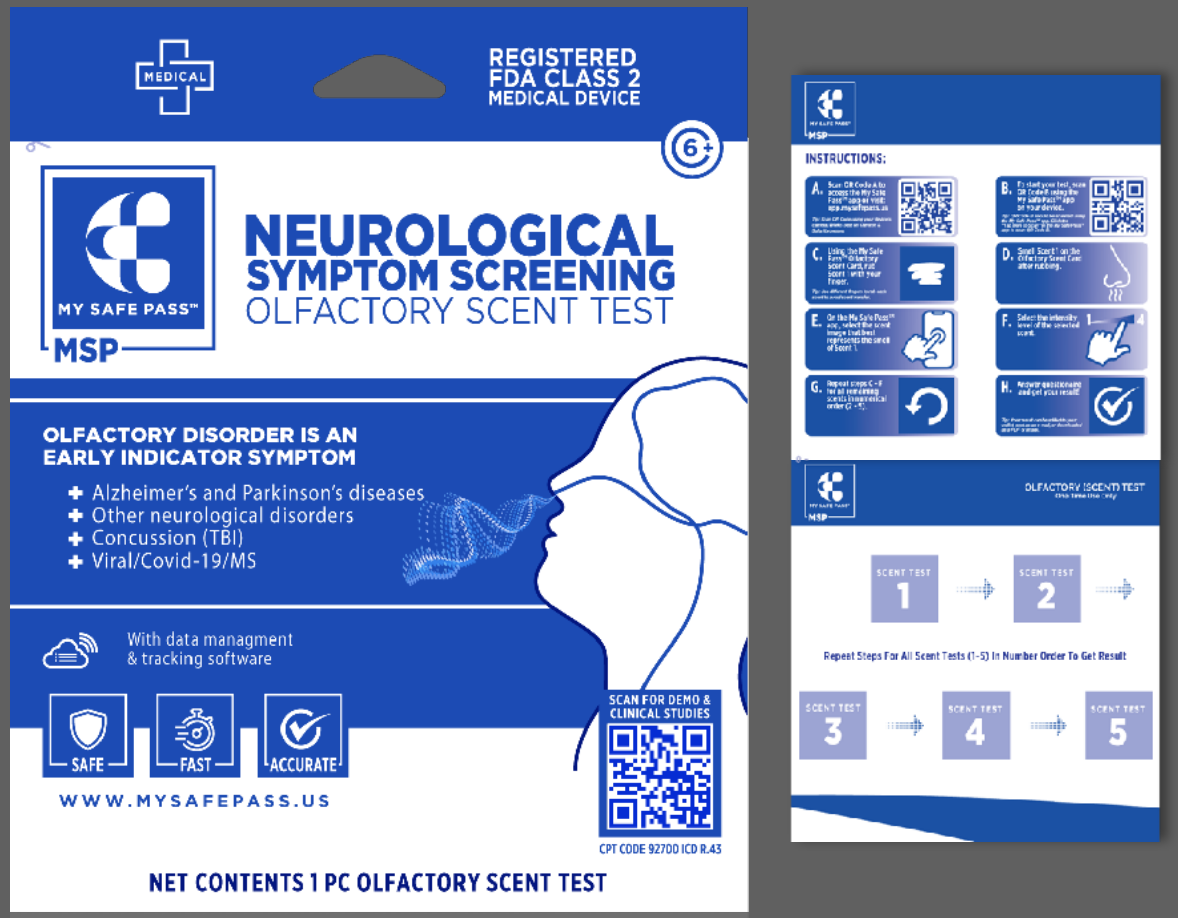
- Save your PASSED result to wallet.
- Scannable QR Code can be used to validate results.
- Show PASSED or FAILED for validation of results with participating partners.
- A FAILED result will prompt you to seek additional attention from a health care provider.
- Allows for instant patient diagnosis from 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.*



MSP Neurological Symptom Screening Test Kit

Olfactory loss, the diminished sense of smell, is a significant symptom associated with various neurological conditions. By utilizing MY SAFE PASS™ , healthcare professionals can quickly and accurately assess the presence of olfactory loss, aiding in the early detection and diagnosis of neurological disorders. The test's non-invasive nature and ease of use make it an accessible tool for patients of all ages. By identifying olfactory loss as a potential symptom, MY SAFE PASS™ empowers medical practitioners to initiate timely interventions and personalized treatment plans, enhancing the overall management and care of individuals affected by neurological disorders.



Olfactory Disorder and Neurological Diseases

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).

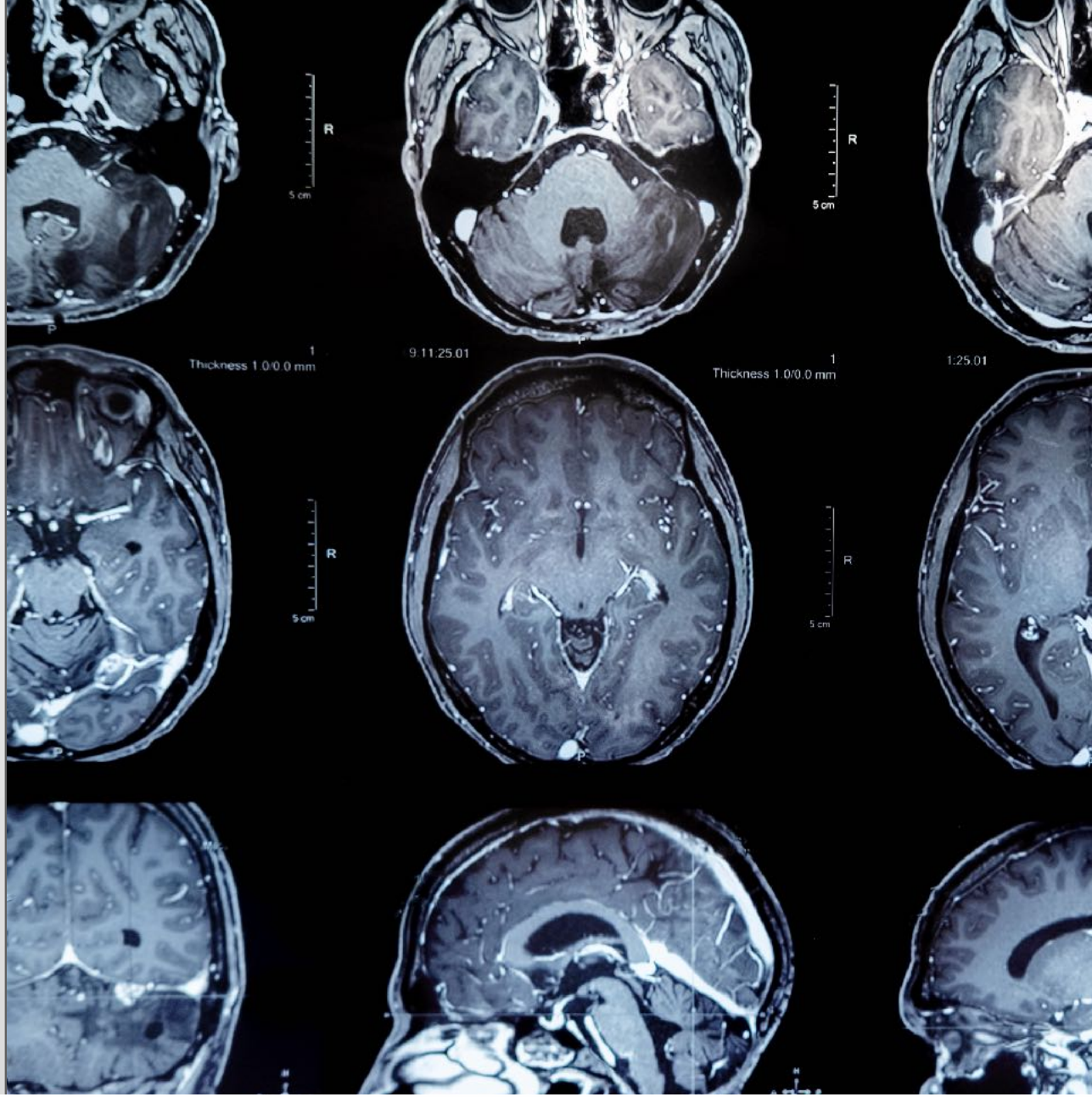
Loss of smell is a hallmark symptom in the earliest stages of many diseases. Recent studies of brains from Alzheimer's and Parkinson's Disease patients reveal structural and biochemical alterations in regions associated with the sense of smell.

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.

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

Olfactory Disorder and 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



1. *Nature Neurology*

MSP Concussion Symptom Screening Test Kit

MY SAFE PASS™ offers significant benefits as a symptom indicator for concussions, catering to a wide range of scenarios, including football players, EMS personnel, and individuals with falls or head trauma injuries. Concussions are a common concern in contact sports and accidents involving head injuries. MY SAFE PASS™ provides a valuable solution for quick symptom screening, including the assessment of olfactory loss, a prominent indicator of concussions. Football players can utilize the test to promptly identify potential head injuries on the field, while EMS personnel can leverage it to rapidly screen individuals involved in accidents. Additionally, MY SAFE PASS™ can be used by medical professionals to assess symptoms in individuals who have experienced falls or head trauma. By incorporating MY SAFE PASS™ into these contexts, timely detection of concussions is enabled, allowing for immediate medical attention and appropriate care, thus promoting safety and well-being in various settings.

Olfactory Disorder and Concussions

It is of mild TBI, a majority of patients have impaired olfactory functiowell-established that major Traumatic Brain Injury (TBI) can lead to various side effects, including the loss of the sense of smell. However, recent research has unveiled that even minor concussions can have the same effect. In fact, around 65 percent of individuals with mild concussions have reported experiencing these symptoms. During the acute phase n.

To enhance player safety and protect against further injury in contact sports, MY SAFE PASS™ ™ can serve as an additional screening tool for contact sport protocols. Careful treatment of concussions is crucial as symptoms can persist for extended periods. If left untreated, concussion patients face a higher risk of experiencing subsequent concussions, which can significantly worsen both the intensity and duration of symptoms.

Surprisingly, despite the common occurrence of smell loss following head injuries, a test of olfactory function is not currently included in the concussion protocol. This is where our real-time test of olfactory function and CTE (Chronic Traumatic Encephalopathy) comes into play as a game-changer. Administered by a single technician, our 60-second smell test can objectively detect this prevalent consequence of head trauma. MY SAFE PASS™ aids in this regard.

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

MSP Covid-19 Symptom Screening Test Kit

MY SAFE PASS™ offers substantial benefits as a symptom indicator for COVID-19, leveraging the unique characteristic of olfactory loss. Unlike flu or allergies, COVID-19 often presents with the loss of smell as an early and distinct symptom, typically occurring within the first few days of onset. This makes MY SAFE PASS™ a valuable tool for quick and early detection, especially when antigen tests might not yet detect the infection due to the low viral load. By providing a non-invasive and self-administered screening option, MY SAFE PASS™ allows individuals to easily check for unnoticed symptoms. This not only aids in prompt identification of potential COVID-19 cases but also facilitates early isolation and appropriate medical care, contributing to effective control and prevention of transmission.

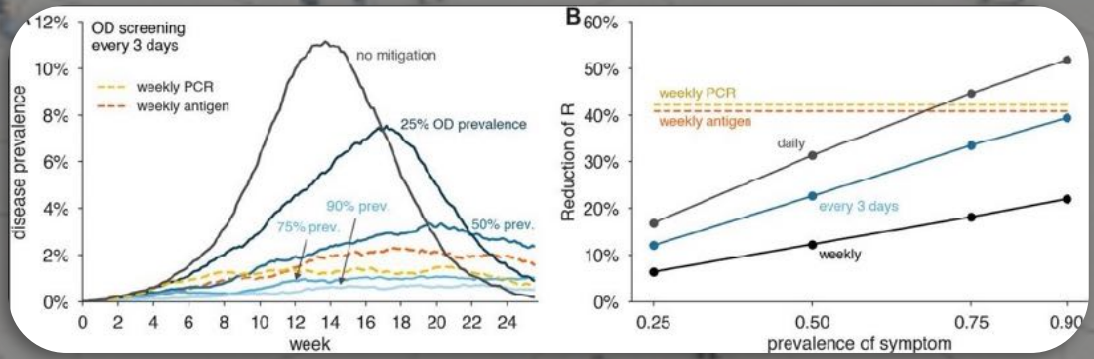
Stop the Spread Early: Covid-19

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]

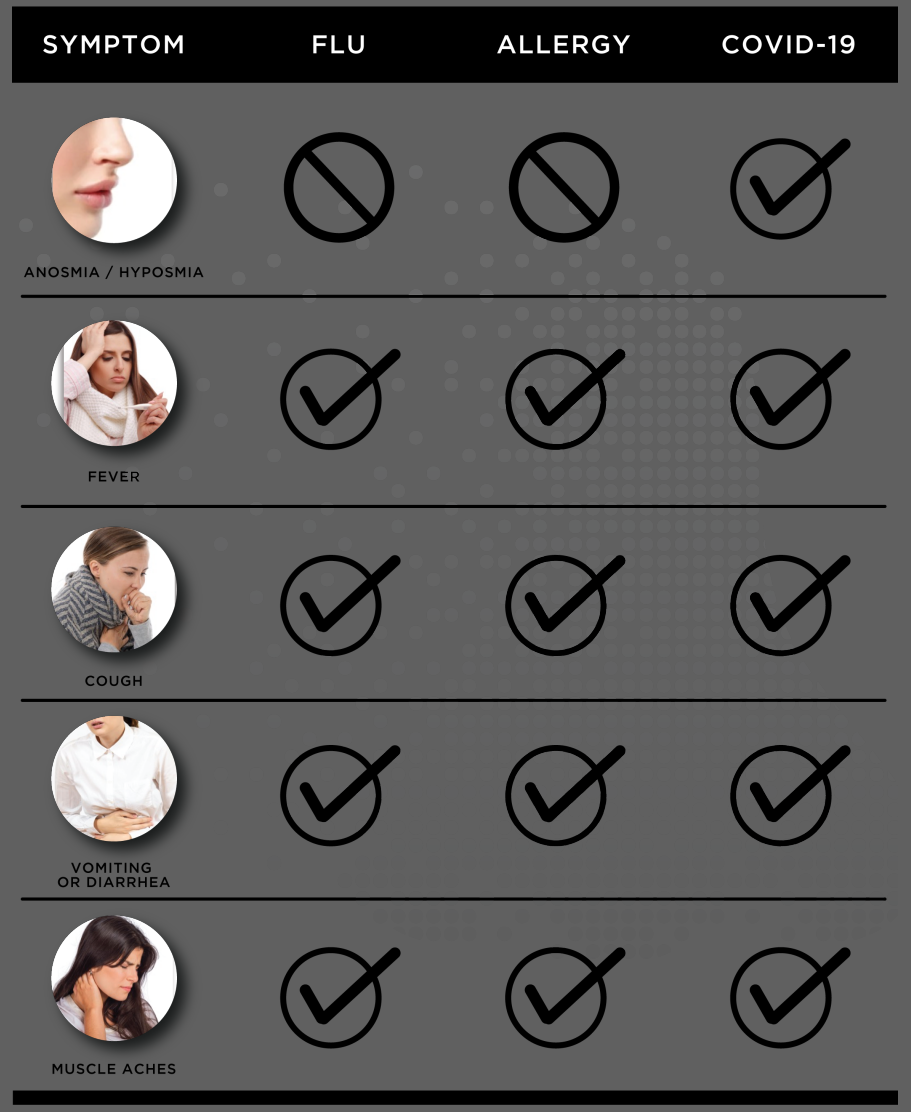
1. Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission | medRxiv

Covid-19: 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

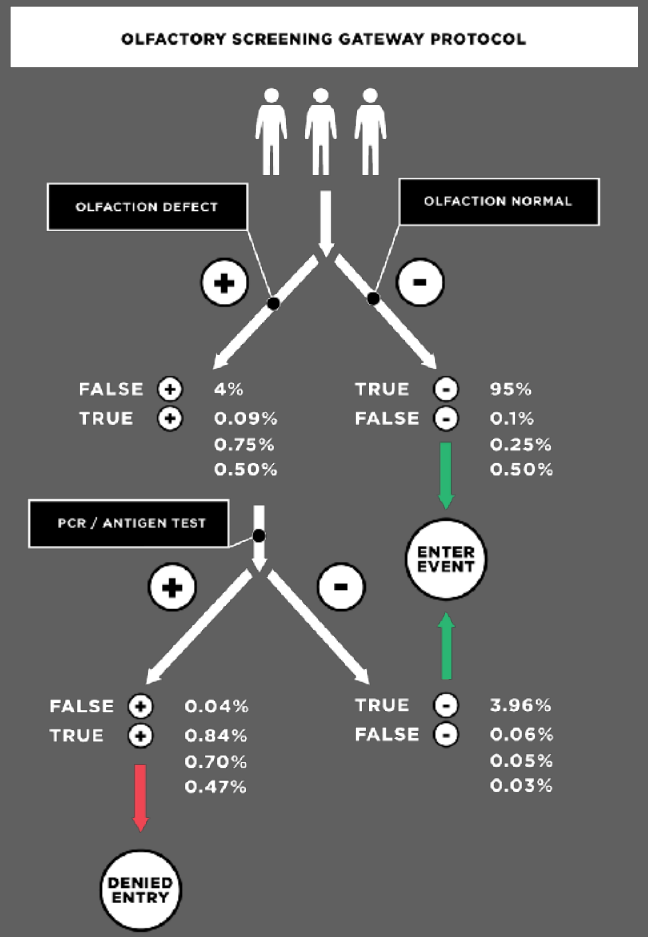


1. Smell and Taste Dysfunction in Patients With COVID-19: A Systematic Review and Meta-analysis
2. https://www.newsobserver.com/news/coronavirus/article243567982.html
3. Fever checks are a flawed way to flag Covid-19 cases. Experts say smell tests might help
4. Augmented Curation of Clinical Notes from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

Real World Modeling Airport Entry Example Covid-19

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.



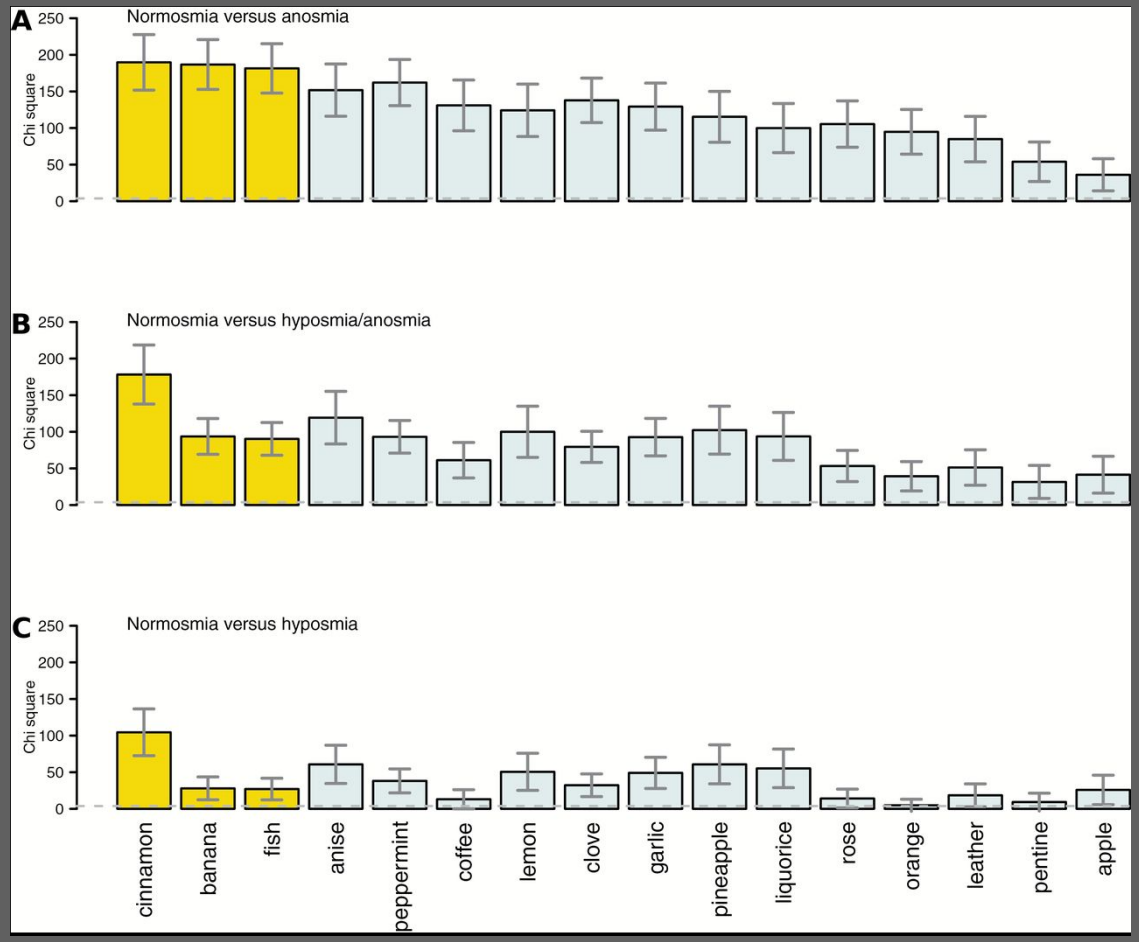
SYMPTOM PREVELANCE	INFECTION REMOVED	FALSE POSITIVES DENIED ENTRY
90%	84%	0.06%
75%	70%	0.05%
50%	47%	0.03%

Clinical Studies

5 Scent odorant olfactory clinical validation studies:

Extensive clinical studies have demonstrated that these five odorants alone are more than sufficient in determining the presence of olfactory loss. The selection of these specific odorants is based on their ability to target various olfactory receptors and represent different odor categories. This streamlined approach ensures a focused and efficient evaluation of the individual's sense of smell. By utilizing a concise set of odorants, MY SAFE PASS™ optimizes the testing process, reducing time and complexity while maintaining a high level of accuracy in identifying olfactory dysfunction. The validation of these five odorants through clinical studies provides confidence in the reliability and effectiveness of the MSP as a valuable tool for assessing olfactory disorders.

1. MSP exceeds minima odorant detection requirements: How Many and Which Odor Identification Items Are Needed to Establish Normal Olfactory Function?
2. Five-item odorant test as an indicator of COVID-19 infection in a general population
3. The usefulness of a quantitative olfactory test for the detection of COVID-19

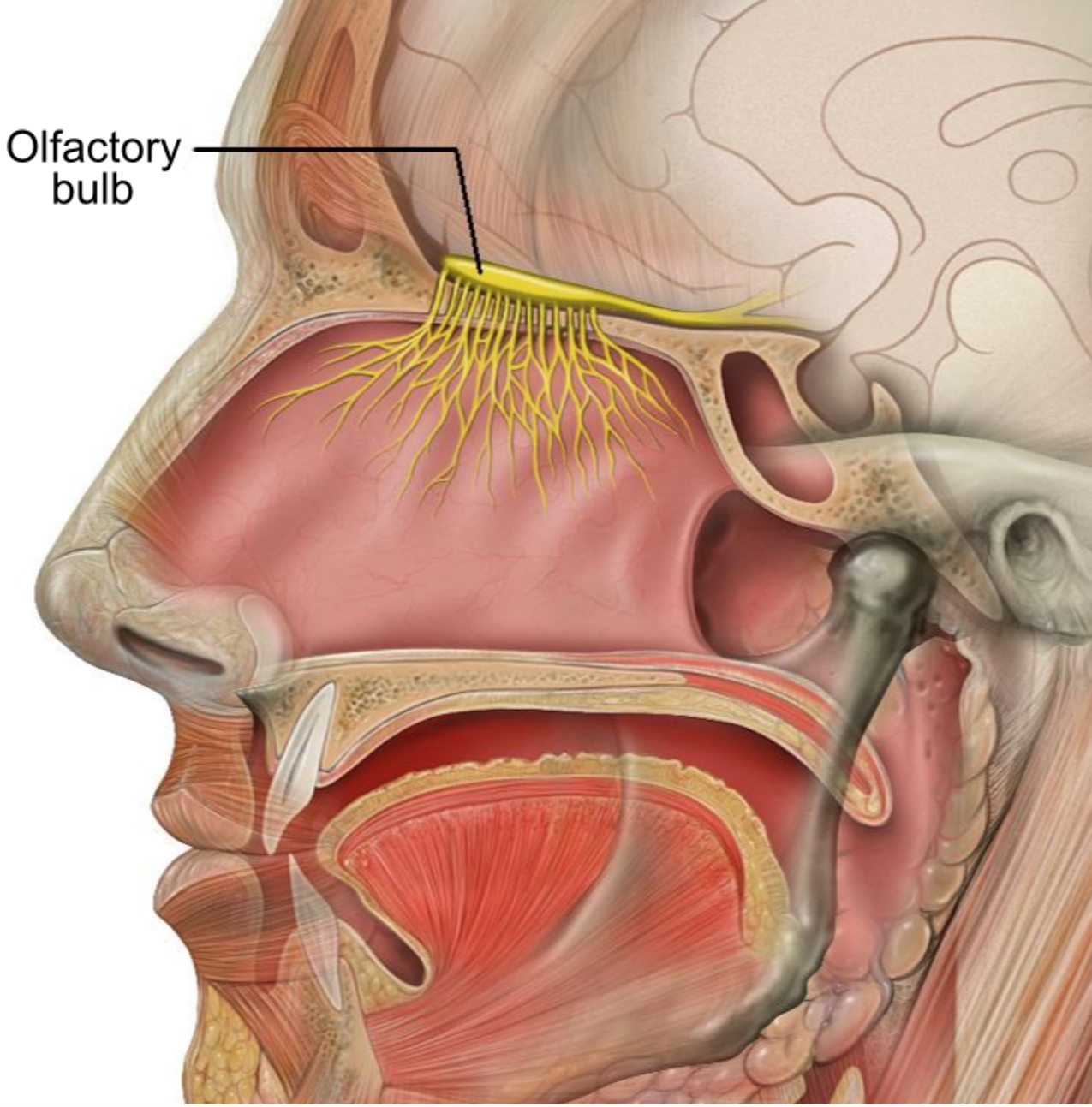


Clinical Studies

Validations and Clinical Studies Concussion:

Multiple clinical studies have consistently established a significant association between concussion and olfactory loss. Individuals who have experienced traumatic brain injury (TBI), ranging from major concussions to minor ones, frequently exhibit noticeably diminished olfactory function. This connection has long been recognized, as it is well-documented that individuals with a major concussion may temporarily lose their sense of smell and experience emotional issues like anxiety and depression. However, recent research has revealed that even individuals who sustain a minor concussion can encounter similar effects. These findings emphasize the importance of assessing olfactory function in individuals with any degree of TBI and recognizing the need for treatment and intervention.

1. ScienceDaily. (2019, July 23). Hit your head, lose your sense of smell. ScienceDaily.
2. Olfactory, cognitive and affective dysfunction assessed 24 hours and one year after a mild Traumatic Brain Injury (mTBI). Journal of Clinical and Experimental Neuropsychology
3. Traumatic brain injury and olfaction: a systematic review. Frontiers in Neurology
4. Increases of Phospho-Tau (Ser202/Thr205) in the Olfactory Regions Are Associated With Impaired EEG and Olfactory Behavior in Traumatic Brain Injury Mice. Research Square
5. Olfactory Dysfunction in Traumatic Brain Injury: the Role of Neurogenesis



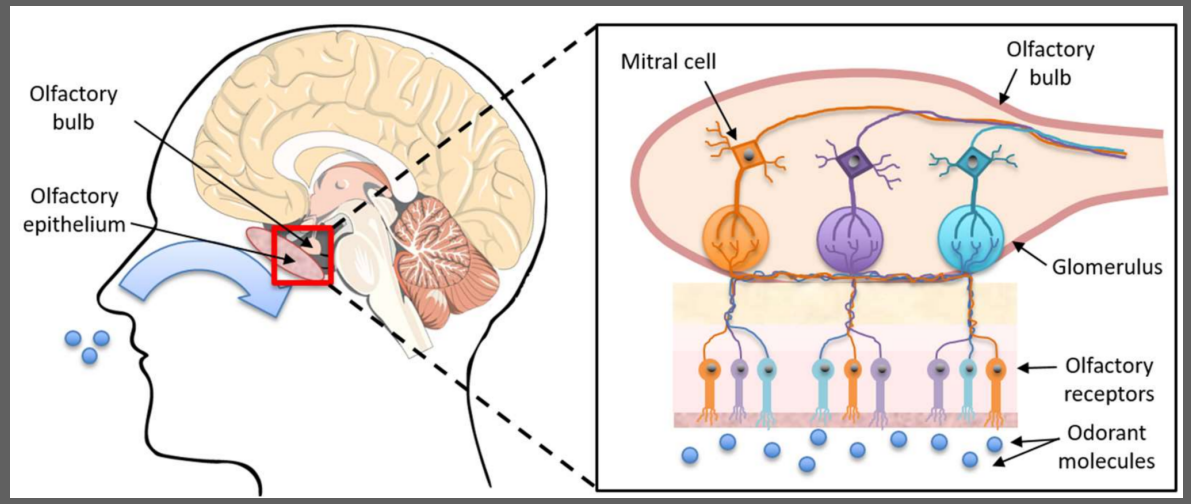
Clinical Studies

Validations and Clinical Studies Neurological Disorders Including Alzheimer's and Parkinson's:

Numerous clinical studies have provided robust evidence supporting the link between olfactory disorders and neurological conditions. Olfactory dysfunction has emerged as a key symptom indicator and a potential biomarker in various neurological disorders. Research has extensively validated the role of olfaction as an early marker of Parkinson's disease and Alzheimer's disease. Patients with these conditions often experience a significant decline in their sense of smell, even in the early stages before other symptoms manifest. Additionally, studies have established a correlation between the loss of smell and cognitive impairment in Alzheimer's disease. The identification of olfactory disorders as a clinical marker and their association with these neurological diseases underscores the importance of assessing olfactory function as a diagnostic tool and potential therapeutic target in the management of these conditions.

1. Olfaction as an early marker of Parkinson's disease and Alzheimer's disease
2. Olfaction, Cognitive Impairment, and PET Biomarkers in Community-Dwelling Older Adults
3. Olfaction, Cognitive Impairment, and PET Biomarkers in Community-Dwelling Older Adults
4. Molecular and Genetic Factors Involved in Olfactory and Gustatory Deficits and Associations with Microbiota in Parkinson's Disease
5. Olfaction, Cognitive Impairment, and PET Biomarkers in Community-Dwelling Older Adults
6. Olfactory Dysfunction in Neurodegenerative Diseases
7. Olfaction as an early marker of Parkinson's disease and Alzheimer's disease

Olfactory Dysfunction as a Global Biomarker for Sniffing out Alzheimer's Disease: A Meta-Analysis



https://www.mdpi.com/2079-6374/8/2/41#

Clinical Studies

Validations and Clinical Studies Olfactory Disorder and Covid-19

Extensive clinical validation has confirmed that olfactory disorder serves as a prominent symptom indicator in COVID-19. 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. 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). Notably, olfactory dysfunction tends to manifest early in the infection, typically occurring between day 1 and day 3 when the viral load is relatively low. This early presentation of olfactory disorder provides a crucial opportunity for early detection and containment of the virus, particularly during a period when antigen tests may not yet yield positive results. By recognizing the presence of olfactory dysfunction as a key symptom in COVID-19, healthcare providers and individuals can be more vigilant in identifying potential cases and taking appropriate measures to prevent further spread of the virus.

1. Smell and Taste Dysfunction in Patients With COVID-19: A Systematic Review and Meta-analysis
2. Elevated ACE2 expression in the olfactory neuroepithelium: implications for anosmia and upper respiratory SARS-CoV-2 entry and replication
3. Augmented Curation of Clinical Notes from a Massive EHR System Reveals Symptoms of Impending COVID-19 Diagnosis
4. Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission
5. The usefulness of a quantitative olfactory test for the detection of COVID-19
6. COVID-19 Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0

"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

Clinical Studies

Validations and Clinical Studies - 5 Scent Odorant Olfactory Testing for Covid-19:

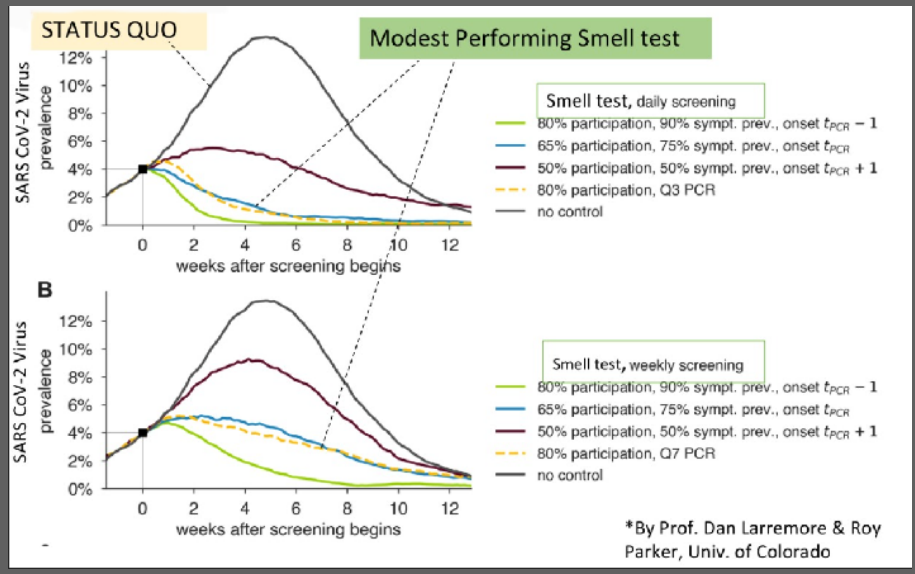
The modeling paper that was published in Nature Communications showed that an olfactory screening every one or two days could outperform weekly PCR tests to mitigate Covid-19 transmission.

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

1. Clinical validation of an open-access SARSCOV-2 antigen detection lateral flow assay, compared to commercially available assays
2. The usefulness of a quantitative olfactory test for the detection of Covid-19.
3. Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission



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Clinical Studies

Validations and Clinical Studies on 5 Point Olfactory Testing More Accurate in Detecting Covid-19 at Low Viral Loads vs. Antigen & PCR Tests

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

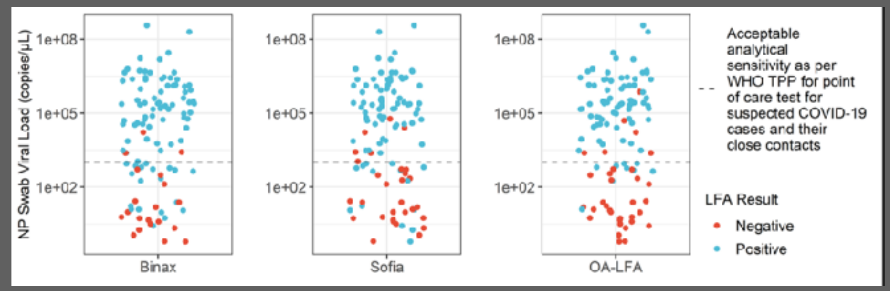
Clinical validation of an open-access SARS-COV-2 antigen detection lateral flow assay, compared to commercially available assays

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 SARSCOV-2 antigen detection lateral flow assay, compared to commercially available assays

Manufacturing

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

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