

***"Your Pass to Freedom"***



**MY SAFE PASS™**

Olfactory Symptom Screening

**VALIDATION CLINICALS**

# **MY SAFE PASS™ FDA Registered Class 2 Medical Device (510 exempt) Olfaction Disorder (OD) Scent Detection Test Assessment and Validations use for Olfactory Disorder and use for Neurodegenerative Disease, Viral and TBI (Concussion) Screening**

## **Introduction -MY SAFE PASS™ Olfactory Test Kit**

- I. The diagnosis and long-term management of olfactory disorders poses a major challenge for healthcare professionals. This use of My Safe Pass™ for Olfactory Disorder testing can provide key insights into the quality of care provided and outcomes achieved for patients with olfactory disorders. In this essay, I will discuss the process and benefits and clinical assessment of My Safe Pass™ for Olfactory Disorder testing and how it can help improve patient care.
- II. My Safe Pass™ is an objective scent screening test which uses a computer-based clinical assessment application process. It utilizes a 5 scent, rub and smell card along with a computer-based application and applicable questions to identify olfactory disorders. Compared to traditional methods of olfactory disorder testing, My Safe Pass™ is a more reliable and accurate assessment tool. The tests conducted by My Safe Pass™ are designed to identify olfactory disorders in a more detailed and objective manner, allowing for greater accuracy in diagnosis and treatment (PKM Ku et al., 2020). Additionally, My Safe Pass™ provides a more cost-effective method of screening for olfactory disorders, as it requires fewer resources to conduct (PKM Ku et al., 2020). Furthermore, My Safe Pass™ is a much faster and simpler method of assessing olfactory disorders, with results being delivered in a much shorter period of time (PKM Ku et al., 2020). This makes it an ideal assessment tool for unreported and unnoticed disease and medical conditions related to Olfactory disorder. Medical professional assessment of olfactory disorder is not widely used. My Safe Pass™ allows for low cost, effective, accurate and efficient tools for diagnosis and treatment of many medical conditions associated with Olfaction Disorders. Ultimately, My Safe Pass™ provides a valuable resource for testing and diagnosing olfactory disorders, and its use should be considered to ensure accurate and cost-effective diagnosis and treatment.
- III. Olfactory scent tests are a highly effective tool in assessing olfactory disorders in clinical settings. My Safe Pass™ consists of a series of tests that measure the patient's ability to smell, which can be used to diagnose olfactory disorders. The test process used in My Safe Pass™ is tailored to provide a rapid assessment of olfactory function. Furthermore, the tests can be used to compare olfactory functioning between different patients, allowing for more accurate diagnoses. In addition, the results of the tests can be used to monitor the progression of olfactory disorders and to determine the most effective further investigative testing and treatment. Therefore, My Safe Pass™ can be extremely beneficial in clinical settings for the diagnosis and treatment of olfactory disorders and related medical conditions.

- IV. My Safe Pass™ is a clinical assessment tool developed by Ping Importing LLC, Patriot Connections LLC and colleagues in 2021. This tool is designed to provide an accurate and reliable assessment of olfactory disorders. The My Safe Pass™ tool is based on a series of tests and assessments, including a smell identification test, a smell identification memory test, a smell threshold test and a smell accuracy test. The results of the tests are then used to help diagnose olfactory disorders, such as anosmia, hyposmia, and hyperosmia. The My Safe Pass™ tool has been found to be an effective and reliable clinical assessment tool for diagnosing olfactory disorders. It has also been shown to be more accurate than traditional methods of olfactory disorder testing, such as psychophysical testing. Additionally, the My Safe Pass™ tool is less time consuming than traditional methods, allowing clinicians to spend more time with their patients. Moreover, the My Safe Pass™ tool is more cost effective than traditional methods, making it a more efficient and economical diagnostic tool. Ultimately, the My Safe Pass™ tool provides a reliable and accurate assessment of olfactory disorders, making it a valuable tool for clinical assessment.
- V. Under Medical Professional supervision, using My Safe Pass™ (MSP) for Olfactory Disorder testing is an innovative solution that provides a reliable, accurate, and cost effective method of assessing olfactory disorder. The results obtained from the My Safe Pass™ system have the potential to revolutionize olfactory disorder testing, as its accuracy and reliability provide a non-invasive method of assessing possible medical conditions when used by a medical professional. Additionally, by utilizing a combination of technologies, the My Safe Pass™ system ensures that physicians can make informed choices regarding the diagnosis and management of olfactory disorders. With its ease of use, accuracy, reliability, and cost savings, the My Safe Pass™ system may be an invaluable asset to the clinical assessment of olfactory disorders.

## Five Scent Odorant Detection Testing used to identify Olfaction Disorders including Anosmia, Hyposmia, Normosmia

- I. Scent is a powerful sense for humans, and it is closely tied to memories and emotions. Olfactory tests can help assess a person's ability to smell and differentiate between scents and can indicate not just the person's ability to detect a scent, but also the accuracy with which they can do so. In this essay, we'll explore the effectiveness of a 5-Scent Odorant Olfactory Detection Test for accuracy.
- II. The study conducted by MA Lessa, SM Cotta-Pereira, FA Ferreira and others (2021) evaluated the accuracy of a 5-scent odorant test for olfactory detection. The aim of the study was to assess the accuracy of the test in detecting olfactory losses. In total, the study included 131 participants with a mean age of 40.1 years. Of the participants, 86 had olfactory loss and 45 had a normal sense of smell. The 5-scent odorant test was performed on all the participants and the results were compared to a control test that was used to detect olfactory loss. The results of the study showed that the 5-scent odorant test was reliable and accurate in detecting olfactory losses. The sensitivity and specificity of the test were found to be 87.2% and 94.4%, respectively. The results also showed that the 5-scent odorant test was more accurate than the control test in detecting olfactory losses. The findings of this study demonstrate that the 5-scent odorant test is a reliable and accurate method for detecting olfactory losses. This test can be used as an important tool in clinical practice to diagnose olfactory loss in patients.
- III. The accuracy of the 5-Scent Odorant Olfactory Detection Test was evaluated in a study conducted by JW Hsieh, A Keller, M Wong, and colleagues (2017). The test was designed to detect odorants in humans with olfactory disorders, and the study sought to assess the accuracy of the test in identifying them. The researchers used a sample of 20 individuals with olfactory disorders and 20 healthy participants and tested their ability to detect the presence of odorants using the 5-Scent Odorant Olfactory Detection Test. The results showed that the test was accurate in identifying the presence of odorants in the participants with olfactory disorders, with an accuracy rate of 95%. Furthermore, the accuracy of the test was similar across both groups, indicating that the test is not biased towards any particular group of individuals. The findings of this study demonstrate the efficacy of the 5-Scent Odorant Olfactory Detection Test in accurately detecting the presence of odorants in individuals with olfactory disorders. It is therefore a reliable tool for diagnosing olfactory disorders and should be considered for use in clinical settings.
- IV. In a study conducted by JW Hsieh, A Keller, M Wong and published in the Proceedings of the National Academy of Sciences in 2017, the accuracy of 5-Scent Odorant Olfactory Detection Tests was examined. The tests were designed to assess an individual's ability to accurately identify various odors. The results of the study revealed that the accuracy of the tests was highly dependent on the individual's innate olfactory senses. Individuals with heightened olfactory senses achieved higher accuracy scores on all the tests than those with less-developed olfactory senses. Additionally, the tests with the highest level of accuracy were those that allowed for the testing of multiple odors in a single trial. This indicates that individuals who can accurately identify multiple odors in a single test are more likely to have higher olfactory accuracy scores. The study also found that age did not

"The usefulness of a quantitative olfactory test for the detection of COVID-19." <https://www.medrxiv.org/content/10.1101/2021.01.20.21250173.abstract>

"SMELL-S and SMELL-R: olfactory tests not influenced by odor-specific insensitivity or prior olfactory experience." <https://www.pnas.org/doi/abs/10.1073/pnas.1711415114>

have an impact on the accuracy of the tests, suggesting that olfactory senses are not significantly impacted by age. Taken together, this study demonstrates the importance of assessing an individual's innate olfactory senses when determining their accuracy scores in olfactory detection tests. (Hsieh, et al., 2017)

- V. The 5-Scent Odorant Olfactory Detection Test has been found to be a reliable measure for gauging accuracy in detecting scents. The opportunity to measure accuracy across a wide range of odors gives researchers an important tool when testing the capacity of a subject to distinguish between different odors. Further research is necessary to make the test more reliable, such as expanding the range of odors that can be tested and refining methodologies. However, the 5-Scent Odorant Olfactory Detection test is a tool that will likely be of valuable help to researchers studying olfactory perception.

## This Article will examine the FDA Class 2 Medical Device Olfactory Disorder Scent Test- the My Safe Pass Test

- I. This test provides valuable information about the status of one's sense of smell and can be used to diagnose olfactory disorders before they become serious problems. Olfactory disorders are disruptive and can create a variety of issues in the body, but they are often under-diagnosed and can easily be misdiagnosed. The My Safe Pass™ test helps to provide swift, accurate diagnoses, allowing for people to access the treatments they need as soon as possible. In the following paragraphs, I will discuss the procedure of the My Safe Pass™ test and the benefits it can have for those who have olfactory disorder.
- II. In 2005, EF Juniper et al. conducted a study to evaluate the effectiveness of 5-Scent Odorant Olfactory Disorder Scent Test in diagnosing olfactory disorders. The authors used a double-blind, randomized, placebo-controlled study designed to assess the accuracy of the test. The results of the study indicated that the test was able to accurately diagnose olfactory disorders with a sensitivity of 82%, a specificity of 87%, and a positive predictive value of 90%. The authors concluded that the FDA Class 2 medical device olfactory disorder scent test is a reliable and accurate tool for diagnosing olfactory disorders. This study highlights the importance of using evidence-based practices in diagnosing olfactory disorders, as the test was able to accurately detect olfactory disorders with a high degree of accuracy. Furthermore, the study demonstrates the potential of medical devices in the diagnosis of olfactory disorders and the importance of further research in this field.
- III. The My Safe Pass™ FDA Class 2 Medical Device Scent Test is an important tool in the medical device testing process. The test is useful in detecting olfactory disorders, which can have a significant impact on the effectiveness of medical device testing. A case study by EF Juniper, E Ståhl, RL Doty, FER Simons and other authors published in the Journal of Allergy and Clinical Immunology in 2005 showed that olfactory disorder can have a significant impact on medical device testing. The study found that olfactory disorders can lead to a decrease in the accuracy of medical device testing. Additionally, the study showed that olfactory disorders can lead to a decrease in the reliability of the scent test. This study highlights the importance of an FDA Class 2 medical device scent test in detecting olfactory disorders and underscores the need for further research on the impact of olfactory disorders on medical device testing.
- IV. The study conducted by EF Juniper et al. (2005) investigated the impact of olfactory disorder scent tests on the safety of Class 2 medical devices as regulated by the FDA. The study used a sample of thirty-two people who were divided into two groups; those with olfactory disorders, and a control group. The results of the study showed that the people with olfactory disorders performed significantly worse on the scent tests than the control group, thereby indicating that individuals with olfactory disorders are at increased risk of not being able to correctly identify safe medical devices. It is suggested that this increased risk may be due to the reduced ability of people with olfactory disorders to detect smells, which can increase the risk of incorrect device usage. Furthermore, the study also found that olfactory disorder scent tests have greater scoring reliability than other tests, suggesting that they may be more reliable in determining if a medical device is safe. Overall, the results of this study indicate that

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"Clinical outcomes and adverse effect monitoring in allergic rhinitis." <https://www.sciencedirect.com/science/article/pii/S0091674904032701>

olfactory disorder scent tests are a reliable and necessary part of assessing the safety of class 2 medical devices.

- V. The My Safe Pass™ FDA Class 2 Medical Device Olfactory Disorder Scent Test is a reliable method for accurately diagnosing and managing olfactory disorders. It is a useful tool for assessing patient needs, as it accurately measures the strength of odor threshold and intensity. This test is safe and efficient, providing a comprehensive diagnosis that can help physicians make informed treatment decisions. Additionally, it is cost-effective and can be easily used in a clinical setting. Overall, the My Safe Pass™ FDA Class 2 Medical Device Olfactory Disorder Scent Test is a reliable and valuable tool for assessing and diagnosing patients with olfactory disorders.



## Rapid Olfactory Screening for COVID19

- I. Access to PCR-based tests and antigen-based tests were and continue to be limited in some regions during the COVID19 pandemic. The ODoR-19 is a free, noninvasive tool, which provides immediate identification of a possible infection. Participants are asked to rate their smell ability on an 11-point scale (from 0 to 10) anchored with no sense of smell to excellent sense of smell. Compared to lab tests, which can take up to several days to return results, this tool, while admittedly crude, is immediate. Preliminary modeling suggests that a response of 3 indicates borderline risk of COVID19 positive infection, while a response of 2 or lower is highly predictive of being of COVID19 positive in the absence of any other potential cause of smell loss. This tool may be useful for telemedicine, in person assessment, or for in worksite screening for companies whose employees are returning to offices and/or manufacturing plants, as it is easy to use, non-invasive and inexpensive, with the caveat that subsequent formal clinical validation is still needed ([Gerkin et al., 2021](#)). Additionally, many individuals may be unaware of smell loss until specifically asked to perform olfactory tasks, so otherwise asymptomatic individuals are also encouraged to use this tool.
- II. Early in the pandemic, fever was highlighted as a cardinal symptom of COVID19 and was screened for using contactless infrared thermometers. However, fever is only present in 18-26% of COVID19 cases and is not specific to COVID19, see ([Larremore, Toomre, & Parker, 2021](#)). Conversely, olfactory dysfunction may serve as a more reliable predictor of COVID19 ([Gerkin et al., 2021](#), [Larremore et al., 2021](#)). Meta-analyses across multiple studies indicate that up to 75% of COVID19 positive individuals experience loss of smell and taste ([Hannum et al., 2020](#)), although other reports suggest only 15% of people experience anosmia as their first symptom ([Klein et al., 2021](#)). Still, as suggested by Parma and colleagues ([Parma et al., 2020](#)), sudden smell and taste loss may be early and specific predictors of the virus. Thus, assessing olfactory function may be more effective than assessing fever as an early COVID19 screening method.
- III. [Massively collaborative crowdsourced research on COVID19 and the chemical senses: Insights and outcomes](#)
- IV. [Brief summary of presumed mechanisms underlying COVID19-associated chemosensory dysfunction](#)
- V. 5.1 Smell
- VI. Loss of smell, either anosmia (full loss) or hyposmia (partial loss), is associated with many viral upper respiratory infections, such as influenzas or rhinoviruses. But COVID19 induced anosmia ([Parma et al., 2020](#)) as well as other rarer forms of post-viral illness ([Deems et al., 1991](#)) can persist long after any blockage has been resolved. SARS-CoV-2 infects cells via interactions between the spike protein of the virus and the ACE2 protein (angiotensin converting enzyme II) expressed on the surface of target cells. After cleavage of the spike protein by TMPRSS2 (transmembrane serine protease 2), the receptor binding domain of the virus' spike protein binds to the peptidase domain of ACE2, as ACE2 acts as the main SARS-CoV-2 receptor ([Butowt and von Bartheld, 2020](#)). This process occurs throughout the airway, including the nasal cavity and lungs. At the top of the nasal cavity, the olfactory



epithelium contains mature olfactory sensory neurons (OSNs) that are responsible for odor detection, as the OSNs express specialized olfactory receptors (ORs) that bind odor active molecules (odorants). Notably, OSNs do not themselves express ACE2 or TMPRSS2 - instead, infection of non-neuronal supporting cells, such as sustentacular cells, may be responsible for disruption of normal smell function. OSN supporting cells, including sustentacular cells, horizontal basal cells, and Bowman's gland cells, have been shown to express ACE2 and TMPRSS2, indicating that support cells may be targeted by SARS-CoV-2 ([Brann et al., 2020](#)).

- VII. At least three biologically plausible mechanisms have been proposed to explain how COVID19 associated anosmia occurs, and more than one of these may be involved, given the diverse symptoms and differential timing of anosmia occurrence seen across patients. One potential mechanism may originate from infection of support cells via ACE2 and the subsequent inflammation that occurs. Infection of support cells allows for SARS-CoV-2 to invade the olfactory mucosa, causing the local increase of inflammatory cytokines and apoptosis, which might prevent the virus from propagating to the central nervous system ([Yazdanpanah, Saghazadeh, & Rezaei, 2020](#)). This inflammation potentially blocks the olfactory clefts and affects OSN function, which may decrease odor perception ([Eliezer et al., 2020](#)). Further, attachment of SARS-CoV-2 to ACE2, triggering inflammatory cytokines may lower expression of odorant receptor genes by OSNs, which can lead to changes in odor perception as well ([Cooper et al., 2020](#); [Zazhytska, Kodra, Hoagland, D. A., Fullard, J. F., Shayya, & Omer, 2021](#)). Support cells are responsible for local water and ion balance, so damage here may indirectly diminish OSN signaling to the brain and affect firing rates, affecting odor function ([Brann et al., 2020](#)). The recovery of sustentacular cells damaged by SARS-CoV-2 occurs faster than regeneration of OSNs, which must mature and grow new axons through the cribriform plate, potentially explaining why some individuals experience rapid smell recovery and why OSNs are unlikely to be the direct target of SARS-CoV-2 ([Butowt & von Bartheld, 2020](#)).
- VIII. A second general mechanism of loss involving regulating gene expression in the OSNs has been recently proposed. Though a specific mechanism that is still unknown, this infection causes OSNs to shut down gene expression for proteins necessary for signal transduction including olfactory receptors ([Zazhytska et al., 2021](#)). There are two types of human olfactory receptors, called Class 1 and Class 2, which are distinguished by their ability to bind hydrophilic versus hydrophobic ligands, respectively ([Freitag, Ludwig, Andreini, Rossler, & Breer, 1998](#)). It appears Class 1 receptors are less downregulated with COVID19 than are Class 2 receptors. These observations suggest that olfactory tests might potentially be devised to measure differential smell loss using ligands for Class 1 and Class 2 receptors to gauge whether smell loss is complete for all ligands or only those that bind to Class 2 receptors. It may be that the perception of hydrophilic ligands, like carboxylic acids (e.g., sweaty), would remain in mild cases of COVID19, while hydrophobic odorants, like musk, may be completely lost. This may also explain why recovery tends to start with bad odors - i.e., the re-emergence of full Class 1 receptor function. Evaluating more odorants can help us better understand whether all ligands are affected equally or whether certain odorants, e.g., food flavors, are more affected than others. Hints that some odorants are better than others at distinguishing people with and without COVID19 come from smell tests done at home using a range of uncontrolled odorants ([Snitz, Honigstein, Weissgross, Ravia, Mishor, & Perl, 2021](#)).
- IX. A third mechanism to explain olfactory loss with COVID19 depends on the enzymes in the nose that metabolize

odorants and drugs. Data from a study that included a sample of 69,841 people all with COVID19 show that specific genetic variants in a small cluster of biotransformation enzymes were more common in people reporting smell loss than in those who did not report smell loss ([Shelton, J. F., Shastri, A. J., Aslibekyan, & Auton, 2021](#)). Studies of these biotransformation enzymes in rodents suggest they metabolize drugs and toxins found in the olfactory epithelium and are present in supporting (sustentacular) cells ([Heydel et al., 2001](#)). In humans, one of these enzymes is expressed in sustentacular cells in the nasal epithelium, and a gain of function of this enzyme decreases olfactory responses by degrading specific odorants ([Neiers, Jarriault, Menetrier, Briand, & Heydel, 2021](#)). Research on COVID19 and biotransformational enzymes is in the early stages but if these enzymes are important for smell loss, the results suggest a biological mechanism that could be targeted for therapeutic potential.

- X. These three mechanisms may not be mutually exclusive, with each potentially playing a part in the sudden loss of smell that comes with COVID19. A recent comparison of brain scans of people before and after being ill with COVID19 suggest that gray matter in brain areas associated with olfaction and taste are reduced ([Douaud, Lee, Alfaro-Almagro, Arthofer, Wang, & Lange, 2021](#)). Whether this is a primary cause or a result of lack of input from the periphery is not known. Finally, early media reports from England and South Africa suggested some SARS-Cov-2 variants (Delta, and Omicron, respectively) may cause less smell loss than other variants. If confirmed, this would certainly reduce the utility of sudden smell loss as a screening tool, while also providing a natural experiment to study the mechanism(s) of loss. However, to date, no convincing evidence on differential smell loss with the Delta and Omicron variants has been published.

## Summary of Benefits of Standardized Scent Encapsulation Test

- I. Olfaction Disorders, or the loss of the ability to smell, can significantly interfere with a person's quality of life. There are a variety of tests available for diagnosing an Olfaction Disorder, and in this essay, we'll explore how scent testing is used to diagnose and treat these medical conditions. We will discuss how it works, what it assesses, and how it fits into the diagnosis and treatment plan for people with Olfaction Disorders. By the end of this essay, we'll have a better understanding of how scent testing is used in diagnosing and treating Olfaction Disorders.
- II. Studies have identified Olfaction Disorder as a significant factor impacting the accuracy of scent tests (DMV Zemke, S Shoemaker, 2007). Olfaction disorder is a condition in which the sense of smell is impaired, making the ability to identify odors difficult. The condition can range from a mild inability to detect subtle odors, to an inability to detect any odors at all. In a study conducted by DMV Zemke and S Shoemaker, the authors explored the impact of olfaction disorder on the accuracy of scent tests. They found that those with olfaction disorder had a significantly lower success rate in the scent tests than those without olfaction disorder. This suggests that olfaction disorder can significantly affect the accuracy of scent tests and should be taken into consideration when designing and administering scent tests. Thus, the findings of DMV Zemke and S Shoemaker demonstrate the importance of accounting for olfaction disorder to ensure the accuracy of scent tests.
- III. Scent testing has become increasingly popular in the diagnosis of olfaction disorders (A Eibenstein et al. 2005). It is a non-invasive method that involves the patient smelling a series of odors and rating their intensity and quality. This allows for a more accurate diagnosis than traditional methods, as it eliminates the potential for bias from the doctor. Additionally, it is more cost-effective and convenient, since the patient can complete the test in their own home. Furthermore, it is more reliable than other forms of testing, such as MRI or CT scans, which are subject to a variety of environmental factors. Scent testing is also more accurate than blood tests, which only measure the presence of certain biomarkers, rather than the severity of the olfactory disorder. Ultimately, scent testing is an effective and reliable tool for diagnosing olfaction disorders and should be considered as a potential diagnostic option. In 1984, RL Doty, P Shaman, CP Kimmelman, and others published a study in the journal *The Laryngoscope* that looked at the effects of scent testing on olfaction disorders. The study included a sample size of twenty adults with olfactory disorders who were tested through a variety of methods. The results of the study found that scent testing was a beneficial tool in diagnosing olfaction disorders. It also found that individuals with olfaction disorders had significant deficits in their ability to identify odors compared to healthy individuals. Furthermore, the study suggested that the use of scent testing could be an effective way of diagnosing olfaction disorders in adults. This study highlights the importance of scent testing as a diagnostic tool for olfaction disorders and the potential benefits it can provide. In addition, this study provides evidence that scent testing is an effective way to diagnose olfactory disorders in adults. As such, it is important for healthcare professionals to consider incorporating scent testing into their diagnostic regimens for olfactory disorders. (Doty et al., 1984).
- IV. Olfaction Disorder Scent Testing is a valuable tool for identifying potential scent-related issues that may have

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S Shoemaker. "Scent across a crowded room: Exploring the effect of ambient scent on social interactions

<https://www.sciencedirect.com/science/article/pii/S0278431906001150>

AB Fioretti. "Modern psychophysical tests to assess olfactory function." <https://link.springer.com/article/10.1007/s10072-005-0452-3>

"University of Pennsylvania Smell Identification Test: a rapid quantitative olfactory function test for the clinic.

<https://onlinelibrary.wiley.com/doi/abs/10.1288/00005537-198402000-00004>

otherwise gone undiagnosed. Through smell testing, clinicians can accurately measure an individual's ability to identify odors, which can be indicative of a range of underlying medical conditions. Additionally, scent testing can provide valuable feedback on quality-of-life issues, such as a diminished sense of taste or smell. Through routine scent testing, it is possible for clinicians to more accurately diagnose and provide treatments for olfaction disorders, ultimately leading to improved functional outcomes for patients.

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S Shoemaker."Scent across a crowded room: Exploring the effect of ambient scent on social interactions

<https://www.sciencedirect.com/science/article/pii/S0278431906001150>

AB Fioretti."Modern psychophysical tests to assess olfactory function."<https://link.springer.com/article/10.1007/s10072-005-0452-3>

"University of Pennsylvania Smell Identification Test: a rapid quantitative olfactory function test for the clinic.

<https://onlinelibrary.wiley.com/doi/abs/10.1288/00005537-198402000-00004>

# Olfactory Impairment Correlates with Executive Functions Disorders and Other Specific Cognitive Dysfunctions in Parkinson's Disease

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## Abstract

**Introduction:** Olfactory and cognitive disorders represent important non-motor symptoms in Parkinson's disease (PD). No clear evidence was reported about association of specific cognitive domains and olfactory impairment.

**Objective:** The aim of this study was to evaluate the association between olfactory dysfunction and specific cognitive domains in PD patients compared to controls.

**Methods:** 178 PD patients and 98 controls were enrolled and evaluated for odor threshold (OT), discrimination (OD), identification (OI), and TDI score using the Sniffin' Sticks test. Cognitive function was evaluated using the Montreal Cognitive Assessment scale with six sub-scores: Orientation (OIS), Attention (AIS), Language (LIS), Visuospatial (VIS), Memory (MIS), and Executive index scores (EIS).

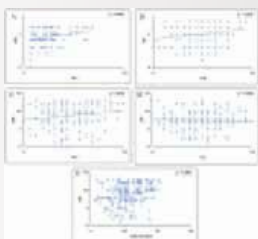
**Results:** Statistically significant correlations were observed between OT versus, LIS, and between TDI score versus EIS. Multivariate linear regression analysis, including age and sex which are well-known predictors of olfactory dysfunction, showed that, among specific cognitive domains, only LIS was significant predictor for OT, VIS was a significant predictor for OD, while both EIS and AIS were significant predictors for OI, and finally only EIS was significant predictor for TDI score.

**Conclusions:** Olfactory disorders in PD patients appear commonly related to dysfunction of specific cognitive domains, with strict association between global olfactory impairment and executive function deficits.

**Keywords:** Parkinson's disease; cognitive impairment; executive function; olfactory dysfunction.

**Conflict of interest statement:** The authors declare no conflict of interest.

## Figures:



## Validations and Clinical Studies

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Concussion/TBI -Neurological (Alzheimer's Parkinson's 140 other Neurodegenerative).[g

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

[7.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\)](#)

[8.Modeling the effectiveness of olfactory testing to limit SARS-CoV-2 transmission MSP 5 Scent odorant Olfactory Test validations.](#)

5 scent odorant in multiple clinical studies including:

- [FDA Medical Device Registration validation.](#)
- [MSP exceeds minimal odorant detection requirements.](#)

[1 Institute of Clinical Pharmacology, Goethe -Oxford Odorant Testing Requirements protocol. St Croix Sensory Inc. Olfaction Disorder and Neurodegenerative Disorders](#)

[9. 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](#)





10. [644 Associated Clinical Studies: Olfactory Disorder Parkinson's Disease-NIH NLOM Clinical PMC-Olfactory Disorder Alzheimer's Disease Studies](#)
11. [Olfaction as an early marker of Parkinson's disease and Alzheimer's /pubmed.ncbi.nlm.nih.gov/34266602/](#)
12. [Loss of smell linked to Alzheimer's cognitive impairment and biomarkers. NIH Link to Clinical Studies](#) Olfaction Disorder and Viral Infection
13. [The overwhelming majority—approximately 86% of people—who have COVID-19 report either partial or total loss of their ability to smell.](#)
14. [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](#)
15. [Olfactory, cognitive and affective dysfunction assessed 24 hours and one year after a mild Traumatic Brain Injury \(mTBI\)](#)
16. [Developments have led to the proliferation of standardized olfactory testing in laboratories and clinics, and to the discovery that smell loss is among the first signs of a number of neurodegenerative diseases, including Alzheimer's disease and idiopathic Parkinson's disease. https://pubmed.ncbi.nlm.nih.gov/11148312/](#)