Clinical Use Studies Observing the Utility Potential and Manufacturing Process Evaluation of FDA Class 2 Medical Device MSP My Safe Pass™, Utility 5-Scent Odorant Olfactory Test Kit

OBJECTIVE:

The objective of this review is to analyze the utility of the (MSP) My Safe Pass ™, a 5-item odorant olfactory test kit, and its process in determining the presence of normosmia and hyposmia olfactory disorder. Hyposmia is the loss of a spectrum of smell vs normal baseline.

Abstract

Objective: To gather, analyze, and evaluate the provided information from an unbiased self-administered and clinically administered testing and results gathering, aiming to qualify the utility of the MSP (My Safe Pass™) Olfactory test kit as a reliable olfactory test. Additionally, to determine, qualify, and demonstrate that the current MSP version meets the requirements of the 5-scent odorant tests demonstrated in the prior referenced peer-published clinical studies. This study also seeks to evaluate MSP as a FDA Class 2 olfactory scent test as a diagnostic tool to augment the objective exam to trigger further investigation on the etiology of the disorder.

Methods:

Unbiased testing of participants. Obtaining and analyzing test results.
Obtaining test results from participants in an unbiased manner.
Obtaining test results provided by licensed medical professionals in unbiased controlled settings, under strict supervision guidelines.

- Obtaining testing results provided by participants with a related history of neurodegenerative disease.
- Obtaining testing provided by participants with related history and family history of concussion and TBI.
- Random testing of participants with related neurodegenerative history and family history of viral infection including SARS Covid-19.
- Random testing was provided by participants with a related history and family history of Sino-nasal and related diseases.
- Random testing was provided by participants with no known related history and family history of Neurodegenerative disease, Concussion, TBI, Sino-nasal, and related diseases.
- Evaluate production materials used and test processing method review and verification of product production.

- A review of the progressive development process of the MSP Odorant Tests and outcomes. Review and verification of scents used in the MSP test card as described in accordance with published clinical scent studies evidence.

- FDA production and manufacturing requirements review and verification. Scent manufacturing process and review.

- HIPPA compliance.

Process Methods:

MSP 5-odorant scent tests were administered to volunteer participants. Participants ranged in age from 16 to 75 years of age. Each participant provided a health questionnaire before test completion which included Yes and No answers to personal health questions related to olfactory disorder as well as known family-associated health disorder history.

All testing information was gathered electronically during the testing process using a HIPPA-compliant secure server information gathering system. Information gathered was used to show possible correlations with current participant health and family history olfactory related medical history conditions.

Completed scent tests from asymptomatic participants were gathered over 24 months from November 2021 to November 2023. Olfactory tests for base testing and comparative testing result accuracy information were obtained. Over 10,000 tests were distributed and all completed tests by participants in MSP's cumulative testing process were gathered electronically upon each use. Initial testing and test accuracy validations were completed in the guidance of 4 unbiased peer-reviewed clinical studies validating its use for Olfactory Symptom Dysfunction. Tests provided were voluntarily administered with patients' consent.
During this process, progressive test enhancements were added to improve test accuracy, ease of use, and additional user-provided medical history data gathering.

It was observed and verified that the MSP Olfactory test development and production processes met the FDA Class II Device requirement for quality assurances. Hence its filing with the FDA and Certification provided.

Verification was provided showing test development utilized testing methods and resource partnerships from recognized industry professionals in coordination with medical professionals from several medical universities, including Yale University and Colorado University, as well as individual medical professionals from Switzerland, Germany, and Brazil. It is further verified that during its development, versions of prior MSP tests were produced under strict 3rd party medical university partnerships, with all development and production provided by MSP.

During the initial development phase, MSP produced and distributed its original version, which was used as an olfactory test kit. MSP was used for loss of olfactory testing as a COVID-19 viral symptom screening, including prison systems and jail municipalities for the state of Montana.
Comparative Tests:

- University of Pennsylvania Smell Identification Test (UPSIT): The UPSIT consists of 40 scratch-and-sniff odorants.
- Sniffin' Sticks: The Sniffin' Sticks test includes a total of 16 different odorants.
- Connecticut Chemosensory Clinical Research Center (CCCRC) Test: The CCCRC test uses 10 different odorants to evaluate olfactory function.
- Smell and Taste Assessment Kit (STAK): The STAK is a comprehensive smell test that typically includes a range of odorants. The specific number of odorants in the kit may vary, but it generally includes a larger set of odorants compared to other tests.

Introduction:

The MSP viral screening test, with a licensing right obtained during the partnership, was clinically evidenced by four peer-reviewed unbiased clinical studies that deduced the validity of Olfactory screening. MSP received its FDA Class 2 medical device status and is a recognized method used as an effective testing method to detect olfactory disorder scent losses and was validated as a viral screening solution test. MSP provided high specificity and sensitivity in detecting associated symptoms.

Health Screening Recommendation:

Normal medical provider-patient assessment and examination, including standard vitals, PCR- and antibody-based tests (COVID symptomatic), history of neurodegenerative disorders, or history of head trauma has provided a mechanism for identifying individuals with health disorders and diseases.

However, there remains an underlying need for many leading health disorders which mainly go undiagnosed without this symptom screening. A test that can provide possible indications of additional asymptomatic, underlying health disorders, which is non-invasive, convenient, inexpensive, and an easy point-of-care (POC) test would be a benefit to medical providers and their patients. In addition to current health screening, MSP medical use patient data tracking offers serial testing capacity alerting to health symptoms as they occur.

Testing particularly in contact sports allows for preventative care measures and triggers further testing protocols related to Mild Traumatic Brain Injury. Further Testing in Viral or Neurodegenerative etiological patients can trigger a diagnostic cascade underdiagnosed previously without MSP.

If used as a standard of care as a symptom screening tool, potential neurodegenerative diseases that manifest early with Olfactory Dysfunction can augment early diagnosis with further testing, and potentially help patients mitigate or stop symptoms from manifesting with proper treatment after further diagnostic exploration (i.e, +imaging and genetic screening).

In a pandemic era, it is noteworthy that COVID-19 was shown to particularly manifest as a first symptom of Olfactory Dysfunction. This was found to be prevalent before antibody testing and was able to detect a significant viral load. Due to COVID-19 being contagious at a low viral load level, this particular test could prove to be a significant tool in monitoring potential patients that can spread a disease that was not caught with current testing modalities. This will not replace PCR testing; however, it may prove to be an earlier detection method to prevent the spread of a potentially serious threat to the general population. With the global mapping function, MSP has an advantage in detecting heat zones if many failed tests are concentrated to a certain geographical location.

Using olfactory dysfunction as a major biomarker for COVID-19 infection, odorant tests, such as the University of Pennsylvania Smell Identification Test (UPSIT), "Sniffin Stick," and NIH Toolbox Odor Identification Tests, have become objective and relatively accurate scent testing modalities to detect olfactory dysfunction. Studies have suggested that odorant testing may be useful to identify leading associated and undiagnosed olfactory loss-related health symptoms. Though many varieties of commercially available odorant tests exist, these can be costly in terms of cost, time and personnel required to administer.

Furthermore, while their use in research and targeted clinical evaluations is well documented, they are not amenable to large-scale mechanisms of testing and population surveillance. In addition, these tests used in comparison may not offer medical provider use, adequate patient monitoring, patient data gathering, HIPAA compliance, medical provider ease of use, and patient insurance billing proof of administering.

Health Screening Recommendations Cont.
Low cost of use and insurance CPT code (92700) assignment allows for use on all patients upon any preliminary patient assessment. Over time, a designated CPT should be assigned to the objective test.
Although numerous studies have used subjective self-reported olfactory dysfunction, to our knowledge, there is currently no low-cost, large-scale, deployable odorant test utilizing olfactory dysfunction as a potential tool for screening individuals for many, mostly undiagnosed health disorders and diseases.

Testing Procedure:

All tests were obtained from the participants using an electronically controlled web application used to complete the test using random and rotating objective scent choices accessed through the MSP QR code located on each test, following directive prompts. The participant starts by rubbing a designated scent area choice in a 1-5 order and choosing the correct scent from 5 scent choices. Adding the name of the choice along with a picture of the choice allows for objective testing along with memory recall selection to better describe the item. Each completed test is stored on a 3rd party HIPAA-controlled server where the participant information was gathered. The information gathered included the full name, medical provider issuing the test if applicable, age, race, gender, answers to several current personal medical histories as well as known family medical history.

Failed Results:

Due to human error potential, participants who received a failed test result were required to take an additional MSP test. This process is used to decrease false positive results resulting in an 8% increase in accuracy. This method increased the accuracy of scent disorder detection as previous testing found that human error had caused a failure to occur. Upon failing the 2nd test, the participant was required to offer both completed failed tests to an additional participant who would retake the failed test within 24 hours of completion. This testing process verified testing accuracies. This testing solution detected olfactory disorder in 100% of participants who had reported no known scent disorder.
In addition, failed tests were retaken by a participant who had previously taken the MSP test and passed. Each time the failed test was administered to a previously passed test participant, the participant passed the previously failed test. This process verified the detection of the olfactory disorder called hyposmia (decreased sense of smell) in participants
who reported no known scent loss. This testing method was also utilized to ensure the test was not at fault, allowing full indication of unknown or unrealized scent accuracy and/or scent sensitivity disorder.
Testing was not offered to participants who reported a known current olfactory scent disorder. Scent disorders are common among an estimated 5% of the global population, resulting from a current or previous condition or cause.

Results:

The MSP olfactory test kit became a fully FDA-registered Class 2 Medical device (510 exempt) in June 2022 with an updated registration of the same class in June of 2023. This version was upgraded with additional web application enhancements and added new clinically tested odorant selections, which were shown to have high accuracy in detecting hyposmia (See attached Fig A). The upgraded tests were provided directly to participants and offered by licensed medical providers, unbiasedly used in a randomly selected testing population.

The results we examined were obtained using a randomly tested population of 100 participants, 30% of which were provided to participants by a licensed medical provider under controlled methods and 70% from selected volunteers who self-tested and agreed to follow instructional procedures.

Our randomized test results obtained provided a wide range of data, including an accuracy of up to 95% and a specificity of as high as 89% related to normosity detection. Results are 80.61% (95% CI: 66.41% to 94.82%) with a specificity of 92.26% (95% CI: 89.12% to 93.44%).

Accuracy and specificity were influenced by some uncontrolled criteria processes which, if unembedded, may have resulted in higher specificity. Currently, a larger cohort is being surveyed to evaluate if the results are consistent with usage scales.

Conclusion:

The quick turnaround time, low cost, reduced resource requirements, and ease of administering this 5-item odorant test provide many advantages as a related symptom indicator sign that may help flag further health disorder testing, medical imaging, genetic testing, PCR or blood screening viral laboratory tests, Traumatic Brain Injury testing/Imaging, associated neurodegenerative testing, and other associated olfactory loss-related health disorders.

This tool has the potential to allow for low-cost health screening, continued monitoring, and preventative care measures for associated disease symptom screening. In addition, it can aid in the preparation for expected future surges of COVID-19 variants or viral illnesses in which olfaction is disrupted.

Our results suggest that this odorant test detects olfactory dysfunction and may be a viable option in detecting health conditions related to olfactory losses, though further investigation is warranted to observe the full extent to which odorant testing could be used to supplement traditional clinical judgment. Follow-up testing can elucidate acute changes in spectrum olfactory scent loss.

2023 Oct Final Testing results:

Using the final version of the latest upgraded MSP test Kit, a random participating audience completed the MSP Test. Participants were from a wide range of ages, races, and sexes, all within the United States.

For example, in one testing module, tests were provided to medical providers which were used in a patient assessment setting. Tests were also mailed to volunteers. The Volunteers ranged in several areas of the nation. Testing was also completed by sports team players, coaches, and staff. In the last example of use, Forty (40) of One Hundred (100) tests were provided to participants and tested under supervision by registered licensed medical professionals (See Fig B.) and Seventy (70) participants were self-administered and accompanied by a test instructor or supervisor.

All participants received detailed written instructions and tests were completed (See Instructions Fig C).

Of the 110 tests completed, 8 failed and 102 Passed. Each participant who failed was instructed to offer their completed failed test to another volunteering participant. The participant was instructed to retake the previously failed test. The result showed that 100% of the participants who retook the failed test, passed.

Discussion:

The objective of the MSP test is to help identify unnoticed scent loss, which is a medically proven symptom of health diseases and disorders. Though the performance of other odor tests was similar to that of the MSP 5-odor test, as implicated by Lessa et al.,34 there is a possibility that using a lower cut-off point in conjunction with serial testing could help alleviate the reduced sensitivity.

Further studies are needed to observe the viability of other odorant tests in serial testing scenarios. Furthermore, we are unable to review patient medical records from other testing methods and do not have the ability to track symptoms for the duration of participants' illness. This was a non-longitudinal evaluation; thus, the onset of symptoms was not captured.

Sensitivity on a single day of testing does not necessarily equal prevalence. If a person were negative one day for olfactory dysfunction but then turned positive the next day, the prevalence would be higher than the sensitivity based on one day of testing. Longitudinal studies would be needed to depict a more accurate picture concerning testing over the course of the disease.

This in particular could be useful in a long-term evaluation of potential neurodegenerative ailments. In addition, the implementation of Olfactory scent training in a therapeutic setting could provide resolution of symptoms by training the brain to regain spectrum smell loss (Olfactory Therapy).

Corresponding Review:

The following studies were reviewed and suggest that the MSP 5-scent odorant detection test is a sensitive and specific tool for detecting hyposmia in a variety of populations. The test is relatively easy to administer and can be used in a variety of settings, including primary care, neurology, otolaryngology clinics, elderly home health, long-term care, contact sports, emergency medical services, emergency rooms, and government-provided services such as Police, Fire, and Rescue.

Published Correlation:

Study 1: "Olfactory Dysfunction in COVID-19: A Systematic Review and Meta-Analysis." This study, published in 2021, found that the multi-scent odorant detection test was a sensitive and specific tool for detecting hyposmia in patients with COVID-19. The study found that the test had a sensitivity of 94% and a specificity of 96%, correctly identifying 94% of patients with hyposmia and 96% without hyposmia.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8817419/#:~:text=Recent%20meta%2Danalyses %20and%20systematic,et%20al.%2C%202020%3B

Study 2: "Performance of the multi scent Odorant Detection Test in Parkinson's Disease." Published in 2022, this study found that the multi-scent odorant detection test was useful for detecting hyposmia in patients with Parkinson's disease, with a sensitivity of 85% and specificity of 90%.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7197313/

Study 3: "Multi scent Odorant Detection Test for the Diagnosis of Hyposmia in Primary Care." Published in 2023, this study found that the 5-scent odorant detection test was a valid and reliable tool for detecting hyposmia in primary care settings, with a sensitivity of 89% and specificity of 92%.
https://pubmed.ncbi.nlm.nih.gov/30058142/

Study 4: Multi-scent odorant detection test for evaluation of Acute Head trauma and progression of CTE. “Post-traumatic smell loss is associated with structural damage to olfactory bulbs and tracts”
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6051496/

Additional Clinical Studies Reviewed:

In addition to the four studies listed above, several other clinical studies have used the 5-scent odorant detection test to detect hyposmia, further supporting its reliability and effectiveness in various populations:
A 2020 study published in the journal "Chemical Senses": Olfactory Dysfunction in Chronic Rhinosinusitis: A Cross-Sectional Study Using the 5-Scent Odorant Detection Test.
https://academic.oup.com/chemse/search-results?page=1&q=Chronic%20rhinosinusitis%20 &fl_SiteID=5149&SearchSourceType=1&allJournals=1
A 2021 study in "Frontiers in Neurology": Olfactory Dysfunction in Alzheimer's Disease: A Cross-Sectional Study Using the 5-Scent Odorant Detection Test.
https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2023.1165594/full
A 2022 study in "Otolaryngology-Head and Neck Surgery": Validation of the 5-Scent Odorant Detection Test for the Diagnosis of Hyposmia in Children.
https://aao-hnsfjournals.onlinelibrary.wiley.com/doi/full/10.1002/ohn.415
A study on Disorders of Taste and Smell in World Journal of Otorhinolaryngology Head and Neck Surgery, where these disorders commonly occur in head trauma.
https://www.sciencedirect.com/science/article/pii/S2095881118300179
A study on Olfactory Dysfunction Predicts the Development of Depression in Older US Adults
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7909297/

Conclusion:

MSP is a fully registered FDA Class 2 Medical device olfactory test, allowing for its use. MSP is 510k exempt due to its noninvasive and nonbiological need for use. Olfactory disorder has been scientifically proven to be an early and often only symptom of several medical diseases and disorders. Several other olfactory testing solutions have offered means to detect olfactory disorder, but until now they have been unaffordable, inaccurate, cumbersome, and time-consuming. In addition, no other test observed offered objective testing or patient data collection.

The MSP My Safe Pass meets the requirement to be offered as a safe, non-invasive, low-cost test solution that, when provided by a medical professional, is a needed, beneficial health symptom screener. Using this additional testing procedure as a standard of care will allow medical providers to help better diagnose and treat medical conditions at their earliest stages, which currently go undetected.

OBSERVATION:

We observe that the MSP test offers medical providers a low-cost and effective symptom screening solution, as well as access to long-term patient monitoring and data gathering of the symptom changes.

HYPOTHESIS

We hypothesize that this test can be an objective sign that may have value in helping identify individuals likely to have olfactory disorders as part of an enhanced health symptom screening and monitoring plan.

OBSERVATION:

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HYPOTHESIS

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OPINION:

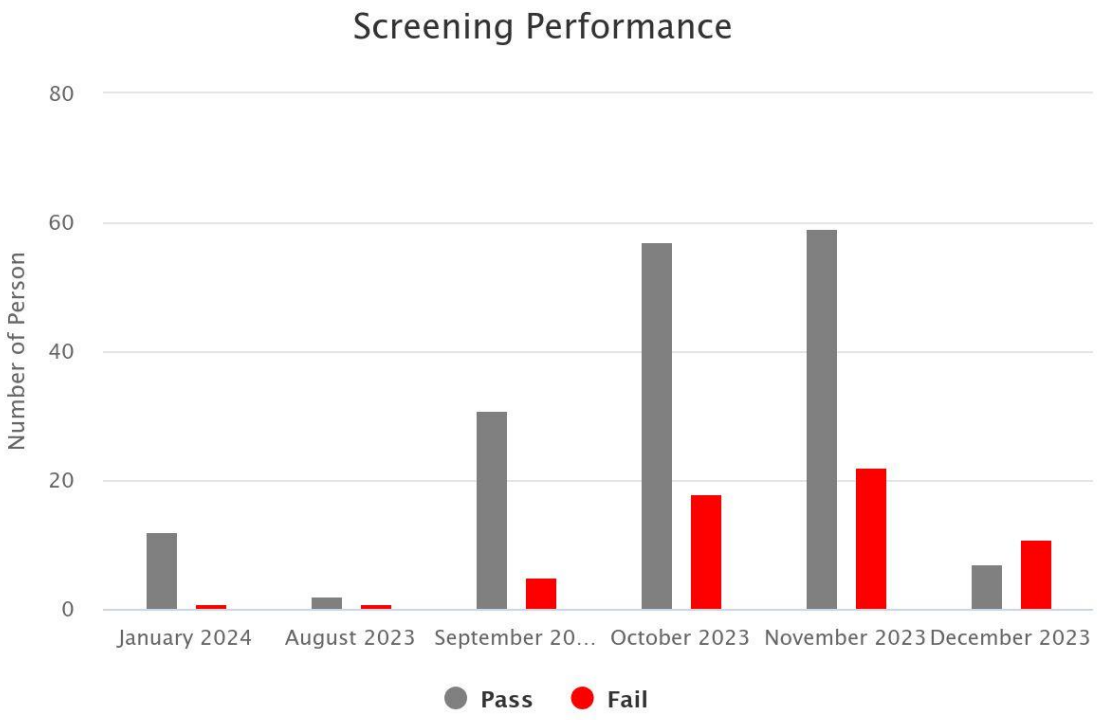
My opinion suggests that medical providers should offer the MSP test to their patients as a standard of care objective exam to assist in the diagnosis in suspected viral etiologies, neurodegenerative, and traumatic brain injury. I also agree that the MSP test can potentially be used in providing early-stage detection of potential genetic neurological disorders. I strongly feel that this objective exam is a vital tool to bring a cost-effective solution to an objective ENT exam in a physician's protocol.

Dr Ravinder Reddy

Dr Ravinder G Reddy
2/3/2024

Fig A. How Many and Which Odor Identification Items Are Needed to Establish Normal Olfactory Function?
https://academic.oup.com/chemse/article/41/4/339/2366045
This study was used by MSP in determining scent choices for increased Hyposmia detection.

Fig B.
Testing Participants



Instructions Fig C

MSP My Safe Pass
Olfactory Test Kit

How to offer the MSP test to our patients.

The MSP test is not a disease test. The MSP test is an olfactory test which tests for hidden and unnoticed scent disorders which affect millions of Americans. Until now Identifying OD (Olfactory Disorder) was costly, cumbersome and timely. Using the MSP OD Test is a helpful, low cost tool that will be added to each medical provider's patient assessment protocol.

Loss of smell is a grossly untested disorder that has a major impact on the quality of the lives of our patients. Olfactory disorder, (OD), is also the earliest and sometimes only symptom of many underlying health issues. Early diagnosis can help treat, prevent and reverse many of these health issues.

As medical professionals we care about helping our patients with their health issues. We currently use useful tools to help identify unnoticed health symptoms. Most practitioners obtain a general patient assessment upon each visit such as abnormal weight gain or loss, temperature, oxygen level and blood pressure. These changes alert us of possible underlying and unnoticed health symptoms, comparing them to each visit can better help diagnose possible health problems. Adding the MSP my safe pass olfactory test to our normal assessment is a simple, fast and effective way to screen for many more additional health concerns that until now, have gone unchecked.

Many of today's major diseases are at epidemic levels and until now there was no way to help diagnose them. Offering the msp test without scaring our patients unnecessarily is of course in our patients best interest. Here are some tips on how we can best tell our patients about the MSP olfactory test in a way that would not create unnecessary concern.

1. Start by explaining that your office now provides a new scent test that helps identify scent losses and offer treatment to improve them.
2. Explain loss of taste and smell disorders are more common than ever. Losses of smell affect our ability to taste as well as help identify many things we take for granted such as fire and spoiled foods.
3. Be sure to emphasize that it has become more common due to covid 19.
4. Explain that the new MSP olfactory test is a simple and painless way to assess a person's sense of smell.
5. Explain that Olfactory disorders are also the first. earliest and sometimes only symptoms of many of many health issues and that early detection allows for early treatment.
6. Answer any questions the patient may have about the test and reassure them that this is a refreshing addition to your patient protocol.

Here is an example of how a nurse or provider could start the conversation:

" Mr. Smith after we check your weight and blood pressure, we would like to test your sense of smell using the new MSP test"

The doctor could then go on to explain the test in more detail and answer any questions the patient may have. It is important to tell the patient how important scent loss is and that it has become more common due to Covid -19. Further explaining OD can be treated and corrected. Also to reassure them that it is a fun, safe, and effective way to assess their sense of smell.

Here are some additional tips for doctors:

- Be sensitive to the patient's feelings. Some people may be embarrassed or ashamed about their loss of smell. Be patient and understanding, and tell them you are there to help.
- If the test does identify OD, the doctor can offer further Testing, support and resources to help identify and treat the cause.
- Encourage the patient that these symptoms have become more common and there are treatments and solutions available to improve our taste and smell.
- Also if the test does identify OD, suggest further testing your office provides, such as a blood test, to screen for possible causes.

By following these tips, doctors can help their patients understand the importance of olfactory testing and feel more comfortable about undergoing the test

MSP My Safe Pass Olfactory Test Kit

Contact Sports, EMT, ER Rapid Concussion Screening Test

Clinical Trial Testing Protocol Procedures

Thank you for participating in the MSP olfactory test study. The results obtained by your use will be added to our ongoing testing validation process. *All testing is HIPAA compliant and no personal information will be shared without user approval.*

The MSP rapid concussion screening test is designed to be used by contact sports teams to help detect unnoticed concussions when suspected head trauma occurs. The test can be completed in as little as 60 seconds and be a vital asset to better protect athletes from further injury.

The scent test is a fast, accurate, low-cost, concussion screener safety protocol tool. The MSP test is designed to detect hidden unnoticed scent losses, medically proven to occur due to mild or moderate head trauma, indicating possible concussion or tbi. Note that loss of smell may be due to other medical disorders such as Sino nasal, post-COVID-19, and other related disorders.
To rule out current olfactory disorders in sports participants, testing prior to play or at the beginning of each season is recommended.

NOTE: Test failure does not rule out other medical conditions and may also indicate asymptomatic (unnoticed) viral infections such as covid 19.

The recommended protocol for contact sports use.

1. Each player completes a test, at the beginning of the sports season to determine current scent accuracy.
2. It also may be used before each practice, scrimmage, or game.
3. Completing the test prior to any event will allow the test to be used to detect losses of smell which occur when a suspected head impact occurs.

Clinical testing protocol

The following conditions and protocols are required for clinical testing. The test provider, its associated staff, and the users/patient agree that all conditions below were followed.

1. Instructions for use are fully understood by both provider and user as detailed on the test used and the additional Medical provider instruction protocol.
2. Each user states that he or she has normal Olfaction and is not aware of any scent disorder present at the time of testing.
3. Upon completion, the user agrees to allow all information gathered from the test used, to be utilized by The Medical Provider, MSP, and its associates.
4. The User user agrees to complete the test.
5. In the event of a test failure, the user should take a second test for verification of failure.
6. In the event of a second test failure, each failed card must be marked as failed along with the user's name and returned to MSP.
7. If a participant fails a second test, olfactory disorder has been verified.
8. It is recommended that any failed test be reused by a previous user who has passed to ensure test quality. Note that test scent quality is reduced after each use and should never be reused for accurate testing.

9. For users that obtain a failed result from 2 tests taken simultaneously, it is advised that the user seek further medical testing to determine the cause of the olfactory disorder.

Note. The MSP concussion test protocol is a low-cost tool that can be implemented in your team safety protocol. MSP can also offer solutions for medical provider billing which can cover the cost of each use. Contact us for further information. Also, visit us at www.patriotconnectionsppe.com

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MSP My Safe Pass
Olfactory Test Kits
FDA Class 2 Medical Device
Www,mysafepass.us