

HOUND LABS CLINICAL STUDY REPORT

THE ACCURACY OF CANNABIS BREATH TESTING

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EXECUTIVE SUMMARY

Workplace safety, risk mitigation, and employee fairness are key elements of an effective drug testing program. As cannabis laws expand and evolve, employers must find new ways to measure cannabis exposure and balance these concepts. Employers are searching for reliable solutions that deliver accurate and objective results to address workplace cannabis use. The advancement of recent use cannabis breath testing provides an ideal solution to help employers account for changing laws and societal views and the increase in cannabis use among employees.

TECHNICAL CONTRIBUTORS + SCIENTIFIC ADVISORS

Neeraj Kochhar, MD – Clinical Study Primary Investigator

A board-certified physician, Dr. Kochhar maintains a private medical practice in California. He is a sought-after scientific consultant for Silicon Valley medical technology companies, having served as the Primary Investigator for Emerja Corp, Lucira Health, and Hound Labs, as well as an advisor to MD Kinect (VMDoc) and Health 360. Dr. Kochhar formerly served as the Chief of Medical Staff at El Camino Hospital and was selected for the Sanofi Advisory Board in 2024.

R.H. Barry Sample, Ph.D. – Senior Science Consultant

Dr. Sample is a renowned consultant in forensic and analytical toxicology, anti-doping, and workforce drug testing with more than 40 years of experience in leading science and technology initiatives. A former Senior Director of Science and Technology for Quest Diagnostics where he was responsible for the production and introduction of new products and services, Dr. Sample currently serves as the Senior Science Consultant for Quest's Employer Solutions division and sits on the Hound Labs Scientific Advisory Board as Senior Science Consultant. He received his bachelor's degree in chemistry and his doctorate in pharmacology from Indiana University.

Debkishore Mitra, Ph.D. – Chief Technology Officer, Hound Labs

Dr. Mitra excels at the commercialization of tools and technologies involving the advancement of microfluidic and bioengineering platforms. He has an extensive background in product development, infectious disease biology, and assay



development. Dr. Mitra completed his Ph.D. in bioengineering at the University of California, Berkeley, and the University of California, San Francisco.

Tamanna Prashar – Chief Operating Officer, Hound Labs

Ms. Prashar is an accomplished healthcare executive with significant experience in driving operational scale, achieving supply chain efficiencies and process improvements in complex global corporations. Formerly the Executive Vice President of Operations and Supply Chain at Lucira Health, Ms. Prashar also previously led supply chain and operations functions at Vyair Medical and Cepheid. She earned an MBA from the University of Minnesota’s Carlson School of Management.

“The technology used for testing breath for cannabis use is as accurate as that used for any other workforce drug test.”

– Dr. Barry Sample, Workforce Drug Testing Expert



WORKDAY CANNABIS BREATH TESTING

Workplace drug testing programs long relied on conventional tests using oral fluid, urine, and hair specimens to assess the use of drugs by a donor. With longer windows of detection, these tests often identify the historical or, in the case of hair, 'lifestyle' use of drugs. However, in today's environment when more employees than ever before are using cannabis legally outside of work, it is more relevant for employers to focus detection on the recent or 'workday' use of THC, the principal psychoactive compound in cannabis. "Many employers want to ensure that employees are fit for duty when they show up to work and stay fit for duty throughout the workday," says a global substance prevention program leader for one of the world's largest oil and gas operators. "The ultimate value of a workplace drug testing program is to keep employees and the public safe from the impacts of drugs and alcohol in the workplace."

Marijuana users are 63% more likely to work for a company that does not have a workplace drug testing program.

Source: [SAMHSA - National Survey on Drug Use and Health, 2022](#)

Introducing a new sample type into the drug testing industry presents some unique challenges. Collectors, test administrators, and laboratory and program managers all demand rigorous research and scientific proof before lending support to any new biological matrix, collection method, or testing procedure. However, there is widespread acknowledgment that a new type of test is needed to address increasing cannabis use and its associated risks in the workplace. "We have an antiquated drug testing program, and now we're stuck in a position where the laws are changing faster than our technology," says one manufacturing employer. "We're looking for a way to continue testing and have a safe work environment."

"Drug testing has never been about impairment. It's about deterring drug use and helping employers ensure they have a drug-free, safe, and productive workforce."

– Dr. Barry Sample, Workforce Drug Testing Expert



As the next revolution in the drug testing industry, breath analysis presents a new testing method to address the challenge of isolating workday cannabis use. Because THC remains in the breath for only a short period of time after use, this sample type is ideal for employers seeking to detect and deter workday use. In developing breath testing, researchers carefully examined collection and testing procedures to ensure the accuracy, reliability, and credibility of this method.

THC accounts for more than 50% of all positive drug tests.

Source: [Quest Diagnostics](#)

For more than a decade, Hound Labs rigorously developed and validated its breath testing technology. Researchers conducted these tests in the laboratory, in the field, and via numerous clinical studies. Findings from cannabis inhalation studies summarized in this report continue to support the performance and reliability of breath testing as a measure of recent cannabis use.

Employers must understand their specific needs and business objectives regarding drug testing. This knowledge helps to ensure they select the best drug testing method in alignment with their criteria. This report explores three performance characteristics of recent use breath testing – THC detection window, THC cutoff concentrations, and potential THC environmental interference. Through this report, employers will gain a broader understanding of the importance of detection windows, the relevance of cutoff concentrations, and the impact of environmental factors on drug test results.

“I had to fire my best shift manager. He said he used marijuana last week but there was an incident, and the test was positive. I believe his marijuana use wasn’t the reason for the incident, but I had to follow the policy.”

– Transportation Employer



KEY TERMINOLOGY

Below are the definitions of terms used throughout this report to discuss the science and technology behind drug testing.

Accuracy	The degree to which the measured concentration of an analyte aligns with a known reference value.
Cutoff concentration	The concentration of a drug analyte below which a specimen is considered negative and at or above which a specimen is considered non-negative or positive.
Detection Window	The period of time after use in which a drug has a high likelihood of being detected at or above a specified cutoff concentration.
Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)	An analytical tool that physically separates analytes in a complex sample/specimen (through liquid chromatography) followed by their mass-based detection and quantification (using tandem mass spectrometry).
Limit of Quantification	The smallest amount of an analyte that is reliably measured within a specified accuracy and precision.
Sensitivity	The ability to detect an analyte when it is present.
Specificity	The ability of an assay to detect a specific analyte of interest without interference from other compounds in the sample.

Individuals aged 18 to 34 years old have the highest marijuana usage rates among all age groups.

Source: [NSDUH](#)

DEFINING WORKDAY TESTING

The terms workday, recent, and proximate use testing are relatively new drug testing terminology. Legacy test types have longer windows of detection that reflect past use and may lead employers to potentially, and unfairly, penalize applicants and employees who render a positive result for THC despite it being a legal drug in many

states. Hair testing, for example, reflects a long-term pattern of repetitive use going back up to 90 days, and urine may detect chronic frequent cannabis use for more than a month. While oral fluid test providers regularly refer to a saliva test as a ‘recent use’ solution, cannabis can be detected in oral fluid immediately after use and for as long as “24 hours in occasional users and 48 hours in frequent users at a 2 ng/mL THC cutoff concentration,” according to the U.S. Department of Health and Human Services.ⁱ

“Urine and oral fluid testing may claim to be recent use, but breath testing truly demonstrates proximate use,” says Dr. Barry Sample, a leading workforce drug testing expert and Senior Science Consultant for Hound Labs. “The window of detection is narrowly limited to when people are reporting for work and starting to perform their duties, helping to ensure employers are meeting their drug testing program goals, while not necessarily impinging upon what somebody is doing on their off-duty time.”

The window of detection of a test is an important parameter. THC and its metabolites that are detectable in other test types like urine and hair may remain in a person’s system for weeks or even months after use, but the potential safety-impacting effects of the drug have likely long subsided. Even the window of detection of an oral fluid test extends outside of the typical workday. As one employer told us, “I recently had to fire one of our better employees after a safety incident. He wasn’t impaired, but we had to follow the policy.”

Breath testing introduces a new sample type for cannabis detection that delivers the shortest detection window. Pioneering this method, Hound Labs introduced the HOUND® CANNABIS BREATHALYZER in 2023. This solution is the only breathalyzer that simultaneously collects a donor’s breath sample and an environmental air sample to rule out potential false positive tests. Both samples are sent to a partner laboratory for Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) testing. The breath test specifically targets active THC, isolating use that occurred within three hours before test performance, a timeframe that presents the greatest threat to workplace safety.



CLINICAL STUDIES EXECUTIVE SUMMARY

Hound Labs initiated clinical studies to evaluate the performance and reliability of cannabis breath testing. Since inhalation remains the most popular way to consume cannabis,ⁱⁱ the initial studies aimed to determine the window of THC detection post-cannabis inhalation, validate the THC cutoff concentrations for cannabis breath testing, and confirm that environmental THC concentrations do not affect test findings. Studies were performed under Institutional Review Board-approved protocols using LC-MS/MS methods.

RESULTS IN BRIEF

- THC is detectable within minutes after use and considers any environmental THC that may be present.
- 53% of donors rendered positive cannabis results at 2 hours while 3% rendered positive cannabis results at 3 hours after inhalation.
- The screening and confirmation cutoff concentrations for the THC breath testing assay is 20 pg/mL.

Before clinical testing, the partner laboratory validated its LC-MS/MS method to confirm that only active delta-8 tetrahydrocannabinol (d8-THC or delta-8-THC) and delta-9 tetrahydrocannabinol (d9-THC or delta-9-THC) molecules are detectable at pg/mL concentrations without interference from other drugs and cannabinoids including cannabidiol (CBD). The data demonstrate the test delivers accurate results that align with the high degree of accuracy of LC-MS/MS lab-based tests. “[Cannabis breath testing] uses industry-standard laboratory testing processes and uses the same technology for confirmatory testing that is required by various regulatory bodies, including the U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA),” says Dr. Sample. “Using that industry-standard technology one can have confidence in the accuracy of test results.”



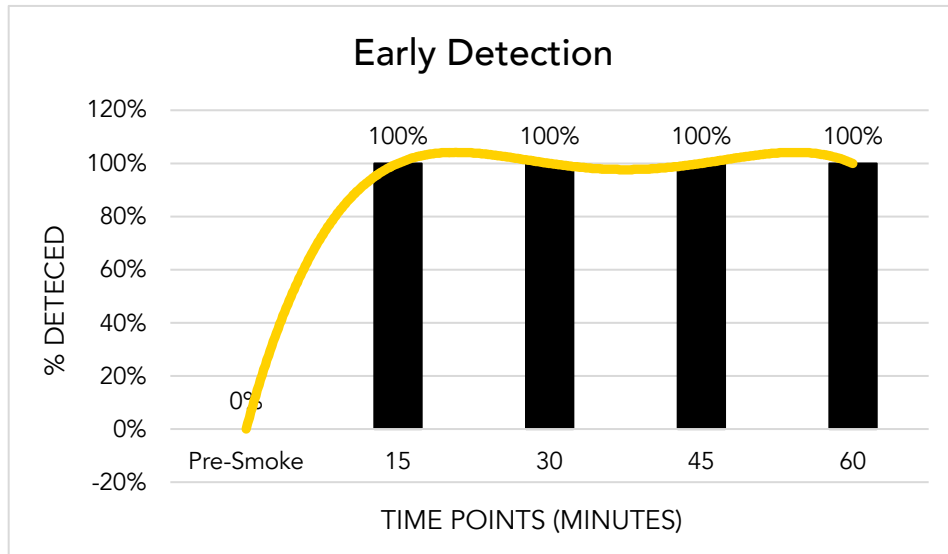
A cutoff concentration is the minimum quantity of a drug analyte needed for a test to render a non-negative result. Standard THC cutoff concentrations for assessing cannabis use in lab-based and point of collection urine and oral fluid tests are measured in nanograms/mL (billionth of a gram). Detecting THC in breath requires a greater degree of analytical sensitivity, measured in picograms/mL (trillionth of a gram). The screening and confirmation cutoff concentrations for the cannabis breath test are 20 pg/mL, which are 200x lower than the oral fluid detection cutoff of 4 ng/mL.

The THC concentration from the donor cartridge is corrected for ambient environmental THC concentrations during confirmatory testing. Study data confirm the cannabis breath test can detect delta-9-THC in the donor's breath within minutes after inhalation and for approximately two to three hours thereafter, aligning test results to reflect use that occurs during the workday.

WINDOW OF THC DETECTION

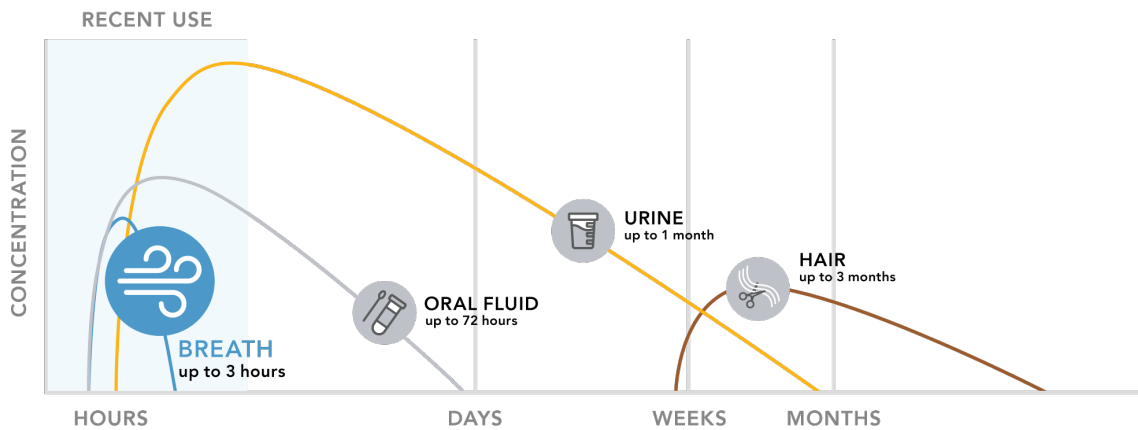
A window of detection indicates how long a test will detect a drug in a biological sample, and it varies depending on the sample type used. In cannabis testing, breath is the only sample type to offer objective and reliable results indicating recent use that occurs during or immediately before the workday. Other test types like urine and hair detect THC metabolites that remain detectable for weeks or even months after use.

In one of the Hound Labs' clinical inhalation studies, researchers examined how quickly a breath test could accurately detect cannabis after a person inhaled the drug. Before inhalation, all participants tested negative for THC. Within minutes after inhalation, all participants tested positive for delta-9-THC. This trend continued for the next hour of testing, with all participants testing positive for cannabis use (at 20 pg/mL cutoff) every 15 minutes. These data verify the ability of breath testing to detect cannabis immediately after use. In comparison, drugs typically appear in urine at a cutoff concentration of 50 ng/mL much later after use.ⁱⁱⁱ



“Effects from smoking cannabis products are felt within minutes and reach their peak in 10-30 minutes. Typical marijuana smokers experience a high that lasts approximately 2 hours.”
 – National Highway Traffic Safety Administration Drugs and Performance Fact Sheets

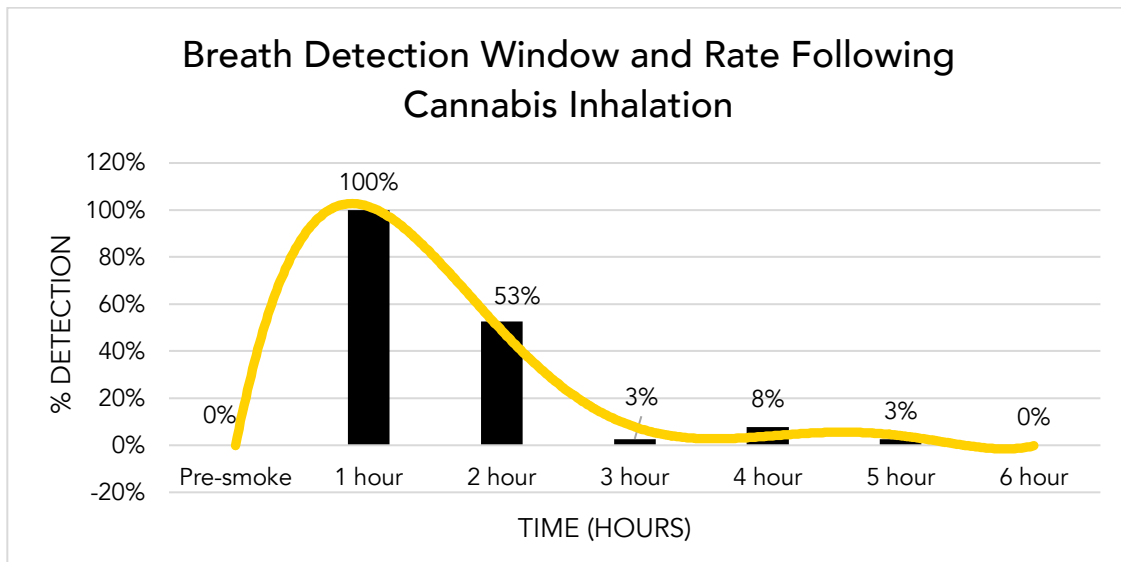
Cannabis Detection Windows



THC, the psychoactive compound in cannabis, is detected in breath, oral fluid, and blood. THC-COOH, a metabolite of THC, is detected in urine and hair.

<https://houndlabs.com/2018/09/06/how-long-can-marijuana-be-detected-in-drug-tests/>

Clinical studies also confirmed the detection window of a cannabis breath test only extends for 2-3 hours after use. Study participants were requested to abstain from cannabis use for 12 hours prior to the study commencing. Between the second and third hour, the percentage of donors who tested positive fell below 50%. And by the sixth hour, all participants tested negative. When examined as a whole, these breath testing results establish both the THC detection window and positivity rate.



The results verify that a cannabis breath test is a scientifically valid drug screen capable of detecting active delta-9-THC molecules in the breath. “THC can reliably be detected immediately after consumption and taper off beyond five or six hours, supporting our detection window of two to three hours,” says Dr. Debkishore Mitra, Chief Technology Officer at Hound Labs.

The narrower window of detection of breath testing helps employers enforce policies that distinguish between past cannabis use and recent cannabis use correlating more closely to the workday. With this approach, employers can continue testing for THC while aligning with emerging workplace cannabis laws that prohibit the discrimination of off-duty cannabis use.



“Our studies consistently demonstrate that THC is not detectable beyond six hours. If an employee uses cannabis the night before work, they will not test positive the next day.”

– Dr. Debkishore Mitra, Chief Technology Officer at Hound Labs

SPECIFICITY: IDENTIFYING ONLY THC

Specificity in drug testing defines a test’s ability to correctly identify the target analyte. Interference occurs when a test lacks specificity and can’t distinguish between the analyte of interest and substances that are chemically or structurally similar. In these cases, the drug test may produce a false-positive result. False positives occur when a test indicates an individual’s use of a drug, even though they have not consumed that substance. Interference is of particular importance in THC testing because the cannabis plant is known to contain more than 100 different cannabinoids.

The laboratory testing process uses LC-MS/MS analysis to conduct two-tiered screening and confirmatory testing, as well as the analysis of an environmental (ambient air) sample collected during donor sampling to support the accuracy of results. The LC-MS/MS method specifically identifies and quantifies delta-8-THC and delta-9-THC present in the breath specimen, without interference from THC metabolites, other cannabinoids, and other drugs. Results clearly support a high degree of specificity for THC breath testing, isolating detection only to active THC. This shows the test can accurately detect recent cannabis use without identifying other cannabinoids or cannabinoid metabolites.

PASSIVE EXPOSURE

Passive exposure can occur when someone is exposed to a drug but doesn't ingest or use the drug directly. In the case of workplace drug testing, someone who is due to take a drug test may claim they were in an environment where drugs were being used and therefore, may test positive for the drug in question.



Since inhalation remains the most popular way to consume cannabis,^{iv} the topic of passive exposure is an important consideration for cannabis testing programs. Employees may worry they will be unfairly punished if they test positive for cannabis, even if they didn't recently use the drug. The Hound Labs breath test resolves this by collecting a simultaneous air sample and correcting the donor sample THC concentrations accordingly. "An ambient air sample ensures the environment is suitable for collecting a breath sample for THC," says Dr. Mitra.

If the ambient air sample indicates that the collection site environment has unacceptable levels of ambient THC, the lab will return an invalid result. This result acts as a trigger for the collector to consider ways to improve the collection site environment. Such measures may include installing air filters or finding collection locations isolated from suspected cannabis use.

"There are a number of safeguards in place to help ensure the accuracy and reliability of a breath test."

– Dr. Barry Sample, Workforce Drug Testing Expert

To simulate a passive exposure scenario, Hound Labs performed a breath collection study of non-smokers who were near someone smoking cannabis. While 100% of participating smokers rendered a positive breath testing result after smoking, not a single non-smoker had a positive result after being passively exposed to cannabis smoke in the environment. These results confirm that being near cannabis smokers does not lead to a positive breath test via passive exposure. Furthermore, these results further demonstrate the sensitivity of a cannabis breath test as a reliable measure of recent cannabis use. "This means there is an extremely low risk of air contamination impacting a donor specimen," says Dr. Kochhar. "Collecting an environmental air sample basically mitigates this risk."

"This study indicates cannabis breath testing can correctly identify the active THC molecule without interference from ambient air THC and that it can correctly quantify the amount of THC in the specimen."

– Neeraj Kochhar, MD, BioCube Clinical Study Investigator



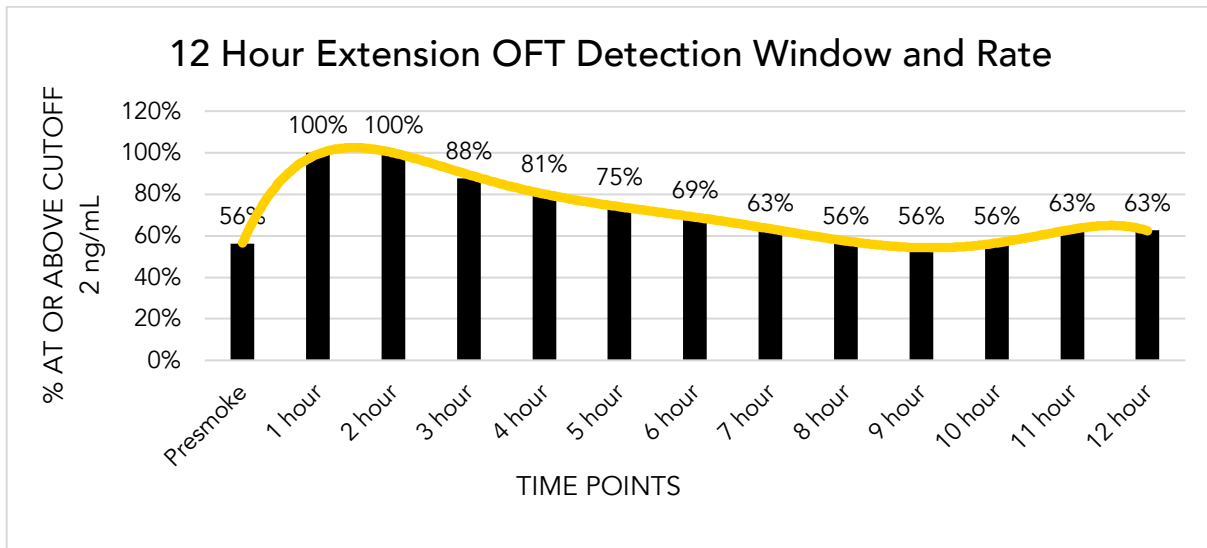
COMPARING BREATH TO ORAL FLUID

Second in popularity to urine drug testing, oral fluid testing is leveraged by an increasing number of employers. Oral fluid tests are available as both on-site and lab-based products and have some unique advantages over urine including an observed collection where it is more difficult to adulterate the sample. However, oral fluid's window of THC detection is approximately 24 hours, extending well beyond the workday. Employers, especially in states where cannabis use is legal, tend to prefer the window of THC detection to reflect use just prior to or within the workday.

"We onboard employees every two weeks. We get between 20 and 50 candidates, usually 30-50% will fail for THC."

– Gaming Employer

The initial Hound Labs study compared the detection window of breath to oral fluid over a timeframe of six hours and found the majority of oral fluid samples to be positive at the 6-hour time point. Hence, an additional study focused solely on oral fluid follow study participants out to twelve hours to compare the oral fluid detection window to the workday. Oral fluid collections were performed hourly using the Quantisal™ lab-based oral fluid device. The goal of this study was to collect empirical data to reliably demonstrate the window of detection of oral fluid testing extending beyond a typical 8-hour workday – using the standard 2 ng/mL oral fluid cutoff. Participants were asked not to use cannabis for at least 12 hours before reporting to the study.



It is evident that, like breath testing, oral fluid testing detects THC almost immediately after a person uses cannabis; but it is also clear that its window of detection extends significantly longer than that of breath. At the 8-hour mark, 56% of participants tested positive for THC in their oral fluid. Meanwhile, this report demonstrates the window of detection for breath testing is between 2–3 hours, well within the standard workday. “Clearly, this study demonstrates there is a divide between oral fluid’s definition of recent use versus what breath shows as proximate use. You can see the differentiation when you observe both specimens are 100% positive at two hours, but only oral fluid is showing positives at the 8-hour time point,” says Dr. Mitra.

Assuming an employer uses oral fluid tests for pre-employment purposes, they may make adverse decisions based on past cannabis use that extends beyond the workday. Under some state laws, this could represent non-compliance that could lead to additional costs, disruptions, and litigation risks.

“We just had a hiring event. Nearly 70 people showed up, and after we told them they would be tested for THC, most of them didn't show up the next day, and a few failed the drug test. We lost 100% of our candidates that day.”

– Construction Employer



WHY BREATH?

The ability to measure THC accurately and objectively in breath holds wide-ranging benefits for the drug testing industry. These collective clinical study results signify a milestone in Hound Labs' mission to provide employers with easy-to-deploy, high-value solutions to detect and deter workday cannabis use. Leveraging these solutions empowers employers to execute testing policies that balance workplace safety with employee fairness, thereby mitigating costs and risks for their companies, customers, and the public.

ⁱ [Department of Health and Human Services](#)

ⁱⁱ [Annals of Internal Medicine](#)

ⁱⁱⁱ [National Library of Medicine](#)

^{iv} [Annals of Internal Medicine](#)

The HOUND® CANNABIS BREATHALYZER is intended to detect recent cannabis use. It does not measure whether, or how much, a person is impaired. It is intended solely for the use in employment, law enforcement, and insurance settings. It should not be used for any medical or therapeutic purposes, or for any Federal drug testing programs, such as programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.

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