Division of Dockets Management Department of Health and Human Services Food & Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

CITIZEN PETITION

Request that The Commissioner of Food and Drugs Revise Labeling, Issue a Public Communication to Employers and Law Enforcement, and Provide Transparency Regarding 510(k) Clearance of Psychemedics Corporation's Cannabinoid Hair Testing Device (K111929)

I. Action Requested

We submit this citizen petition under 21 C.F.R. § 10.30 and the Administrative Procedure Act. This petition concerns Psychemedics Corporation's cannabinoid hair testing device cleared by the FDA (K111929) (referred to as "the Device" or "the Psychemedics Device"). It requests that the Commissioner of the Food and Drug Administration (FDA), through the Center for Devices and Radiological Health (CDRH), take the following actions to address concerns regarding Psychemedics Corporation's cannabinoid hair testing Device:

1. **Labeling Change**: Recommend or Order Psychemedics to revise the "Instructions for Use" for the Device to read:

"The Psychemedics Microplate EIA for Cannabinoids in Hair is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cannabinoid metabolites in hair using a 11-nor-9-Carboxy- Δ 9-THC calibrator at a cut off of 10 pg/10 mg hair";

alternatively, the FDA should order Psychemedics to provide a disclaimer on the Device that it does *not* identify whether any test subject used marijuana but only detects the presence or absence of cannabinoid metabolites in hair, which could have occurred without the subject using marijuana.

¹ Where appropriate, the Device and its predicate (K011426) are referred to as "the Devices" or "the Psychemedics Devices."

- 2. **Issue Public Communication**: Disseminate a letter addressed to employers, contractors, and state and federal law enforcement (1) clarifying that the Device cannot reliably distinguish intentional use from unintentional exposure and (2) recommending a more comprehensive approach to identification of intentional use of marijuana.
- 3. **Publish Data for Devices**: Publicly disclose specific investigation findings regarding the Devices as well as relevant policies and data to ensure accountability and protect public trust.

II. Statement of Grounds

The basis for this request is described in this section. First, we explain the FDA's authority to take the requested actions. Second, we provide details about the Devices. Third, we explain the specific concerns regarding the Device.

A. FDA Authority

Under the Federal Food, Drug, and Cosmetic Act (FDCA) and relevant regulations, the FDA has authority to regulate devices and their label(ing). The FDA "clears" Class II devices for which general and special controls are sufficient to provide reasonable assurance of safety and effectiveness.² General controls include the provisions of the FDCA applicable to all devices, such as labeling provisions. Special controls are technical, performance, and other requirements specific to a particular device. When classified as a Class II device, the FDA generally does not require human clinical trials to demonstrate safety and effectiveness. If a Class II device is "purported or represented to be for a use in supporting or sustaining human life," the FDA may require the manufacturer to meet certain performance standards "that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance."³

After a device is cleared by the FDA for particular indications as stated on the FDA-reviewed labeling, it may be sold and marketed for its indicated uses. Once cleared, the FDA has authority to take various actions with respect to the device. For example, the FDA can recommend or order the device manufacturers to include certain safety or risk information on labeling or otherwise notify providers about important safety or risk information.⁴ The FDA may also disseminate information about a device when it presents "imminent danger to health or gross deception of the consumer." Finally, the FDA has authority to communicate important safety information to the public, in the form of letters to affected parties, typically in the form of Communication Letters or It Has Come To Our Attention Letters.

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² 21 U.S.C. § 360c(a).

³ 21 U.S.C. § 360c(a)(1)(C)(ii)(I)-(II).

⁴ See generally 21 U.S.C. § 352.

⁵ 21 U.S.C. § 375.

In addition to its authority to clear devices, the FDA has authority to publish information about the devices it clears. While it does not publish trade secrets,⁶ it can publish the investigations or summaries of the investigations it relied on in making its clearance decision that are not trade secrets. It frequently publishes such information for a variety of devices, notably nearly all devices that receive Premarket Approval.

B. Factual Background

The FDA cleared the Psychemedics Device—an enzyme immunoassay (EIA) device for detecting cannabinoids in hair samples— on May 1, 2012, using another Psychemedics device (K011426) as its predicate.⁷ Both Devices were cleared under the classification in 21 C.F.R. § 862.3870, which describes "[a] cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marihuana, in *serum*, *plasma*, *saliva*, *and urine*." Importantly, this regulation does *not* include hair testing systems. Because the FDA cleared the predicate under a classification that does not include hair as a substrate for testing, the clearance created a daisy chain effect: the EIA was cleared based on the RIA, but the RIA was cleared under a classification that did not match the predicate device features.

Further, the regulation is not meant for devices that definitively determine cannabis use. Instead, "measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use." This is particularly important because the Psychemedics Device is marketed for identifying marijuana use in employment and insurance contexts, including by federal, state, and municipal law enforcement agencies. The Psychemedics Device purports to do this by detecting cannabinoid metabolites, such as 11-nor-9-carboxy-THC (THC-COOH), in hair, relying on cutoff thresholds to infer use. Yet cannabinoid metabolites are detectable in hair in both purposeful use and in the case of inadvertent exposure. So while hair testing can detect cannabinoids, it cannot definitively confirm marijuana use because "external contamination" is always possible.

For this reason, firms in forensic, employment, and insurance settings may rely on urine, blood, and/or saliva testing, supported by standardized protocols and validated cut-off levels to

⁶ 21 U.S.C. § 360j(c); 21 C.F.R. § 20.61. See 21 U.S.C. § 331.

⁷ FDA 510(k) Summary for K111929 (Psychemedics Corporation), available at https://www.accessdata.fda.gov/cdrh_docs/pdf11/K111929.pdf (last accessed Oct. 10, 2025). The predicate devices—the Psychemedics device K011426—is a Radioimmunoassay hair test for Cannabinoids, which the FDA cleared on date May 3, 2002. Because device K011426 has been discontinued, this Citizen Petition requests no action with regard to it.

⁸ 21 C.F.R. § 862.3870(a) (emphasis added).

⁹ 21 C.F.R. § 862.3870(a).

¹⁰ See, e.g., Trusted Hair Drug Testing, Since 1986 | Accurate & Court-Admissible Results, PSYCHEMEDICS, https://www.psychemedics.com/ (last visited Oct. 14, 2025). See also Exhibit A.

¹¹ Bjoern Moosmann, Nadine Roth & Volker Auwärter, *Finding Cannabinoids in Hair Does Not Prove Cannabis Consumption*, 5 SCI REP 14906 (2015).

¹² R M White, Drugs in Hair. Part I. Metabolisms of Major Drug Classes.

accurately identify marijuana <u>use</u>. Urine testing, the most common method, detects THC-COOH with a detection window of days to weeks, using cut-off levels (e.g., 50 ng/mL for screening, 15 ng/mL for confirmation) established by the Substance Abuse and Mental Health Services Administration (SAMHSA).¹³ Blood and saliva testing, with shorter detection windows (hours to days), are used for detecting recent use, employing initial screening (e.g., enzyme immunoassays) followed by confirmatory testing using gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-mass spectrometry (LC-MS) for high specificity and sensitivity.¹⁴ SAMHSA's Mandatory Guidelines emphasize confirmatory testing to ensure accuracy in high-stakes contexts.

By contrast, hair testing of the kind used in the Psychemedic's Device detects THC-COOH over a longer period (months) and faces additional challenges, including false positives from passive exposure (e.g., inadvertent inhalation of marijuana smoke), as well as variability in cannabinoid incorporation due to hair type, hair treatments, and growth rates.¹⁵ Additionally, unlike standardized cut-offs for urine or blood, no universal cut-off level for THC-COOH in hair that reliably distinguishes intentional use from unintentional exposure.^{16,17} These limitations undermine the accuracy of hair testing in employment and insurance settings, risking inappropriate job loss or denial of opportunities.

Given the unreliability of hair testing to accurately identify marijuana use, the FDA should evaluate the Psychemedics label or labeling of hair testing for cannabinoids. Although confirmatory testing is required for the Device, cut-off levels for even these secondary confirmatory tests of THC-COOH using GC-MS or LC-MS for hair testing have not been standardized and have also not been validated to differentiate the distinction between use and passive exposure. In any case, the Device does not include either the GC-MS or LC-MS confirmatory tests.

¹³ Donna M. Bush, *The U.S. Mandatory Guidelines for Federal Workplace Drug Testing Programs: Current Status and Future Considerations*, 174 FORENSIC SCIENCE INTERNATIONAL 111 (2008) (SAMHSA's guidelines specify validated cut-off levels and confirmatory testing [e.g., GC-MS] for urine to ensure accurate detection of marijuana use.).

¹⁴ ANALYTICAL AND PRACTICAL ASPECTS OF DRUG TESTING IN HAIR (Pascal Kintz ed., 2006) (GC-MS and LC-MS are critical for confirming marijuana use due to their high specificity, while hair testing is limited by contamination and variability risks).

¹⁵ Frank Musshoff & Burkhard Madea, *Review of Biologic Matrices (Urine, Blood, Hair) as Indicators of Recent or Ongoing Cannabis Use*, 28 THERAPEUTIC DRUG MONITORING 155 (2006) (Variability in cannabinoid incorporation into hair and lack of standardized cut-offs limit its reliability for distinguishing use from exposure.).

¹⁶ Bjoern Moosmann, Nadine Roth & Volker Auwärter, *Hair Analysis for THCA-A*, *THC and CBN after Passive in Vivo Exposure to Marijuana Smoke*, 6 DRUG TESTING AND ANALYSIS 119 (2014) (Cut-off levels for THC-COOH in hair cannot definitively rule out passive exposure).

¹⁷ Michelle Taylor et al., Comparison of Cannabinoids in Hair with Self-Reported Cannabis Consumption in Heavy, Light and Non-Cannabis Users, 36 DRUG AND ALCOHOL REVIEW 220 (2017) (No universally accepted cut-off level can reliably distinguish active use from passive exposure due to individual variability and environmental factors); Moosmann, Roth, and Auwärter, *supra* note 16.

C. Specific Concerns

The Psychemedics Device raises two concerns. First, the FDA classified the Psychemedics Device under a classification for cannabinoid testing that expressly does not include hair testing. Second, the Device's instructions for use do not accurately describe the Device's limitations and appropriate uses.

1. <u>Improper Classification</u>

Although the Psychemedic's Device tests for cannabinoids, the FDA has classified them into a classification that includes detection only "in serum, plasma, saliva, and urine." Because hair is not included in the regulatory classification, it is unclear how the general and special controls of this classification provide a reasonable assurance of safety and effectiveness. In other words, the general and special controls applied to K011426 (RIA-based) and K111929 (EIA-based) as Class II devices for hair testing may not provide reasonable assurance of safety and effectiveness.

2. Instructions for Use

Because the Psychemedic's Device does not measure marijuana use but instead only the presence of cannabinoid metabolites in hair, the indications for use could warrant an official notification under 21 U.S.C. § 375. At a minimum, they may confuse consumers and users about the Device's ability to accurately identify marijuana use rather than the presence of cannabinoids due to passive exposure (e.g., inadvertent inhalation of marijuana smoke). For example, although the indications for use of the device (K111929) state that the Device is intended "for the preliminary qualitative detection of cannabinoids in human head and body," it goes on to state this detection is "for the purpose of identifying marijuana use." The latter claim could suggest to the user or consumer that the test can distinguish between intentional marijuana use and passive exposure, both of which can result in detectable THC-COOH in hair. But hair testing cannot reliably differentiate use from exposure. Cannabinoid metabolite levels in hair, specifically THC-COOH, cannot accurately distinguish intentional marijuana use from unintentional exposure due to the risk of passive exposure and the lack of standardized cut-offs. To avoid this confusion, the instructions for use should note explicitly that this test cannot identify marijuana use, as stated in our Requested Actions.

These concerns have real-world impact. For example, the Psychemedics Device is used in employment settings, particularly for law enforcement officers.²¹ Because positive test results may

^{18 21} C.F.R. § 862.3870.

¹⁹ 510(k) Decision Summary, available at https://www.accessdata.fda.gov/cdrh_docs/reviews/K111929.pdf (last accessed October 15, 2025).

²⁰ Marilyn A. Huestis et al., *Cannabinoid Concentrations in Hair from Documented Cannabis Users*, 169 FORENSIC SCIENCE INTERNATIONAL 129 (2007) (Hair testing for cannabinoids is susceptible to false positives from environmental exposure, necessitating confirmatory methods.).

²¹ Exhibit A.

reflect only passive exposure rather than intentional marijuana use, consumers (employers) may erroneously believe that a positive result definitively proves marijuana use when it showed only marijuana exposure. This kind of misunderstanding can cause significant harm to individuals who are deemed marijuana users, and may result in inappropriate medical care or adverse employment decisions. To ensure consumers and users understand the limitations of the Device, the FDA should undertake the requested actions.

D. Summary of Request

For the reasons stated, the petitioner requests that the FDA take the following actions:

1. **Labeling Change**: Recommend or Order Psychemedics to revise the "Instructions for Use" for the Device to read:

"The Psychemedics Microplate EIA for Cannabinoids in Hair is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cannabinoid metabolites in hair using a 11-nor-9-Carboxy- Δ 9-THC calibrator at a cut off of 10 pg/10 mg hair";

alternatively, the FDA should order Psychemedics to provide a disclaimer on the Device that it does *not* identify whether any test subject used marijuana but only detects the presence or absence of cannabinoid metabolites in hair, which could have occurred without the subject using marijuana.

- 2. **Issue Public Communication**: Disseminate a letter addressed to employers, contractors, and state and federal law enforcement (1) clarifying that the Device cannot reliably distinguish intentional use from unintentional exposure and (2) recommending a more comprehensive approach to identification of intentional use of marijuana.
- 3. **Publish Data for Devices**: Publicly disclose specific investigation findings regarding the Devices as well as relevant policies and data to ensure accountability and protect public trust.

E. Environmental Impact Statement

This Petition is subject to statutory exemption.

F. Economic Impact Statement

This information can be furnished to the FDA commissioner upon request.

III. Certification

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

By: Harmed Americans for Reform in Medical-Device Safety Corp. (HARMS)

/s/ Hooman Noorchashm

Hooman Noorchashm MD, PhD, President, HARMS

/s/ Michael K. Paasche-Orlow

Michael K. Paasche-Orlow MD, MA, MPH, Treasurer, HARMS

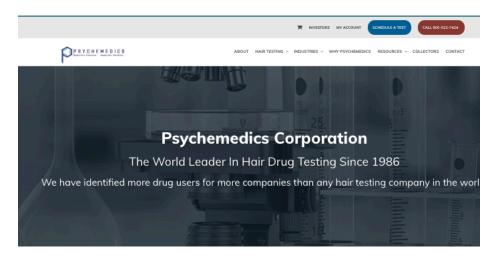
/s/ David A. Simon

David A. Simon PhD, JD, LLM, Clerk, HARMS

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Exhibit A Psychemedics Website Pages



Why Choose Psychemedics Hair Drug Test?

We invented the science that re-invented hair drug testing.

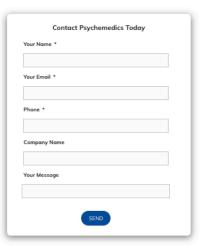
Psychemedics pioneered the first commercially-available hair drug testing analysis in 1986 and continues to innovate today. Tapping into the scientific principle that when drugs are ingested and metabolized, they are deposited and held in hair. The Psychemedics company developed the technology that reinvented the hair drug testing industry.

We are the only hair drug testing company with potented technology to extract virtually 100% of the drug from the hair and identify both types and quantity consumed for up to 90 days. Psychemedics has helped Fortune 500 companies, numerous international organizations, many of the largest police departments, transportation companies, rehabilitation programs, manufacturing companies, schools, service/gaming companies, and parents worldwide.

Why Choose Psychemedics? Superior Science. Superior Results

Our team includes scientists, toxicologists, lab technicions, program consultants, and a network of industry experts. With over 30 years as the pioneer and industry leader of hair testing, Psychemedics is a hair drug testing company that empowers global organizations with the confidence to make policy decisions based on our test results.

- We invented hair testing and have been doing it longer than anyone.
 Our scientists have published the most scientific research.
 We own nine patents the most in the industry, by for.
 Our process has been published, peer-reviewed, and validated.
 Our test results have been upheld in courts across the country.
 We are the only lab with FDA 510(k) clearance for every screen





We Create Safer, Drug-Free Environments Every Day

Petrochemical



Over 4000 Oil & Gas, Petrochemical, and Contractor companies have chosen Psychemedics as their hair drug testing lab.

Learn More

Education



Public, Faith-based, and Elite Private school educators know a drug-free campus saves lives.



Transportation



Transportation firms use Psychemedics to create drug-free workforces, safer roadways, and better businesses.

Leam More

Law Enforcement



A drug-free police force is a goal, and Psychemedics is the preferred tool for large and small police forces across the U.S.



Manufacturing



Some of the largest manufacturing firms chaose Psychemedics to help create safer factories and workplaces.

Learn More

Services Industries



The biggest names in Retail, Hospitality, and Gaming rely on Psychemedics to lower the liabilities drug use brings.



Why Our Clients Choose Psychemedics



Unrivaled Detection

A Psychemedics hair test detects 2-3X more users than other hair tests, and 6-10X the number detected with urine. Our patented process is the reason why.



Unmatched Deterrence

Certainty of detection is a powerful deterrent to drug use. Our clients have seen positive rates drop by 30-60% after instituting a Psychemedics hair testing program.



Unbeatable RO

The true measure of testing value is "Cost Per User" detected. The cost for each user identified with Psychemedics is 2X lower than other hair tests and 5X lower than urinallysis.



More Reasons to Choose Psychemedics

Award Winning Customer Service

Recognized by Benchmark Portal for "superior customer service."

Same-day account setups

We offer same-day account setups and multi-language formats. Our online scheduling reduces time and complexity when you need to test.

Quick response to calls

Our supportive and tenured customer service team averages call wait times of less than twenty seconds.

Easy order options

Multiple options for easy supply orders and electronic Chain of Custody Forms let you get what you need when you need it.



Best Turnaround Time of Any Hair Testing Lab

95% of screened negatives reported back on the same day

The best turnaround time of any hair testing lab equips our clients with the information they need to make time-sensitive pre-employment or employee decisions.

The lowest percentage of Canceled Tests & Retests

Our percentage of canceled tests, resulting from the insufficient sample and paperwork errors, regularly average less than 1.0-1.5%. This means fewer retests, less hassle for your company, and less stress on the people you test.



Customized Reporting Solutions

Personalized Results Portal

The Personalized Results Portal provides our clients online access to their results, custady and control forms, and customized reports and statistics. Our on-request reports help to track program progress against objectives.

Annual client reports enable you to benchmark vs. your peers Psychemedics releases annual client reports that provide testing history, results, and comparisons of your results to those in your industry group.

Simple Interface and Integrations

An Interface with Third-Party Administrators and Medical Review Officers allows a Psychemedics hair testing program to integrate with other programs and IT systems easily.



Superior Research and Development

Frequent addition of drugs to our standard panel

Our cutting-edge research and development team stays on top of the latest drug trends, resulting in the frequent addition of drugs to our test panels.

Nine industry patents held by Psychemedics

Psychemedics holds nine unique industry patents and continues to innovate today.

Most published work in peer-reviewed journals

Our scientists are credited with the most published work on hair testing in peerreviewed journals than any source in the world.

Can you spot three drug users in this crowd?

Psychemedics can.

It is what we do every day.

The Psychemedics Advantage

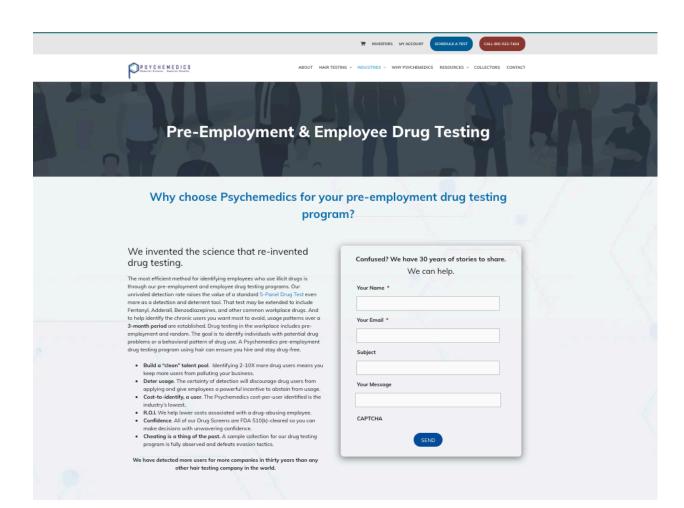
Your objective is a drug-free workplace or campus.

Your challenge is to Detect and Deter every drug user.

Unrivaled Detection. Unmatched Deterrence

That is the Psychemedics Advantage.

https://www.psychemedics.com/



Employee Drug Screening Facts

Why Do Employers Drug Test?

Many employers require drug tests for employees to create a safe and productive working environment. Drug testing policies help maintain employee morale, productivity and limit additional costs like extra liability and health care claims related to drug abuse. Also, some jobs require equipment and machinery operation that could be impaired by drug abuse, which is dangerous for the employees, customers, and employers. To create the safest working environment, employers should implement workplace drug testing, policies, and programs.

Learn more about the importance of effective drug testing.

Drug Users Impact Quality and Productivity

Beyond higher absenteeism, accident rates, workers' compensation, and turnover costs, one of the often forgotten impacts of companies employing a drug user is their effect on quality and productivity. Beyond the financial impact of reduced quality and productivity, there is also the long-term risk of losing market share to competitors providing a better product or service. If that happens, the estimated \$7,000 to \$10,000 cost appears small in comparison.

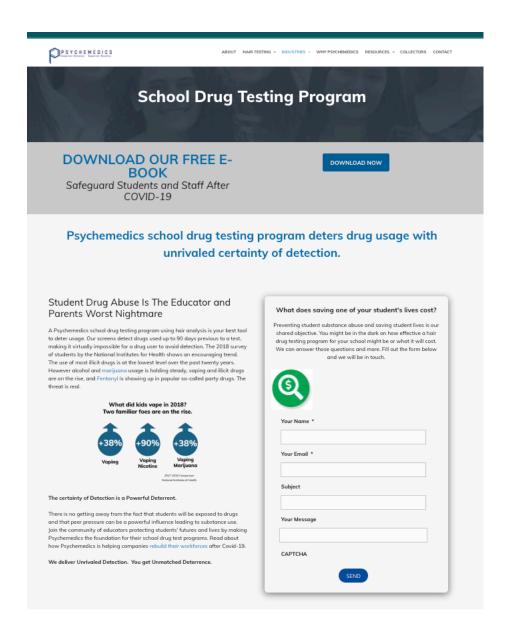
Pre-Employment Drug Testing

A pre-employment drug test is administered during a screening process when a person accepts an after of employment. Passing the test is normally a condition-of-employment. The test's purpose is to identify applicants who may or may not comply with the hiring company's drug policies. Most Psychemedics clients focus on identifying chronic abusers of prescription or illicit drugs, and the 90-day detection window of our tests makes it possible to identify those individuals. Our tests are completely confidential, disclosed only to the company requesting the screen and never to the individual tested.

Employer Drug Testing Laws

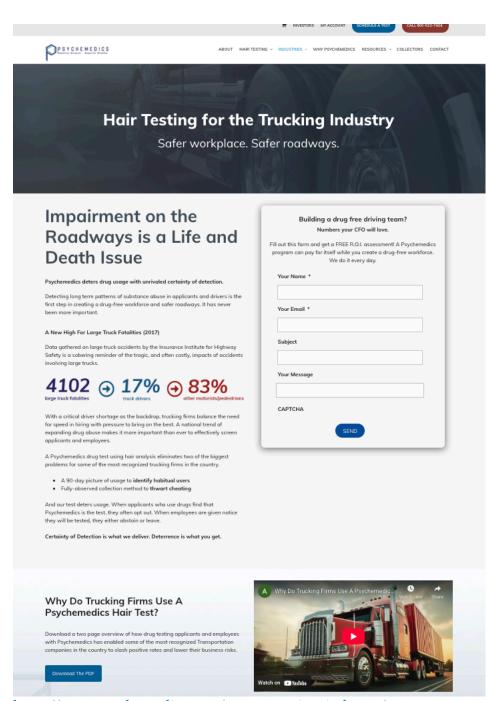
In most cases, employers are fully granted the right to test their employees for drug abuse. Some states do restrict employers from randomly drug testing employees who are not in safety-sensitive positions. Certain individuals with a history of alcoholism anafor drug addiction could qualify as individuals with disabilities under the Americans with Disabilities Act, a non-discriminatory status. To learn more about the legality of drug testing in the workplace and drug testing rights, please visit Workplace Fairness.

https://www.psychemedics.com/why-drug-test/

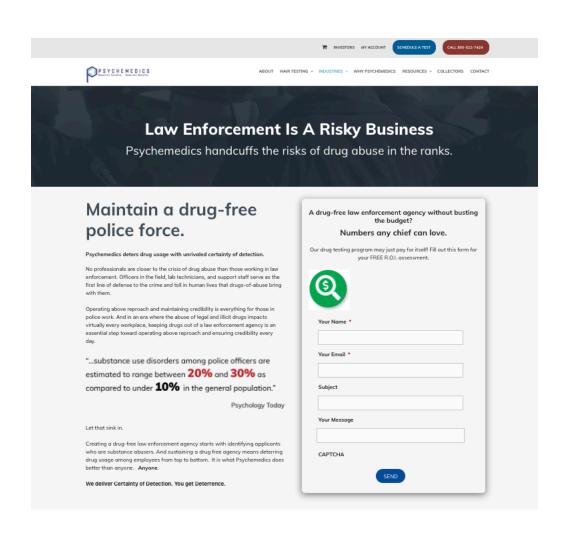


Psychemedics empowers public, private and faith-based schools to create drug-free campuses, preserve futures and save lives.

https://www.psychemedics.com/school-drug-testing/



https://www.psychemedics.com/transportation-industry/



Psychemedics helps the country's most respected law enforcement agencies reduce operational and financial risks that always accompany drug abuse.

Over thirty years, Psychemedics has detected more drugs for more organizations than any hair testing company in the world.



Unrivaled Detection



Unmatched Deterrence



Unparalleled Legal Record

Psychemedics' patented drug screens and extensive wash process deliver the best detection rates in the industry. Clients identify as many as 10X more users than urine and up to 3X more than other hair tests.

Certainty of detection is a powerful deterrent to drug use. SAMSHA studies show that drug users are less likely to apply at companies that test. Our unrivaled detection rates delivers certainty of Detection that Deters usage. The results of a Psychemedics hair test have withstood challenges in courts at multiple levels. And the company has a full-time legal counsel on staff dedicated 100% to hair testing that assists clients when needed.

Things You Should Know

Five Reasons Psychemedics Is The World Leader For Drug Testing With Hair

All Hair Testing Is NOT The Same

https://www.psychemedics.com/law-enforcement/