

Oral Fluid Screening Solutions

Intercept® Oral Fluid Drug Test
Just the Facts



OraSure Technologies

The Facts About Intercept® Oral Fluid Drug Testing

There is no shortage of misinformation surrounding the science of drugs of abuse testing. Oral fluid drug testing, being one of the newer technologies, is no exception to this fact. The team of scientists working for OraSure Technologies has led the drug testing industry and the scientific community with the research and tools that have pioneered this highly accurate and efficient method of testing for drugs of abuse. Our Company has been selling drugs of abuse collection devices and laboratory detection kits since 1999, and continues to provide reliable and trusted brands with many long-time customers. OraSure has banded its team of experts and an extensive library of scientific articles to bring you the facts surrounding Intercept® Oral Fluid Drug Test... a Reliable and Trusted Brand for Over 10 Years.

What are the benefits of the Intercept® Oral Fluid Drug Test?

As the leader of oral fluid drug testing, our mission for over 10 years has been to provide our customers with the most technologically advanced drug testing solutions with our Intercept® Oral Fluid Collection Device and Intercept® Drugs of Abuse Assays.

In leading this frontier of innovation, OraSure Technologies understands the importance to provide superior products and services to our customers. And because we value these distinctions, OraSure has sustained a long-proven history of positive customer

experiences. In fact, the Intercept® Oral Fluid Collection Device consistently has been named the most recognized brand in the oral fluid drug testing market.¹

Extensive Drug Assay Menu²⁻¹¹

Since our 1999 launch, OraSure has developed and received FDA clearance for 9 principle drugs of abuse assays. If FDA clearance is important to you, the Intercept® Collection Device and assays offer you the most complete drug assay menu of any of our competitors—as illustrated in the chart below.

FDA-510K Cleared Assays¹²

Assay Menu	Intercept®	Oral-Eze®	Quantisal™	Lin-Zhi International
Amphetamine	✓	✓	✓	✓
Methamphetamine (Including Ecstasy)	✓	✓	✓	✓*
Cocaine/Metabolite	✓	✓	✓	✓
Opiates	✓	✓	✓	✓
Marijuana (THC)	✓	✓		
Phencyclidine	✓	✓		
Barbiturates	✓			
Benzodiazepines	✓			
Methadone	✓			

*Not Approved for Ecstasy

Legally Proven¹³⁻¹⁷

Pioneering this new technology required years of studies to master the pharmacokinetic characteristics of drugs of abuse in oral fluid. And because we were so successful in our development, our collection device and assays have prevailed in numerous legal challenges that unproven devices cannot claim.

The ruling for each of these challenge cases concluded that the Intercept® Oral Fluid Drug Test results are recognized and accepted for the science, chain of custody, specimen collection procedure, test procedure, interpretation of test results, and confirmation test results. Our Intercept® Collection Device and assays provided evidentiary value in each of these cases. [*Medina County State of Ohio v. Albert Hoelscher / Imperial Oil Ltd. v. Communications, Energy & Paperworkers Union of Canada / Medina County v. Hixon / Family Court of the State of New York*].

Scientifically Proven¹⁸

As your partner in advanced testing solutions, we know that in the drug testing market, word gets around. That's why our reputation is so important to us and we let our scientific data speak for itself.

Our wealth of published data reflecting over 4.5 million specimens undeniably illustrates our commitment to excellence in drug testing with comparable positivity rates to traditional "gold standard" urine drug testing.

NIDA-5 Drug Panel	Intercept®	Urine Analysis ¹
Overall positive rate	4.1%	4.4%
Amphetamine	0.17%	0.42%
Methamphetamine	0.24%	0.17%
Cocaine Metabolite	0.82%	0.58%
THC	2.5%	2.3%
Opiates ²	0.60%	0.35%
PCP	0.02%	0.02%

Sample, *et al*, Positive Prevalence Rates in Drug Tests for Drugs of Abuse in Oral-Fluid and Urine, SOFT 2010.

1 Includes test results for other "non-NIDA-5" drugs such as barbiturates and benzodiazepines.

2 ~50% OF and ~8% Urine Opiates included hydrocodone and hydromorphone.

N=4.59 million Intercept® Devices.

OraSure Technologies continues to serve as a partner with our customers delivering expertise in a market we have pioneered and led. So whether working closely with a customer to deliver a custom drug testing program, or with client staff to deliver a value-added feature, you can expect to receive superior quality and performance with the Intercept® brand and your OraSure partner.

What are the collection times with the Intercept® device?

We know that time means money to our customers which is why you can count on *only a 5-minute* collection compared to our competition which can be twice as long or longer. But time saving technology is not the only advantage we offer. Our collection process has a 99.8% proven collection adequacy history on millions of specimens.¹⁹

What are the test turnaround times with Intercept®?

Specimens with any of our lab partners are tested the same day they are received. Negative test results are typically reported the same day. Positive screen results will be confirmed and reported within 72 hours of specimen receipt.

What is the difference between an Intercept® collected specimen and a neat specimen?

There really isn't a difference. It's like reporting temperature in a celsius versus a fahrenheit reading for the same temperature. It's a simple calculation factor.

Some oral fluid collection devices contain a diluent, such as the Intercept® device. Using the 'neat' designator is a way to standardize so one device and test can be compared to another.

Technical discussions on neat oral fluid specimen collection versus diluted oral fluid specimen collections have continued for the past 5 years within the

Substance Abuse and Mental Health Services Administration (SAMHSA) as they examine and prepare to draft revision proposals to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

In preparation of this anticipated change, newer entries to the collection device market are expressing the cutoffs in neat concentrations versus diluted. Not unlike Intercept® collected specimens, the ratio of neat to buffer diluted specimens is about 1 to 3. While the cutoffs for neat oral fluid may appear higher, the assays designed for detection are expected to capture the same positivity rates as diluted specimens and therefore will have no negative bearing on drug testing programs.

What should I consider when making a collection device change?

When choosing to make a switch it is best for you to look for these 7 things concerning the device and laboratory:

1. FDA clearance is a critical issue when considering any testing method. If a program or result is ever challenged it makes a company's defense a lot easier if the employer can substantiate the integrity of the device and the assays used with an FDA clearance. The OraSure Intercept® Collection Device and lab-based screening assays are the only lab-based oral fluid testing product line with a compliment of 9 assays cleared by the FDA²⁻¹¹... that's quite a distinction.
2. A history of proven performance. Look for a company that can provide an established track

record with products that are time-tested and accepted by the FDA and the scientific community.

3. A user-friendly device. Not all devices operate the same; some are more difficult to use than others... the best advice here is to “try it before you buy it”.

4. Legal support from the product manufacturer... not all state laws permit oral fluid testing though most do. Your supplier should be able to answer state and federal law questions for you.

5. Independent scientific data to back up accuracy claims. Not all manufacturers can provide such data; a buyer should insist on it.

6. Lengthy shelf-life.

7. Collector training is critical if the employer plans to have employees conduct collections. Look for a solid training program that contains FAQs and a proficiency test to ensure your employees are properly trained and fully understand the collection and testing process.

I use the Intercept®. What do I have to do to make a laboratory switch?

Intercept® is currently available through several SAMHSA-certified, toxicology/forensic and criminal justice laboratories. Each of these laboratories are prepared to offer you competitive pricing and reporting services for the Intercept® Collection Device.

Switching from one laboratory to another can best be accomplished with the following steps:

Step 1. Identify your new lab partner. OraSure is ready to assist you in assessing which lab(s) you will need based on your current testing program. Many of these labs offer extensive services that may enhance your current programs.

Step 2. Finalize price negotiations (if applicable) and contract with your new lab partner. Each of the laboratories are prepared to provide competitive pricing and programs to meet your needs.

Step 3. Disseminate new materials to your customer base. Your new lab partner and OraSure will be available to assist you.

Step 4. Training and policy amendments. Since you are already trained with the Intercept® Collection Device, **NO** training or drug policy amendments will be necessary. This will be business as usual for you and your accounts.

The OraSure Difference

While this document should answer many questions surrounding Intercept® Oral Fluid Drug Testing, more may arise as new products enter the market. OraSure is committed to developing and delivering innovative diagnostic solutions to meet tomorrow's challenges. Our long established expertise in oral fluid drug testing delivers trusted and reliable value to our customers while working in partnership towards a common goal.

Our dedicated field-based consultants are available to answer any questions you may have, assist with your training efforts, and provide the necessary support and expertise for your drug testing programs and policies.

Partner with OraSure and the Intercept® brand for your Oral Fluid Drug Testing Needs... a Reliable and Trusted Brand for Over 10 Years

References / Resources

1. 2010 Industry Survey on Drug Testing, WFC & Associates.
2. Intercept® Oral Fluid Drug Test Collection Device Package Insert, Item#3001-0885-0611.
3. Amphetamine-Specific Intercept® Micro-Plate EIA Package Insert, Item#3001-1053-0508.
4. Barbiturates Intercept® Micro-Plate EIA Package Insert, Item#3001-1055-0508.
5. Benzodiazepines Intercept® Micro-Plate EIA Package Insert, Item#3001-1056-0508.
6. Cannabinoids Intercept® Micro-Plate EIA Package Insert, Item#3001-1057-0508.
7. Cocaine Metabolite Intercept® Micro-Plate EIA Package Insert, Item#3001-1058-0508.
8. Methadone Intercept® Micro-Plate EIA Package Insert, Item#3001-1059-0508.
9. Methamphetamine Intercept® Micro-Plate EIA Package Insert, Item#3001-1054-0508.
10. Opiates Intercept® Micro-Plate EIA Package Insert, Item#3001-1060-0508.
11. PCP Intercept® Micro-Plate EIA Package Insert, Item#3001-1061-0508.

Regulatory Reference:

12. The Intercept® oral fluid drug testing system is cleared by the FDA and filed with the following numbers:

FDA Clearance 510K Numbers	Intercept® Device/Assay
K011057	Oral Fluid Collection Device
K992918	Amphetamine Specific Microplate
K001976	Barbiturates Microplate
K013882	Benzodiazepines Microplate
K002375	Cannabinoids Microplate
K001197	Cocaine Microplate
K002010	Methadone Microplate
K993208	Methamphetamine Microplate
K981341	Opiates Microplate
K000399	PCP Microplate

13. Kadehjian, L., Legal Issues in Oral Fluid Testing. *Forensic Science International*, 2005; 150: pp. 151-160.
14. Family Court of the State of New York, Rockland County, ruling dated August 15, 2005.
15. Medina County, OH. *State of Ohio v. Hixon*, Case No. 04CR 171, filed January 25, 2006.
16. Median County, OH. *State of Ohio v. Albert Hoelscher*, Case No. 04-CR-0358, filed July 19, 2005.
17. Ontario, Canada. *Imperial Oil Ltd. v. Communications, Energy & Paperworkers Union of Canada, Local 900*, filed December, 2006.
18. Sample, *et al*, Positive Prevalence Rates in Drug Tests for Drugs of Abuse in Oral-Fluid and Urine, SOFT 2010.
19. Data on file provided by Quest Diagnostics, 2010.

To learn more about OraSure's fine line
of oral fluid testing tools, go to
www.orasure.com or call
1-800-ORASURE.

The Value of a Reliable and Trusted Brand



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