



# INTERCEPT® QUESTIONS AND ANSWERS

## DETECTION/CUTOFFS

- 1) **How does the detection window for Intercept® compare with other methods such as urine?**
  - Just like traditional urine testing, the window of detection in oral-fluid is different for each drug. Oral-fluid testing identifies recent usage-that may be missed by urine testing. For most drugs, the maximum window of detection in oral-fluid is about one-to-two days. By contrast, urine testing relies on drugs or their metabolites retained in the body’s waste supply and does detect some drugs for a longer period (1 to 3 days). Moreover, oral-fluid testing may detect drug use 1 to 2 hours after ingestion/use. Urine testing usually requires 2-6 hours to detect use after ingestion/use.
- 2) **How does the positivity rate for Intercept® compare with urine?**

Oral-Fluid vs. Urine  
(January – December 2003)

	<b>Intercept®</b>	<b>Urine non-DOT</b>
<b>Overall Positive</b>	<b>4.3%</b>	<b>5.0%</b>
<b>BY DRUG</b>		
<b>Amphetamines*</b>	<b>0.13%</b>	<b>0.49%</b>
<b>Methamphetamine</b>	<b>0.46%</b>	<b>N/A*</b>
<b>Cocaine</b>	<b>1.23%</b>	<b>0.74%</b>
<b>Marijuana</b>	<b>2.13%</b>	<b>2.96%</b>
<b>Opiates</b>	<b>0.66%</b>	<b>0.34%</b>
<b>PCP</b>	<b>0.04%</b>	<b>0.03%</b>

\* An “Amphetamines” screen in urine detects both amphetamine and methamphetamine. In oral-fluid, separate screens are used to comprehensively detect both amphetamine and methamphetamine

**3) What are the cutoffs and analytes for the Intercept® test:**

DRUG CLASS	INITIAL TEST LEVEL	CONFIRMATORY LEVEL	CONFIRMATORY METHOD*
AMPHETAMINE	100 ng/mL	40 ng/mL	GC/MS
METHAMPHETAMINES	40 ng/mL		
METHAMPHETAMINE		40 ng/mL	GC/MS
MDA		40 ng/mL	GC/MS
MDMA		40 ng/mL	GC/MS
COCAINE METABOLITES	5 ng/mL		
BENZOYLECGONINE		2 ng/mL	GC/MS
MARIJUANA	1 ng/mL	0.5 ng/mL	GC/MS
OPIATES	10 ng/mL		
MORPHINE		10 ng/mL	GC/MS
CODEINE		10 ng/mL	GC/MS
HYDROMORPHONE		10 ng/mL	GC/MS
HYDROCODONE		10 ng/mL	GC/MS
6-MONOACETYLMORPHINE		10 ng/mL	GC/MS
PHENCYCLIDINE	1 ng/mL	0.5 ng/mL	GC/MS

\* GC/MS includes GC/MS/MS which may be used for some analytes.

## **TECHNICAL**

**4) What methodology is used?**

- A two-tiered testing process is used:
  - A portion of the oral-fluid sample is first screened using Enzyme Linked Immunosorbent Assay (ELISA), a proven reliable methodology for routine drug testing.
  - Any samples that are presumptively positive in the screening process are then confirmed, utilizing another portion of the oral-fluid sample, using either gas chromatography/mass spectrometry (GC/MS) or gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS)

**5) What is ELISA?**

- ELISA is an acronym for enzyme-linked immunosorbent assay. ELISA assays are heterogeneous non-isotopic assays that usually have an antibody immobilized onto a solid support. The ELISA assay uses a microtiter plate that has the antibody to the drug, drug metabolite or drug class coated to each well of the microtiter plate.

**6) What is the difference between EIA and ELISA?**

- EIA is the more traditional enzyme immunoassay. The technology has been widely used for the analysis of drugs of abuse. It is homogenous in nature meaning that the analysis is

performed without any physical separation during the analysis. ELISA is heterogeneous — the microtiter plate is washed before the reaction is allowed to go to completion. In general, ELISA assays may offer greater sensitivity than most EIA procedures.

**7) Is ELISA forensically defensible?**

- Yes, the technology is well established and has been used in many formats for the analysis of drugs of abuse, therapeutic drug monitoring (TDM) and serology (antibody tests) and blood banking procedures. Furthermore, ELISA technology is used extensively in the pharmaceutical industry for new drug screening and development.

**8) What is the difference between GC/MS and GC/MS/MS?**

- GC/MS is the more traditional confirmation method for drugs of abuse testing. Both technologies produce a “molecular fingerprint” of the drug or compound being analyzed and provide definitive identification. GC/MS/MS, a newer technology also known as “tandem MS”, generally provides greater sensitivity which is often required for the analysis of alternative specimens.

**9) What is the turnaround time?**

- The laboratory receives the oral-fluid samples via overnight or Quest Diagnostics courier. Testing is performed the day the samples arrive and negative results are reported the same day. Positive results are confirmed, reviewed, and reported within 72 hours of receipt.

**10) What drugs are tested with Intercept<sup>®</sup>?**

- The drugs tested for are the following: Amphetamines, Methamphetamines (including MDMA and MDA), Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone, 6-monoacetylmorphine), Cocaine (Metabolites), THC, and PCP.

**11) What are the order codes for Intercept<sup>®</sup>?**

- The bundled code is 38535N. The unbundled code is 38534N.

**12) Where is the testing performed?**

- The Intercept<sup>®</sup> test is performed at either our Atlanta or Van Nuys SAMHSA-certified laboratory.

**13) Can the Intercept<sup>®</sup> test detect Ecstasy?**

- Yes, Ecstasy is reported under the "Methamphetamines" group.

**14) Can the Intercept® test detect synthetic opiates?**

- Yes, in addition to codeine, morphine, and 6-monoacetylmorphine, the Intercept® "Opiates" test detects hydrocodone and hydromorphone. All five of these opiates are reported if detected in the oral-fluid specimen.

**15) Can the Intercept® test detect oxycodone?**

- No, the Intercept® test has poor cross-reactivity with oxycodone and should not be used to detect oxycodone abuse.

**16) How long are positive (non-negative) specimens retained by the laboratory?**

- Non-Negative specimens are retained for a minimum of 12 months (the same as a non-negative urine specimen).

## **REPORTING**

**17) How are the results reported?**

- As with all laboratory-based testing, results are logged in the laboratory information system and reported to the client by confidential fax, direct interface, printer, or voice response.

## **ADULTERATION**

**18) Can an oral-fluid test be beaten?**

- We have not found any adulterants that can beat the test at this time. Of course, donors may attempt to introduce something onto the pad or collection vial. This risk is minimized because every collection is directly and easily observed.

**19) How does the laboratory determine if the specimen is human saliva?**

- With every specimen, the laboratory performs an IgG test. This test will determine if the specimen is human saliva and if there is sufficient saliva to perform the drug testing. The IgG test is a specimen validity test.

## **COLLECTION/SUPPLIES**

**20) Who collects the sample?**

- The beauty of the oral-fluid collection is that the donor controls his or her sample under direct visual supervision. The “collector” really is an observer and has a small role in the “chain of custody”-the process most often legally challenged. If the donor wants to challenge the collection, the only person to challenge is the donor. The entire process takes just 5 minutes.

**21) What is on the pad and why is it so salty?**

- The pad is treated with a salt solution to enhance collection. The salt solution is non-harmful and non-toxic.

**22) Is the pad safe to put in my mouth?**

- Yes, all of the ingredients on the pad are on the FDA generally recognized as safe (GRAS) list.

**23) What is the blue liquid in the vial?**

- The blue liquid is a non-toxic preservative that keeps the oral-fluid sample from deteriorating during shipment to the laboratory.

**24) How do you know if you have collected enough sample?**

- If the donor keeps the collection pad in his or her mouth for at least three minutes (and no more than 5 minutes), as indicated on the package, there is enough to test. The collection pad is treated with salts to stimulate oral-fluid secretion, making the process very reliable. In fact, based on existing experience, only 1 in 10,000 samples are insufficient for testing.

**25) Will recent oral surgery (root canals, extraction's, etc.) or sutures make a difference?**

- Neither will affect the collection; however, if sutures are located between the lower cheek and gum, it is better to collect the sample from the opposite side of the mouth.

**26) When collecting an oral-fluid specimen, I noticed a small amount of blood on the collection pad. Is this normal?**

- Although this is not common, it may occur in some individuals and should not adversely affect the specimen collected.

**27) How long is the specimen stable after it has been collected?**

- In clinical tests, OraSure has determined that the specimen is stable for 21 days after it is collected.
- Non-Negative specimens tested by the laboratory are stable for at least 1 year when stored frozen.

**28) Can I use my urine custody and control form?**

- There is an alternative specimen custody and control that should be used. It is intended for lab based testing of oral-fluid and hair specimens.

**29) Can the test be run if I use the regular urine custody and control form by mistake or I have run out of the alternate custody and control form?**

- Yes but the tamper proof evidence tape on the urine custody and control form is designed for the urine bottle and is too long for the oral-fluid vial.

**30) What if the donor is taking medications and wants to write the names of the medications on the custody and control form?**

- For privacy reasons, the names of medications that the donor may be taking must *not* be listed on the custody and control form. However, as a reminder, the donor may list them on the back side of their copy of the form in case the donor is contacted by a Medical Review Officer.

**31) How do I collect a split specimen?**

- Have the donor place simultaneously two swabs in their mouth, one on each side of the mouth. After the specimen is collected on the swab, have them place one swab in one plastic vial and the other swab in the other plastic vial.

**32) Isn't oral-fluid a hazardous fluid?**

- No. Because the testing methodology is not classified as a “dental process”, OSHA does not consider oral-fluid collections hazardous.

**33) If I run out of the collection devices, can I use anything else?**

- No, the specimen can only be collected in an Intercept<sup>®</sup> collection device.

**34) Do I order the Intercept<sup>®</sup> collection device from OraSure or Quest Diagnostics?**

- You should order the Intercept<sup>®</sup> collection device from Quest Diagnostics. You can order these supplies just the same as you would order the routine custody and controls forms and the urine collection kits. Either call 800-877-7484 or you may use our e-mail ([poct.es@questdiagnostics.com](mailto:poct.es@questdiagnostics.com)) or fax line (267-200-0329).

**35) What is the shelf life of the Intercept<sup>®</sup> collection device?**

- Between 12 and 15 months.

**36) What do I receive when I order Intercept<sup>®</sup> collection devices?**

- Intercept<sup>®</sup> collection device and a specimen transportation bag (i.e. chain-of-custody bag) for each Intercept<sup>®</sup> device ordered.
- Custody and Control Forms must be ordered separately.
- If the specimens are shipped to the laboratory by overnight courier, airbills for shipping the specimen to the Atlanta laboratory are included with each order of Intercept<sup>®</sup> collection devices.

## **REGULATIONS**

**37) Can the Intercept<sup>®</sup> test be used for Department of Transportation (DOT) testing?**

- No, the DOT has not approved either oral-fluid or hair for testing at this time.

**38) Is the Intercept<sup>®</sup> test FDA-cleared?**

- Yes, it is FDA-cleared.

## **TRANSPORTATION**

**39) How do I get the specimen to the laboratory?**

- The oral-fluid specimen should be sent via Quest Diagnostics courier to either our Atlanta or Van Nuys laboratories or by overnight courier to our Atlanta laboratory.