

Executive Summary

Oral fluid has been recognized as a valid specimen for pharmacokinetic studies, therapeutic drug monitoring and for the detection of illicit drugs, with initial studies published more than 20 years ago. With respect to substance abuse testing, oral fluid made significant advancements in the delivery of test specimens for the insurance market, beginning in 1995. Within five years, more than two million oral fluid samples were being collected annually for risk-assessment purposes.

Beginning in 1996, oral fluid testing for an expanded drug panel could be seen in forensic testing laboratories. In 1998, oral fluid tests for the NIDA-5 panel of commonly abused drugs (marijuana, cocaine, opiates, amphetamines and PCP) received 510(k) clearance from the FDA, opening the door to commercialization in non-forensic settings.

OraSure Technologies, Inc., manufactures the FDA-cleared Intercept® oral fluid testing system, including an oral fluid specimen collection device and oral fluid diagnostic kits for laboratory-based specimen analysis.

- The specimen collection device consists of an absorbent pad affixed to a collection wand, and a vial for secure transport to the laboratory. Collection requires less than five minutes.
- The laboratory kits are ELISA (enzyme-linked immunosorbent assay) technology, a quantitative in vitro test that exposes the specimen to an antibody specific for the substance to be detected. A positive result is indicated by a treatment yielding a color in proportion to the amount of drug in the specimen.

Since January 2001, more than 1,000,000 Intercept oral fluid specimens have been collected for drug-free workplace programs. Four nationally recognized laboratories offer oral fluid testing services. At least three manufacturers have commercialized products.

Intercept specimens and assays have been the subject of several published scientific studies on the effectiveness of oral fluid as a substance abuse testing medium. Four of the studies have been published in the peer-reviewed *Journal of Analytical Toxicology*.

The Food & Drug Administration has cleared the Intercept assays as equivalent to standard urine testing. The laboratories running Intercept tests are of the highest quality. Their urine testing programs are routinely inspected and certified by the Substance Abuse and Mental Health Services Administration. The labs participate in proficiency testing programs each quarter from Cardiff Research Institute, U.K.

SAMHSA is currently considering oral fluid testing for federal programs. OraSure Technologies has participated with SAMHSA since 1998 in developing guidelines for oral fluid testing programs. Our laboratories successfully completed voluntary proficiency testing program programs requested by SAMHSA to evaluate their oral fluid procedures.

Product Features & Benefits

<ul style="list-style-type: none"> • Oral fluid collection 	<ul style="list-style-type: none"> • Non-invasive for employee testing • Retains dignity for male or female donors • Able to be handled without biohazard disposal • Protects against "shy bladder" syndrome
<ul style="list-style-type: none"> • Easy to collect 	<ul style="list-style-type: none"> • Employers can manage collections and eliminate costly off-site collection step • Workers return quickly to their job • Testing can be done anytime, anywhere, improving deterrence • Special facilities not necessary
<ul style="list-style-type: none"> • Collection is observed 	<ul style="list-style-type: none"> • Employers eliminate opportunity for specimen tampering <ul style="list-style-type: none"> ◦ Masking agents ◦ Hydration / dilution ◦ Substitution of "clean" specimen • Employers are certain donor provided specimen
<ul style="list-style-type: none"> • Specimen is securely sealed 	<ul style="list-style-type: none"> • Specimens can be shipped in non-hazardous containers • Specimens can be sent via overnight courier • Specimens are secure in "chain of custody" that begins and ends with the donor to be tested
<ul style="list-style-type: none"> • Laboratories are certified 	<ul style="list-style-type: none"> • Laboratories hold SAMHSA certifications for their federally regulated urine testing programs • Specimens are routed under strict custody and control within the lab • Laboratories have qualified scientists overseeing process • Laboratories use screening and confirmation algorithm upheld by the Supreme Court in urine cases

Intercept® Oral fluid collection

The specimen collection device consists of an absorbent pad affixed to a collection wand, and a vial for secure transport to the laboratory. Collection requires less than five minutes. The pad is placed in the buccal cavity between the lower cheek and gum to collect the oral fluid. A coating of salts aids in collecting the specimen, a mixture of gingival crevicular fluid and saliva referred to as oral fluid.

The donor being tested secures the specimen pad in the specimen vial. A tamper-resistant "chain of custody" seal is applied over the vial. Absent a seal, the laboratory will not accept the specimen.

Storage and shipping requirements

The specimen vial is transported to the laboratory by courier or commercial overnight carrier. Because the sealed oral fluid specimen is not considered a biohazard, no special storage or shipping requirements apply.

Laboratory custody and control

The laboratory receives the specimen under strict custody and control (accessioning). Samples are identified by barcodes on the specimen vial that match information recorded by the Collector on a Custody and Control Form. Specimens are logged into the laboratory's information system (LIS) and tracked throughout the testing process.

Laboratory analysis

Specimens are first analyzed using the Intercept oral fluid micro-plate assays. The laboratory kits are ELISA (enzyme-linked immunosorbent assay) technology, a quantitative in vitro test that exposes the specimen to an antibody specific for the substance to be detected. A positive result is indicated by a treatment yielding a color in proportion to the amount of drug in the specimen.

Any specimen that produces a positive result in the screening step is then subjected to a gas chromatography, mass-spectrometry (GCMS) confirmation test. The Supreme Court has upheld this process of independent screening and confirmation methods.

Reporting

The laboratory reports results of specimens that test negative in either step to the employer. The laboratory reports results of specimens that test positive at confirmation to a Medical Review Officer. The MRO contacts the donor to identify any medical explanations for the positive test, and then reports final findings to the employer.

FDA review

The Food & Drug Administration evaluates assays for safety, efficacy and ability to meet performance claims in their package inserts. The FDA has issued 510(k) clearance for the Intercept oral fluid specimen collection device and related drugs of abuse assays.

Experience from SAMHSA inspections

The Substance Abuse and Mental Health Services Administration inspects and certifies laboratories involved in federal testing programs. The laboratories contracted to analyze Intercept specimens are SAMHSA-certified for their federally regulated urine testing programs. The laboratories are committed to handling their oral fluid specimens with the same integrity of Custody and Control and scientific staff as the urine specimens they process for federal testing.

DHHS/DOT federal mandated programs

The federal government requires testing for federal employees and contractors under guidelines developed by the Department of Health and Human Services. The program allows laboratory-based urine testing only. Hair and oral fluid options are currently being developed. The Dept. of Transportation adopted the HHS guidelines for mandated testing of "safety sensitive" employees in the transportation industry (pilots, truck drivers, etc.).

State restrictions

Regulations in 46 states allow oral fluid testing for drug-free workplace programs. Montana limits drug testing to safety-sensitive employees covered by the federal program. Three states, Oklahoma, Maine and Hawaii, do not allow oral fluid testing because legislative or regulatory guidelines were developed prior to the introduction of oral fluid testing. Louisiana, Iowa, Maryland and North Carolina most recently approved oral fluid as a valid testing medium.