

On-Site Oral Screening Device

FREQUENTLY ASKED QUESTIONS

What is the On-Site Oral screening device?

The On-Site Oral screening device offers an easy-to-use, non-invasive method for the detection of multiple drugs in oral fluids. This cutting-edge technology offers a unique, gender-neutral design that eliminates urine collection. With the On-Site Oral screening device, your agency can reduce collection-site fees, the need for special equipment, same sex collectors and complicated training. This test can be performed on-site anytime, anywhere and offers quick results.

How does the On-Site Oral screening device work?

The On-Site Oral screening device is a lateral flow, chromatographic immunoassay for the qualitative detection of multiple drugs and their metabolites in oral fluids based on the principle of competitive binding. Simply drop the collected oral fluid specimen into the device sample well and read in 10 minutes. It's that easy!

As with all of Redwood Biotech/Redwood Toxicology Laboratory's (RTL) products, a detailed product insert is included with every order. Telephonic training is provided to all clients via our toll-free hotline at (877) 444-0049.

What is the principle of the On-Site Oral screening device?

The oral fluids test is based on competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a portion of the oral fluid sample migrates across the membrane. If no drug is present above the cut-off, the sample will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region. The presence of a drug above the cut-off concentration will saturate all the binding sites of the antibody and a line will not form in the test region. The lateral flow is the migration and competition across the membrane.

To serve as a procedural control, a colored line will appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

What are the benefits of On-Site Oral testing vs. other drug testing methods?

There are numerous benefits to using the On-Site Oral screening device.

- Eliminate urine collections and collector fees
- Observable, gender-neutral collections without privacy issues

- Non-invasive
- Easy to read test results
- Testing integrity (difficult to adulterate)
- Results available in 10 minutes—allows for immediate decision or treatment

Complete testing kit includes all components for testing including an easy-to-follow product insert. Telephonic training and support is available via Redwood Biotech/RTL's toll-free hotline.

What is the detection window compared to other drug testing methods?

Saliva and blood have similar detection windows. Testing saliva/blood will detect drug use faster than testing urine. Saliva/blood may detect drug ingestion within minutes while drug detection in urine may take 6-8 hours post ingestion.

What are the cut-off levels for the On-Site Oral screening device?

The On-Site Oral screening device cut-off concentrations for amphetamine, methamphetamine, THC, PCP, cocaine, and opiates are as follows:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (MAMP)	d-Methamphetamine	50 ng/mL
Marijuana (THC)	THC-COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Cocaine (COC)	Benzoylcegonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL

What is the analytical sensitivity of the On-Site Oral screening device?

A PBS pool was spiked with drugs to target concentrations of $\pm 50\%$ cut-off and $\pm 25\%$ cut-off and tested with the On-Site Oral screening device. The results are summarized below.

Drug concentration (Cut-off range)	n	COC		mAMP		PCP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0
Cut-off	30	20	10	23	7	22	8
+25% Cut-off	30	6	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Drug concentration (Cut-off range)	n	THC		MOP		AMP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	24	0	28	2	30	0
Cut-off	30	15	10	23	7	22	8
+25% Cut-off	30	11	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Does the test quantify the concentration of drugs present in the oral fluids sample?

A positive test result does not indicate the concentration of drug in the sample. All positive results are presumptive and should be confirmed by an alternate method (e.g. GC/MS or GC/MS/MS). Negative results may not necessarily indicate a drug-free sample. Drug may be present in the sample below the cut-off level of the assay.

What type of agencies can use the On-Site Oral screening device?

Everyone can benefit from using the On-Site Oral screening device, particularly agencies in the pre-employment, workplace and corrections arena.

How is the oral fluids specimen collected?

The donor actively swabs the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, gently press the sponge between the tongue and teeth to ensure complete saturation (about 3 minutes).

If the donor has a dry mouth, can they have a drink of water?

A drink of water may be given to the donor. It is best to wait for about 10 minutes after the drink before attempting another collection.

How do I know the test device is working properly?

A control line will be present if the test is working properly. If a control line does not appear, repeat the test. Insufficient specimen volume or incorrect procedural techniques are most likely the reasons for control line failure. Review the procedure and repeat the test using a new device. If further assistance is required, please contact Redwood Biotech/Redwood Toxicology Laboratory via our toll-free hotline.

Can the test be adulterated?

The test is virtually impossible to adulterate. Make sure the donor has not eaten or had anything to drink for a minimum of 10 minutes prior to testing.

How do I know if the test is negative?

If the test is negative, red lines appear in the control region (C) and next to each particular drug name in the test region. The negative result indicates that the drug concentration is below the detectable level. The shade of red in the test region will vary, but it should be considered negative, even if there is a faint pink line.

How do I know if the test is positive?

If the test is presumptive positive, red lines appear in the control region (C), and no line appears in the test region next to a particular drug name. This positive result indicates that the drug concentration is above the detectable level. All positive results are presumptive and should be confirmed by an alternate method (e.g. GC/MS or GC/MS/MS).

What if the test line is very faint?

The shade of red in the test region will vary, but it should be considered negative whenever there is even a faint pink line.

Is it possible to confirm positive results?

To confirm a positive result, send the original leftover oral fluid specimen to Redwood Toxicology Laboratory, Inc. (RTL) for confirmation via gas chromatography/mass spectrometry (GC/MS). Place the security seal over the screw cap, put the collection chamber in a plastic baggie and mail to RTL. Results are available via fax and U.S. mail. For laboratory support, contact RTL's Client Services Department at (800) 255-2159.

What is the shelf life of the On-Site Oral screening device?

The test has a shelf life of 18 months.

What is the recommended storage temperature for the On-Site Oral screening device?

Store as packaged in the sealed pouch at 2-30°C (36-86°F).

How can I order the On-Site Oral screening devices?

To order the On-Site Oral screening devices, call Redwood Biotech/Redwood Toxicology Laboratory toll-free at (877) 444-0049. A sales associate will assist you in placing your order.

Oral Fluid THC Explanation

Due to limitation of current testing technologies the detection of cannabinoids (THC) in oral fluids is problematic. There is very little evidence that THC in blood returns to oral fluids once it is absorbed into the bloodstream. However, the active component of marijuana, delta-9-THC, can be detected in oral fluid. During marijuana use (smoke or oral use) THC is deposited in the oral cavity and can be detected for approximately 12 - 24 hours after use. To optimize the detection of marijuana, Redwood Biotech/Redwood Toxicology Laboratory suggests, if marijuana use is suspected, to either submit the oral fluid to Redwood Toxicology Laboratory, Inc. for delta-9-THC GC/MS testing or to simultaneously collect and screen a urine specimen for THC-COOH (primary metabolite in urine).



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