

Confidence in testing.

OrAlert™

substance abuse screening device

Product Training
Presentation





The information in this presentation is a general overview on using the OrAlert™ substance abuse screening device.

Product Training Contents:

- OrAlert™ overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation

OrAlert technical information

It is important to read the package insert before using the OrAlert screening device.

Screening Results:

The OrAlert is used for **Forensic Use Only**. Positive results obtained with this device are presumptive.

Additional testing is necessary to **confirm** the presumptive positive results. Positive results should be “confirmed” by an **alternate method such as GC/MS** (Gas Chromatography/Mass Spectrometry).

Professional judgment should be applied to any drug of abuse test result, particularly with preliminary positive results.

The OrAlert screening device is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine, benzodiazepines and their metabolites in oral fluids. For forensic use only.



Product overview

OrAlert product overview

OrAlert™ combines proven technology and screening accuracy. Look no further than OrAlert to provide reliable saliva drug screening. Ideal for most testing environments.

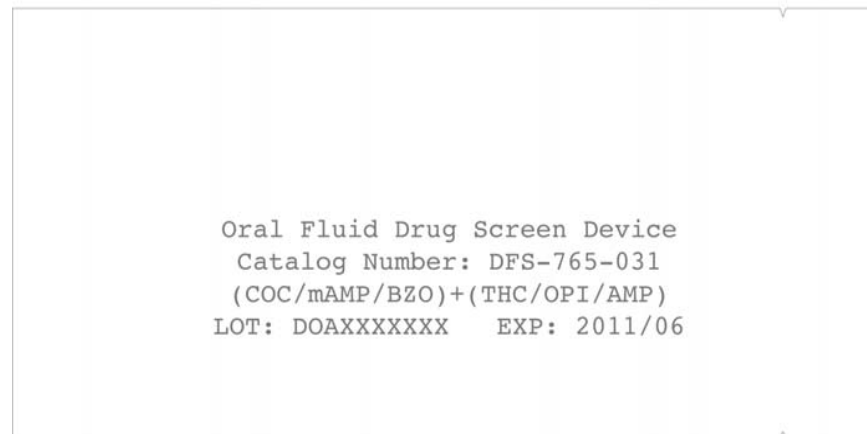
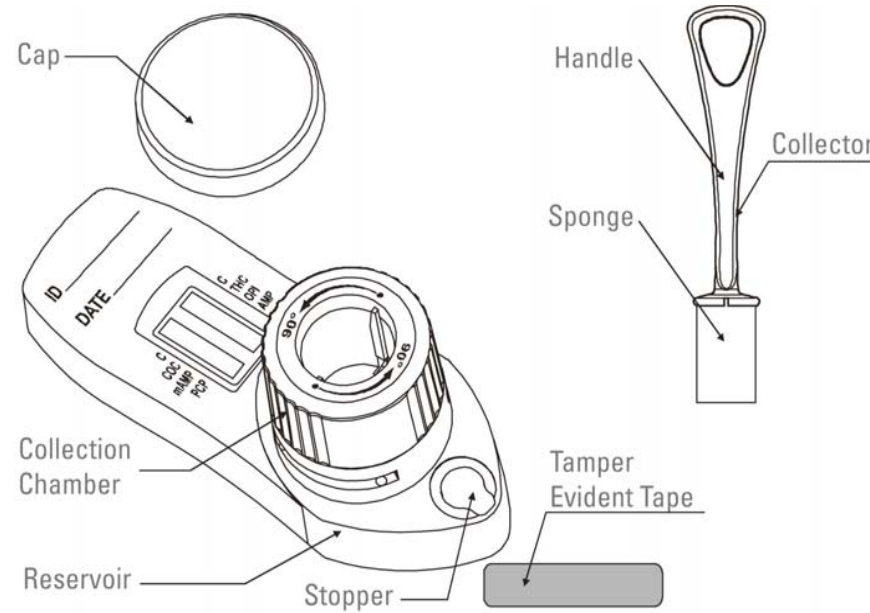


FEATURES & BENEFITS

- Tests include: AMP, M-AMP, BZO, COC,
- OPI, PCP and THC
- Improved sensitivity of parent THC
- Zero collector exposure to specimen
- Split specimen well
- Results in under 10 minutes

* See page 8 for abbreviations and cut-off levels

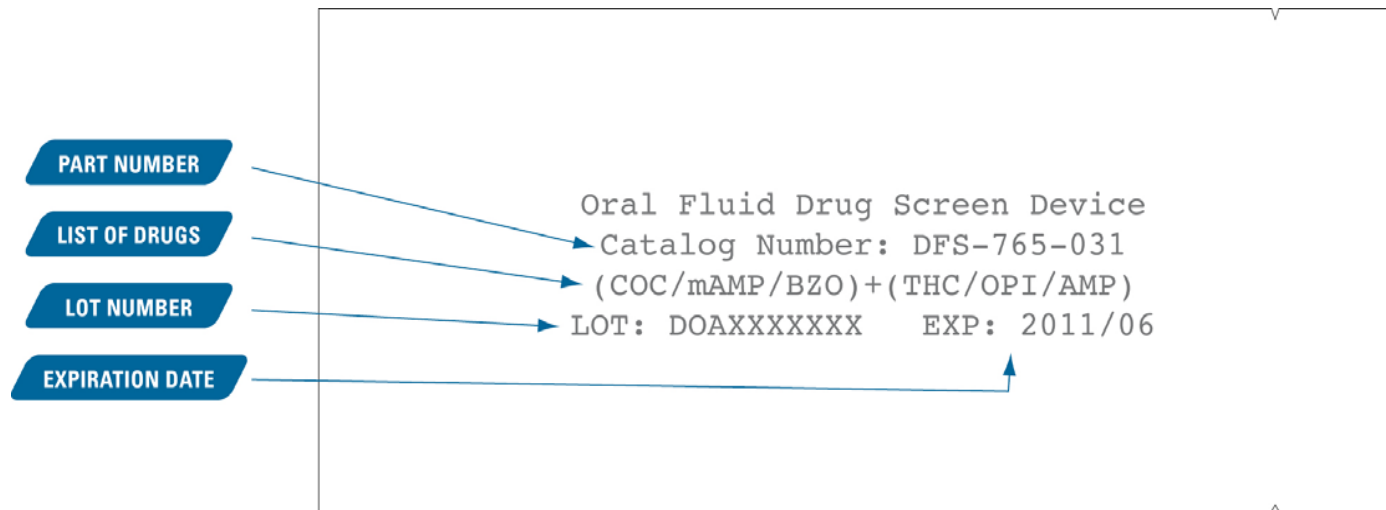
OrAlert components



Foil Pouch

OrAlert packaging

The lot number, expiration date, part number and a list of abbreviated* drugs screened are on the back of the foil pouch.



* See page 8 for abbreviations and cut-off levels

OrAlert cut-off levels

DRUG	TARGET DRUG	CUT-OFF
Amphetamine (AMP)	D-Amphetamine	50 ng/mL
Cocaine (COC)	Benzoylcegonine	20 ng/mL
Marijuana (THC)	Δ 9-THC	100 ng/mL
Methamphetamine (M-AMP)	D-Methamphetamine	50 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	10 ng/mL

Drug detection times

Drug	Detection Time
Amphetamine (AMP) Cocaine (COC) Methamphetamine (M-AMP) Opiates (OPI) Phencyclidine (PCP) Benzodiazepines (BZO)	<u>Up to 48 hours</u> <i>(approximate)</i>

Drug	Detection Time
Marijuana (THC)	<u>Up to 14 hours</u> <i>(approximate)</i>



Collection procedure

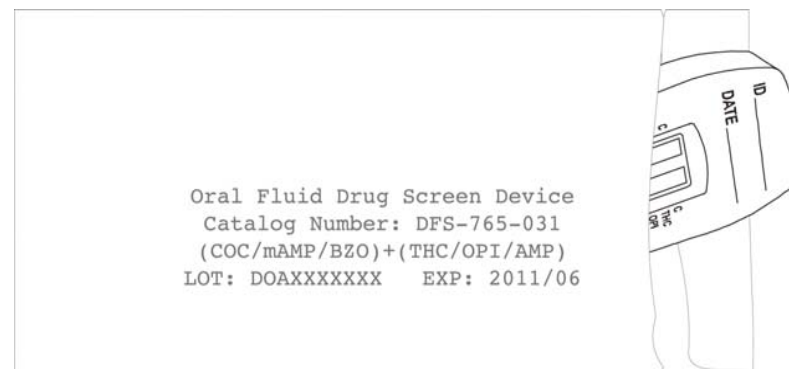
Collecting specimen

Bring the pouch to room temperature before opening it. Remove the test and cap from the sealed pouch and use the test as soon as possible.

Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

Remove the collector from the sealed pouch.

Remove test device from pouch



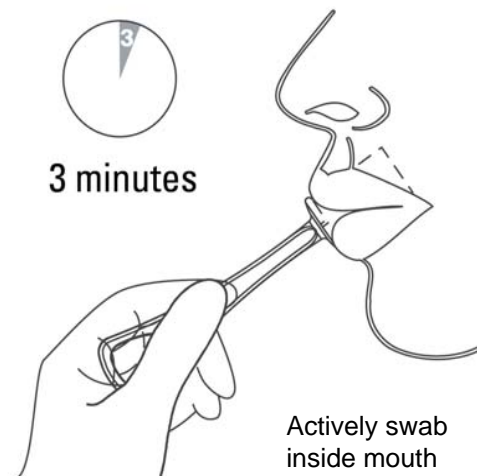
Remove collection device

Collecting specimen

Insert the sponge end of the collector into the mouth.

Actively swab the inside of the mouth and tongue to collect oral fluid for a total of **3 minutes** until the sponge becomes fully saturated.

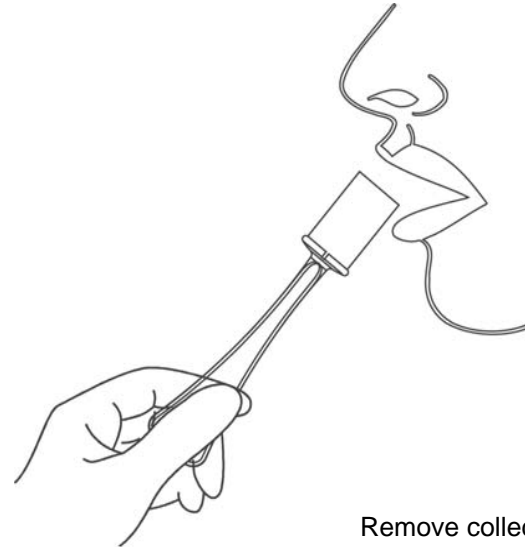
Gently pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.



Collecting specimen

Remove collector from mouth.

NOTE: The device may be left in the mouth longer than 3 minutes to “fully saturate” the sponge.



Remove collector after 3 minutes when fully saturated

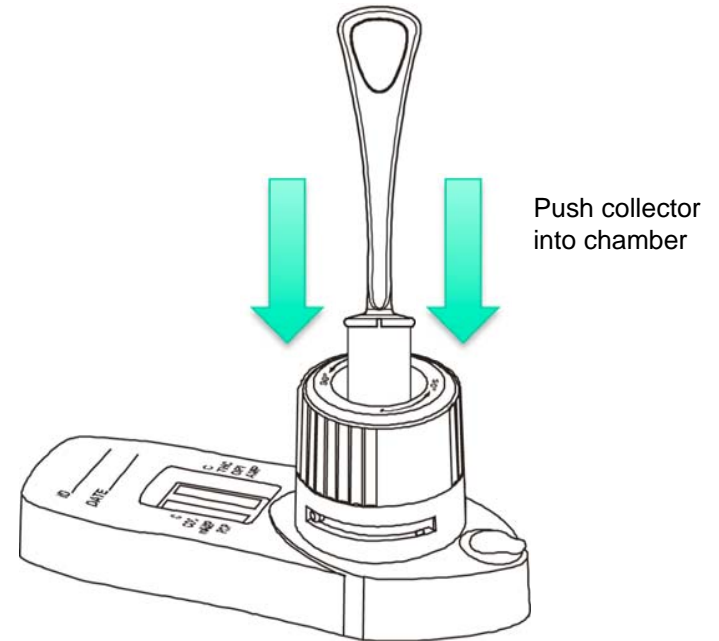


Testing procedure

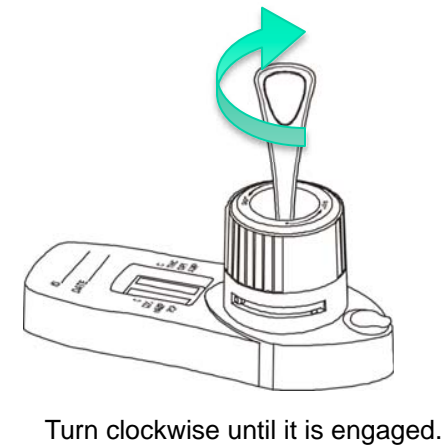
Testing procedure

With the test device on a flat surface, insert the collector into the test device by aligning the notches on the collector with the tracks on the inside of the collection chamber.

Push the collector into the chamber.

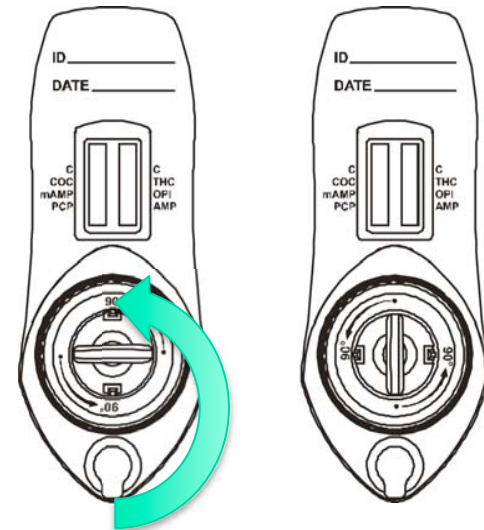


Turn the collector clockwise until it is engaged. Wait 1 minute.



Testing procedure

After 1 minute, rotate the collection chamber counterclockwise and **set the timer for 9 minutes**.



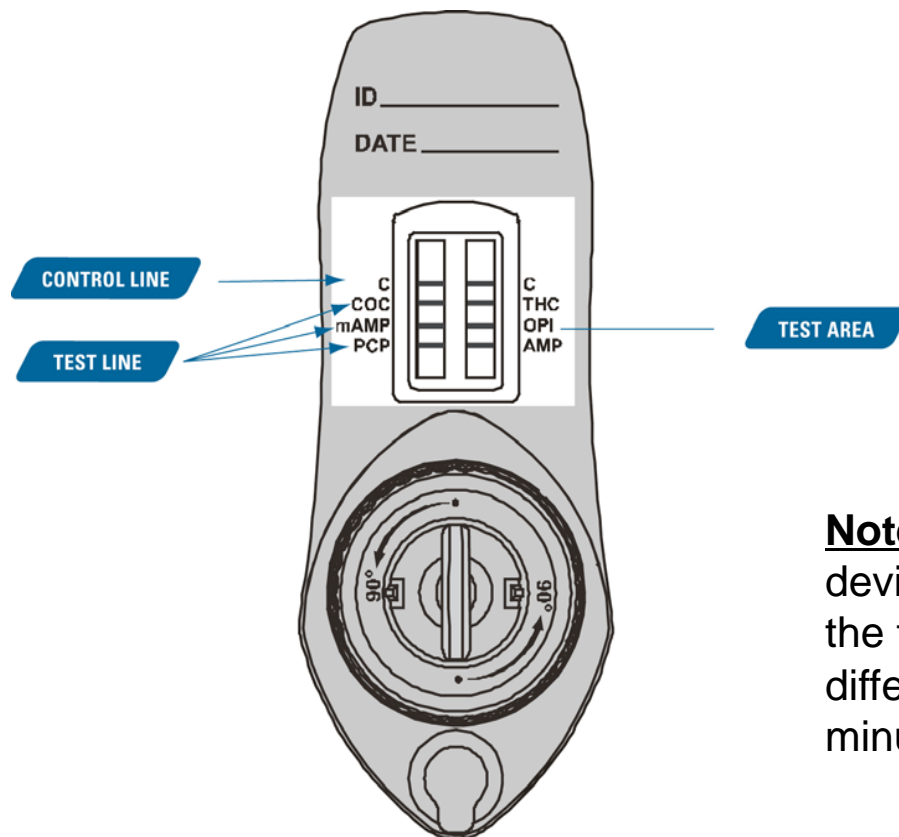
Rotate collection chamber 90° counterclockwise



Reading results

Reading results

Wait for colored lines to appear. Read test results at **9 minutes**. Do not interpret results after 1 hour as false results may occur. **NOTE:** Any line at all in the test area is to be interpreted as negative.



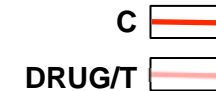
Note: As oral fluid wicks up the test device a “pink” color may be seen in the test area. Lines will develop at different rates. Wait the entire 9 minutes before reading results.

Result interpretation

NEGATIVE

The control line must be red to indicate the test is valid. Any visible line, even a faint line, indicates a negative result. *See example page 22.*

NEGATIVE RESULT



PRESUMPTIVE POSITIVE*

The control line must be red to indicate the test is valid. The test area must be snow white to be considered positive. *See example page 23.*

POSITIVE RESULT



Additional testing is necessary to **confirm the presumptive positive results. Positive results should be "confirmed" by an **alternate method such as GC/MS** (Gas Chromatography Mass Spectrometry).*

INVALID

When there is no line in the control line area, the result is invalid. If an invalid result is obtained repeat the test using a new test device.

INVALID RESULT



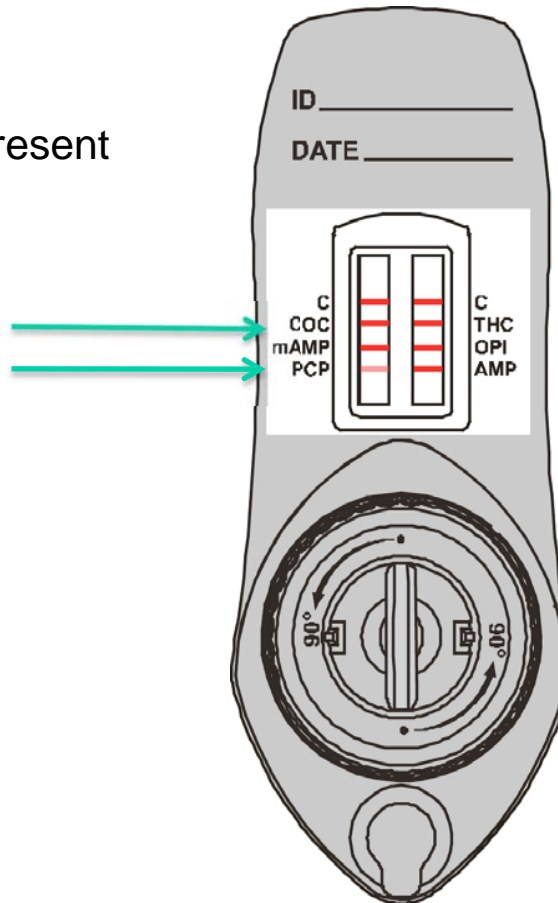
If the problem persists, contact RTL Client Services at:
(800) 255-2159, ext. 4399

Reading results

Negative Example

NEGATIVE = line is present

Any visible line, even a faint line, indicates a negative result.

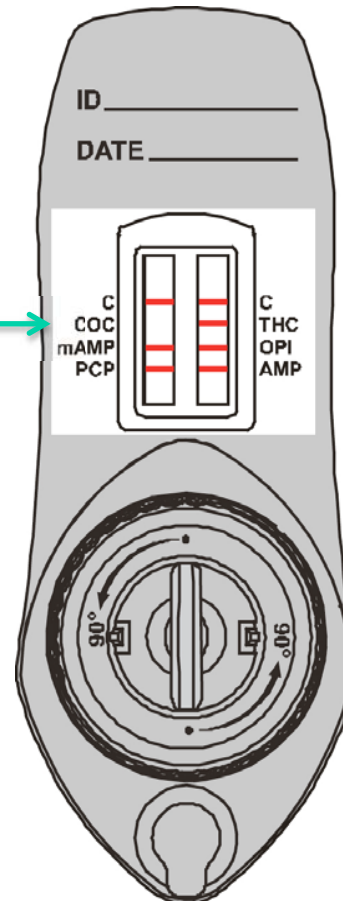


Reading results

Presumptive Positive Example

POSITIVE = line is not present

Presumptive positive for cocaine (no line is present).

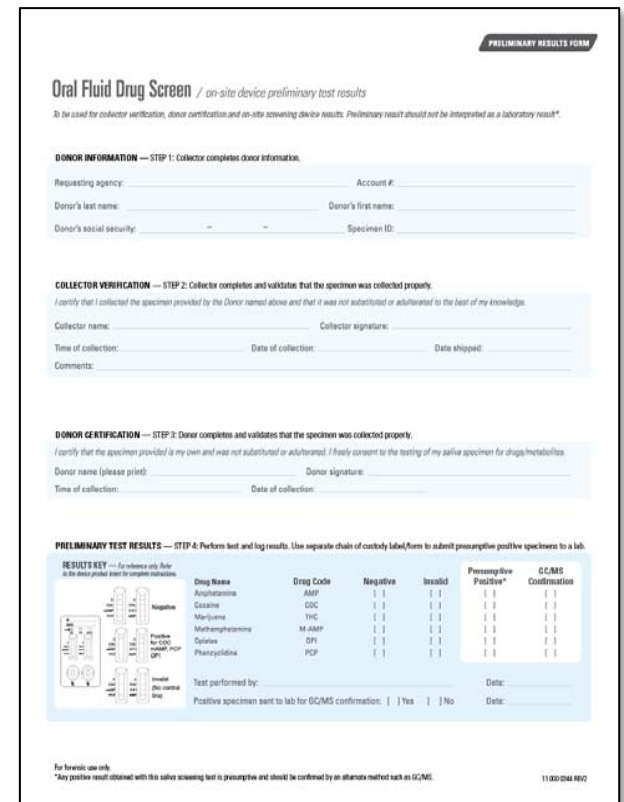


Logging on-site test results

Use a **Preliminary Result Form** to log on-site drug test results. Printed forms are available by request. A PDF form can also be downloaded from our website at: www.redwoodtoxicology.com/documents/products/saliva-prelim_result_form.pdf

Forms are for your internal use. These forms are not lab test request forms (for further confirmation testing). Please use the Lab Test Requisition Forms provided by your laboratory for confirmation testing.

Redwood Toxicology Laboratory provides confirmation testing for many Reditest® on-site screening devices. For more information about this service, call (800) 255-2159.



PRELIMINARY RESULTS FORM

Oral Fluid Drug Screen / on-site device preliminary test results

*To be used for collector verification, donor certification and on-site screening device results. Preliminary result should not be interpreted as a laboratory result.**

DONOR INFORMATION — STEP 1: Collector completes donor information.

Requesting agency: _____ Account #: _____
Donor's last name: _____ Donor's first name: _____
Donor's social security: - - - - - Specimen ID: _____

COLLECTOR VERIFICATION — STEP 2: Collector completes and validates that the specimen was collected properly.

I certify that I collected the specimen provided by the Donor named above and that it was not substituted or adulterated to the best of my knowledge.

Collector name: _____ Collector signature: _____
Time of collection: _____ Date of collection: _____ Date shipped: _____
Comments: _____

DONOR CERTIFICATION — STEP 3: Donor completes and validates that the specimen was collected properly.

I certify that the specimen provided is my own and was not substituted or adulterated. I freely consent to the testing of my saliva specimen for drugs/herbals.

Donor name (please print): _____ Donor signature: _____
Time of collection: _____ Date of collection: _____

PRELIMINARY TEST RESULTS — STEP 4: Perform test and log results. Use separate chain of custody label/form to submit presumptive positive specimens to a lab.


RESULTS KEY — For reference only. Refer to the device packet insert for complete instructions.

Drug Name	Drug Code	Negative	Invalid	Presumptive Positive*	GC/MS Confirmation
Amphetamine	AMP				
Cocaine	COC				
Marijuana	THC				
Methamphetamine	M-AMP				
Opioids	OPI				
Phencyclidine	PCP				

Test performed by: _____ Date: _____
Positive specimen sent to lab for GC/MS confirmation: () Yes () No Date: _____

For forensic use only.
*Any positive result obtained with this saliva screening test is presumptive and should be confirmed by an alternate method such as GC/MS.

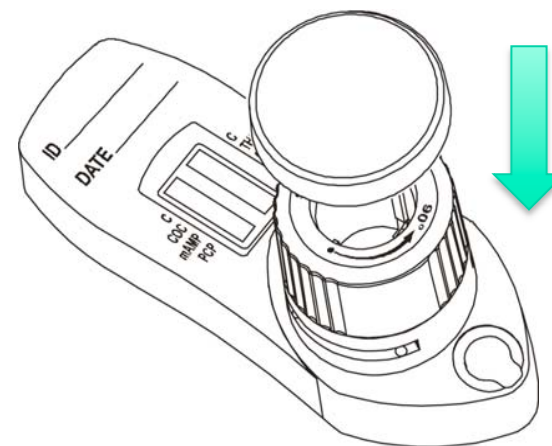
11-000-0344 REV0



Shipping specimens to the laboratory

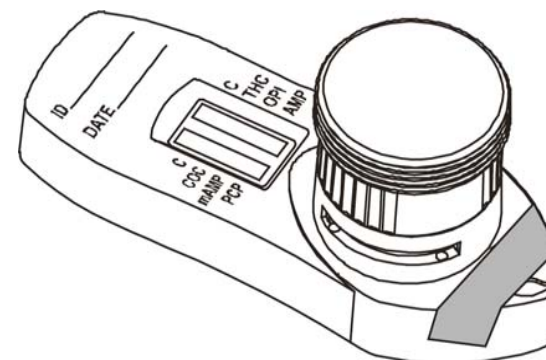
Shipping specimens

If positive results are observed, remove the collector by turning it counterclockwise and pulling. Secure the cap over the collection chamber.



Remove collector and secure cap

Seal the reservoir with tamper evident tape and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the stopper.



Seal reservoir with tamper evident tape

Shipping specimens



For instruction on how to send presumptive positive specimens to the lab, please view the next document in the training series: **“Specimen Labeling & Shipping”**.

View online here:

www.redwoodtoxicology.com/resources/documents/labeling_shipping.pdf



*If you have additional questions about your device please
contact
a Sales or Client Services representative:*

Redwood Toxicology Laboratory, Inc.

Reditest® Screening Devices

3650 Westwind Blvd.

Santa Rosa, CA 95403

www.redwoodtoxicology.com

Sales Inquiries **(800) 255-2159** or 877-444-0049

Client Services **(800) 255-2159, ext. 4399** or 707-577-7959, ext. 4399

Confidence in testing.

Thank you for your time.



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