

Confidence in testing.

# Reditest<sup>®</sup> 6 Cassette

CLIA Waived  
substance abuse screening device

Product Training  
Presentation





The information in this presentation is a general overview on using the Reditest® 6 Cassette substance abuse screening device.

### Product Training Contents:

- 6 Cassette overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation

## 6 Cassette technical information

*It is important to read the package insert before using the 6 Cassette screening device.*

### **Screening Results:**

The CLIA waived 6 Cassette is used for **Screening 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 6 Cassette screening device is a rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For in vitro diagnostic use only.*

# 6 Cassette CLIA waived info

Any agency performing medical testing using a “waived” device, must have either a:

**CLIA License, or**  
**CLIA Certificate of Waiver.**

The FDA does not regulate drugs of abuse testing in:

**Forensic**                      **Probation**  
**Parole**                        **Work Environments**

*therefore CLIA requirements do not apply.*

For further information on the CLIA program visit:

<http://www.fda.gov/cdrh/clia>





## Product overview

# 6 Cassette product overview



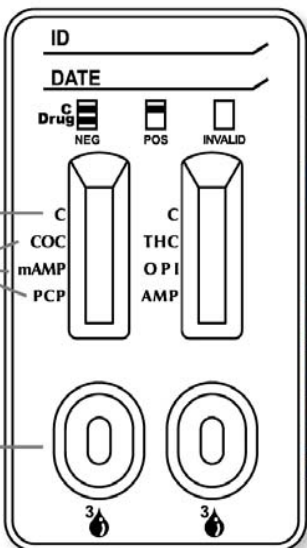
## FEATURES & BENEFITS

- Available tests include: \*AMP, COC, THC, M-AMP, OPI and PCP
- Simple to use pipette and cassette
- Results in 5 minutes
- CLIA Waived and FDA 510(k) cleared to market


\* See page 8 for abbreviations and cut-off levels

# 6 Cassette components

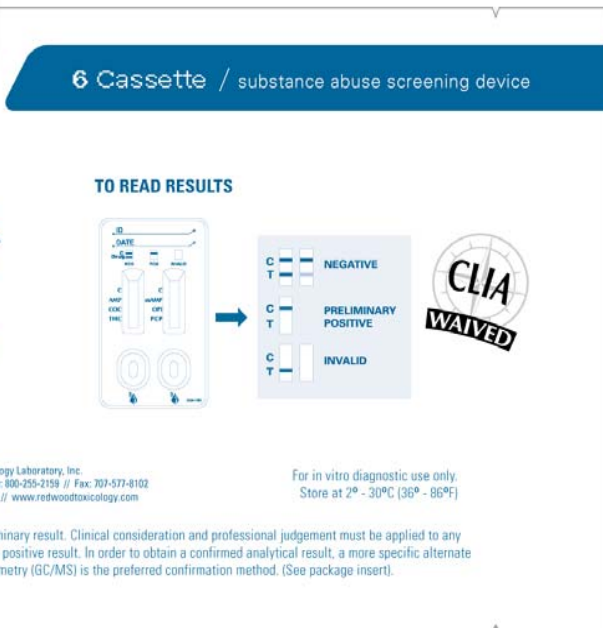
6 Cassette Device



Pipette



Pouch



**6 Cassette / substance abuse screening device**

**TO READ RESULTS**

C	T	NEGATIVE
C	T	PRELIMINARY POSITIVE
C	T	INVALID

**CLIA WAIVED**

**REDWOOD TOXICOLOGY LABORATORY**

Manufactured in China for Redwood Toxicology Laboratory, Inc.  
 On-site Devices: 877-444-0049 // Laboratory: 800-255-2159 // Fax: 707-577-8102  
 3050 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

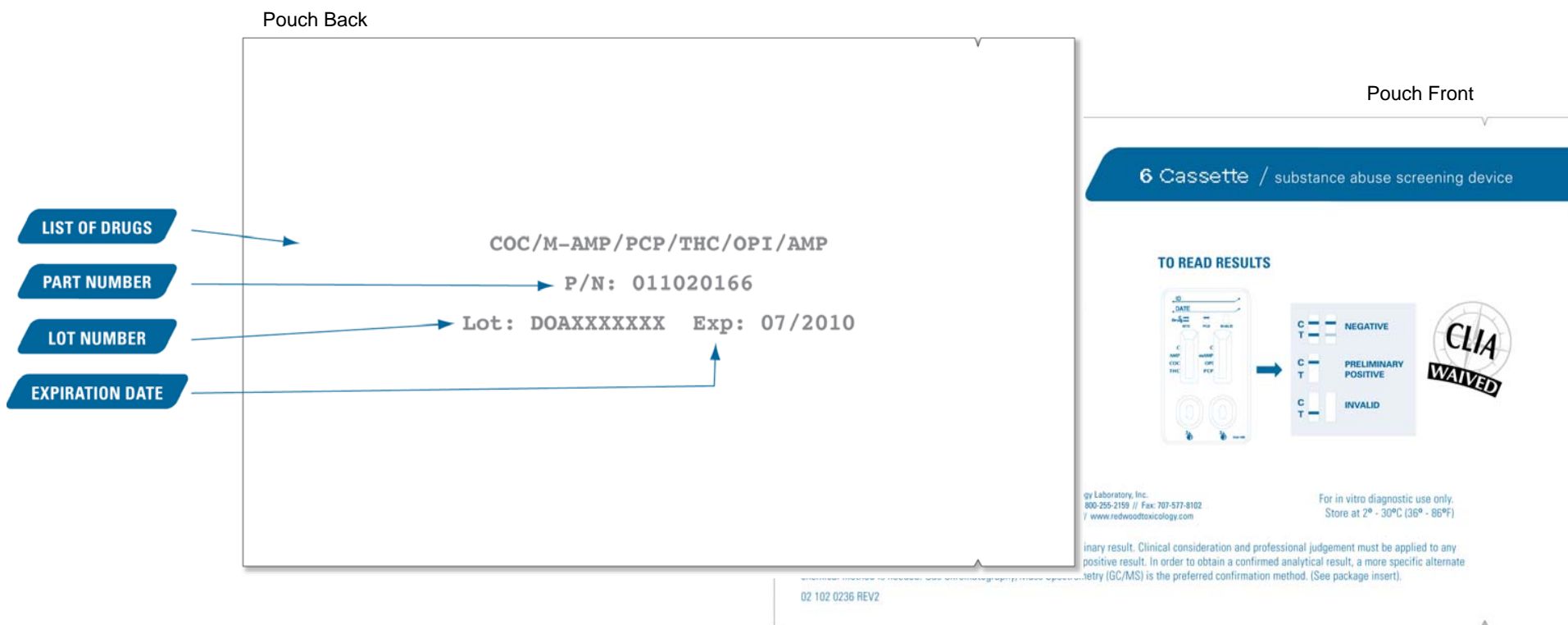
For in vitro diagnostic use only.  
 Store at 2° - 30°C (36° - 86°F)

Redwood Toxicology Laboratory, Inc. assays provide only a preliminary result. Clinical consideration and professional judgement must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmation method. (See package insert).

02 102 0236 REV2

# 6 Cassette foil pouch

The foil pouch contains the following information: list of drugs (abbreviations\*) screened, part number, lot number and expiration date.



\* See page 8 for abbreviations and cut-off levels

# 6 Cassette cut-off levels

DRUG	TARGET DRUG	CUT-OFF
<b>Amphetamine (AMP)</b>	D-Amphetamine	*1,000 ng/mL
<b>Cocaine (COC)</b>	Benzoyllecgonine	*300 ng/mL
<b>Marijuana (THC)</b>	11-nor- $\Delta^9$ -THC-9 COOH	*50 ng/mL
<b>Methamphetamine (M-AMP)</b>	D-Methamphetamine	1,000 ng/mL
<b>Opiates (OPI 2)</b>	Morphine	2,000 ng/mL
<b>Phencyclidine (PCP)</b>	Phencyclidine	25 ng/mL

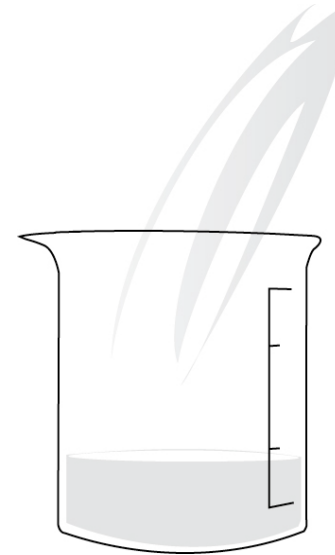
\* Meets SAMHSA cut-off levels.



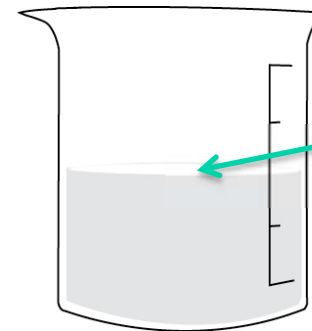
## Collection procedure

# Collecting specimen

Collect urine specimen in a collection container.



Fill the cup to at least **1/3 full**.  
This helps ensure proper specimen volume for initial test and possible confirmation tests.



Fill at least 1/3 full

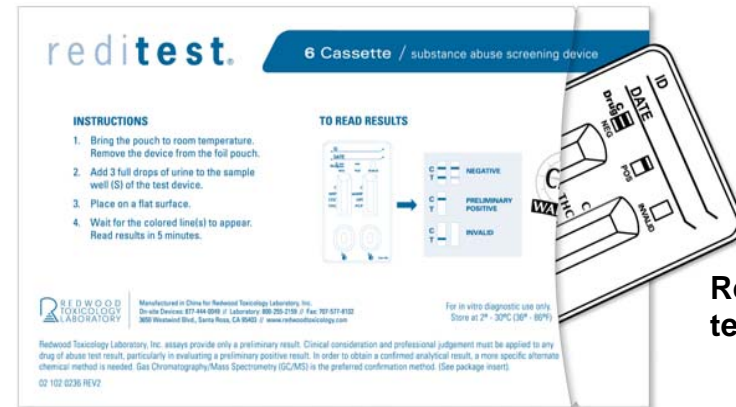


# Testing procedure

# Testing procedure

Open the foil pouch and remove the 6 Cassette device.

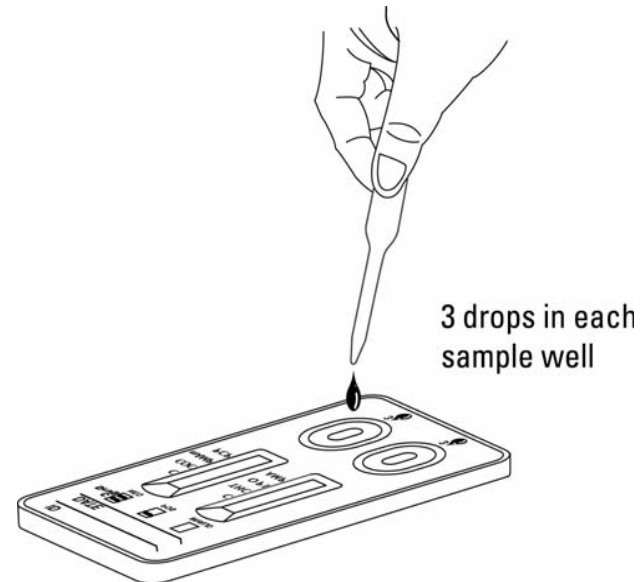
**NOTE:** The desiccant pouches are part of the packaging, they are not a part of the screening device.



Remove test cassette

**Place cassette on a flat surface.**

Holding the pipette vertically, transfer **3 drops** of urine into each sample well.

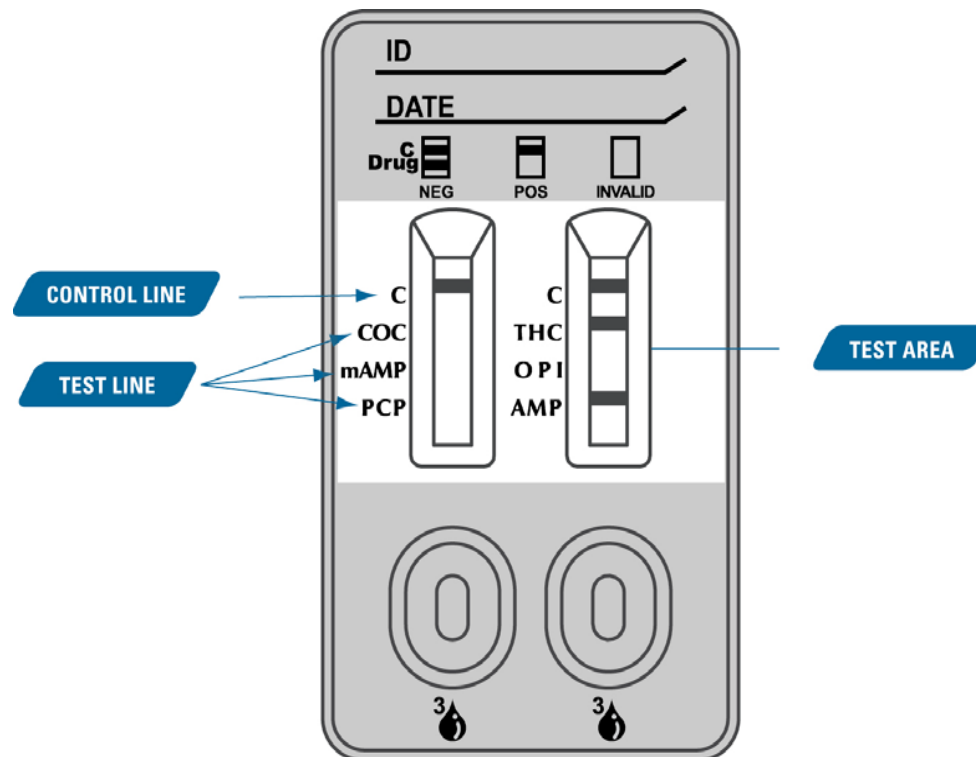




# Reading results

# Reading results

Read test results at **5 minutes**. Do not interpret results after 4 hours as false results may occur. **NOTE:** Any line at all in the test area is to be interpreted as negative.



# 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.

## NEGATIVE RESULT

CTL 

DRUG 

---

## POSITIVE

The control line must be red to indicate the test is valid. The test area must be snow white to be considered positive.

## POSITIVE RESULT

CTL 

DRUG 

---

## 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

CTL 

DRUG 

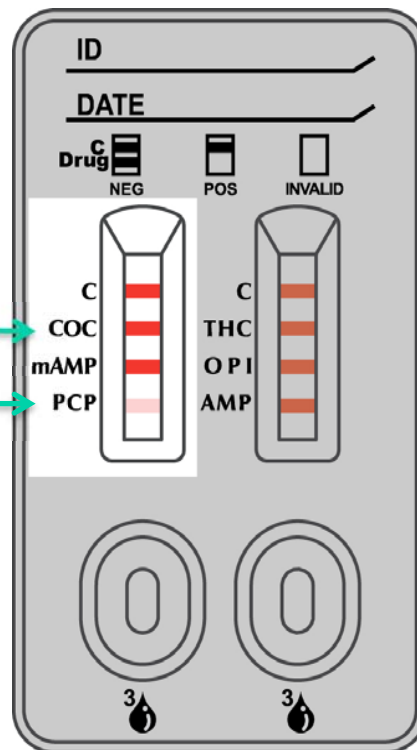
If the problem persists, contact RTL Client Services at:  
**(800) 255-2159, ext. 4399**

# Reading results

## *Negative Example*

**NEGATIVE** = line is present

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

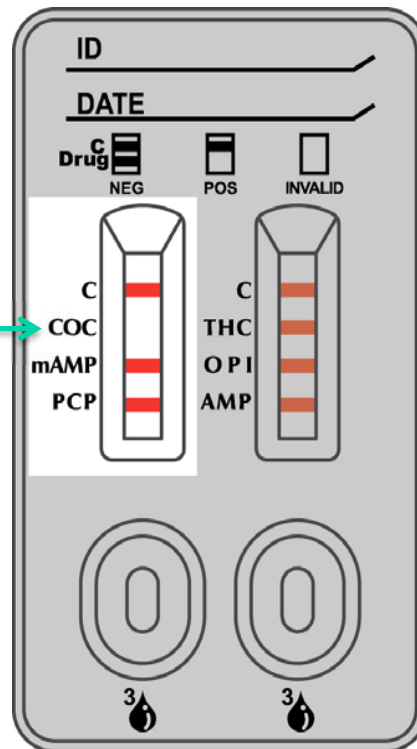


# Reading results

## *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/urine-prelim\\_result\\_form.pdf](http://www.redwoodtoxicology.com/documents/products/urine-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**

Urine 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 confirmed laboratory result.\*

**DONOR INFORMATION — STEP 1:** Collector completes donor information.

Requesting agency: \_\_\_\_\_ Account #: \_\_\_\_\_  
 Donor's last name: \_\_\_\_\_ Donor's first name: \_\_\_\_\_  
 Donor's ID number: \_\_\_\_\_ 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. The specimen temperature and color were within acceptable range.

Collector name: \_\_\_\_\_ Collector signature: \_\_\_\_\_  
 Date of collection: \_\_\_\_\_ Time 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 urine specimen for drugs/toxicities.

Donor name: \_\_\_\_\_ Donor signature: \_\_\_\_\_  
 Date of collection: \_\_\_\_\_ Time 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.

Name of test device: \_\_\_\_\_ Number of drugs tested by device: \_\_\_\_\_

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

**NEGATIVE EXAMPLE**  
 Control (C or Ct):    
 Drug name (that Drug):

**POSITIVE EXAMPLE**  
 Control (C or Ct):    
 Drug name (that Drug):

**INVALID EXAMPLE**  
 Control (C or Ct):    
 Drug name (that Drug):


**SCREENING RESULTS LOG** — not to be interpreted as laboratory result.

Drug Name	Drug Code	Negative	Invalid	Presumptive Positive*	GC/MS Confirmation
Amphetamine	AMP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate	SAB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepine	SZD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Buprenorphine	BUP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine	COC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy	MDMA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana	TNC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone	MTD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine	M-AMP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiate	OPI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone	OXY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phencyclidine	PCP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Propoxyphene	PPX	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tri-Cyclic Antidepressants	TCA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Test performed by: \_\_\_\_\_ Date: \_\_\_\_\_  
 Positive specimen sent to lab for GC/MS confirmation:  Yes  No Date: \_\_\_\_\_

\*For professional in vitro diagnostic use only.  
 \*Any positive result obtained with this urine screening test is presumptive and should be confirmed by an alternate method such as GC/MS.

11 000 0101 REV9



# Shipping specimens to the laboratory

# 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](http://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](http://www.redwoodtoxicology.com)

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

Client Services **(800) 255-2159, ext. 4399** or 707-577-7959, ext. 4339

Confidence in testing.

Thank you for your time.



 REDWOOD  
TOXICOLOGY  
LABORATORY™  
an  inverness medical company