

Confidence in testing.

EZ Split Key

substance abuse screening device

Product Training
Presentation





The information in this presentation is a general overview on using the EZ Split Key substance abuse screening device.

Product Training Contents:

- EZ Split Key overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation

EZ Split Key technical information

It is important to read the package insert before using the EZ Split Key screening device.

Screening Results:

The EZ Split Key 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 EZ Split Key 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.



Product overview

EZ Split Key product overview

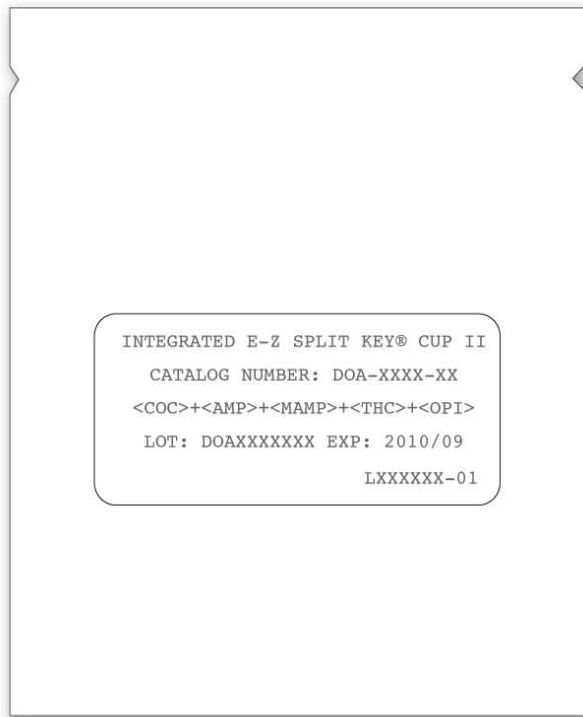


FEATURES & BENEFITS

- Available tests include: *AMP, BAR, BZO, COC, M-AMP, MDMA, MTD, OPI, PCP, TCA, THC, OXY
- All-inclusive collection cup and test panel *(multiple drug configurations available)*
- Minimizes collector exposure to urine
- Performance comparable to laboratory screening methods
- Secure activation key limits donor access to test
- Collector can test at own convenience
- FDA – 510(k) cleared to market

* See page 8 for abbreviations and cut-off levels

EZ Split Key Components

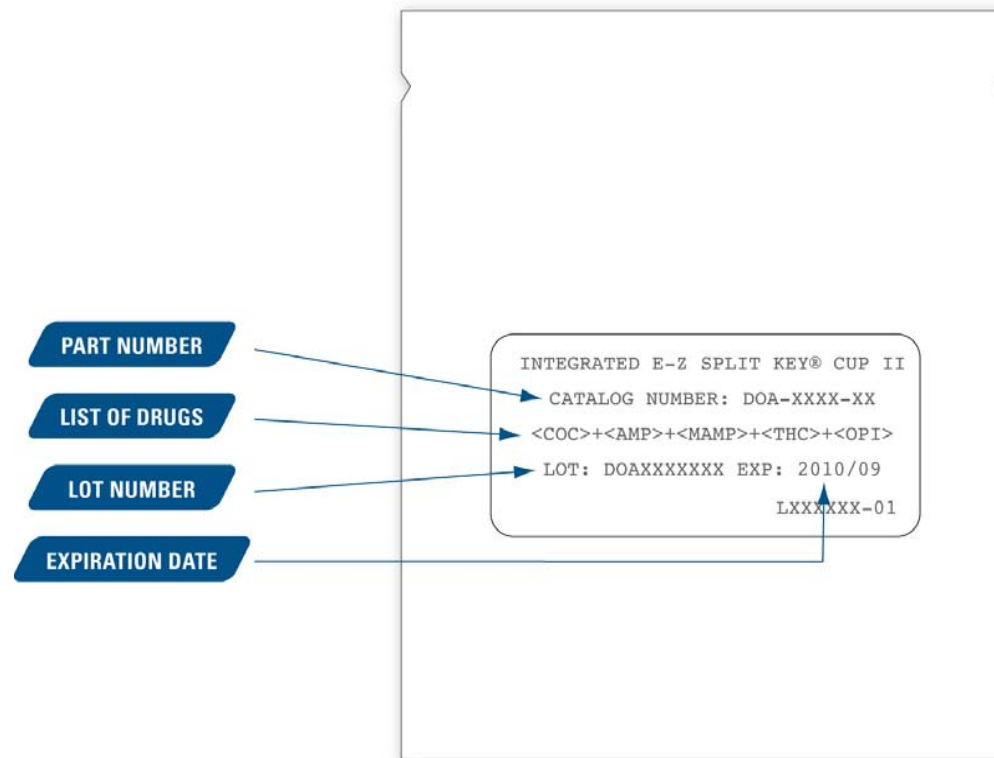


Pouch



EZ Split Key foil pouch

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



* See page 8 for abbreviations

EZ Split Key Cup cut-off levels

DRUG	TARGET DRUG	CUT-OFF
Amphetamine (AMP)	D-Amphetamine	*1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	*300 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	*50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methylenedioxy-methamphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Methamphetamine (M-AMP)	D-Methamphetamine	1,000 ng/mL
Opiates		
OPI 300	Morphine	300 ng/mL
OPI 2000	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	*25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

* Meets SAMHSA cut-off levels.

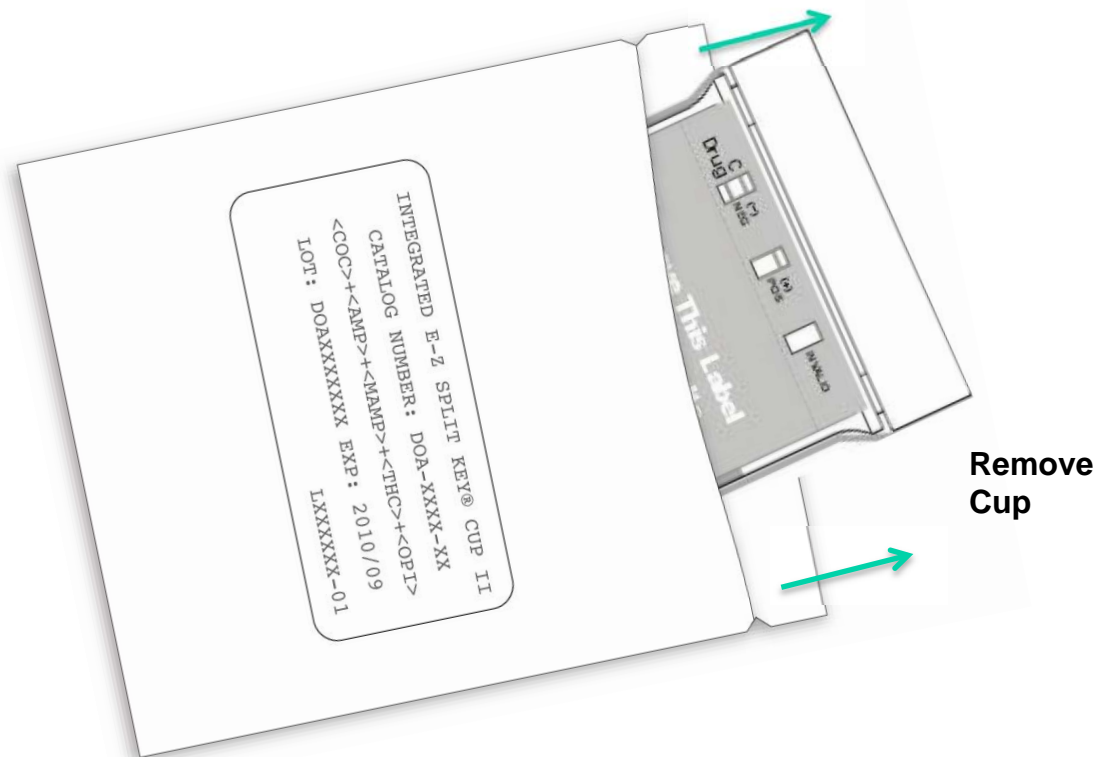


Collection procedure

Specimen collection

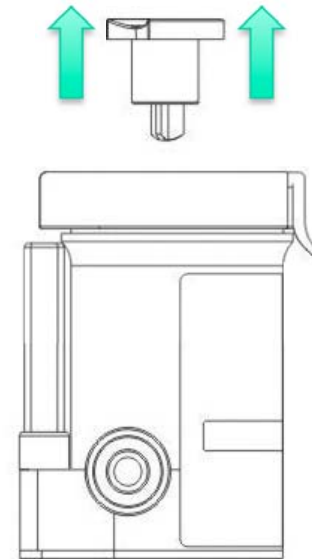
Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.

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

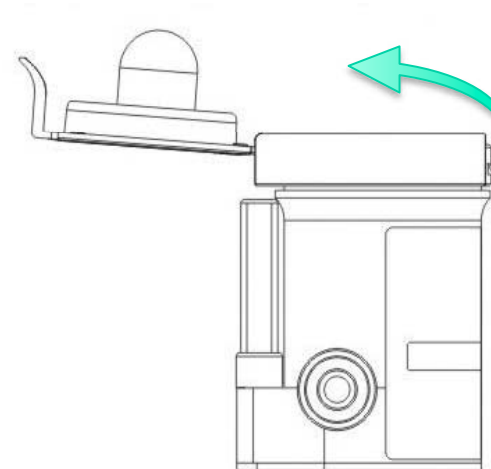


Specimen collection

Remove the key by twisting it from the center of the cup cap.



Open cap with the Pull Tab.
(Key is held by technician.)

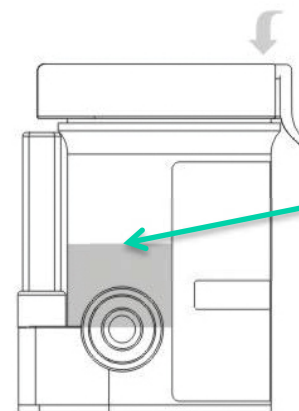
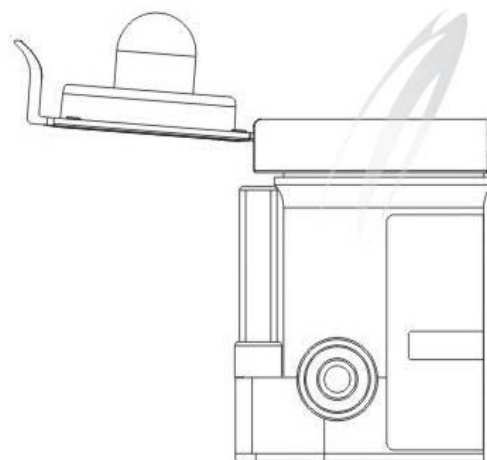


Specimen collection

Collect urine specimen in the EZ Split Key Cup.

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

Secure cap by pressing down on the Pull Tab until an audible click is heard.

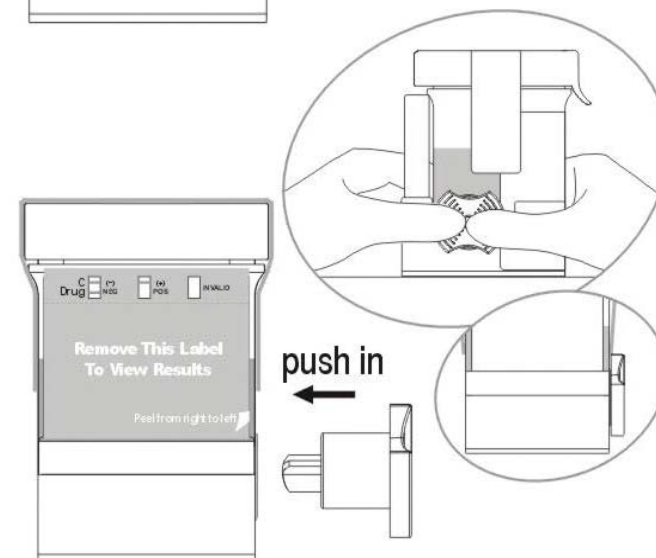


Fill at least 1/3 full

Specimen collection

Check cap for tight seal.
Technician dates and initials the security seal and attaches the security seal over the cup cap.

Place the cup on a flat surface.
The technician inserts the key to a **fully closed position** to initiate the test.

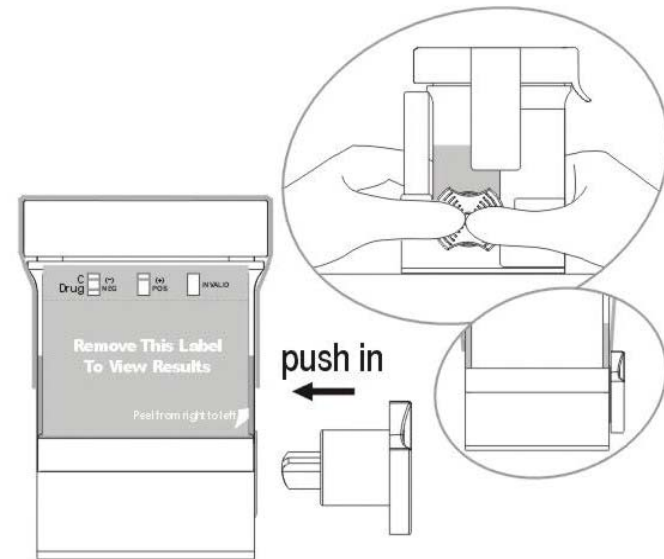




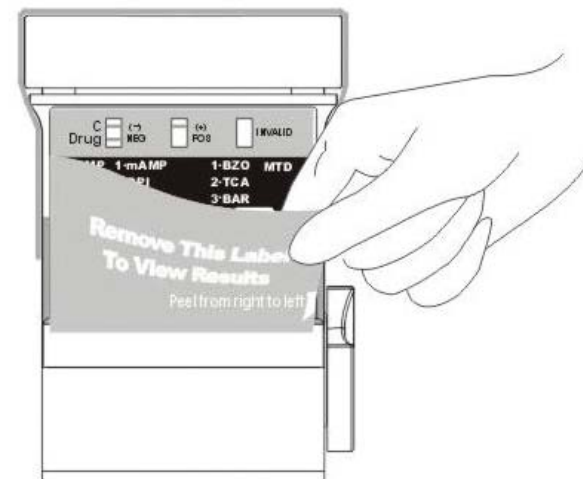
Testing procedure

Testing procedure

Place the cup on a flat surface. The technician inserts the key to a **fully closed position** to initiate the test.



Remove the peel off label covering the test results.



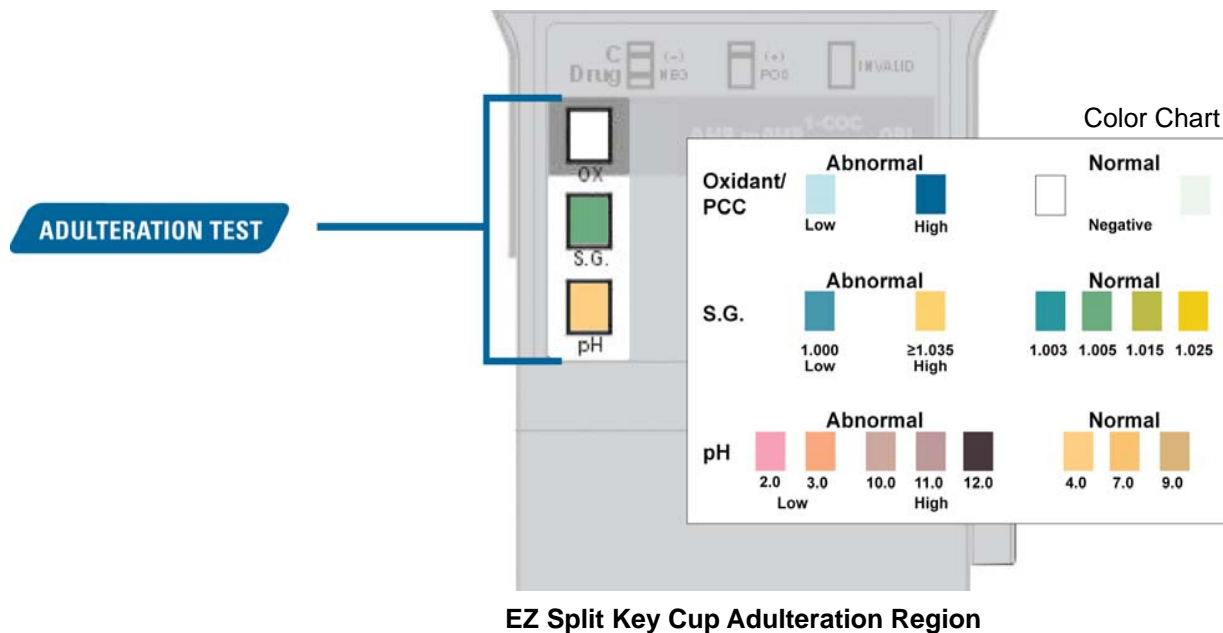


Reading results

Reading adulteration results *(if applicable on your device)*

FOR CUPS WITH ADULTERATION

If adulteration is included on the test cup, read the specimen validity test (S.V.T.), between **3 and 5 minutes**. Compare the colors on the adulteration strip to enclosed color chart. If the results indicate adulteration, do not read the drug test results.





Compare the colors on the adulteration strip to the color chart.

Result interpretation

NEGATIVE

The control line (C) must be red to indicate the test is valid. Any visible line, even a faint line, indicates a negative result.



NEGATIVE RESULT

C  *Test is valid*
T  *Line is present*

POSITIVE

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



POSITIVE RESULT

C  *Test is valid*
T  *Line is not present*

INVALID

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

INVALID RESULT

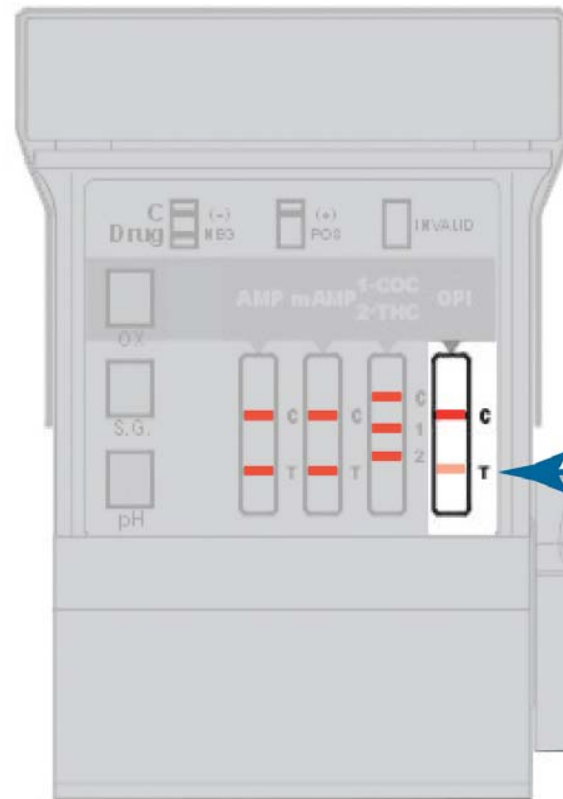
C  *Test is not valid*
T 

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

Reading results

Negative Example

NEGATIVE = line is present

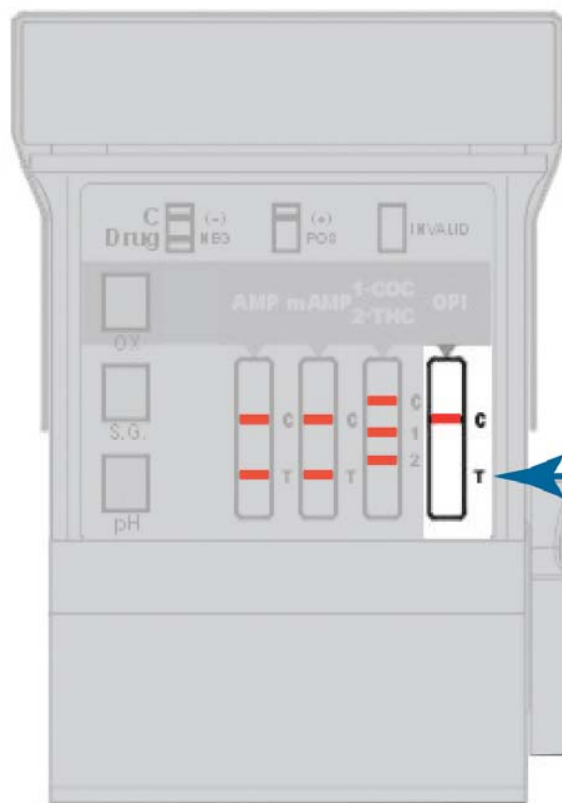


Any visible line, even a faint line, indicates a negative result.

Reading results

Presumptive Positive Example

POSITIVE = line is not present



Presumptive positive for opiates (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

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.	SCREENING RESULTS LOG — not to be interpreted as laboratory result.				Presumptive Positive*	GC/MS Confirmation
	Drug Name	Drug Code	Negative	Invalid		
NEGATIVE EXAMPLE Control (C or C1) Drug name (that Drug)	Amphetamine	AMP	1	1	1	1
	Barbiturate	BAB	1	1	1	1
	Benzodiazepine	BZD	1	1	1	1
	Buprenorphine	BUP	1	1	1	1
	Cocaine	COC	1	1	1	1
	Ecstasy	MDMA	1	1	1	1
	Marijuana	THC	1	1	1	1
	Methadone	MTD	1	1	1	1
	Methamphetamine	M-AMP	1	1	1	1
	Opiate	OPI	1	1	1	1
	Oxycodone	OXY	1	1	1	1
	Phencyclidine	PCP	1	1	1	1
	Propoxyphene	PPX	1	1	1	1
	Tri-Cyclic Antidepressants	TCA	1	1	1	1

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.

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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



*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

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Thank you for your time.



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