

Confidence in testing.

iScreen™ iCup®

substance abuse screening device

Product Training
Presentation





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

Product Training Contents:

- iCup® overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation

iCup[®] technical information

It is important to read the package insert before using the iCup[®] screening device.

Screening Results:

The iCup[®] 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 iCup[®] 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

iCup[®] product overview

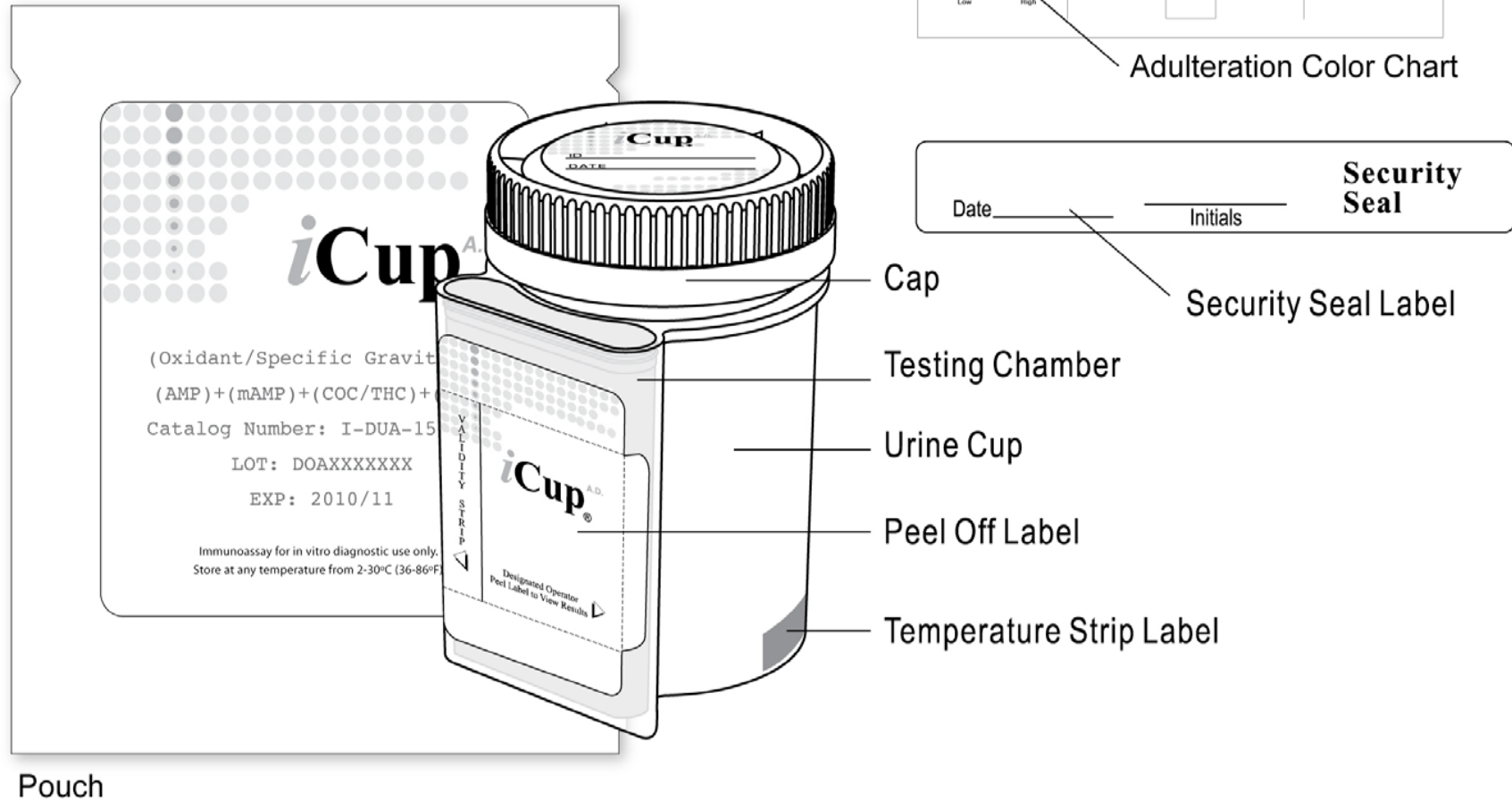
FEATURES & BENEFITS

- Available tests include: *AMP/BAR/BUP/BZO/COCAINE/THC/MTD/M-AMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA
- Available with Specimen Validity Tests (S.V.T.) for Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine
- Self contained cup minimizes collector exposure to urine
- Performance comparable to laboratory screening methods
- Drug test results in 2-5 minutes
- Built-in validity test
- All devices are FDA – 510(k) cleared to market, certain devices available CLIA waived
- NIDA 5 cut-off levels meet SAMHSA guidelines

* See page 8 for abbreviations and cut-off levels



iCup[®] components



iCup[®] foil pouch

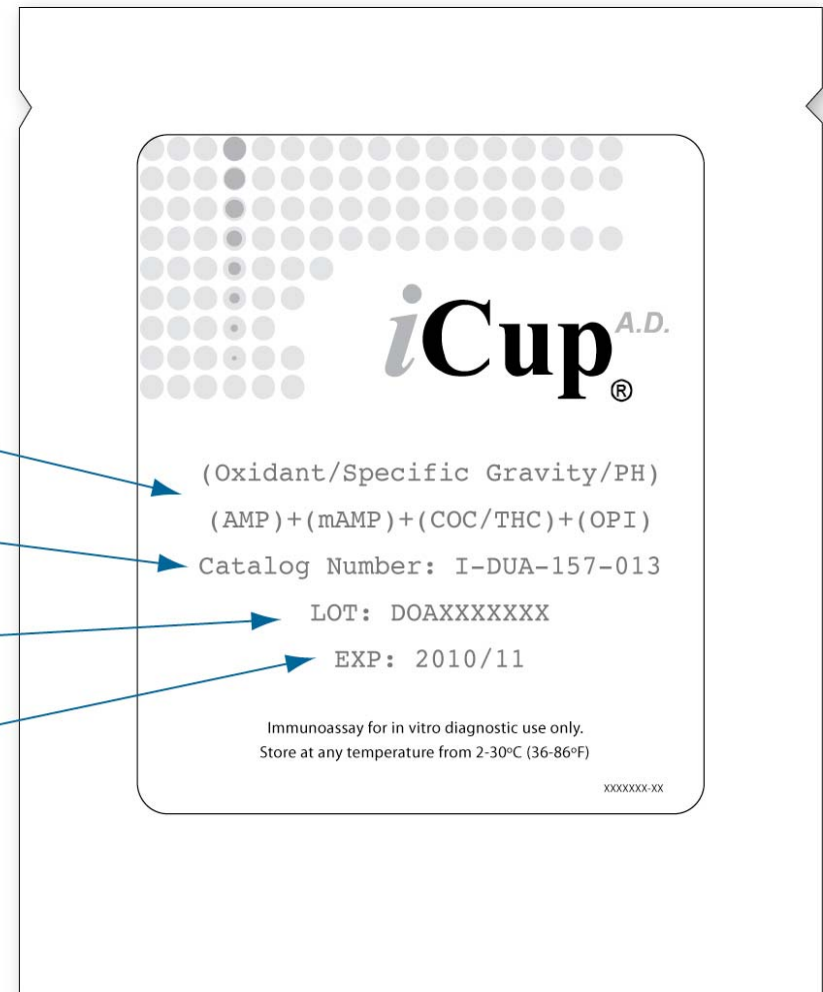
The foil pouch contains the following information: list of drugs* screened, part number, lot number and expiration date.

LIST OF DRUGS

PART NUMBER

LOT NUMBER

EXPIRATION DATE



The test devices must remain in the sealed pouch until use. Storage temperature is between 36-86°F (2-8°C). DO NOT FREEZE. Do not use beyond the expiration date.

* See page 8 for abbreviations

iCup[®] cut-off levels

DRUG	TARGET DRUG	CUT-OFF LEVEL
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Amphetamine (AMP)	D-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (M-AMP 1,000)	D-Methamphetamine	1,000 ng/mL
Methamphetamine (M-AMP 500)	D-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Opiate (MOP 2,000)	Morphine	2,000 ng/mL
Opiate (OPI 300)	Morphine	300 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

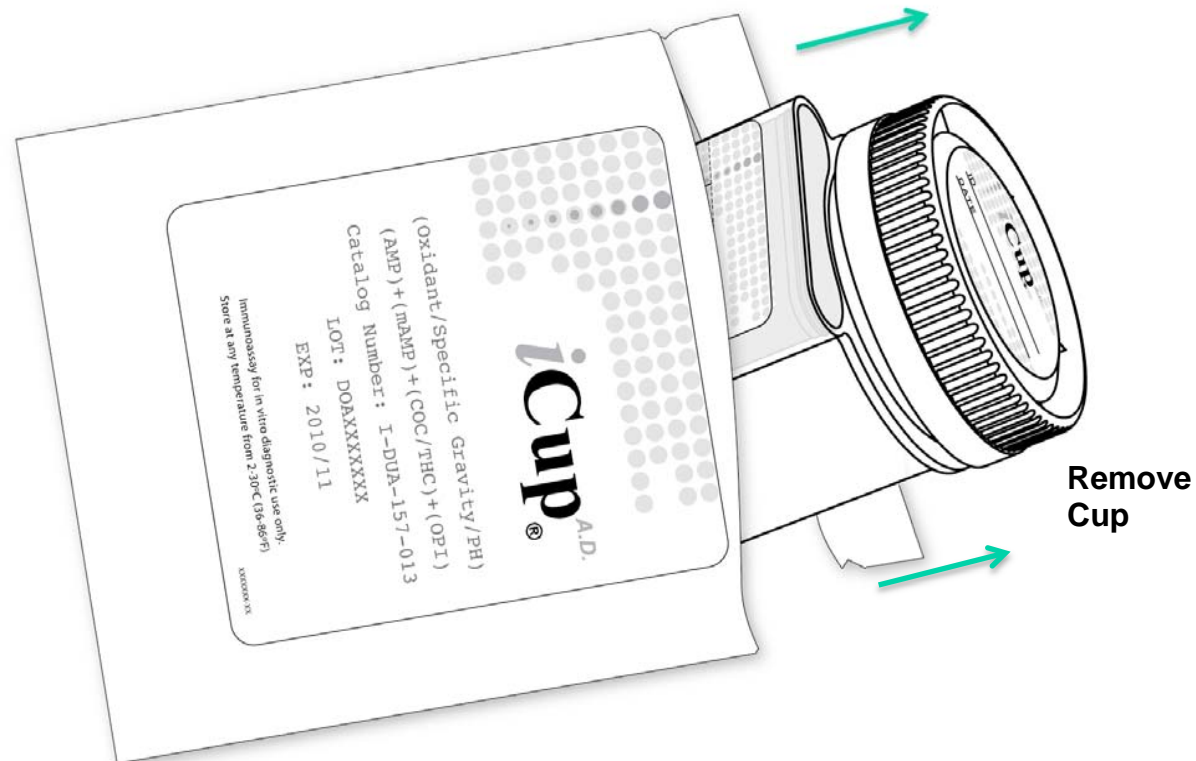


Collection procedure

Remove cup from sealed pouch

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

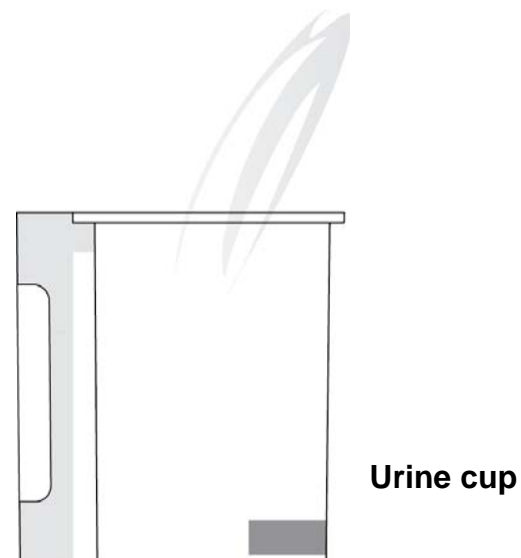
NOTE: *The desiccant pouches are part of the packaging, they are not a part of the screening device.*



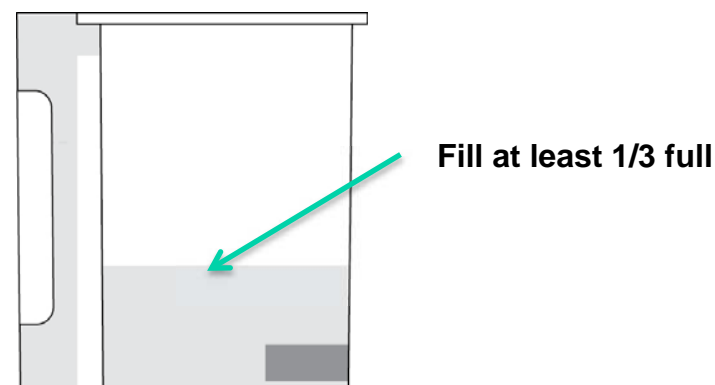
Collect urine specimen

Remove the cap from the urine cup.

Donor provides urine specimen in the collection cup.

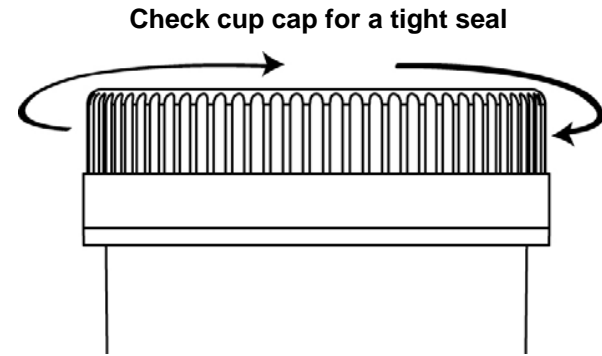


Fill the cup to at least **1/3 full**.
This ensures sufficient specimen volume is available for initial screen and possible confirmation testing.

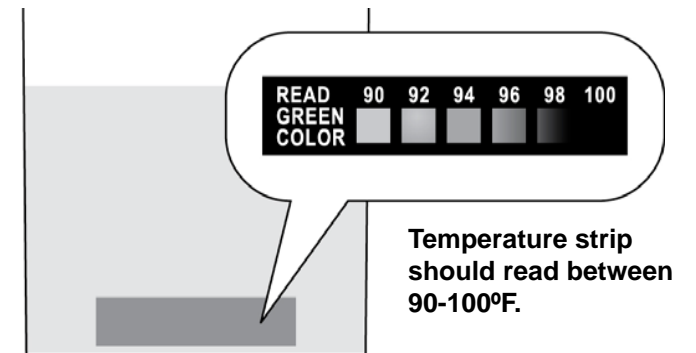


Collection procedure

Technician replaces and secures the cap while the cup is on a flat surface.



Temperature is read at 2-4 minutes.
Verify the range is between 90-100°F.

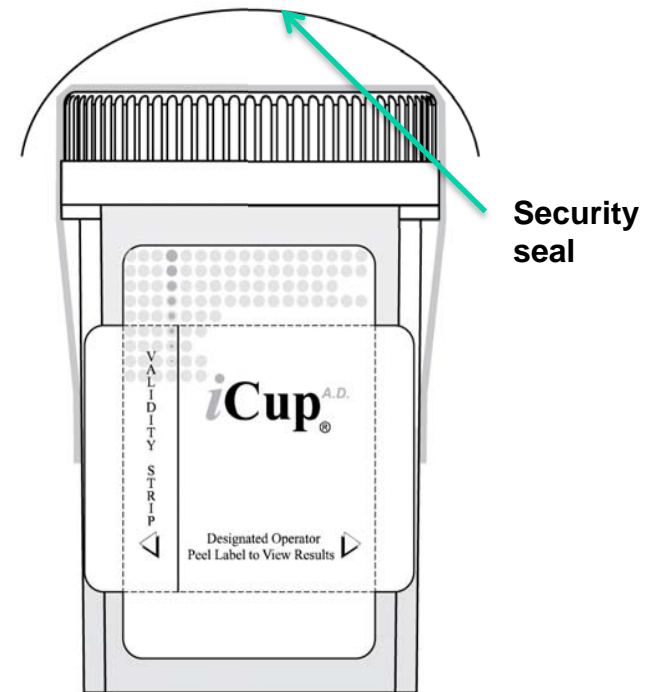


Collection procedure

Donor dates and initials the security seal.
(The technician/collector may also date or initial the security seal).



The technician attaches the security seal over the cup cap.





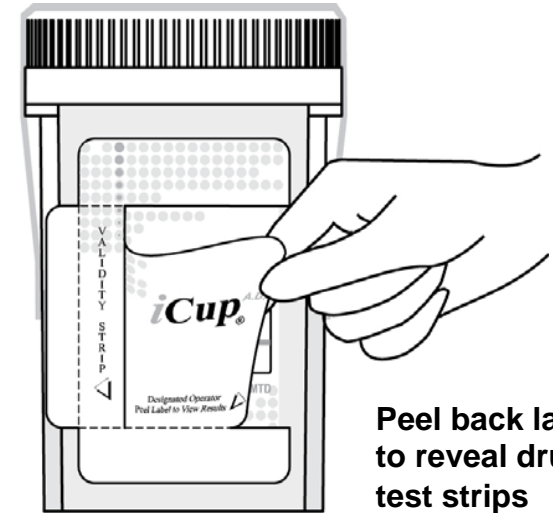
Reading results

Reading results

Technician peels off the label to reveal drug test strips.

The technician peels off label to reveal adulteration strip(s), if applicable.

NOTE: order can be reversed.



Peel back label to reveal drug test strips



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

FOR CUPS WITH ADULTERATION

Read adulteration test results between **2-5 minutes**. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.

ADULTERATION TEST

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

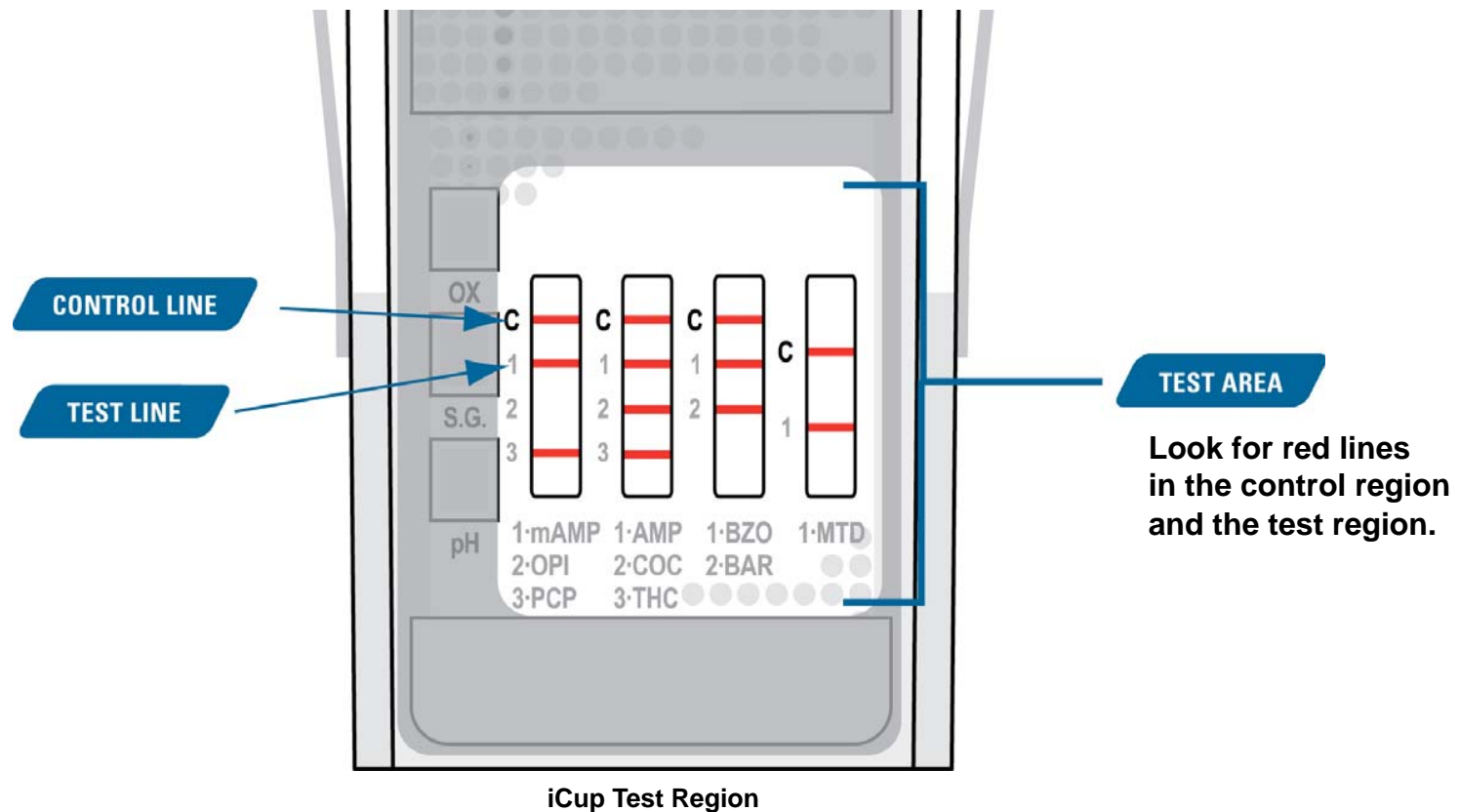
	Abnormal	Normal	Normal	Abnormal	
OX	Low	High			NIT
PCC				20mg/dL Negative	50mg/dL Low 100mg/dL High
S.G.	1.000 Low	≥1.035 High	1.003 1.005 1.015 1.025	Negative	Low High
pH	2.0 Low	3.0 10.0 11.0 High	4.0 7.0 9.0	100mg/dL 20mg/dL	0mg/dL 10mg/dL
					CRE

Adulteration Test Region

Adulteration Color Chart

Reading drug test results

Read the drug test results at **5 minutes**. Do not interpret results after 60 minutes as false results may occur.

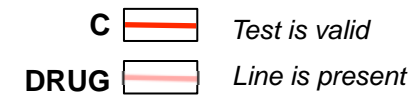


Result interpretation

NEGATIVE

A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. Any visible line, even a faint line, indicates a negative result.

NEGATIVE RESULT



PRESUMPTIVE POSITIVE

A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The test area must be snow white to be considered positive.

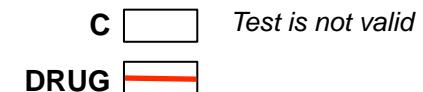
POSITIVE RESULT



INVALID

No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the likely reasons for control line failure. If an invalid result is obtained repeat the test using a new device.

INVALID RESULT



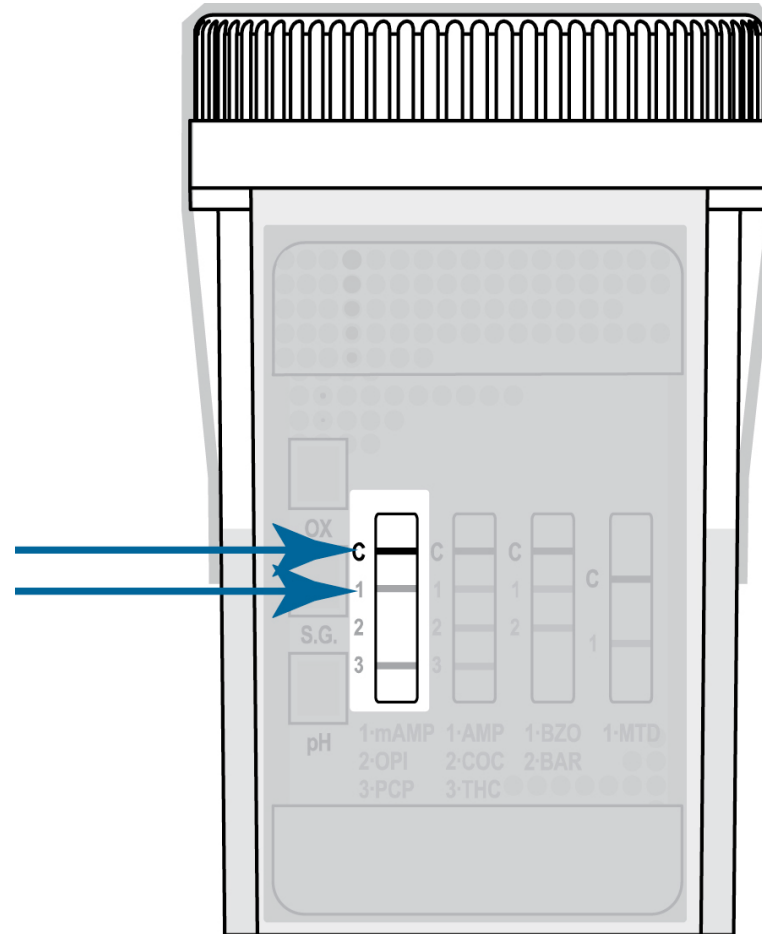
If the problem persists, contact RTL Client Services at: **(800) 255-2159, ext. 4399.**

Reading results

Negative Example

NEGATIVE = line is present

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

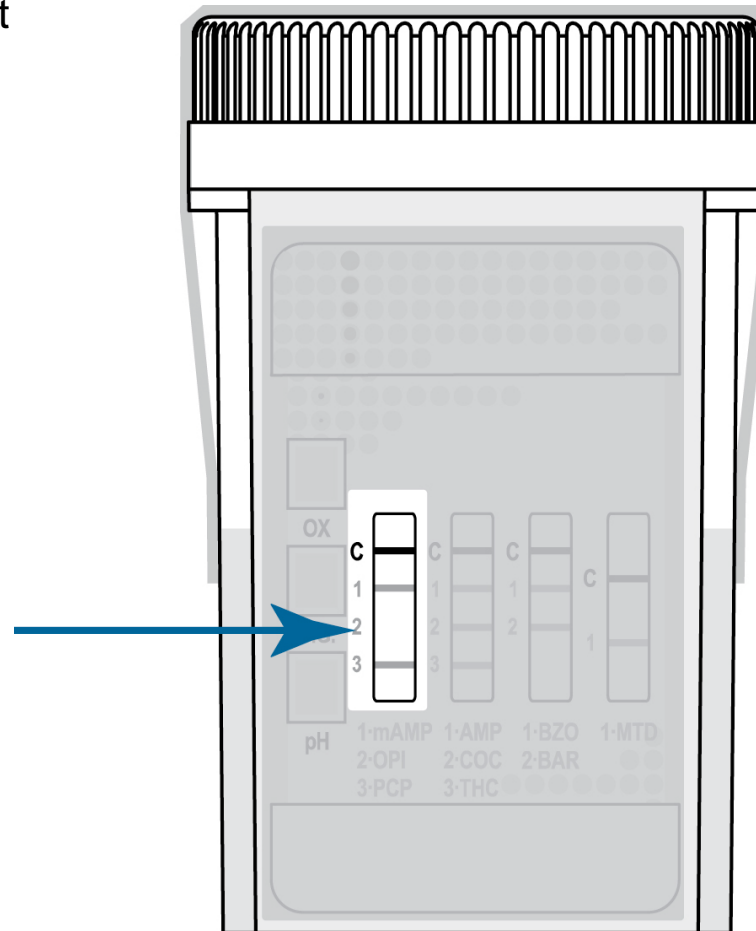


Reading results

Presumptive Positive Example

POSITIVE = line is not present

Presumptive positive for opiates (no line is present).




Logging on-site test results

A **photocopy** of the results can be made by placing the entire cup with the card face down on the copier.

Use a **Preliminary Result Form** to log on-site drug test results. Printed forms are available by request. 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.



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. 4339

Confidence in testing.

Thank you for your time.



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