



Integrated EZ Split Key[®] Cup

Substance abuse screening device



PRODUCT TRAINING PROCEDURES



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

Product Training Contents:

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



EZ Split Key Cup technical information

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

Screening Results:

The EZ Split Key Cup 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) or LC/MS/MS (Liquid Chromatography/Tandem 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 Cup product overview

FEATURES & BENEFITS

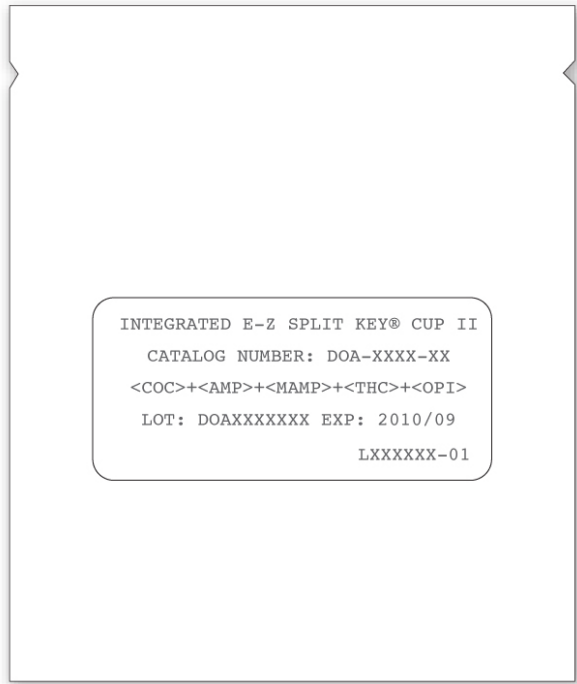
- Available tests include: *AMP, BAR, BUP, BZO, COC, M-AMP, MDMA, MTD, OPI, PCP, TCA, THC, PPX, OXY
- Specimen validity test options available
- Minimizes collector exposure to urine
- Performance comparable to laboratory screening methods
- Secure activation key limits donor access to test
- Collector can test at own convenience
- FDA – 510(k) cleared to market



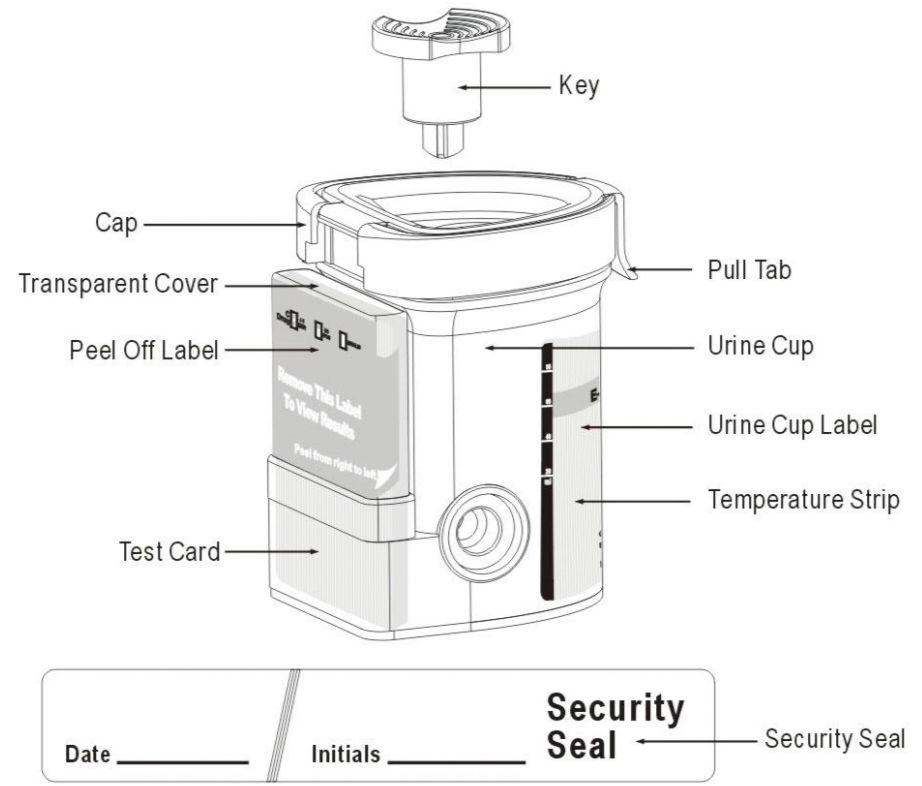
* See page 8 for abbreviations and cutoff levels



EZ Split Key Cup components

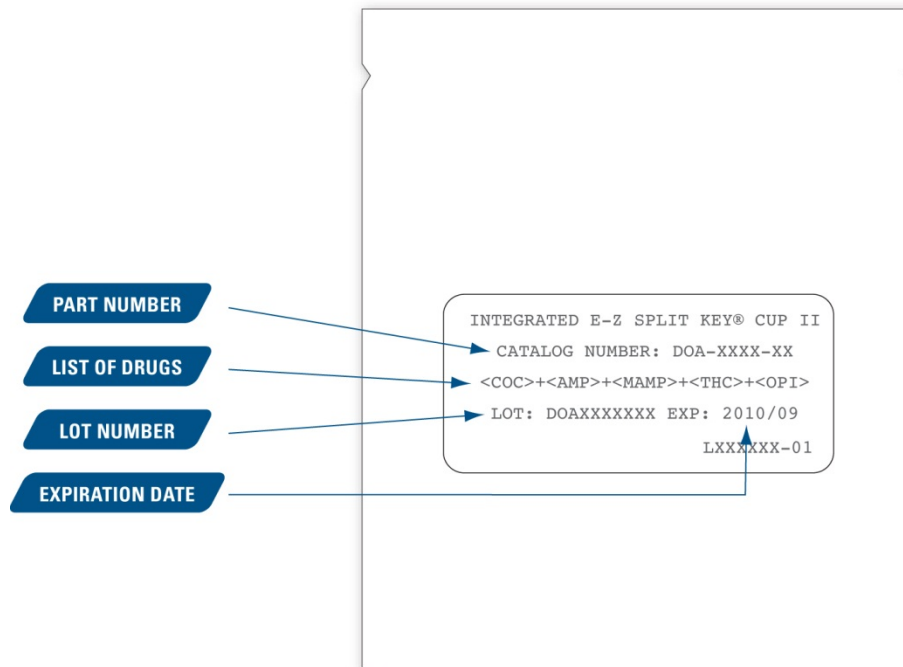


Pouch



EZ Split Key Cup 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 cutoff levels

Drug	Target Drug	Cutoff
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoyllecgonine	300 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Methamphetamine (M-AMP)	D-Methamphetamine	1,000 ng/mL
Opiates OPI 300 OPI 2000	Morphine Morphine	300 ng/mL 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

Collection procedure

Specimen collection

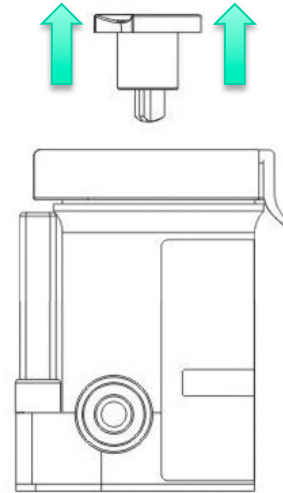
Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.

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

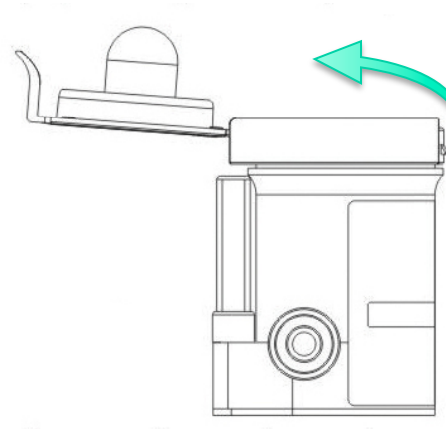


Specimen collection

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



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

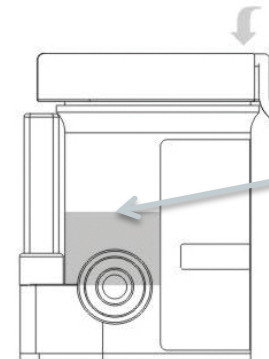
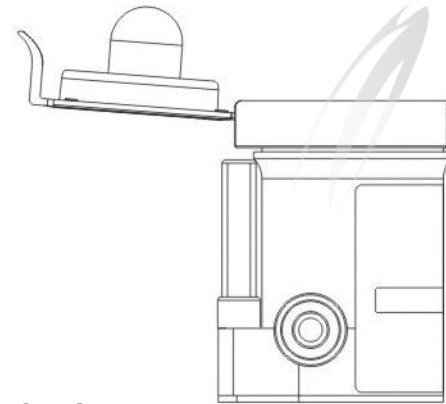


Specimen collection

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.

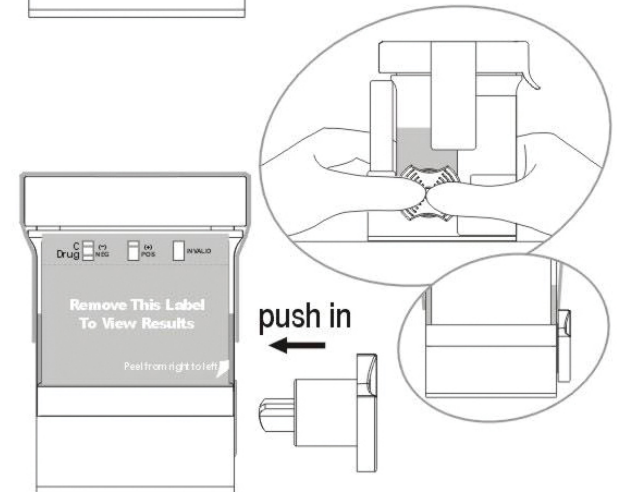


Fill at least 1/3 full

Specimen collection

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

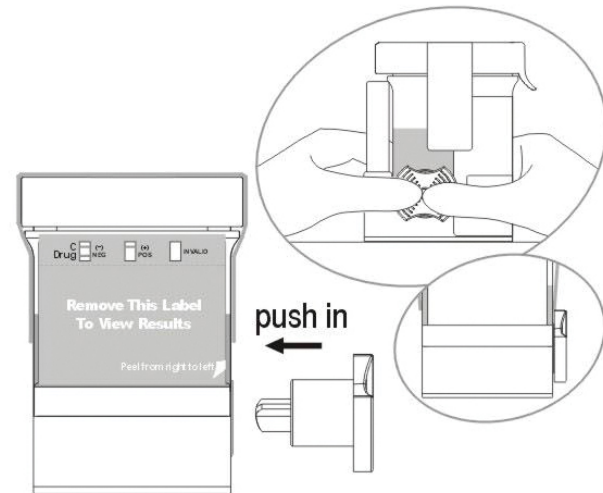
Place the cup on a flat surface. The technician inserts the key to a **fully closed position** to initiate the test.



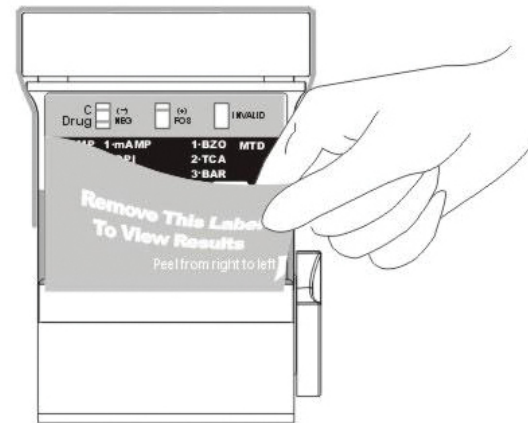
Testing procedure

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.



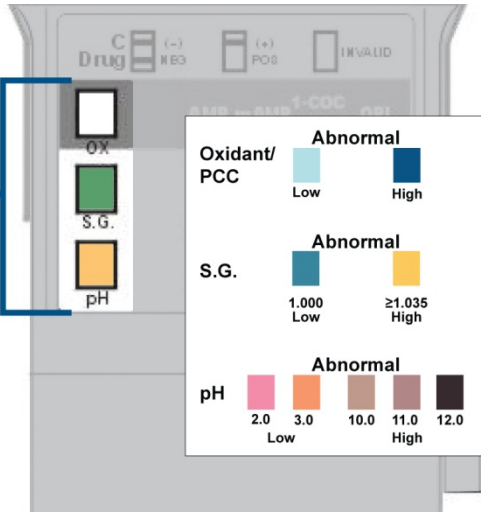
Reading results

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.

ADULTERATION TEST



Color chart

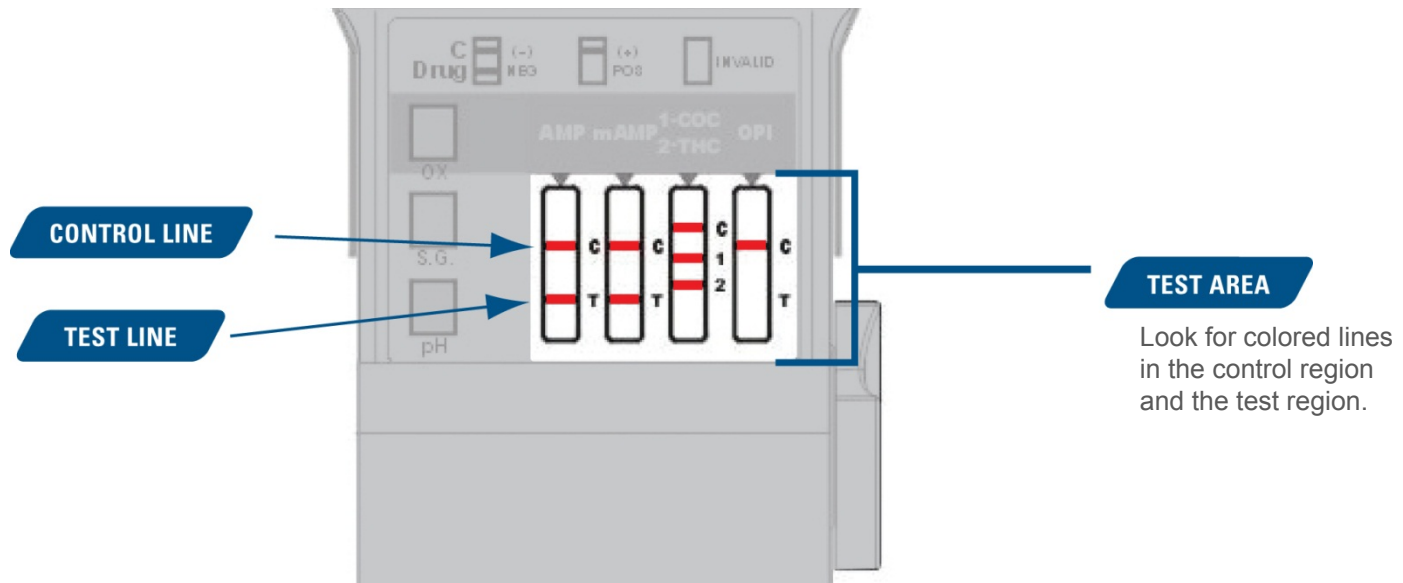
Oxidant/ PCC	Abnormal		Normal	
	Low	High		
S.G.	Abnormal		Normal	
	1.000 Low	≥1.035 High	1.003	1.005 1.015 1.025
pH	Abnormal		Normal	
	2.0	3.0 10.0 11.0 12.0	4.0	7.0 9.0
	Low	High		

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

EZ Split Key Cup Adulteration Region

Reading drug test results

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



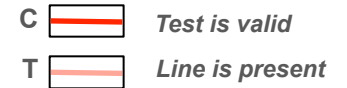
EZ Split Key Cup Test Region

Result interpretation

NEGATIVE

The control line must be colored to indicate the test is valid.
Any visible line, even a faint line, indicates a negative result.
See example page 20.

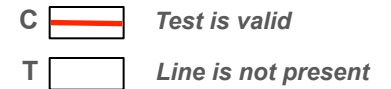
NEGATIVE RESULT



POSITIVE

The control line must be colored to indicate the test is valid.
The test area must be snow white to be considered positive.
*See example page 21. *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).*

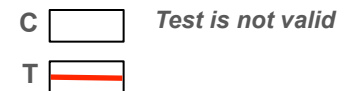
POSITIVE RESULT



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



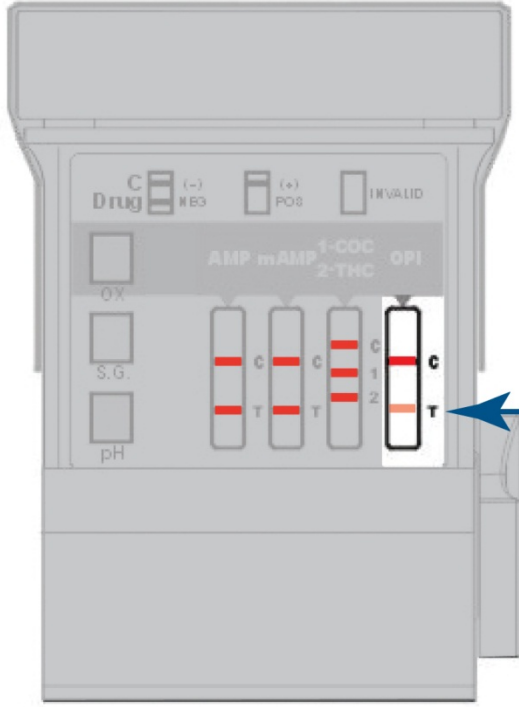
If the problem persists, contact RTL Client Services at:
(800) 255-2159, option 1.



Reading results

Negative Example

NEGATIVE = line is present



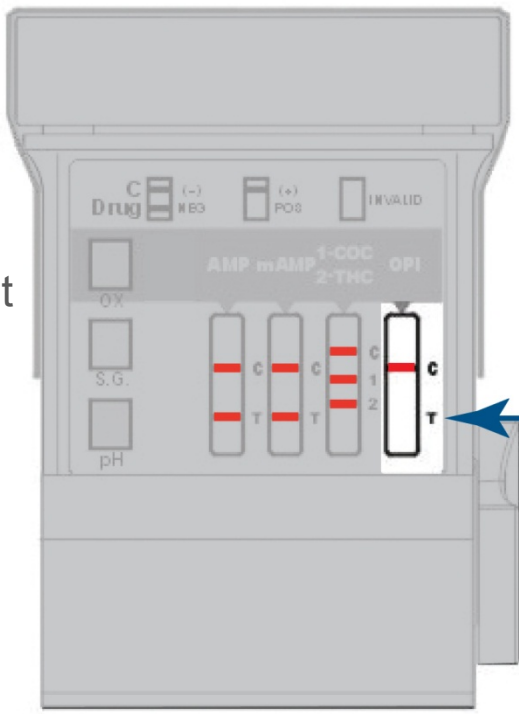
Any visible line, even a faint line, indicates a negative result.



Reading results

Presumptive Positive Example

POSITIVE = line is not present



Presumptive positive for opiates (no line is present).