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
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

- Key
- Cap
- Transparent Cover
- Pull Tab
- Urine Cup
- Urine Cup Label
- Temperature Strip
- Peel Off Label
- Test Card
- Security Seal

INTEGRATED E-Z SPLIT KEY® CUP II
CATALOG NUMBER: DOA-XXXX-XX
<COC>++<AMP>++<THC>++<OP1>
LOT: DOAXXXXXX EXP: 2010/09
LXXXXX-01

Pouch

©Alere. All rights reserved. Proprietary & confidential.
The foil pouch contains the following information: part number, list of drugs (abbreviations*) screened, lot number and expiration date.

* See page 8 for abbreviations
<table>
<thead>
<tr>
<th>Drug</th>
<th>Target Drug</th>
<th>Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine (AMP)</td>
<td>D-Amphetamine</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Barbiturates (BAR)</td>
<td>Secobarbital</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepines (BZO)</td>
<td>Oxazepam</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Cocaine (COC)</td>
<td>Benzoylcegonine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Marijuana (THC)</td>
<td>11-nor-Δ9-THC-9 COOH</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Methadone (MTD)</td>
<td>Methadone</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Methylenedioxymethamphetamine (MDMA)</td>
<td>D,L Methylenedioxy-methamphetamine</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (M-AMP)</td>
<td>D-Methamphetamine</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPI 300</td>
<td>Morphine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>OPI 2000</td>
<td>Morphine</td>
<td>2,000 ng/mL</td>
</tr>
<tr>
<td>Oxycodone (OXY)</td>
<td>Oxycodone</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>Phencyclidine</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Propoxyphene (PPX)</td>
<td>Propoxyphene</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Tricyclic Antidepressants (TCA)</td>
<td>Nortriptyline</td>
<td>1,000 ng/mL</td>
</tr>
</tbody>
</table>
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.
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.

Color chart

Compare the colors on the adulteration strip to the 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.

EZ Split Key Cup Test Region

Look for colored lines in the control region and the test region.
**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.

**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).*

**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. 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).
Additional support services
Additional support services

SENDING SPECIMENS TO THE LABORATORY  » Download PDF
For instruction on how to send presumptive positive specimens to the lab, please review the next document in the training services: “Shipping & Labeling Protocol”.

COLLECTION AND REPORTING MANAGEMENT  » Learn more
Take advantage of RTL’s powerful collection and reporting system. Schedule donors, manage on-site tests, view reports and route presumptive positive specimens to the lab.

PRELIMINARY RESULT FORMS  » Download PDF
Log on-site results by downloading a Preliminary Result Form PDF. Printed form pads are available by request. These forms are not lab test request forms (for further confirmation testing).