



CONFIRM BIOSCIENCES

Confirm Biosciences Split Key Cup
Substance Abuse Screening Device





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

Product Training Contents:

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



Split Key technical information

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

Screening Results:

The 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 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.



Confirm Bio Split Key Cup Product Overview

FEATURES & BENEFITS

- Lot number and expiration date are included on the test kit pouch
- Available tests include: AMP, BAR, BZO, COC, M-AMP, MDMA, MTD, OPI, PCP, TCA, THC, OXY, BUP
- 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

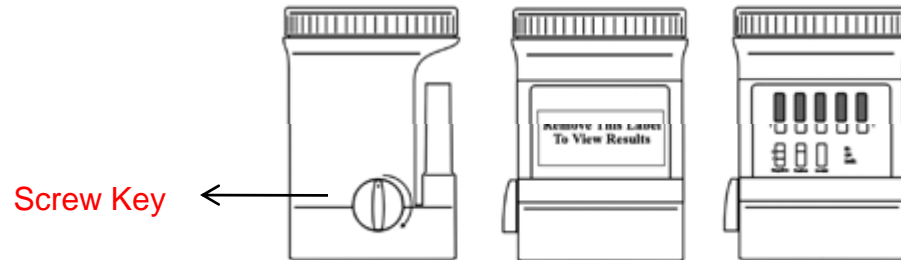


Confirm Bio Split Key Cup CUT Off Levels

Test	Description	Cut-Off Level
AMP	Amphetamine	1000 ng/mL and 300 ng/mL
BAR	Barbiturates	200 ng/mL
BZD	Benzodiazepine	300 ng/mL
COC	Cocaine	300 ng/mL
MET	Methamphetamine	1000 ng/mL
MOR/OPI	Morphine/Opiates	2000 ng/mL
MOR/OPI300	Morphine/Opiates	300 ng/mL
MTD	Methadone	300 ng/mL
OXY100	Oxycodone	100 ng/mL
OXY300	Oxycodone	300 ng/mL
PCP	Phencyclidine	25 ng/mL
TCA	Tricyclic Antidepressants	1000 ng/mL
THC	Marijuana	50 ng/mL
XTC	Ecstasy	500 ng/mL



Collection Procedure



Test must be in room temperature (10°C to 30°C). Bring the test cup with the sample to room temperature prior to testing. The test is performed by a technical not the sample donor.

1. After the urine has been collected, place the test cup on a flat surface.
2. Insert the screw key to the key hole, then twists screw key from left to right till to a full position at one time.
3. Wait for 5 minutes, remove the label and read the result. **Do not read results after 5 minutes.**



Testing Procedure

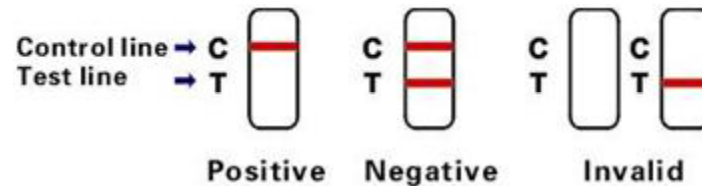


- Place the cup on a flat Surface
- The technician inserts the key to a **fully closed position to initiate the test**
- Remove the peel off label covering the test results.



Reading Results

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



Persumptive Positive (+): A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

Negative (-): A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid: If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen.

Note: **Any visible line, even a faint line, indicates a negative result.**

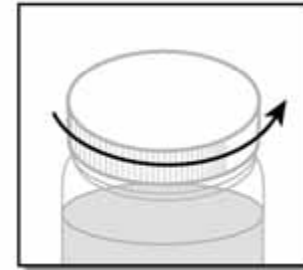


Shipping Specimens to the Lab

Secure collection containers

URINE COLLECTION CUPS: Double check to make sure the cup lid or cap is tightened securely. These cups are provided with your chain of custody forms

All on-site device samples & lab urine samples: After labeling and sealing the specimen tightly, place it into the plastic baggie with absorbent material. Ensure baggie is sealed. Store in a secure area until the specimen is ready to be shipped to the laboratory.



Ensure the lid/cap is tightly sealed prior to labeling.



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Drug Test Forms

Test requisition forms will be provided when ordering tests through the lab.

The sample cannot be processed without the information supplied on the test request form. If the test request form does not accompany the specimen, testing will be delayed.

For each specimen, the form should be completed with a water-resistant marker, such as a blue or black ball point pen (red color is not recommended since it tends to rub off).

NON FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

CONFIRM BIOSCIENCES (888) 5 CONFIRM (888) 525-6343 Fax: (878) 802-5075

BARCODE: 0123456789
SPECIMEN ID NO.

PASSCODE: 0123 3001 LAB ACCESSION NO.

STEP 1: COMPLETED BY COLLECTOR / EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No. Employer Name: _____ Address: _____ City: _____ State, Zip: _____ Tel: _____ Fax: _____

B. MRO Name, Address, Phone and Fax No. Dr. Charles H. Moorefield, MD Medical Review Office 2191 Julian Ave # 2 Palm Bay, FL 32905 Phone: (321) 728-7113 Fax: (321) 872-0083

C. Donor Name: Last: _____ First: _____ Donor's Employee I.D. No: _____

D. Reason for test: Pre-employment Random Reasonable Suspicion/Cause Post Accident Return to Duty Follow-up Other (specify) _____

E. Drug test to be performed: Hair 5 Drug Panel

STEP 2: COMPLETED BY COLLECTOR / EMPLOYER REPRESENTATIVE

HEAD HAIR BODY _____ REMARKS _____

STEP 3: Collector affixes barcode seal to hair specimen pouch. Collector dates seal. Donor initials seal. Donor completes STEP 5.

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section in STEP 5 of this form was collected, labeled and sealed in accordance with applicable requirements.

X _____ Signature of Collector (PRINT) Collector's Name (First, MI, Last) Time of Collection _____ Date (Mo./Day/Yr.) _____

RECEIVED AT LAB: X _____ Signature of Accessioner (PRINT) Accessioner's Name (First, MI, Last) Date (Mo./Day/Yr.) _____

SPECIMEN SEAL INTACT: Yes No, Enter Remark Below

SPECIMEN RELEASED TO: _____

Laboratory Remarks

STEP 5: COMPLETED BY DONOR

I certify that I provided my specimen to the collector; that I have not adulterated it in any manner; the specimen used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to the specimen is correct.

X _____ Signature of Donor (PRINT) Donor's Name (First, MI, Last) Date (Mo./Day/Yr.) _____

Daytime Phone No. () _____ Evening Phone No. () _____ Date of Birth _____

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable requirements, my determination/verification is: NEGATIVE POSITIVE TEST CANCELLED

REMARKS: X _____

Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.) _____

Please place Hair Pouch Seal over flap on Hair Specimen Pouch

HAIR POUCH SEAL: BARCODE 0123456789 SPECIMEN ID NO. Donor's initials _____ Date (Mo./Day/Yr.) _____

COPY 1 - LABORATORY / MEDICAL REVIEW OFFICER COPY

PRESS HARD - YOU ARE MAKING MULTIPLE COPIES



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Fill out all the yellow fields in the form

Security Label: After filling out the form place the Security label over the top of the cap, down the sides of the bottle. Have the donor initial the Security label

Once the form has been completed the collection cup and chain form are now ready to be shipped back

Please ship Specimens back to:
Confirm Biosciences
6310 Nancy Ridge road, # 103
San Diego, CA 92121
800-908-5603

NON FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

CONFIRM BIOSCIENCES (888) 5 CONFIRM (888) 525-6343 Fax: (878) 907-5675

PASSCODE: 0123

BARCODE: 0123456789 SPECIMEN I.D. NO.

3001 LAB ACCESSION NO.

STEP 1: COMPLETED BY COLLECTOR / EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone and Fax No.
Employer Name: _____ Dr. Charles H. Moorefield, MD
Address: _____ Medical Review Office
City: _____ State, Zip: _____ 2191 Julian Ave # 2
Tel: _____ Fax: _____ Palm Bay, FL 32905
Phone: (321) 728-7113 Fax: (321) 872-0083

C. Donor Name: Last: _____ First: _____

Donor's Employee I.D. No. _____

D. Reason for test: Pre-employment Random Reasonable Suspicion/Cause Post Accident Return to Duty Follow-up
 Other (specify) _____

E. Drug test to be performed: Hair 5 Drug Panel

STEP 2: COMPLETED BY COLLECTOR / EMPLOYER REPRESENTATIVE

HEAD HAIR BODY _____ REMARKS _____

STEP 3: Collector affixes barcode seal to hair specimen pouch. Collector dates seal. Donor initials seal. Donor completes STEP 5.

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section in STEP 5 of this form was collected, labeled and sealed in accordance with applicable requirements.

X _____ Signature of Collector (PRINT) Collector's Name (First, MI, Last) Time of Collection AM PM Date (Mo./Day/Yr.)

RECEIVED AT LAB: X _____ Signature of Accessioner (PRINT) Accessioner's Name (First, MI, Last) Date (Mo./Day/Yr.)

SPECIMEN SEAL INTACT Yes No, Enter Remark Below

SPECIMEN RELEASED TO: _____

Laboratory Remarks

STEP 5: COMPLETED BY DONOR

I certify that I provided my specimen to the collector, that I have not adulterated it in any manner, the specimen used was sealed with a tamper-evident seal in my presence, and that the information provided on this form and on the label affixed to the specimen is correct.

X _____ Signature of Donor (PRINT) Donor's Name (First, MI, Last) Date (Mo./Day/Yr.)

Daytime Phone No. () _____ Evening Phone No. () _____ Date of Birth / /

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable requirements, my determination/verification is: NEGATIVE POSITIVE TEST CANCELLED

REMARKS _____

X _____ Signature of Medical Review Officer (PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

HAIR POUCH SEAL

Please place Hair Pouch Seal over flap on Hair Specimen Pouch

BARCODE: 0123456789 SPECIMEN I.D. NO.

Donor's Initials _____ Date (Mo./Day/Yr.) _____

COPY 1 - LABORATORY / MEDICAL REVIEW OFFICER COPY

PRESS HARD - YOU ARE MAKING MULTIPLE COPIES

Note: Instruct the donor to initial the security seal. Collector should verify the info provided by the donor and validate that the specimen was collected correctly.