



inverness medical innovations

Drugs of Abuse Business Unit iScreen OFD Training





The iScreen OFD

- iScreen OFD Oral Fluid Test Device
 - Rapid on-site drug screening test device for the detection of drugs in oral fluid
 - Collect anywhere, anytime
 - Results within minutes
- iScreen OFD is available with up to 6 different drugs

AMP: Amphetamines mAMP: Methamphetamine/MDMA

COC: Cocaine OPI: Opiates

PCP: Phencyclidine THC: Marijuana

- Gather all necessary testing supplies
 - iScreen OFD device in foil pouch
 - Drug screening chain of custody (COC) form
 - Timer or stop watch
 - Lab supplies for shipping of presumptive positive tests if necessary



Drug configurations may vary





Chain of Custody Form (COC)

Step 1

Step 2

Step 3

Step 4

REDWOOD TOXICOLOGY LABORATORY ORAL FLUID DRUG TESTING CUSTODY & CONTROL FORM Inversess Medical group of companies 1500004799 STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE COMPANY-EMPLOYER NAME (ACCOUNT NO / ADDRESS CLIENT NAME / ADDRESS GSI Commerce Inc. Account # INT0174 229 Hollie Drive Martineville, VA 24112 Phone: (276) 670-6107 Fac: (276) 670-6127 or EMPLOYEE U.D. NO. ID VERIFIED BY: PHOTO ID ... EMPLOYER RIJR ... DONOR NAME: Last REASON FOR TEST: Po Englishment Reason: Reasonable Engineer/Cause Anti-Assister DONOR CONSENT: I contrib that I provided my specimen so the collector, that the specimen container was smalled with a ranger ground sent to my presence and that the information provided on that forms and on the label offered to the apacience curvature in accreas. I havely give permitation for the nature of the results of these tests to the my health care provider. In the case of accessing for couplesposes or pre-propioperans, I also authorize release of the results of those test to my couplespor or prespective ampliture and I or their curvatorized health care provider. Evening Phone: ___ TEP 3: COMPLETED BY COLLECTOR — SELECT TYPE TEST (Check one below) ☐ LAB ORAL DRUG TEST—pre-ordered penal ON-SITE SCREENING DEVICE—preliminary results (Review lab parel below) PRESUMPTIVE Lot #: ______ Exp. Date:____ DRUG NAME POSITIVE Amphatamine (AMP) Berzodiazenines (BZO) Cocaine (DDC) Ess Date: Mariuma (THC) Methamphetamine (M-AMP) Opiates (OPI) Phenoystidine (PCP) Spread performed by: STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY COLLECTOR CERTIFICATION: Locally that the specimen given to see by the discor identified above year collected, Jahnfed, renied & released as noted in accordance with applicable requirements. SPECIMEN RELEASED TO: (check coef ☐ Fedbe D DHL El Crusier RECEIVED AT LABORATORY SPECIMEN SEAL INTACT? LABELS MATCH? ON COPY 1 DO NOT WRITE IN THIS AREA we labels before writing on them. Place center of label over cap of specimen container 1500004799 Security Seal Donor Initials EDWOOD TOXICOLOGY LABORATORY

Redwood Toxicology Laboratory // 3050 Westwird Blvd. Sonta Rosa, CA 95433 // Laboratory phone: 800-255-2159

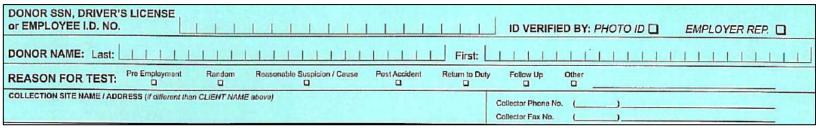


1 OF 5 LABORATORY COPY

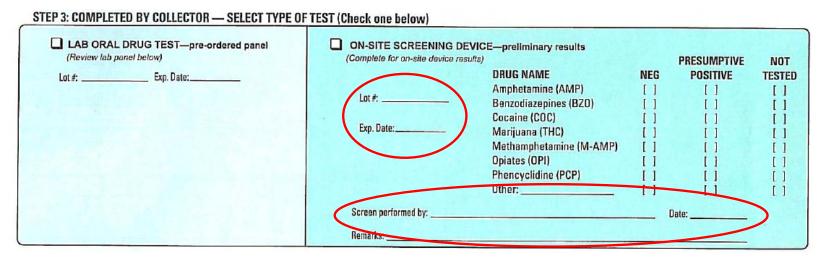
The Process: Performing the Drug Screen

Completing the Chain of Custody (COC)

- Test Administrator Performs Following
 - Verify donor Photo ID Complete Step 1 of the COC Form



- Record Device Lot and Expiration in Step 3
- Print collector/administrator name and date





The Process: Performing the Drug Screen

Give Test Device to Donor

Note: Test Administrator should not handle the test device once handed to the donor, until the security seal has been applied and Chain of Custody has been established.

- Instruct donor to open device
- Have donor remove plastic sponge protector and discard

Sponge Protector

Set aside blue device cap

Verify that plastic port seal is on cap

If not, remove from pouch and insert into cap





*i*Screen[™]

The Process: Sample Collection

- Instruct donor on proper procedure for saliva collection
 - Ensure that the donor has not placed anything in mouth for at least 10 minutes prior to collection. Including food, drink, tobacco products, gum, candy, etc.
 - Actively swab inside of mouth and top of tongue

for 3 minutes

- Allow saliva to saturate sponge
- Sponge should soften completely





The Process: Initiating Test



- Donor secures blue cap onto the test device
 - The test device should be held vertically and inserted into the blue cap, tightening until the red arrow on the test device is aligned with one of the white marks on the cap.
 - Once the cap is in place, the saliva will wick up the test strips – you will see a pink migration indicating proper saliva flow.
 - If either of the test strips fails to wick, have the donor loosen the blue cap ½ to ¾ of a turn and then re-tighten. This allows the air pressure within the device to equalize and the sample to flow properly.

Failure to wick properly can be caused by insufficient sample volume, extremely viscous saliva, or an air bubble blocking the flow.

The Process: Securing the Device

Test Completion

- Instruct donor to initial and date the silver security seal included in test kit box
 - Donor will place this security seal over device
- Have the donor initial and date the security seal from the bottom of the COC form
 - Remove security seal/barcode from COC form and apply to the back of the test device lengthwise

Security Seal Danor Initials ______ Date Collected _____ 1500004799

KEEP THE TEST DEVICE IN VIEW OF BOTH THE DONOR AND ADMINISTRATOR UNTIL DEVICE IS SEALED WITH SECURITY SEAL

ADMINISTRATOR SHOULD NOT HANDLE DEVICE UNTIL SECURITY SEALS ARE IN PLACE





Applicant Signature/Collector Signature

Instruct donor to sign, date and provide contact info in Step 2

Once completed and signed, p. 5 of the form may be given to the donor as a record.

STEP 2: COMPLETED BY DONOR						
DONOR CONSENT: I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper proof seal in my presence and that the information provided on this form and on the label affixed to the specimen container is correct. I hereby give permission for the release of the results of these tests to the my health care provider. In the case of screening for employment or pre-employment, I also authorize release of the results of these test to my employer or prospective employer and / or their authorized health care provider. X						
Signature of Donor	(Print) Donor's Name (First, MI, Last)	Date (Mo/Day/Yr)				
Daytime Phone:	Evening Phone:	Date of Birth: (Mo/Day/Yr)				

DONOR MAY NOW BE DISMISSED

Administrator must sign, date and print name in Step 4, and if sending to the lab for confirmation testing, check appropriate "Specimen Release To" box

STEP 4: CHAIN OF CUSTODY – INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY COLLECTOR CERTIFICATION: I certify that the specimen given to me by the donor identified above was collected, labeled, sealed & released as noted in accordance with applicable requirements. SPECIMEN RELEASED TO: (check one) Signature of Collector Time of Collection UPS UPS ☐ FedEx Other: DHL ☐ Courier (Print) Collector's Name (First, MI, Last) Date (Mo/Day/Yr) RECEIVED AT LABORATORY SPECIMEN SEAL INTACT? LABELS MATCH? ☐ Yes ☐ No ☐ Yes ☐ No Date (Mo/Day/Yr)



- Interpret the test results at 10 minutes
- Results are stable for up to one (1) hour
- Each test strip in the device includes an internal procedural Control
 (C) ensuring proper device function.
- Control lines should form next to the C on each of the test strips.
- Test interpretation:
 - A line next to the drug name indicates a negative result for that drug.
 - The absence of a line next to the drug name indicates a presumptive positive for that drug.

Drug screen results should NEVER be given to donor.



Invalid Test Result

- Each test strip within the device includes an internal procedural Control (C) ensuring proper device function.
- Control lines should form on both test strips, indicating the test functioned properly.
- The <u>absence</u> of a Control line in either of the test strips indicates the test is INVALID.
- Discard the test device.
- Perform another test with a new sample and a new device.





Negative Test Result

- The appearance of a line next to every drug name and BOTH control areas
- Record results of test in Step 3 on COC form
- File in accordance with company policy
- Discard test device
- Any indication of a line regardless of intensity is correctly interpreted as a negative test result.

		PRESUMPTIVE	NOT
DRUG NAME	NEG	POSITIVE	TESTED
Amphetamine (AMP)	[X]	[]	[]
Benzodiazepines (BZO)	[]	[]	K]
Cocaine (COC)	[X]	[]	[]
Marijuana (THC)	[X]	[]	[]
Methamphetamine (M-AMP)	[X]	[]	[]
Opiates (OPI)	X]	[]	[]
Phencyclidine (PCP)	[X]	11	[]
Other:	[]	[]	X]





Presumptive Positive Test Result

- The absence of a line next to the drug name indicates a presumptive positive for that drug.
- Example shows: presumptive positive test result for THC
- Record results of test in Step 3 on COC form

		PRESUMPTIVE	NOT
DRUG NAME	NEG	POSITIVE	TESTED
Amphetamine (AMP)	[X]	[]	[]
Benzodiazepines (BZO)	[]	[]	X]
Cocaine (COC)	X]	[]	[]
Marijuana (THC)	[]	X)	[]
Methamphetamine (M-AMP)	X)	[]	[]
Opiates (OPI)	[X]	[]	[]
Phencyclidine (PCP)	X1	[1]	[]
Other:	[]	[]	X]





Sending Sample to the Lab

Prepare device for shipment to lab for confirmation

- Take page 1 of the custody and control form labeled "Laboratory Copy" and insert into lab transport pouch
- Place test device in lab transport pouch on the side with the absorbent pad
- Place lab pouch into transport bag and apply air bill
- Schedule package pick up with freight carrier
- You are done!







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