



DrugCheck® Single and Multi-Drug Dip Test

Training and Certification

This training package is a general overview on operating and interpreting the DrugCheck[®] Single and Multi-Drug Dip Cards.



Training covers:

- Technical information
- Product overview
- Specimen collection and testing procedure
- Result interpretation
- Additional support services



TECHNICAL INFORMATION

Please review the product's Instructions for Use (Package Insert) and Procedure Card prior to using this device.

The DrugCheck® Single and Multi-Drug Dip Cards are lateral flow chromatographic immunoassay devices for the qualitative detection of multiple drugs and drug metabolites in urine.

As with all immunoassay urine screens, the DrugCheck® Dip Card only provides a preliminary analytical result. In order to obtain a confirmed analytical result a more specific laboratory method such as GC/MS (Gas Chromatography-Mass Spectometry) or LC/MS/MS (Liquid Chromatography Tandem Mass-Spectometry) is required. Professional judgement and clinical consideration should be applied to any Drugs of Abuse (DOA) test result especially when preliminary positive results are obtained.

The DrugCheck® Dip Card is for in-vitro diagnostic use only.



PRODUCT OVERVIEW

This training applies to all versions of the DrugCheck® Dip Card whether it is private label or a different configuration. The cups may or may not include Adulteration Testing (SVT - Specimen Validity Testing).

Features & Benefits:

- Tests for up to 14 drugs, alcohol and/ adulteration in urine
- Flat panel device to photocopy or scan results
- Results in as little as 5 minutes
- Available in a wide variety of test configurations
- 510K Cleared & CLIA-Waived options available
- Made in the U.S.A.







Drug	Cutoff
Alcohol	0.02%
Amphetamine	500*, 1000*, 300
Barbiturate	300*
Benzodiazepine	300*, 200
Buprenorphine	10*, 5
Cocaine	150*, 300*
Cotinine	200
EDDP/Methadone	300*, 100
EtG (Ethyl glucuronide)	500
Fentanyl	10
GHB	10
K2	20
Ketamine	1000
Marijuana	20*, 50*
MDMA/Ecstasy	500*
Methadone	300*
Methamphetamine	500*, 1000*, 300
Methylenedioxypyrovalerone	1000
	Alcohol Amphetamine Barbiturate Benzodiazepine Buprenorphine Cocaine Cotinine EDDP/Methadone EtG (Ethyl glucuronide) Fentanyl GHB K2 Ketamine Marijuana MDMA/Ecstasy Methadone Methamphetamine

Cutoffs ng/mL except alcohol (BAC) & GHB ($\mu g/mL$). *510(k) cleared

Test Strip	Drug	Cutoff
OPI OPI PI OPI OPI	Opiates	300*, 2000*
(Y OXY OXY	Oxycodone	100*
PCP PCP P PCP PCF	Phencyclidine	25*
PPX PPX PX PPX PPX	Propoxyphene	300
IL TML TML	Tramadol	50
TCA TCA CA TCA TCA	Tricyclic Antidepressants	1000*
6ACM 6ACM CM 6ACM 6A	6-Acetylmorphine	10
CLO CLO CLO	Clonazepam	150, 400
RIT RIT RIT RIT RIT RIT RIT RI	Methylphenidate	300, 1000
QL MQL MQL N L MQL MQL MQ	Methaqualone	300
LSD LSD LSD L D LSD LSD LSD	Lysergic Acid Diethylamide	20
ZOL ZOL ZOL ZO L ZOL ZOL ZOL	Zolpidem	50
OP ZOP ZOP ZOP	Zopiclone	50
AB GAB GAB G GAB GAB GAB	Gabapentin	1000
GB PGB PGB P PGB PGB PGB	Pregabalin	500
RA KRA KRA K A KRA KRA KRA	Kratom (Mitragynine)	300
K3 K3 K3 K3 K (3 K3 K3 K3 K3	K3	50
K4 K4 K4 K4 K (4 K4 K4 K4 K4	K4	50



PRODUCT STABILITY, STORAGE & PRECAUTIONS

- Test device must remain in sealed pouch until ready for use.
- Product should be stored at a temperature 36°F 86°F.
- Do not freeze test devices or expose to heating sources.
- This device is for in-vitro diagnostic use only.
- Test device should be used according with applicable Federal, State or Municipal regulations.
- Product is stable through the expiration date printed on the test pouch. Do not use after the date of expiration.



86°F

PERFORMING THE DRUG SCREEN - GATHER YOUR TESTING SUPPLIES

Materials Provided:

- 25 Individually Pouched Test Devices
- Package Insert (Instructions for Use)
- Adulteration Color Key (if applicable)

Recommended But Not Provided:

- Sterile Collection Cups with Temperature Strip
- Laboratory Custody and Control Forms (COC or CCF)
- Timer
- External Controls
- Gloves





SPECIMEN COLLECTION & TESTING PROCEDURE

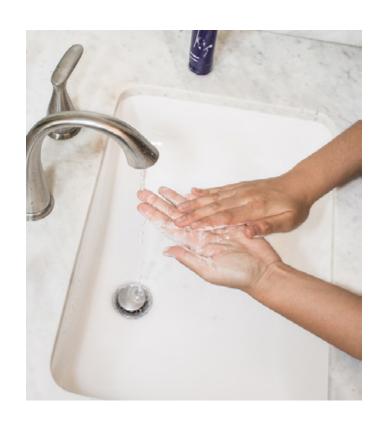
- 1. Have available for use a Chain of Custody Form (COC or CCF) or Test Results Template.
- 2. Require the donor to provide Photo ID.
- 3. Ask donor to remove any unnecessary clothing and empty all pockets.
- 4. Keep all backpacks, wallets and purses out of the restroom in a secure area (i.e. locked cabinet).
- 5. Secure the restroom. Turn off water sources (toilet and sink faucets). Ensure toilet tank is secure and bluing tablet has been added to water. Inspect bathroom and remove any cleaners/substances.





SPECIMEN COLLECTION & TESTING PROCEDURE (CONTINUED)

- 6. Have donor wash hands prior to conducting test.
- 7. Provide the urine cup to the donor to provide specimen. Instruct donor not to flush toilet or turn on water and to open door when complete.
- 8. Ensure donor provides at least 30 mL of urine.
- 9. Visually inspect foil package containing dip card to ensure the pouch has not been compromised.





TESTING PROCEDURE

- 1. Check temperature (normal range from 90°F 100°F or 32°C 38°C) and observe specimen for foreign material and/or discoloration. If the specimen is not within range it is considered invalid and must be recollected.
- 2. Lower the dip card into the urine specimen ensuring the bottom of the test strips contact the urine. The plastic housing should not touch the urine to avoid flooding device.
- 3. Replace test cap to cover test strips and lay flat.
- 4. Drug test results to be read at 5 minutes. Please read adulterant strips at 1 minute and alcohol strips at 2 minutes.
- 5. Secure collection cup by tightening lid as far as it will turn. Apply security seal and have donor and test administrator both sign and date the seal as well as initial and date the DrugCheck® label. This urine sample may require sending to a laboratory for confirmation services.

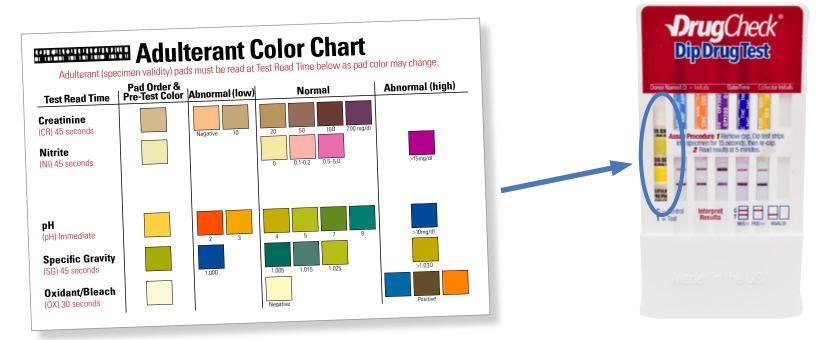




INTERPRETING THE RESULTS

Adulterant strips test for oxidants, specific gravity and pH. Specimens that have not been adulterated will display normal color range on the pad. Abnormal results (high or low) require collection of a new specimen and re-testing. Read adulterant results at 1 minute.

NOTE: Results must be read at 1 minute as pad color may change.

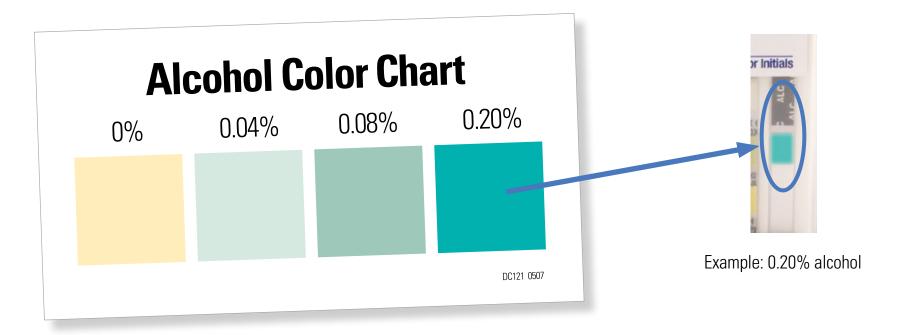




INTERPRETING THE RESULTS

Alcohol strips test for the presence of alcohol at specific thresholds. Use the Alcohol Color Chart to compare with the color pad on the test strip. Read alcohol results at 2 minutes.

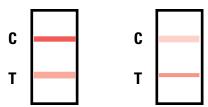
NOTE: Results must be read at 2 minutes as pad color may change.



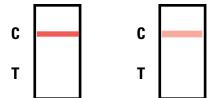


INTERPRETING THE RESULTS

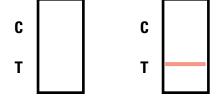
NFGATIVE Two lines appear. One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level. NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative if a line is visible. There is no meaning attributed to the line color intensity or width.



POSITIVE One line appears in the control region (C). No line whatsoever appears in the test region (T). The lack of a line in the test region (T) indicates a preliminary positive result for the corresponding drug of that specific test region. Send this urine specimen to a certified laboratory for a more specific confirmation by GC/MS.



INVALID Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact your supplier for technical support.







ADDITIONAL SUPPORT

To perform test it is recommended that operator use a sterile collection device with a temperature strip. It is also recommended that external controls be run with each new lot of test devices. For assistance in obtaining collection devices and/or approved controls or other supplies please contact our Customer Service Dept at 888-466-8433 or by emailing orders@drugcheck.com.

