CareHealth America

A W.H.P.M. Company

DrugCheck® NxScan Onsite Cup

Training and Certification

DrugCheck® NxScan Cup Training

This training package is a general overview on operating and interpreting the DrugCheck® NxScan Onsite Cup.

Training covers:

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

DrugCheck® NxScan Cup Training

TECHNICAL INFORMATION

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

The DrugCheck® NxScan Onsite Cup is a lateral flow chromatographic immunoassay device for the qualitative detection of multiple drugs and drug metabolites in urine.

As with all immunoassay urine screens, the NxScan Onsite Cup 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® NxScan Onsite Cup is for in-vitro diagnostic use only.

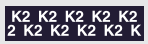
DrugCheck® NxScan Cup Training

PRODUCT OVERVIEW

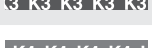
This training applies to all versions of the DrugCheck® NxScan Onsite Cup whether it is private label or a different configuration. The cups may or may not include Adulteration Testing (SVT - Specimen Validity Testing).

Features & Benefits:

- Tests for up to 14 drugs, alcohol and/or adulteration in urine
- Flat panel device to photocopy or scan results
- Self contained cup minimizes collector exposure to urine
- 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.

Test Strip	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

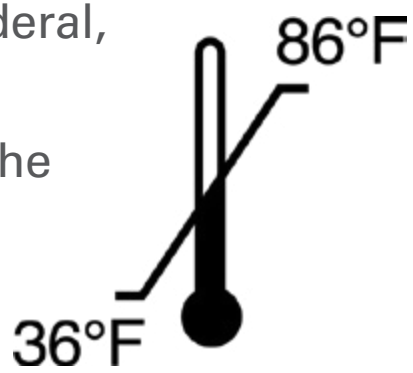
*Cutoffs ng/mL except alcohol (BAC) & GHB (µg/mL). *510(k) cleared*

Test Strip	Drug	Cutoff
	Opiates	300*, 2000*
	Oxycodone	100*
	Phencyclidine	25*
	Propoxyphene	300
	Tramadol	50
	Tricyclic Antidepressants	1000*
	6-Acetylmorphine	10
	Clonazepam	150, 400
	Methylphenidate	300, 1000
	Methaqualone	300
	Lysergic Acid Diethylamide	20
	Zolpidem	50
	Zopiclone	50
	Gabapentin	1000
	Pregabalin	500
	Kratom (Mitragynine)	300
	K3	50
	K4	50

DrugCheck® NxScan Cup Training

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.



DrugCheck® NxScan Cup Training

PERFORMING THE DRUG SCREEN – GATHER YOUR TESTING SUPPLIES

Materials Provided:

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

Recommended But Not Provided:

- Laboratory Custody and Control Forms (COC or CCF)
- Timer
- External Controls
- Gloves

DrugCheck® NxScan Cup Training

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.

DrugCheck® NxScan Cup Training

SPECIMEN COLLECTION & TESTING PROCEDURE (CONTINUED)

6. Visually inspect foil package containing test device to ensure the pouch has not been compromised. Tear open the pouch and remove device.

7. Have donor wash hands prior to conducting test.

8. 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.

9. Ensure donor provides at least 30 mL of urine.

DrugCheck® NxScan Cup Training

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. Pull privacy label and read drug test strip results at 5 minutes. Please read adulterant strips at 1 minute and alcohol strips at 2 minutes.

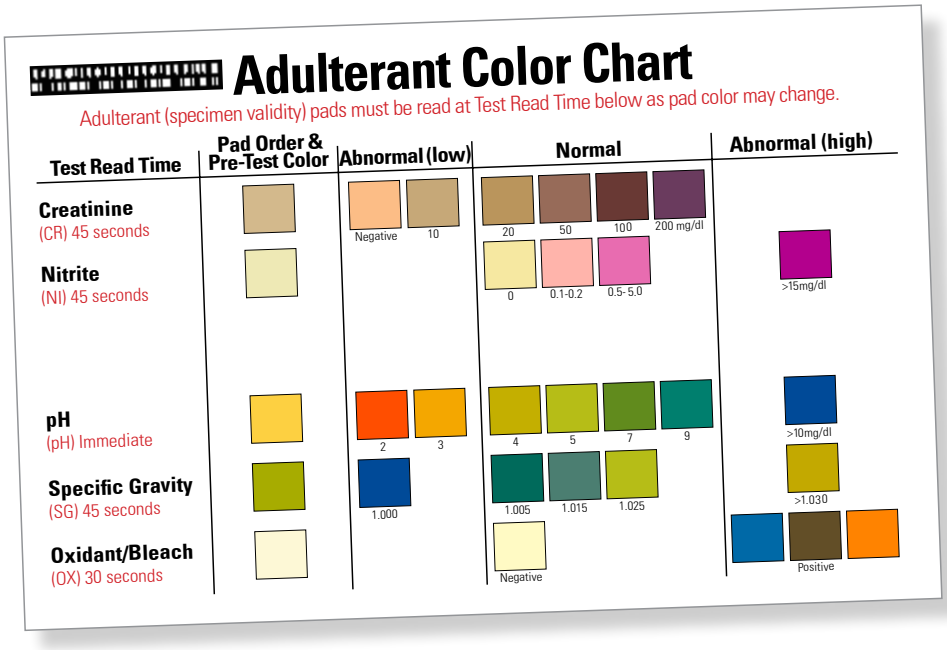
3. Secure container by tightening lid as far as it will turn. Apply security seal and have donor and test administrator both sign and date the seal as well as initial and date the NxScan label.

DrugCheck® NxScan Cup Training

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.



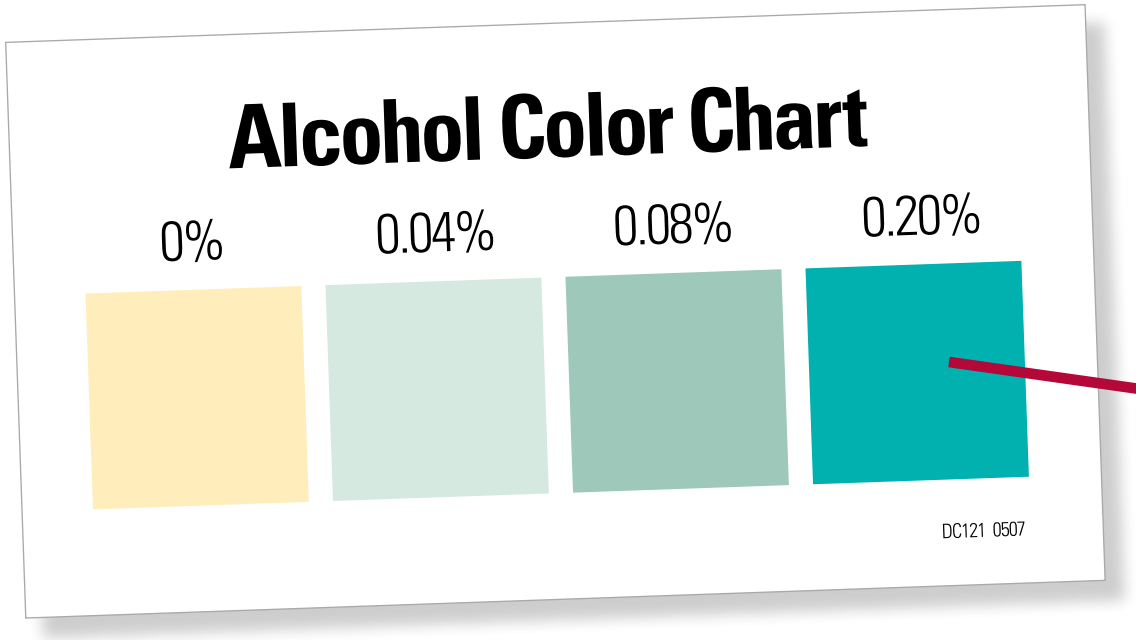
CareHealth America
A W.H.P.M. Company

DrugCheck® NxScan Cup Training

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.

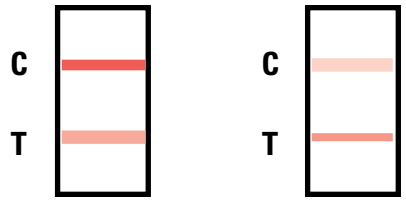


Example: 0.20% alcohol

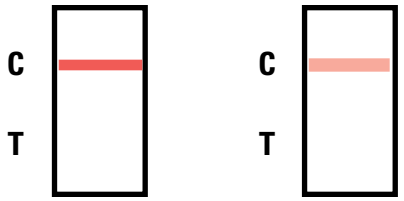
DrugCheck® NxScan Cup Training

INTERPRETING THE RESULTS

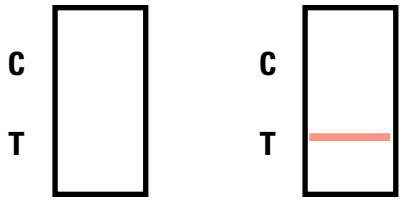
NEGATIVE Two lines appear. One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level. NOTE: The shade of color in the test line region (T) will vary, but it should 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.



DrugCheck® NxScan Cup Training

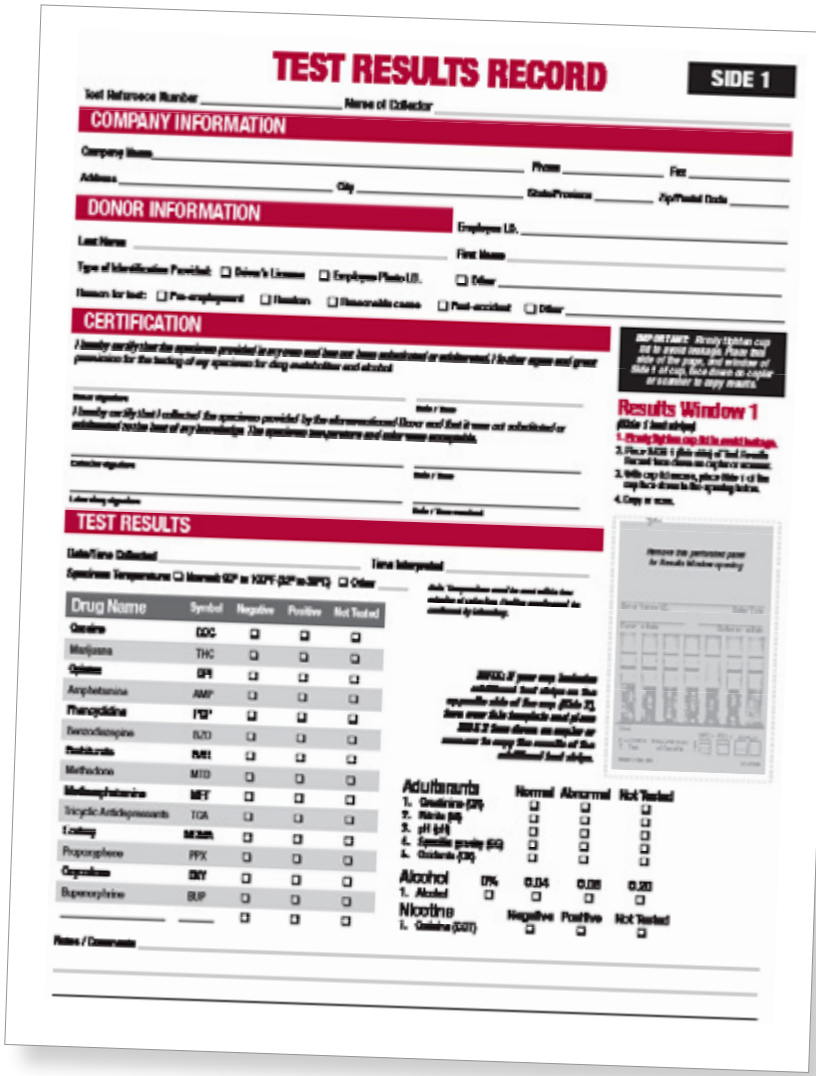
RECORDING THE RESULTS

Ensure that lid is firmly tightened. With Test Results Record template on copier or scanner, place NxScan cup face down in the Results Window opening of the template (optional).

Copy or scan results using Test Results Record template (optional). Cups containing test strips on front and back will require turning over the template and cup to copy/scan opposite sides.

Fill out Test Results Record with complete donor and test information.

Firmly tighten cup lid to avoid leakage. Copy or scan results for permanent record.



DrugCheck®

ADDITIONAL SUPPORT

It is recommended that external controls be run with each new lot of test devices.

For assistance in obtaining approved controls or other supplies please contact our Customer Service Department at 888-466-8433 or by emailing orders@drugcheck.com.

CareHealth America

A W.H.P.M. Company

507-526-3951 | 888-466-8433 | drugcheck.com | 1550 Industrial Dr, Blue Earth, MN 56013