

NexScreen Drug Screen Cup

Package Insert for OTC Use

For *in vitro* diagnostic use only

The NexScreen Cup offers a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drugs	Cutoff (ng/ml)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI300	Opiates	300
OPI	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

Instructions For Use:

Storage and Stability

The test must remain sealed until directly prior to use and is stable through the expiration date printed on the sealed pouch. Store the sealed pouch either at room temperature or refrigerated (2-30°C). Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

Before Testing

Read the instructions completely.

Check the expiration date of the device on the pouch/box. Do not use after the expiration date.

Have a watch, clock or timer ready.

The following items are needed to ship non-negative samples for confidential confirmation lab testing:

- Pre-addressed shipping box/LabPak
- Plastic single specimen bag
- Identification label (Chain of Custody and security label)

Performing The Test

Step 1: Take Out the Test Device

Read the instructions/handbook and then remove the NexScreen Cup device from the sealed foil pouch.

Step 2: Donor Voids Into the Cup

Provide the NexScreen Cup device to donor to provide their urine specimen. Instruct the donor to provide at least 30 mL of urine

Step 3: Read Result

Check the temperature of the specimen using the strip affixed on the side of the container within 5 minutes.



Continued on next page.

Step 3: Read Result Cont.

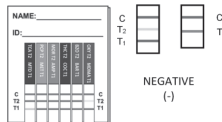
Read results after 5 minutes. Do not wait longer than 60 minutes.

A red or pink line must appear next to the letter "C" (control) on all of the test strips. The appearance of a red or pink line next to the letter "C" on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

• Negative Result:

A red or pink line next to the "T1" or "T2" (drug test line) under the drug name indicates a negative result for that drug.

If a test line appears next to the "T1" or "T2" for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.

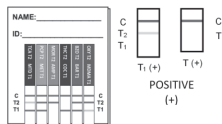


• Preliminary Positive Result:

If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug.

Send the sample to a laboratory for confirmation testing.

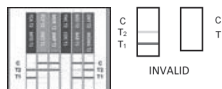
The illustration on the right shows preliminary positive results for AMP and THC, but negative for all other drugs.



• Invalid Result:

A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter "C" on the first strip (MTD, TCA) and fourth strip (COC, THC). The test results for those two test strips are invalid.



Questions and Answers

NexScreen is user friendly, if you have question about the test or result, please call NexScreen helpline [888-956-8989](tel:888-956-8989) or by email info@NexScreen.com. In addition, the NexScreen team is available to answer your question weekdays from 8 am to 5 pm MST.

What does my test results mean?

Q. The drug line is lighter than control line. Does it mean the drug is present in the urine?

A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. What does a Preliminary Positive Result mean?

A. The sample may contain one or more of the drugs being tested for. It is possible to get a "preliminary positive" when someone has not taken the drug. We recommend you send the urine to our laboratory for additional confirmation testing. Additional fees may apply.

- Medicinal such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine. To find more information on false positive results caused by prescription drugs, see www.drugs.com/article/false-positive-drug-tests.html.

Q. What does a Negative Result mean?

A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. What does an Invalid Result mean?

A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact your sales representative.

Laboratory Confirmation Testing:

Q. How can a Preliminary Positive Result be confirmed?

Continued on next page.

Laboratory Confirmation Testing Cont:

A. The urine specimen needs to be sent to a laboratory for confirmation testing. If you do not have a laboratory setup, you can contact NexScreen via email info@NexScreen.com to setup that process.

Other Questions:

Q. When is the best time to take the test?

A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:



Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/ml	2-7 hours	2-4 days
Cocaine (COC)	150 ng/ml	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/ml	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/ml	2 hours	2-3 days
Marijuana (THC)	50 ng/ml	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/ml	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/ml	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/ml	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/ml	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/ml	1-3 hours	1-2 days
Methadone (MTD)	300 ng/ml	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/ml	2-7 hours	2-4 days
EDDP	300 ng/ml	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/ml	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. How much urine do I need?

A. The NexScreen Cup requires just 30 mL of urine. Fill the collection cup of the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Q. Do I have to wait the full 5 minutes before reading the test?

A. Yes, we recommend that you wait the full 5 minutes before reading the result. Do not wait longer than 60 minutes.

Q. Are there any factors that could affect the drug testing result?

- A. Yes, certain factors may affect the drug testing result.
1. Certain over the counter medicines and prescription medicines may cause a preliminary positive result.
 2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
 3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
 4. Failure to use the NexScreen Cup as directed may result in an inaccurate screening result.
 5. The following compounds are detected positive in urine by the NexScreen Cup. Concentrations are given in ng/ml; percent cross-reactivity is shown.

Compound	Concentration	%	Compound	Concentration	%
AMP					
D-Amphetamine	500	100%	MDA	8,000	6.5%
L-Amphetamine	50,000	1%	Phentermine	45,000	1.1%
BAR					
Secobarbital	300	100%	Butalbital	300	100%
Amobarbital	2,500	12%	Cyclopentobarbital	500	60%
Aprobarbital	500	60%	Phenobarbital	300	100%
Butobarbital	100	300%	Pentobarbital	250	120%
BUP					
Buprenorphine	10	100%			
BZO					
Oxazepam	300	100%	Lorazepam	3,900	7.7%
Alprazolam	200	150%	Lorazepam-glucuronide	5,000	6%
Bromazepam	1,000	30%	Nitrazepam	250	120%
Clobazam	200	150%	Norchlordiazepoxide	500	60%
Clorazepate	750	40%	Nordazepam	390	76.9%
Desalkylflurazepam	1,200	25%	Nordiazepoxide	400	75%
Diazepam	1,000	30%	Temazepam	150	200%
Flunitrazepam	250	120%	Triazolam	2,500	12%
α -Hydroxylprazolam	1,900	15.8%			
COC					
Benzoylcegonine	150	100%	Cocaine	5,000	3%
Cocaethylene	50,000	0.3%	Ecgonine	50,000	0.3%
EDDP					
EDDP	300	100%			
MET					
D-Methamphetamine	500	100%	MDEA	30,000	1.7%
D-Amphetamine	50,000	1%	MDMA	3,500	14.3%
L-Amphetamine	50,000	1%	Mephentermine	75,000	0.7%
1R,2S(-)-Ephedrine	100,000	0.5%			
MDMA					
(+/-)-MDMA	500	100%	(+/-)-MDEA	500	100%
(+/-)-MDA	3,900	12.8%			

Compound	Concentration	%	Compound	Concentration	%
OPI300					
Morphine	300	100%	Levorphanol	50,000	0.6%
Codeine	100	300%	Morphine 3-glucuronide	400	75%
Ethylmorphine	100	300%	Norcodeine	6,000	1.9%
Heroin	8,000	37.5%	Oxycodone	75,000	0.4%
Hydrocodone	1,250	24%	Thebaine	90,000	0.3%
Hydromorphone	2,500	12%			
MTD					
Methadone	300	100%			
OPI					
Morphine	2,000	100%	Hydromorphone	5,000	40%
Codeine	1,800	111.1%	Morphine-3-glucuronide	2,600	76.9%
Ethylmorphine	1,500	133.3%	Oxycodone	70,000	2.9%
Heroin	11,000	18.2%	Thebaine	95,000	2.1%
Hydrocodone	5,000	40%			
OXY					
Oxycodone	100	100%	Hydrocodone	5,000	2%
Codeine	50,000	0.2%	Hydromorphone	25,000	0.4%
Ethylmorphine	50,000	0.2%	Oxymorphone	12,500	0.8%
PCP					
Phencyclidine	25	100%	4-Hydroxy-PCP	1,500	1.7%
TCA					
Nortriptyline	1,000	100%	Doxepine	1,000	100%
Amitriptyline	4,000	25%	Imipramine	1,000	100%
Clomipramine	2,000	50%	Promethazine	1,000	100%
Desipramine	500	200%	Trimipramine	5,000	20%
THC					
11-nor- Δ^9 -THC-9-COOH	50	100%	(-)- Δ^8 -THC	20,000	0.3%
(+/-)-11-Hydroxy- Δ^9 -THC	5,000	1%	(-)- Δ^9 -THC	20,000	0.3%

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are

available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.

Quality control testing should be performed with each new lot, with each new shipment, and every thirty days to check storage conditions. External controls can be purchased from NexScreen.

Performance Characteristics

A. Accuracy

The accuracy of the NexScreen was evaluated in comparison to GC/MS and LC/MS. 40 drug-free urine samples collected from presumed non-user volunteers were tested with the NexScreen. Of these 40 negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 40 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy and discordant results on the Cup format is shown in the following tables:



Summary of Accuracy Results on the NexScreen Cup

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						% Agreement
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	
AMP/ 500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/ 300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/ 10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/ 150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/ 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/ 500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/ 300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%

Summary of Accuracy Results on the NexScreen Cup Cont.

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						% Agreement
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	
OPI/ 2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/ 100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/ 25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/ 1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/ 50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the NexScreen Cup

Drug Test/ Cutoff (ng/ml)	NexScreen Cup Result	Result w/GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Pos	477	Amphetamine
BAR/300	Pos	265	Barbital
	Pos	286	Barbital
BUP/10	Pos	8	Buprenorphine
	Pos	9	Buprenorphine
BZO/300	Pos	244	Oxazepam
	Pos	252	Oxazepam
	Pos	295	Oxazepam
COC	Pos	146	Benzoylcgonine
EDDP/300	Pos	250	EDDP
	Pos	263	EDDP
	Pos	275	EDDP
MDMA/ 500	Pos	368	MDMA
	Pos	381	MDMA
MET/ 500	Pos	394	Methamphetamine
	Pos	461	Methamphetamine
	Pos	478	Methamphetamine

Drug Test/ Cutoff (ng/ml)	NexScreen Cup Result	Result w/GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
OPI/300	Pos	260	Morphine
	Pos	263	Morphine
	Pos	292	Morphine
MTD/300	Pos	266	Methadone
	Pos	273	Methadone
OPI/2000	Pos	1,898	Morphine
	Pos	1,990	Morphine
OXY/100	Pos	88	Oxycodone
	Pos	98	Oxycodone
PCP/25	Pos	99	Oxycodone
	Pos	22.9	Phencyclidine
PPX/300	Pos	242	Norpropoxyphene
	Pos	285	Norpropoxyphene
TCA/ 1000	Pos	786	Nortriptyline
	Pos	859	Nortriptyline
THC/50	Pos	49	11-nor- Δ^9 -THC-9-COOH

Performance Characteristics Cont.

B. Analytical Sensitivity/Precision

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the NexScreen Card and Cup.

C. Analytical Specificity

The following compounds are detected positive in urine by the NexScreen Cup. Concentrations are given in ng/ml; percent cross-reactivity is shown.



Compound	Concentration	%	Compound	Concentration	%
AMP					
D-Amphetamine	500	100%	MDA	8,000	6.5%
L-Amphetamine	50,000	1%	Phentermine	45,000	1.1%
BAR					
Secobarbital	300	100%	Butalbital	300	100%
Amobarbital	2,500	12%	Cyclopentobarbital	500	60%
Aprobarbital	500	60%	Phenobarbital	300	100%
Butobarbital	100	300%	Pentobarbital	250	120%
BUP					
Buprenorphine	10	100%			
BZO					
Oxazepam	300	100%	Lorazepam	3,900	7.7%
Alprazolam	200	150%	Lorazepam-glucuronide	5,000	6%
Bromazepam	1,000	30%	Nitrazepam	250	120%
Clobazam	200	150%	Norchlordiazepoxide	500	60%
Clorazepate	750	40%	Nordazepam	390	76.9%
Desalkylflurazepam	1,200	25%	Nordiazepoxide	400	75%
Diazepam	1,000	30%	Temazepam	150	200%
Flunitrazepam	250	120%	Triazolam	2,500	12%
α -Hydroxylprazolam	1,900	15.8%			
COC					
Benzoyllecgonine	150	100%	Cocaine	5,000	3%
Cocaoethylene	50,000	0.3%	Ecgonine	50,000	0.3%
EDDP					
EDDP	300	100%			

Compound	Concentration	%	Compound	Concentration	%
MET					
D-Methamphetamine	500	100%	MDEA	30,000	1.7%
D-Amphetamine	50,000	1%	MDMA	3,500	14.3%
L-Amphetamine	50,000	1%	Mephentermine	75,000	0.7%
1R,2S(-)-Ephedrine	100,000	0.5%			
MDMA					
(+/-)-MDMA	500	100%	(+/-)-MDEA	500	100%
(+/-)-MDA	3,900	12.8%			
OPI300					
Morphine	300	100%	Levorphanol	50,000	0.6%
Codeine	100	300%	Morphine 3-glucuronide	400	75%
Ethylmorphine	100	300%	Norcodeine	6,000	1.9%
Heroin	8,000	37.5%	Oxycodone	75,000	0.4%
Hydrocodone	1,250	24%	Thebaine	90,000	0.3%
Hydromorphone	2,500	12%			
MTD					
Methadone	300	100%			
OPI					
Morphine	2,000	100%	Hydromorphone	5,000	40%
Codeine	1,800	111.1%	Morphine-3-glucuronide	2,600	76.9%
Ethylmorphine	1,500	133.3%	Oxycodone	70,000	2.9%
Heroin	11,000	18.2%	Thebaine	95,000	2.1%
Hydrocodone	5,000	40%			
OXY					
Oxycodone	100	100%	Hydrocodone	5,000	2%
Codeine	50,000	0.2%	Hydromorphone	25,000	0.4%
Ethylmorphine	50,000	0.2%	Oxymorphone	12,500	0.8%
PCP					
Phencyclidine	25	100%	4-Hydroxy-PCP	1,500	1.7%
TCA					
Nortriptyline	1,000	100%	Doxepine	1,000	100%
Amitriptyline	4,000	25%	Imipramine	1,000	100%
Clomipramine	2,000	50%	Promethazine	1,000	100%
Desipramine	500	200%	Trimipramine	5,000	20%
THC					
11-nor- Δ^9 -THC-9 COOH	50	100%	(-)- Δ^8 -THC	20,000	0.3%
(+/-)-11-Hydroxy- Δ^9 -THC	5,000	1%	(-)- Δ^9 -THC	20,000	0.3%

Performance Characteristics Cont.

D. Interference

The following compounds were evaluated for potential positive or negative interference with the NexScreen Cup. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the NexScreen Cup. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL when tested with the NexScreen Cup:

Acetaminophen	Diphenhydramine	Nicotine
Acetone	Dopamine	(+/-)-Norephedrine
Albumin	(+/-)-Isoproterenol	Oxalic acid
Ampicillin	1R,2S(-)-Ephedrine	Penicillin-G
Ascorbic acid	Erythromycin	Pheniramine
Aspartame	Ethanol	Phenothiazine
Aspirin	Furosemide	L-Phenylephrine
Atropine	Glucose	B-Phenylethylamine
Benzocaine	Guaiacol glyceryl ether	Procaine
Bilirubin	Hemoglobin	Quinidine
Caffeine	Ibuprofen	Ranitidine
Chloroquine	(+/-)-Isoproterenol	Riboflavin
(+)-Chlorpheniramine	Ketamine	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Suindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	
4-Dimethylaminoantipyrine	Niacinamide	

Adulteration Test

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The NexScreen adulteration test is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration.

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dl. Values outside this range generally indicate a manipulated test.

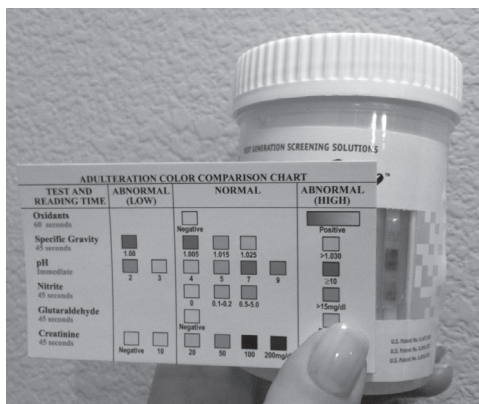
Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dl is considered adulterated.

Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may cause disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

Procedure For Drug Test With Adulteration Test

Preparation:

1. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.
3. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
4. Collect urine in the cup.
5. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
6. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



ADULTERATION COLOR COMPARISON CHART			
TEST AND READING TIME	ABNORMAL (LOW)	NORMAL	ABNORMAL (HIGH)
Oxidants 60 seconds		Negative	Positive
Specific Gravity 45 seconds	1.00	1.005 1.015 1.025	>1.030
pH Immediate	2 3	4 5 7 9	>10
Nitrite 45 seconds		0 0.1-0.2 0.5-5.0	>5mg/dl
Glutaraldehyde 45 seconds		Negative	Positive
Creatinine 45 seconds	Negative 10	20 50 100 200mg/dl	

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