

# DRUGCHECK<sup>®</sup> Test Cup NxStep OnSite<sup>®</sup> Instructions

## INTENDED USE

The DRUGCHECK<sup>®</sup> test cup is an immunochromatographic assay for rapid qualitative detection of up to ten drugs of abuse and their principal metabolites in urine at specified cutoff concentrations. It is not intended for over the counter sale to laypersons. The DRUGCHECK<sup>®</sup> test cup can be composed from a 4-panel up to a 10-panel configured out of the following drugs as listed below:

ABBREVIATION	TARGET ANALYTE	CUT-OFF (ng/mL)
AMP	AMPHETAMINE	1,000
BAR	BARBITURATES	300
BZO	BENZODIAZEPINES	300
COC	COCAINE	300
THC	MARIJUANA	50
MET	METHAMPHETAMINE	1,000
MTD	METHADONE	300
OPI	OPIATES	300
OPI	OPIATES	2,000
OXY	OXYCODONE	100
PCP	PHENCYCLIDINE	25
PPX	PROPOXYPHENE	300

This device has the option of built-in adulteration test strips. The strip's results provide information regarding urine sample tampering by checking the pH, Specific Gravity, Nitrite and Creatinine levels.

*Note: The test provides only preliminary test data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

## SUMMARY AND EXPLANATION OF THE TEST

The DRUGCHECK<sup>®</sup> test cup uses an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need for instrumentation. The method employs a unique mixture of antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economic concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs according to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services.

## PRINCIPLE OF THE TEST

The DRUGCHECK<sup>®</sup> test cup is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of up to ten drugs from a single urine sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a colored line in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen-antibody complex and preventing the development of a colored line in the Test Zone.

Regardless of the drug levels in the sample, a colored line is produced in each Control Zone by a parallel immunochemical reaction. The presence of this colored line in the control region serves as 1) verification that sufficient volume is added and 2) that proper flow is obtained.

## MATERIALS PROVIDED

- 25 Test cups with strips containing dye-conjugated antibody and immobilized antigen in a protein matrix with sodium azide.
- Test Instructions.
- Color chart (for cups with Adulteration strips)

## MATERIALS NEEDED BUT NOT PROVIDED

- Timing device (i.e., timer, clock, watch, etc.)

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For *professional* use only.
- Do not use the test device beyond the expiration date.
- Use a new device for each urine test to avoid cross contamination of urine samples. The DRUGCHECK<sup>®</sup> test cup cannot be reused.
- Urine specimens may be infectious; properly handle and dispose of all urine and urine reaction devices in a biohazard container.
- Visually inspect the foil package to ensure it has not been compromised before beginning the test. If the package does not reach you intact, the integrity of the test cup may be compromised.

## STORAGE AND STABILITY

Store test kit below 28°C (83°F); do not freeze. If stored at 2°-8°C (36°F-46°F), allow the test kit to reach room temperature 15°-28° (59°-83°F) before performing the test. The Test cup will be stable until the expiration date as printed on the foil package.

## SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup with a minimum of 30ml volume and do not require any special handling or pre-treatment. The DRUGCHECK<sup>®</sup> test cup employs a thermal strip to validate the urine collection. This device should be checked immediately after collection.

*Note:* Urine specimens can be transferred from a urine collection container into the DRUGCHECK<sup>®</sup> test cup if necessary.

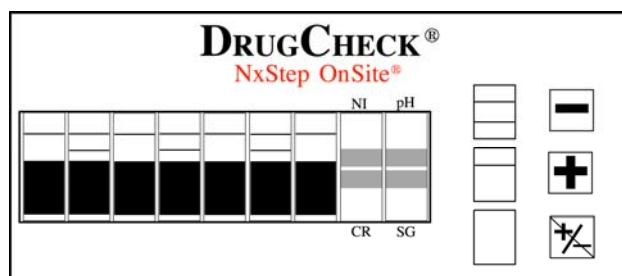
## TEST PROCEDURE

Do not break the seal of the protective pouch until ready to begin testing.

- Tear open the foil pouch and remove the test cup.
- Issue the device to the individual to be tested.
- Have them urinate directly into the DRUGCHECK<sup>®</sup> test cup. Ensure the specimen is above the minimum level line on the test label.
- If adulteration strips are included, wait one minute and immediately read the adulteration strips results by comparing them to the color chart provided. Color comparison must be performed under a good light source. Changes in color after 2 minutes are of no diagnostic value. If results show that the urine sample was adulterated, do not read the drug test result.
- The cup must be returned immediately to the collector. Authorized personnel at collection sites to remove tear-off label and read the results at five minutes post collection.

*NOTE:* In order to prevent any incorrect results, the test results should **not** be interpreted after 8 minutes.

## INTERPRETATION OF RESULTS



Each of the tests is read individually and independently of one another.

**Positive:** A colored line is visible in each Control Zone. No color line whatsoever appears in the appropriate Test Zone, indicating a preliminary positive result for the corresponding drug of that specific Test Zone. Send this urine specimen to a certified laboratory for confirmation.

**Negative:** A colored line is visible in each Control Zone and in the appropriate Test Zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

**Invalid:** If a colored line is not visible in the Control Zone, the test is invalid. Another test should be run to re-evaluate the specimen. Each strip in the DRUGCHECK<sup>®</sup> test cup is read and functions independently. An invalid result on one test strip does not invalidate other results derived from the same device.

*Note: There is no meaning attributed to the line color intensity or width. Any evidence of a line should be considered a line.*

- Adulteration Strip Results are obtained by direct comparison of the reacted strips with the color blocks. Adulterated urine will show result colors under the "Abnormal" block colors of the color chart. Unadulterated samples will show strip colors similar to the "Normal" block colors of the color chart.

pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

**Specific Gravity:** Random urine may vary in specific gravity from 1.003 – 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 – 1.022. Elevated urine specific gravity values may be obtained in the presence of moderate quantities of protein. A urine specimen with a specific gravity level of less than 1.003 can be an indication of substitution. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is substituted.

**Creatinine:** Daily creatinine excretion, related to muscle mass of the human body, is usually constant. A urine specimen with creatinine levels of less than 5 mg/dl is an indication of substitution. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, samples with creatinine level of lower than 20 mg/dl should be considered diluted.

**Nitrite:** Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In the DRUGCHECK® test cup with adulteration nitrite levels above 15 mg/dl are considered abnormal.

**QUALITY CONTROL**

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

**LIMITATIONS OF THE TEST**

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate in detecting the urine drug levels (accuracy is a function of the specific strip) there is the possibility false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g., technical or procedure errors associated with the testing.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels or level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents can cause erroneous test results when added to urine specimens regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

**PERFORMANCE CHARACTERISTICS**

1. **Sensitivity:** The DRUGCHECK® test cup detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
2. **Precision:** The DRUGCHECK® test cup produced a 100% precision level when tested with drug standards at 50% above and 50% below cut-off concentration levels.  
  
The precision was determined by replicate assays with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable interlot variation when testing both positive and negative spiked samples across three (3) different lots of devices.
3. **Accuracy:** In addition to in-house performance testing, where there were no inappropriate reactions and there was no interaction between any of the strips. During clinical trials, the clinical specimens were evaluated using the DRUGCHECK® test cup compared to previously FDA cleared predicate assay and confirmatory method GC/MS.

The individual results from the study are as follows:

3.01 **AMPHETAMINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	46	1
DRUGCHECK® Negative	1	78
When compared to predicate kit, the relative sensitivity between positive samples was 97.9%. The relative specificity between negative samples was 98.7%. The accuracy with respect to predicate kit was 98.4%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	45	1
DRUGCHECK® Negative	1	79
When compared with GC/MS, the relative sensitivity between positive samples was 97.8%. The relative specificity between negative samples was 98.8%. The accuracy with respect to GC/MS was 98.41%.		

3.02 **BARBITURATES**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	56	0
DRUGCHECK® Negative	0	58
When compared to predicate kit, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to predicate kit was 100%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	54	2
DRUGCHECK® Negative	2	58
When compared with GC/MS, the relative sensitivity between positive samples was 96.4%. The relative specificity between negative samples was 96.7%. The accuracy with respect to GC/MS was 96.5%.		

3.03 **BENZODIAZEPINES**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	42	0
DRUGCHECK® Negative	1	79
When compared to predicate kit, the relative sensitivity between positive samples was 97.67%. The relative specificity between negative samples was 100%. The accuracy with respect to predicate kit was 99.18%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	40	2
DRUGCHECK® Negative	1	79
When compared with GC/MS, the relative sensitivity between positive samples was 97.6%. The relative specificity between negative samples was 97.5%. The accuracy with respect to GC/MS was 97.5%.		

3.04 **COCAINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	53	2
DRUGCHECK® Negative	2	83
When compared to predicate kit, the relative sensitivity between positive samples was 96.36%. The relative specificity between negative samples was 96.6%. The accuracy with respect to predicate kit was 97.1%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	49	4
DRUGCHECK® Negative	3	84
When compared with GC/MS, the relative sensitivity between positive samples was 94.2%. The relative specificity between negative samples was 95.5%. The accuracy with respect to GC/MS was 95%.		

3.05 **MARIJUANA**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	62	1
DRUGCHECK® Negative	1	75
When compared to predicate kit, the relative sensitivity between positive samples was 98.4%. The relative specificity between negative samples was 98.7%. The accuracy with respect to predicate kit was 98.5%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	60	3
DRUGCHECK® Negative	3	72
When compared with GC/MS, the relative sensitivity between positive samples was 95.2%. The relative specificity between negative samples was 96%. The accuracy with respect to GC/MS was 95.65%.		

3.06 **METHAMPHETAMINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	51	1
DRUGCHECK® Negative	1	78
When compared to predicate kit, the relative sensitivity between positive samples was 98%. The relative specificity between negative samples was 98.7%. The accuracy with respect to predicate kit was 98.47%.		
	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	49	2
DRUGCHECK® Negative	2	76
When compared with GC/MS, the relative sensitivity between positive samples was 96.1%. The relative specificity between negative samples was 97.5%. The accuracy with respect to GC/MS was 96.9%.		

### 3.07 METHADONE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	55	0
DRUGCHECK® Negative	0	66

When compared to predicate kit, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to predicate kit was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	52	3
DRUGCHECK® Negative	2	64

When compared with GC/MS, the relative sensitivity between positive samples was 96.3%. The relative specificity between negative samples was 95.2%. The accuracy with respect to GC/MS was 95.9%.

### 3.08 OPIATES 2000

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	65	1
DRUGCHECK® Negative	1	73

When compared to predicate kit, the relative sensitivity between positive samples was 98.48%. The relative specificity between negative samples was 98.64%. The accuracy with respect to predicate kit was 98.57%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	64	2
DRUGCHECK® Negative	2	71

When compared with GC/MS, the relative sensitivity between positive samples was 97%. The relative specificity between negative samples was 97.3%. The accuracy with respect to GC/MS was 97.1%.

### 3.09 PHENCYCLIDINE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	59	0
DRUGCHECK® Negative	0	79

When compared to predicate kit, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to predicate kit was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	55	4
DRUGCHECK® Negative	3	76

When compared with GC/MS, the relative sensitivity between positive samples was 94.82%. The relative specificity between negative samples was 95%. The accuracy with respect to GC/MS was 94.9%.

### 3.10 OPIATES 300

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	69	1
DRUGCHECK® Negative	1	70

When compared to predicate kit, the relative sensitivity between positive samples was 98.57%. The relative specificity between negative samples was 98.59%. The accuracy with respect to predicate kit was 98.58%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	68	2
DRUGCHECK® Negative	2	69

When compared with GC/MS, the relative sensitivity between positive samples was 97.1%. The relative specificity between negative samples was 97.2%. The accuracy with respect to GC/MS was 97.16%.

### 3.11 OXYCODONE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	52	1
DRUGCHECK® Negative	2	59

When compared to predicate kit, the relative sensitivity between positive samples was 96.3%. The relative specificity between negative samples was 98.3%. The accuracy with respect to predicate kit was 97.43%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	51	2
DRUGCHECK® Negative	2	59

When compared with GC/MS, the relative sensitivity between positive samples was 96.2%. The relative specificity between negative samples was 96.7%. The accuracy with respect to GC/MS was 96.5%.

### 3.12 PROPOXYPHENE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
DRUGCHECK® Positive	81	2
DRUGCHECK® Negative	4	68

When compared to predicate kit, the relative sensitivity between positive samples was 95.3%. The relative specificity between negative samples was 97.14%. The accuracy with respect to predicate kit was 96.12%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	81	2
DRUGCHECK® Negative	3	69

When compared with GC/MS, the relative sensitivity between positive samples was 96.4%. The relative specificity between negative samples was 97.2%. The accuracy with respect to GC/MS was 96.77%.

*There were no inappropriate reactions or cross reactivity between strips noted in any of the data collected.*

- Specificity: A study was conducted with the DRUGCHECK® test cup to determine the cross-reactivity of drug-related compound with the test. Substances listed in Table 1 produced results approximately equivalent to the cut-off levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test of concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in Table 2.

**Table 1:** Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test in ng/ml:

The following Amphetamine-related substances yield positive results for

<b>Amphetamines:</b>	
d-Amphetamine	1,000
l-Amphetamine	10,000
3,4 methylenedioxyamphetamine(MDA)	4,500
p-Methoxyamphetamine(PMA)	1,500
Methylenedioxyethylamphetamine(MDEA)	>100,000
Methylenedioxyamphetamin(MDMA)	>100,000

The following Barbiturate-related substances yield positive results for

<b>Barbiturates:</b>	
Secobarbital	300
Alphenal	400
Amobarbital	2,000
Aprobarbital	300
Barbital	300
Butabarbital	300
Butalbital	3,000
Pentobarbital	400
Phenobarbital	300

The following Benzodiazepine-related substances yield positive results for

<b>Benzodiazepines:</b>	
Oxazepam	300
Alprazolam	400
Bromazepam	2,000
Chlordiazepoxide	8,000
Clobazam	400
Clonazepam	5,000
Diazepam	2,000
Estazolam	20,000
Flunitrazepam	1,000
Lorazepam	4,000
Lometazepam	5,000
Nitrazepam	200
Nordiazepam	500
Temazepam	200
Triazolam	8,000

The following Cocaine-related substances yield positive results for **Cocaine:**

Benzoylcegonine	300
Cocaine	50,000
Ecgonine	>100,000
Ecgonine Methyl Ester	>100,000

The following Marijuana-related substances yield positive results for **Marijuana:**

11-nor-Δ-9-tetrahydrocannabinol-9-carboxylic acid	50
11-nor-Δ-8-tetrahydrocannabinol-9-carboxylic acid	50
11-hydroxy-Δ-9-tetrahydrocannabinol	2,500
Δ-9-tetrahydrocannabinol	10,000
Δ-8-tetrahydrocannabinol	8,000
Cannabinol	100,000
Cannabidiol	100,000

The following Methamphetamine-related substances yield positive results for **Methamphetamine:**

d-Methamphetamine	1000
d-amphetamine	40,000
l-Methamphetamine	20,000
Methylenedioxyethylamphetamin(MDEA)	50,000
Methylenedioxymethamphetamin(MDMA)	2,000
3,4 methylenedioxyamphetamin(MDA)	>100,000
p-Methoxyamphetamin(PMA)	>100,000

The following Methadone-related substances yield positive results for **Methadone:**

Methadone	300
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium(EDDP)	50,000
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	50,000

The following Opiates 2000-related substances yield positive results for **Opiates 2000:**

Morphine	2000
6-Acetylmorphine	2000
Codeine	2000
Ethyl morphine	15,000
Hydromorphone	20,000
Hydrocodone	25,000
Oxycodone	>100,000
Oxymorphone	>100,000

The following PCP-related substances yield positive results for **Phencyclidine:**

Phencyclidine	25
Thienylcyclohexylpiperidine	3,000

The following Opiates-related substances yield positive results for **Opiates 300ng/ml:**

Morphine	300
6-Acetylmorphine	300
Codeine	300
Ethyl morphine	2,000
Hydromorphone	3,000
Hydrocodone	3,000

The following Oxycodone-related substances yield positive results for **Oxycodone:**

Oxycodone	100
Hydrocodone	2000
Hydromorphone	5000
Oxymorphone	500
Codeine	80,000

The following Propoxyphene-related substances yield positive results for **Propoxyphene:**

Propoxyphene	300
Norpropoxyphene	20,000

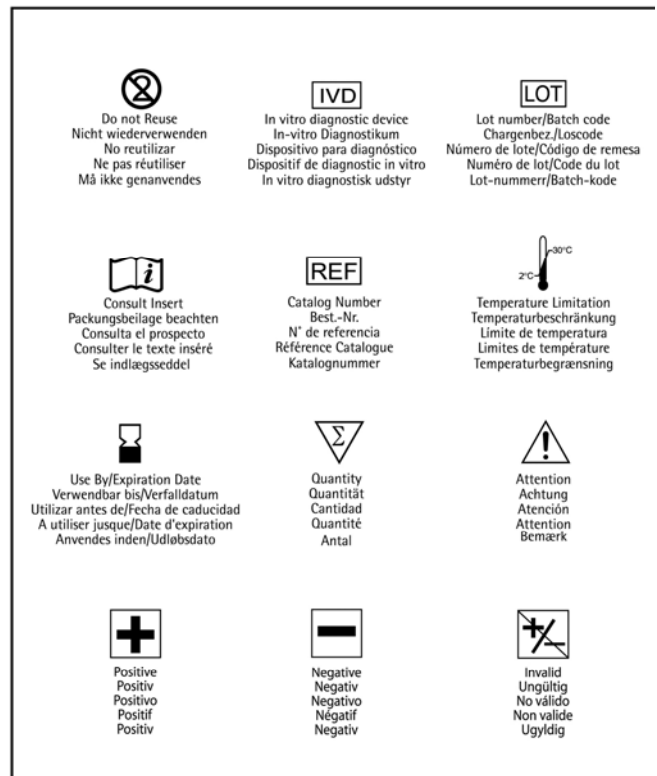
**Table 2:** Compounds tested and found not to cross-react with the test at a 0.1 mg/ml concentration in urine:

Acetaminophen	Furosemide
Acetone	Guaiacol Glyceryl Ether
Albumin	Glucose
Amitriptyline	Hemoglobin
Ampicillin	Isoproterenol
Aspartame	Lidocaine
Aspirin	N-Methyl-Ephedrine
Atropine	(+)-Naproxen
Benzocaine	Oxalic Acid
Bilirubin	Penicillin-G
Caffeine	Pheniramine
Chloroquine	Phenothiazine
Chlorpheniramine	L-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quindine
4-Dimethylaminoantipyrine	Ranitidine
Dopamine	Sodium Chloride
Doxylamine	Sulindac
(+/-)-Ephedrine	Thioridazine
Erythromycin	Tyramine
Ethanol	Vitamin C

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results, e.g., biological, technical or procedural error. The Amphetamine test performance was evaluated using 1000-ng/ml specimens and found no interferences when pH ranges from 4.5 to 8.5 and specific gravity ranges from 1.005 to 1.03.

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