Rapid Response®

Multi-Drug Test Panel (Urine)

REF DX.X -1P29 -25 Product Insert

Catalogue Number	D-1P1-07	D-1P2-07	D-1P3-07	D-1P4-07
	D-1P5-07	D-1P6-07	D-1P7-07	D-1P8-07
	D-1P9-07	D-1P10-07	D-1P11-07	D-1P12-07
	D-1P13-07	D-1P14-07	D-1P15-07	D-1P16-07

For *in vitro* diagnostic use.

This device is intended for use at point of care.

Intended Use

The Rapid Response® Multi-Drug Test Panel (Urine) is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of one to twenty-six of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Parameter	Calibrator	Cut-off (ng/mL)
6-MAM	6-Monoacetylmorphine	10
AMP	Amphetamine	1000*/500
BAR	Secobarbital	300*
BUP	Buprenorphine	10*
BZO	Oxazepam	300
COC	Benzoylecgonine	300*/150
COT	(-)-Cotinine	200*
MDMA	3,4-Methylenediioxy-Methamphetamine	500
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	100*
ETG	Ethyl Glucuronide	500*
FYL	Fentanyl and Fentanyl metabolites	10*
HMO	Hydromorphone	300
K2	JWH-073/JWH-018	50*
KET	Ketamine	1000*
LSD	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	10*
MET	Methamphetamine	1000*/500
MTD	Methadone	300*
MOP	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PGB	Pregabalin	1000*
PPX	D-Propoxyphene	300*
THC	11-nor-Δ9-THC9-COOH	50
TML	Tramadol	100*
ALC	Alcohol	0.02%

The Rapid Response® Multi-Drug Test Panel (Urine) can also come with adulteration strips listed below:

Adulteration (Strip A)	Oxidants / Specific Gravity / PH
Adulteration (Strip B)	Nitrite / Glutaraldehyde / Creatinine

NOTE: These cut-offs with asterisk are not the level recommended by SAMHSA.

This device is used at a point of care, such as a pharmacy, bedside, or healthcare Professional's office. This device is used to obtain visual qualitative result and is intended to assist in the determination of drug compliance.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC/MS) or Liquid Chromatography/ Mass Spectrometry (LC/MS) are the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Warning

This test strip is not designed to test drugs before they are consumed. When used in this way, this test strip may not detect certain drugs, including fentanyl, even if present.

Mise En Garde

Cette Bandelette d'essai n'est pas destinée à analyser les drogues avant leur consommation. Si elle est utilisée à cette fin, elle pourrait ne pas détecter certaines drogues, comme le fentanyl, même si elles sont présentes.

Principle

Drug Testing

The Rapid Response® Multi-Drug Test Panel (Urine) is one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test membrane strips are pre-coated with drug-protein conjugates on the test band(s). For each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate moves along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attaches to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immune-chromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test strip should be discarded.

Alcohol Testing

The alcohol strip is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the specimen, reacts with chemicals on the reaction pad and causes a color change.

Adulteration Testing

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as Creatinine, pH, and Specific Gravity and to detect the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine and is an amino-acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

Nitrite (NIT): Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH.[2] Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLUT): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[3] Glutaraldehyde is not normally found in urine; therefore, detection of Glutaraldehyde in a urine specimen is generally indicates adulteration.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate that the specimen has been altered.

Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.[3] Normal human urine should not contain Oxidants or PCC.

Precautions

- For *in vitro* diagnostic use.
- The pouch containing the test device should be sealed. Discard the test device if the package is ripped or torn.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

Reagents and Materials

Materials provided

- Rapid Response® Multi-Drug Test Panel (Urine)
- Adulteration Color Chart (when applicable)
- Product insert
- Alcohol Color Chart (when applicable)

Materials required but not provided

- Specimen collection container
- Positive and negative urine controls
- Timer

Storage and Stability

The pouched Rapid Response® Multi-Drug Test Panel (Urine) should be stored at normal humidity and room temperature or refrigerated (2-30°C; 36-86°F) until the expiration date stated on the pouch. The product is humidity-sensitive and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded.

Collection and Storage of Specimens

Urine Collection: The Rapid Response® Multi-Drug Test Panel (Urine) is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine may be stored at room temperature (25°C; 77°F) for up to 4 hours or to be refrigerated (2-8°C; 36-86°F) for up to 48 hours prior to performing the test. For prolonged storage up to 15 days, specimens may be frozen and stored below -20°C (-4°F). Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

NOTE: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

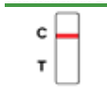
Test Procedure

IMPORTANT: Test device, patient's sample, and controls should be brought to room temperature (15-30°C; 59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Dip the sample pad area of the dipstick card in the urine specimen submerging only up to the "MAX" mark of the edge of the dipstick card.
3. For the adulteration tests, visually compare the color of the reaction pad with the color card, and the results should be read at 2 minutes. Do not interpret the results after 5 minutes.
4. Read the results of the alcohol tests after 2-3 minutes. Color changes that occur after more than 3 minutes have no diagnostic value.
5. The drug strip result(s) should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes, but positive results must be reported at 5 minutes only. Do not interpret the drug strip result(s) after 10 minutes after the addition of sample.
6. For alcohol test, read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the alcohol concentration. Do not interpret the result after 3 minutes.

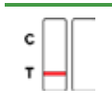
Results Interpretation

The Result of Drug Test Strips:



POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



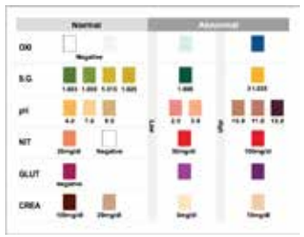
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

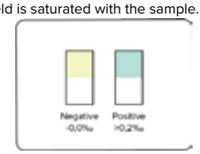
The Result of Adulteration Strips:

The test is evaluated using the supplied Color chart. The results are read by comparing the Color of the test pads with the corresponding pads on the Color chart.



Oxidants/PCC: Normal human urine should not contain Oxidants or PCC.
Specific Gravity: The specific gravity of urine varies from 1.003 to 1.030. Elevated levels of protein in urine may cause abnormally high SG values.
pH: The normal urine pH-value ranges from 4.0 to 9.0. Values below 4 or above 9 indicate adulteration.
Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections.
Glutaraldehyde: Glutaraldehyde is not a natural component of human urine and therefore should not be present in normal urine samples. Its presence in urine indicates possible manipulation. However, a false positive result can occur when there are ketones in the urine. This can occur when a person is suffering from ketoacidosis, is malnourished or has other metabolic abnormalities.
Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

The Result of Alcohol Test Strip:
Negative: No Coloring is visible on the reaction pad. The Color should match 'negative' as shown on the images below.
Positive: The reaction field turns exactly the same Color or similar to 'positive' as shown on the images below.
Invalid: The outer edges of the reaction field produce a slight discoloration, but the majority of the field remains Colorless. Repeat the test with a new test strip. Make sure that the whole reaction field is saturated with the sample.



Quality Control

- Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources and are recommended to be used daily. Use the same assay procedure as with a urine specimen. Controls should be challenging to the assay cutoff concentration. If control values do not fall within established limits, assay results are invalid. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.
- The Rapid Response® Multi-Drug Test Panel (Urine) provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Limitations

The Limitations of Drug Test Strips:
1. The Rapid Response® Multi-Drug Test Panel (Urine) is for in vitro diagnostic use and should be only used for the qualitative detection of drugs of abuse.
2. The assay is designed for use with human urine only.
3. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
4. There is a possibility that technical or procedural error as well as other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
5. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.
6. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.

The Limitations of Adulteration Strips:
1. The Rapid Response® Urine Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Nitrite levels of >20 mg/dL will produce false positive glutaraldehyde results.
3. Urine at different glutaraldehyde concentration will cause OXI/PCC positive color. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, will result in false negative results for the OXI/PCC pad.
4. PCC concentration >50 mg/dL will cause nitrite reagent pad to appear brown color.
5. The urine pH will affect the SG test result. The low pH will increase the SG value, while the high pH will decrease the SG value.
6. Gentisic acid will produce false positive result for OXI/PCC even at 10 µg/mL.

The Limitations of Alcohol Strips:
1. Urine specific gravity be equal or greater than 1.030 will interfere with the test result.
2. The urine pH less than or equal to 5.1 will interfere with the test result.
3. Peroxidases and strong oxidizers concentration ⩾100 µ g/mL will enhance color development.
4. Ascorbic acid, tannic acid, pyrogallol, mercaptans, tosylates, oxalic acid, uric acid, bilirubin, L-dopa, L-methyldopa, methampyrone and dopamine concentration ⩾100 µ g/mL will inhibit color development.

Performance Characteristics

Accuracy

The accuracy of the Rapid Response® Multi-Drug Test Panel (Urine) was established by running urine sample against GC/MS specification. The following results were tabulated:

Specimen	AMP1000	BAR300	BUP10	BZO300
Positive	96.4%	97.4%	100.0%	100%
Negative	95.6%	100%	100.0%	95.2%
Total	96.0%	98.7%	100.0%	97.6%
Specimen	**COC300**	**EDDP100**	**MDMA500**	**MET1000**
Positive	87.5%	100.0%	100%	100.0%
Negative	100%	100.0%	100%	100.0%
Total	93.3%	100.0%	100%	100.0%
Specimen	**MTD300**	**OPI2000**	**OXY100**	**PCP25**
Positive	100.0%	100%	100.0%	93.8%
Negative	100.0%	100%	100.0%	100%
Total	100.0%	100%	100.0%	96.9%
Specimen	**6-MAM10**	**AMP500**	**COC150**	**COT200**
Positive	97.5%	100%	100%	100%
Negative	97.5%	100%	97.5%	100%
Total	97.5%	100%	98.8%	100%
Specimen	**ETG500**	**FYL10**	**HMO300**	**K2 50**
Positive	97.5%	95.0%	100%	97.5%
Negative	100%	97.5%	100%	97.5%
Total	98.8%	96.3%	100%	97.5%
Specimen	**KET1000**	**LSD10**	**MET500**	**MOP300**
Positive	100%	97.5%	100%	100%
Negative	100%	97.5%	100%	100%
Total	100%	97.5%	100%	100%
Specimen	**PGB1000**	**PPX300**	**THC50**	**TML100**
Positive	100%	100%	91.5%	100%
Negative	97.5%	97.5%	100%	100%
Total	98.8%	98.8%	95.7%	100%
Specimen	**ALC**			
Positive	100%			
Negative	100%			
Total	100%			

Precision

Repeatability was evaluated in a study conducted with one operator using urine specimens in replicates of 10 devices.
Reproducibility was evaluated in a study conducted with three operators collecting the data in three runs per day over 17 days.
The Rapid Response® Multi-Drug Test Panel demonstrated acceptable reproducibility and repeatability.

Analytical Sensitivity

The sensitivity of The Rapid Response® Multi-Drug Test Panel (Urine) was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc.	n	AMP 1000		BZO 300		COC 300		MDMA 500	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	5	20	8	17	15	10	10	15
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**OPI 2000**		**PCP 25**		**BAR 300**		**BUP 10**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	7	18	9	16	9	16	5	20
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**EDDP 100**		**MET 1000**		**MTD 300**		**OXY 100**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	7	18	7	18	5	20	3	22
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**6-MAM 10**		**AMP 500**		**COC 150**		**COT 200**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	5	20	2	23	7	18	6	19
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**ETG 500**		**FYL 10**		**HMO 300**		**K2 50**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	4	21	7	18	5	20	7	18
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**KET 1000**		**LSD 10**		**MET 500**		**MOP 300**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	7	18	6	19	7	18	4	21
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25
Drug Conc.	**n**	**PGB 1000**		**PPX 300**		**THC 50**		**TML 100**	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0
50% Cutoff	25	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0
Cutoff	25	5	20	7	18	10	15	6	19
125% Cutoff	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25
3⁄Cutoff	25	0	25	0	25	0	25	0	25

Drug Conc.	n	ALC	
(Cut-off)		Correct	Incorrect
Alcohol free	75	75	0
0.02%	75	75	0
0.04%	75	75	0
0.08%	75	75	0
0.3% (aqueous)	75	75	0

Specificity

The specificity for the Rapid Response® Multi-Drug Test Panel (Urine) has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in drug-free normal human urine. The Rapid Response® Multi-Drug Test Panel (Urine) performance at cutoff point is not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at near 1.005 to 1.03. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below, see the form in the final.

6-MAM 10-related compounds	
6-Monoacetylmorphine	10
Acetylcodeine	>10,000

Buprenorphine	>10,000
Codeine	5000
Diacetylmorphine	1000
Dihydrocodeine	>10,000
Ethylmorphine	>10,000
Hydrocodone	>10,000
Hydromorphone	>100,000
Morphine	100,000
Morphine-3-glucuronide	>10,000
Nalorphine	>50,000
Thebaine	>20,000
AMP 1000-related compounds	
D-Amphetamine	1,000
L-Amphetamine	20,000
D,L-Amphetamine	3,000
Phentermine	30,000
Hydroxyamphetamine	8,000
Methylenedioxyamphetamine (MDA)	1,000
d-Methamphetamine	>100,000
1-Methamphetamine	>100,000
Ephedrine	>100,000
Methylene dioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
AMP 500-related compounds	
D-Amphetamine	500
L-Amphetamine	10,000
D,L-Amphetamine	1,200
Phentermine	15,000
Hydroxyamphetamine	4,000
Methylenedioxyamphetamine (MDA)	500
d-Methamphetamine	>100,000
1-Methamphetamine	>100,000
Ephedrine	>100,000
Methylene dioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
BAR 300-related compounds	
Secobarbital	300
Amobarbital	1,000
Alphenal	62.5
Aprobarbital	250
Butabarbital	100
Butethal	500
Butalbital	5,000
Cyclopentobarbital	500
Pentobarbital	200
Phenobarbital	300
BUP 10-related compounds	
Buprenorphine	10
Buprenorphine–3–β–D–Glucuronide	10
Norbuprenorphine	50
Norbuprenorphine–3–β–D–Glucuronide	100
BZO 300-related compounds	
Oxazepam	300
Alprazolam	125
Bromazepam	625
Chlordiazepoxide	2,500
Clonazepam	2,500
Clobazam	63
Clorazepate	3,330

Desalkylflurazepam	250
Diazepam	250
Estazolam	5,000
Flunitrazepam	375
Lorazepam	1,250
Lormetazepam	1,250
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	25,000
Norchlordiazepoxide	250
Nordiazepam	500
Prazepam	>100,000
Temazepam	63
Triazolam	5,000
COC 300-related compounds	
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000
Norcocaine	100,000
COC 150-related compounds	
Benzoylecgonine	150
Cocaine	500
Cocaethylene	7,500
Ecgonine	15,000
Ecgonine Methyl Ester	50,000
COT 200-related compounds	
(-)-Cotinine	200
(-)-Nicotine	6,250
MDMA 500-related compounds	
3,4-Methylenedioxy-methamphetamine	500
d-Amphetamine	>100,000
l-Amphetamine	>100,000
d-methamphetamine	>100,000
l-methamphetamine	>100,000
3,4-Methylenedioxyamphetamine	2,500
3,4-Methylenedioxyethylamphetamine	156
Paramethoxyamphetamine	50,000
Paramethoxymethamphetamine	>100,000
EDDP 100-related compounds	
D,L 3,4-Methylenedioxy-methamphetamine (MDMA)	500
d-Amphetamine	>50,000
l-Amphetamine	>50,000
d-methamphetamine	>50,000
l-methamphetamine	>50,000
3,4-Methylenedioxyamphetamine (MDA)	5,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
Paramethoxyamphetamine (PMA)	50,000
Paramethoxymethamphetamine (PMMA)	100,000
ETG 500-related compounds	
Ethyl Glucuronide	500
Ethanol	>100,000
D-Glucuronic Acid	>100,000
Morphine-3-b-D-glucuronide	>100,000
FYL 10-related compounds	
Fentanyl and Fentanyl metabolites	10
Fentanyl	100
Norfentanyl	>10,000
HMO 300-related compounds	
Hydromorphone	300
Acetylcodeine	4,000

Buprenorphine	>10,000
Codeine	3,000
Diacetyl Morphin	3,000
Dihydrocodeine	4,000
Ethylmorphine	4,000
Hydrocodone	300
Morphine	2,500
6-Monoacetylmorphine	3,000
Morphine-3-glucuronid	2,500
Nalorphine	12,500
Thebaine	>20,000
Methadone	>100,000
Oxazepam	>100,000
Oxycodone	100,000
EDDP	>100,000
K2 50-related compounds	
JWH-018-5-Pentanoic acid	50
JWH-073-4-Butanoic acid	50
KET 1000-related compounds	
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	>100,000
Dextrorphan tartrate	>100,000
D-Norpropoxyphene	31,250
Meperidine	12,500
Mephentermine hemisulfate salt	50,000
Methadone	12,500
D-Methamphetamine	12,500
3,4-Methylenedioxyethylamphetamine (MDEA)	25,000
Nordoxepin hydrochloride	25,000
Phencyclidine	5,000
Promazine	8,000
Promethazine	25,000
LSD 10-related compounds	
Lysergic acid diethylamide	10
MET 1000-related compounds	
D(+)-Methamphetamine	1,000
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10,000
D/L-Methamphetamine	1,000
p-Hydroxymethamphetamine	10,000
D-Amphetamine	>100,000
L-Amphetamine	>100,000
Chloroquine	50,000
(+/-)-Ephedrine	4,000
L-Methamphetamine	10,000
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100,000
(+/-)3,4-methylenedioxymethamphetamine (MDMA)	500
β-Phenylethylamine	7,500
Trimethobenzamide	20,000
MET 500-related compounds	
D(+)-Methamphetamine	500
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	5,000
D/L-Methamphetamine	500
p-Hydroxymethamphetamine	5,000
D-Amphetamine	>100,000
L-Amphetamine	>100,000
Chloroquine	40,000
(+/-)-Ephedrine	2,000
L-Methamphetamine	5,000
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100,000
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	400

β-Phenylethylamine	4,000
Trimethobenzamide	10,000
MOP 300-related compounds	
Morphine	300
Acetylcodeine	150
Buprenorphine	>10,000
Codeine	250
Diacetyl Morphin	250
Dihydrocodeine	586
Ethylmorphine	200
Hydrocodone	12,500
Hydromorphone	12,500
6-Monoacetylmorphine	250
Morphine-3-glucuronid	2,500
Nalorphine	25,000
Thebaine	25,000
MTD 300-related compounds	
Methadone	300
α-Methadol	2,000
Doxylamine	5,000
EDDP	>100,000
EMDP	>100,000
LAAM HCl	10,000
OPI 2000-related compounds	
Morphine	2,000
Acetylcodeine	2,500
Codeine	1,000
Ethyl Morphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Thebaine	13,000
Morphine-3- β-glucuronide	> 100,000
Procaine	> 100,000
Levorphanol	> 100,000
Oxycodone	> 100,000
Oxymorphine	> 100,000
Rifampicine	>100,000
OXY 100-related compounds	
Oxycodone	100
Dihydrocodeine	>100,000
Codeine	>100,000
Hydromorphone	>100,000
Morphine	>100,000
Buprenorphine	>100,000
Ethylmorphine	>100,000
Oxymorphone	100
Hydrocodone	3125
PCP 25-related compounds	
Phencyclidine	25
4-hydroxyphencyclidine	75
PGB 1000-related compounds	
Pregabalin	1,000
Gabapentin	>20,000
PPX 300-related compounds	
D-Propoxyphene	300
Norpropoxyphene	333
THC 50-related compounds	
11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	50
11-Nor-Δ^8-Tetrahydrocannabinol-9-COOH	50

Cannabinol	20,000
Δ^8-Tetrahydrocannabinol	15,000
Δ^9-Tetrahydrocannabinol	15,000
Cannabidiol	>100,000
11-Nor-Δ^9-THC-carboxy glucuronide	75
(-)-11-nor-9-carboxy-Δ^9-THC	50
TML 100-related compounds	
Tramadol	100
(+/-)Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000
(+)-Chlorpheniramine	>100,000
Alcohol Strip	
Acetone	0.25%
2-Butanol	0.50%
1-Butanol	0.025%
Glycerol	1.00%
Isopropanol	1.00%
Methanol	0.0001%

Non Cross-Reacting Compounds

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100µg/mL (Substance with asterisk tested at concentration exceeding 100 µg/mL, according to CLSI EP07-A2 "Interference Testing in Clinical Chemistry, 2nd Edition") are summarized below.

Acetaminophen*(200µg/mL)	Acetophenetidin
Acetone	Albumin *(60000µg/mL)
Aminopyrine	Amitriptyline
Amoxicillin	Ampicillin
Apomorphine	Ascorbic acid
Aspartame	Aspirin*(700µg/mL)
Atropine	Benzilic acid
Benzocaine	Benzoic acid
Bilirubin *(200µg/mL)	Caffeine
Chloral hydrate	Chloramphenicol
Chloroquine(Except MET)	Chlorothiazide
(±) Chlorpheniramine	Chlorpromazine
Clonidine	Cortisone
Creatinine	Deoxycorticosterone
Dextromethorphan	Dextrorphan tartrate
Diclofenac	Diflunisal
Digoxin	4-Dimethyllaminoantiyrine
Dopamine	Ecgonine methylester
(-)-Ephedrine	(+/-)-Ephedrine (Except MET)
β-Estradiol	Erythromycin
Estrone-3-sulfate	Ethanol
Ethyl p-aminobenzoate	Fenfluramine
Furosemide	Gentisic acid
Glucose *(10000µg/mL)	Guaiacol Glyceryl Ether
Hemoglobin *(2000µg/mL)	Hydralazine
Hydrochlorothiazide	Hydrocortisone
O-Hydroxyhippuric acid	3-Hydroxytyramine
Ibuprofen *(500µg/mL)	Imipramine
Isoproterenol	Isoxsuprine
Ketamine	Ketoprofen
Labetalol	Lidocaine
Loperamide	Meperidine
Meprobamate	Methadone (Except MTD)
Methoxyphenamine	Methylphenidate
Nalidixic acid	(+)-Naproxen *(500µg/mL)
Niacinamide	Nifedipine
Norethindrone	Noscapine
(±)-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin G
Pentazocine	Perphenazine
Phenelzine	Pheniramine
Phenothiazine	b-Phenylethyl-amine
Prednisone	Prednisolone
Procaine	(±)-Propranolol
Protonix	Pseudoephedrine
Quinine	Quinidine
Ranitidine	Serotonin (5-Hydroxytyramine)
Sertraline	Sulfamethazine
Sulindac	Tetrahydrocortisone 3-(β-Dglucuronide)
Tetrahydrocortisone 3-acetate	Tetrahydrozoline
Thiamine	Thioridazine
Triamterene	Trimeprazine
Trifluoperazine	Trimethoprim
DL-Tryptophan	Tyramine
Venlafaxine	Verapamil
Zomepirac	

Bibliography

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.
6. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986, 1734.
7. Tsai, S.C. et.al. Determination of Five Abused Drugs in Nitrite-Adulterated Urine by Immunoassays and Gas Chromatography–Mass Spectrometry. J. Anal. Toxicol. 1998; 22 (6): 474
8. Cody, J.T. Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
9. Mikkelsen, S.L. et.al. Adulterants causing false negatives in illicit drug testing. Clin. Chem. 1988; 34(11): 2333-2336
10. Hardman J, Limbird LE (Eds). Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th Ed., McGraw-Hill Publishing. 2001, 1010.

Glossary of Symbols

Consult instructions for use	Tests per Kit	Do Not Reuse	
Store between 2˚C to 30˚C (36˚F to 86˚F)	Use by	Catalogue #	
Lot Number	For *in vitro* diagnostic use only	Manufacturer	

BTNX Inc.
722 Rosebank Road,
Pickering, ON, L1W 4B2
Canada
Technical Support: 1-888-339-9964