Dia Sure

Multi-Drug Rapid Test Panel W/WO Adulteration (Urine)

MD-U516 **Product Insert**

INTENDED USE

The Multi-Drug Rapid Test Panel W/WO Adulteration (Urine) is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of one to twenty-nine 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
ACE	Acetaminophen	5000
AMP	d-Amphetamine	1000/500/300
BAR	Secobarbital	300/200
BUP	BUP-3-D-Glucuronide	10/5
BZO	Oxazepam	500/300/200/100
COC	Benzoylecgonine	300/200/150/100
COT	(-)-Cotinine	600/300/200
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300/100
ETG	Ethyl Glucuronide	500
FYL	Fentanyl	20/10
HMO	Hydromorphone	250
K2	JWH-073/JWH-018	50
KET	Ketamine	1000/300
LSD	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	50/20
MDMA	3,4-Methylenedioxy-MET	1000/500
MET	Methamphetamine	1000/500/300
MOP	Morphine	300/200/100
MPD	Methylphenidate	1000/300
MQL	Methaqualone	300
MTD	Methadone	300/200
OPI	Morphine	2000/1000
OXY	Oxycodone	300/100
PCP	Phencyclidine	25
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ^9-THC-9-COOH	300/200/150/50/25
TML	Tramadol	300/100
ZOL	Zolpidem Phenyl-4-carboxylic	50
Adulteration（Strip A）	Oxidants / Specific Gravity / pH	
Adulteration（Strip B）	Nitrite / Glutaraldehyde /Creatinine	

The DOA test 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.

The Urine Adulteration Test Strips (Urine) are a semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine. This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a laboratory for confirmation.

PRINCIPLE

The Multi-Drug Rapid Test Panel W/WO Adulteration (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 move 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 attach 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.

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 Creatine, 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 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 commonly used adulterant.[3] Normal human urine should not contain Oxidants or PCC.

REAGENTS AND MATERIALS

Materials Provided

- Multi-Drug Rapid Test Panel W/WO Adulteration (Urine)
- Adulteration Color Chart (when applicable)
- Product Insert

Materials Required but Not provided

- Specimen collection container
- Timer

Positive and negative urine controls

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- The pouch containing the test device should be sealed. Discard the test device if 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.

STORAGE AND STABILITY

The pouched Multi-Drug Rapid Test Panel W/WO Adulteration (Urine) should be stored at normal humidity and room temperature or refrigerated (2-30ºC; 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.

SPECIMEN COLLECTION AND STORAGE

Urine Collection: The Multi-Drug Rapid Test Panel W/WO Adulteration (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.

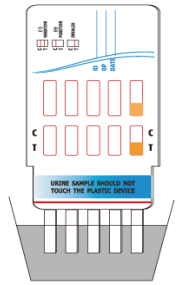
Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine maybe stored at room temperature (25ºC; 77°F) for up to 4 hours or to be refrigerated (2-8ºC; 36-86°F) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20ºC (-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.

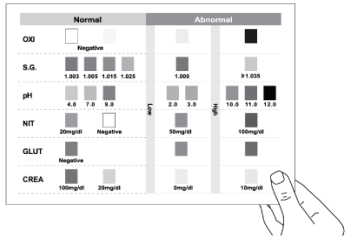
Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

RTANT 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 strip or dipstick card in the urine specimen submerging only up to the "MAX" mark of the dipstick strip or 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. 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.

INTERPRETATION OF RESULTS

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: For specific color please reference the Adulteration Color Chart.

NOTE: The 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.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive

Glutaraldehyde results.

Glutaraldehyde: Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.

Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

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 as per facilities quality control testing protocol. 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 Multi-Drug Rapid Test Panel W/WO Adulteration (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 OF THE TEST

1. The Multi-Drug Rapid Test Panel W/WO Adulteration (Urine) is for laboratory 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 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.

PERFORMANCE CHARACTERISTI

A. Accuracy

Accuracy of the DOA Test Panels was established by running urine sample against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	6-MAM10	ACE5000	AMP1000	AMP500	AMP300	BAR300	BAR200	BUP10
Positive	96.8%	96.1%	95.8%	95.9%	96.1%	97.8%	96.6%	100%
Negative	100%	100%	100%	100%	100%	98.1%	97.0%	100%
Total	98.2%	98.1%	98.1%	98.1%	98.1%	98.0%	96.8%	100%

Specimen	BUP5	BZO500	BZO300	BZO200	BZO100	COC300	COC200	COC150
Positive	100%	98.0%	95.3%	97.4%	95.9%	98.2%	95.7%	96.0%
Negative	100%	100%	92.9%	98.2%	98.0%	98.1%	98.1%	94.0%
Total	100%	99.0%	93.9%	97.9%	97.0%	98.2%	97.0%	95.0%

Specimen	COC100	COT600	COT300	COT200	EDDP300	EDDP100	ETG500	FYL20
Positive	98.2%	96.5%	97.9%	97.7%	98.6%	95.8%	100%	96.8%
Negative	98.1%	98.0%	98.1%	97.9%	100%	100%	100%	100%
Total	98.2%	97.2%	98.0%	98.0%	99.1%	98.1%	100%	98.3%

Specimen	FYL10	HMO250	K2 50	KET1000	KET300	LSD50	LSD20	MDMA1000	MDMA500
Positive	94.4%	95.9%	98.9%	98.0%	98.3%	100%	100%	98.5%	100%
Negative	100%	100%	100%	98.6%	98.4%	100%	100%	98.2%	100%
Total	97.2%	98.0%	99%	98.3%	98.3%	100%	100%	98.3%	100%

Specimen	MET1000	MET500	MET300	MOP300	MOP200	MOP100	MPD1000	MPD300
Positive	96.8%	96.9%	96.8%	96.8%	96.1%	96.1%	96.5%	97.7%
Negative	100%	100%	100%	97.9%	100%	100%	98.3%	98.4%
Total	98.3%	98.3%	98.4%	97.3%	98.1%	98.1%	97.4%	98.1%

Specimen	MQL300	MTD300	MTD200	OPI2000	OPI1000	OXY300	OXY100	PCP25	PPX300
Positive	98.4%	96.1%	97.3%	97.6%	96.5%	98.0%	96.1%	97.8%	97.8%
Negative	98.0%	100%	100%	98.4%	96.0%	97.0%	100%	100%	100%
Total	98.2%	98.1%	98.7%	98.1%	96.3%	97.0%	98.1%	98.9%	99%

Specimen	TCA1000	THC300	THC200	THC150	THC50	THC25	TML300	TML100	ZOL50
Positive	92.1%	96.6%	96.1 %	98.4%	96.8%	96.8 %	98.4%	96.6%	96.3%
Negative	100%	100%	100 %	98.3%	98.3%	98.3 %	100%	98.2%	98%
Total	96.8%	98.4%	98.1 %	98.4%	97.5%	97.5 %	99.1%	97.4%	97.1%

B. Analytical Sensitivity

The sensitivity of Rapid 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	n	6-MAM10		ACE5000		AMP1000		AMP500		AMP300		BAR300		BAR200		BUP10	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	25	25	19	31	16	34	14	36	20	30	11	39	15	35	25	25
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug	n	BUP5		BZO500		BZO300		BZO200		BZO100		COC300		COC200		COC150		COC100	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	21	29	12	38	17	33	11	39	11	39	11	39	18	32	24	26	23	27
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	COT600		COT300		COT200		EDDP300		EDDP100		ETG500		FYL20		FYL10	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0	50	0	47	3	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	42	8	50	0	50	0
Cutoff	50	15	35	17	33	13	37	24	26	25	25	18	32	22	28	25	25
125%	50	0	50	0	50	0	50	0	50	0	50	5	45	0	50	0	50
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug	n	HMO25		K2 25		KET100		KET300		LSD50		LSD20		MDMA100		MDMA50		MET100	
(Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	25	25	16	34	16	34	20	30	22	28	22	28	25	25	13	37	23	27
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutof	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MET500		MET300		MOP300		MOP200		MOP100		MPD1000		MPD300		MQL300	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	10	40	15	35	18	32	18	32	20	30	24	26	22	28	14	36
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MTD300		MTD200		OPI2000		OPI1000		OXY300		OXY100		PCP25		PPX300	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	6	44	12	38	23	27	13	37	19	31	19	31	9	41	20	30
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	TCA1000		THC300		THC200		THC150		THC50		THC25		TML300		TML100		ZOL50	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	9	41	15	35	17	33	19	31	17	33	11	39	11	39	15	35	16	34
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3╳ Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

C. Specificity

The specificity for the Multi-Drug Rapid Test Panel W/WO Adulteration (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 Multi-Drug Rapid Test Panel W/WO Adulteration (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		**KET 300 related compounds**	
6-Monoacetylmorphine	10	Ketamine	300
Acetylcodeine	>10,000	Norketamine	300
Buprenorphine	>10,000	Dextromethorphan	>100,000
Codeine	>10,000	Dextrorphan tartrate	>100,000
Diacetylmorphine	1,000	D-Norpropoxyphene	25,000
Dihydrocodeine	>10,000	EDDP	>100,000
Ethylmorphine	>10,000	Meperidine	10,000
Hydrocodone	>10,000	Mephentermine hemisulfate salt	50,000
Hydromorphone	5,000	Methadone	10,000
Morphine	10,000	D-Methamphetamine	10,000
Morphine-3-glucuronide	>10,000	3,4-Methylenedioxyethylamphetamine	25,000
Nalorphine	5,000	Nordoxepin hydrochloride	25,000
Thebaine	>20,000	Phencyclidine	4,000
ACE 5000 related compounds		Promazine	6,000
Acetaminophen	5,000	Promethazine	25,000
Acetophenetidine	7,500	**LSD 50-related compounds**	
AMP 1000 related compounds		Lysergic acid diethylamide	50
d-Amphetamine	1,000	**LSD 20-related compounds**	
l-Amphetamine	>100,000	Lysergic acid diethylamide	20
d-methamphetamine	>100,000	**MDMA 1000 related compounds**	
l-methamphetamine	>100,000	3,4-Methylenedioxy-methamphetamine	1,000
3,4-Methylenedioxyamphetamine	1,250	d-Amphetamine	>100,000
3,4-Methylenedioxy-methamphetamine	>100,000	l-Amphetamine	>100,000
3,4-Methylenedioxyethylamphetamine	>100,000	d-methamphetamine	>100,000
Paramethoxyamphetamine	625	l-methamphetamine	>100,000
Phentermine	1,250	3,4-Methylenedioxyamphetamine	3,000
Tyramine	>100,000	3,4-Methylenedioxyethylamphetamine	500
AMP 500 related compounds		Paramethoxyamphetamine	50,000
d-Amphetamine	500	Paramethoxymethamphetamine	>100,000
l-Amphetamine	50,000	**MDMA 500 related compounds**	

3,4-Methylenedioxyamphetamine	625	3,4-Methylenedioxy-methamphetamine	500
Phentermine	1,250	d-Amphetamine	>100,000
Paramethoxyamphetamine	625	l-Amphetamine	>100,000
Tyramine	>100,000	d-methamphetamine	>100,000
AMP 300 related compounds		l-methamphetamine	>100,000
d-Amphetamine	300	3,4-Methylenedioxyamphetamine	2,500
l-Amphetamine	50,000	3,4-Methylenedioxyethylamphetamine	156
Mephentermine hemisulfate salt	>100,000	Paramethoxyamphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	625	Paramethoxymethamphetamine	>100,000
Phentermine	625	**MET 1000 related compounds**	
Paramethoxyamphetamine (PMA)	625	d-Methamphetamine	1,000
Paramethoxymethamphetamine (PMMA)	>100,000	Chloroquine	25,000
Tyramine	>100,000	Fenfluramine	12,500
BAR 300 related compounds		l-Methamphetamine	10,000
Secobarbital	300	Mephentermine hemisulfate salt	31,250
Allobarbital	1,250	3,4-Methylenedioxyethylamphetamine	50,000
Alphenal	625	3,4-Methylenedioxy-methamphetamine	313
Amobarbital	625	Paramethoxymethamphetamine	625
Aprobarbital	188	(-)-Ephedrine	4,000
Butabarbital	94	**MET 500 related compounds**	
Butalbital	2,500	d-Methamphetamine	500
Butethal	200	Chloroquine	12,500
Cyclopentobarbital	400	Fenfluramine	12,500
Pentobarbital	1,000	l-Methamphetamine	3,125
Phenobarbital	300	Mephentermine hemisulfate salt	25,000
BAR 200 related compounds		MDEA	12,500
Secobarbital	200	MDMA	1,875
Allobarbital	820	PMMA	625
Alphenal	500	(-)-Ephedrine	2,000
Amobarbital	500	**MET 300 related compounds**	
Aprobarbital	130	d-Methamphetamine	300
Butabarbital	70	Chloroquine	7,500
Butalbital	1,800	Fenfluramine	12,500
Butethal	150	l-Methamphetamine	10,000
Cyclopentobarbital	300	Mephentermine hemisulfate salt	31,250
Pentobarbital	730	MDEA	50,000
Phenobarbital	200	MDMA	313
BUP 10 related compounds		PMMA	625
Buprenorphine	10	(-)-Ephedrine	2,000
Buprenorphine–3–β–D–Glucuronide	10	**MOR 300 related compounds**	
Norbuprenorphine	50	Morphine	300
Norbuprenorphine–3–β–D–Glucuronide	100	Acetylcodeine	150
BUP 5 related compounds		Buprenorphine	>10,000
Buprenorphine	5	Codeine	250
Buprenorphine–3–β–D–Glucuronide	5	Diacetyl Morphin	250
Norbuprenorphine	25	Dihydrocodeine	586
Norbuprenorphine–3–β–D–Glucuronide	50	Ethylmorphine	200
BZO 500 related compounds		Hydrocodone	12,500
Oxazepam	500	Hydromorphone	12,500
BZO 300 related compounds		6-Monoacetylmorphine	250
Oxazepam	300	Morphine-3-glucuronid	2,500
Alprazolam	125	Nalorphine	25,000
Bromazepam	625	Thebaine	25,000
Chlordiazepoxide	2,500	**MOR 200 related compounds**	
Clobazam	63	Morphine	200
Clonazepam	2,500	Acetylcodeine	100
Clorazepate	3,330	Buprenorphine	2,000
Desalkflurazepam	250	Codeine	170
Diazepam	250	Diacetyl Morphin	168
Estazolam	5,000	Dihydrocodeine	395
Fentanyl	>100,000	Ethylmorphine	135

Flunitrazepam	375	Hydrocodone	8,350
Flurazepam	>100,000	Hydromorphone	8,350
Lorazepam	1,250	6-Monoacetylmorphine	170
Lormetazepam	1,250	Morphine-3-glucuronid	1,670
Medazepam	>100,000	Nalorphine	16,666
Midazolam	>100,000	Thebaine	16,666
Nitrazepam	25,000	**MOR 100 related compounds**	
Norchlordiazepoxide	250	Morphine	100
Nordiazepam	500	Codeine	100
Prazepam	>100,000	Diacetylmorphine (Heroin)	100
Temazepam	63	Ethylmorphine	100
Triazolam	5,000	Hydromorphone	500
BZO 200 related compounds		Hydrocodone	500
Oxazepam	200	6-Monoacetylmorphine	100
Alprazolam	83	Morphine-3-β-d-glucuronide	2,000
Bromazepam	417	Oxycodone	20,000
Chlordiazepoxide	1,667	Oxymorphone	20,000
Clobazam	42	Promethazine	>100,000
Clonazepam	1,667	Rifampicine	8,400
Clorazepate	2,220	Thebaine	8,400
Desalkflurazepam	167	Trimipramine	20,000
Diazepam	167	**MPD 1000 related compounds**	
Estazolam	3,333	Methylphenidate	1000
Fentanyl	>100,000	**MPD 300 related compounds**	
Flunitrazepam	250	Methylphenidate	300
Flurazepam	>100,000	**MQL 300 related compounds**	
Lorazepam	833	Methaqualone	300
Lormetazepam	833	Amitriptyline	50,000
Medazepam	>100,000	Carbamazepine	20,000
Midazolam	>100,000	Nortriptyline	50,000
Nitrazepam	16,667	Phenytoin	40,000
Norchlordiazepoxide	167	Theophylline	40,000
Nordiazepam	333	**MTD 300 related compounds**	
Prazepam	>100,000	Methadone	300
Temazepam	42	(-)-alpha-methadol	2,000
Triazolam	3,333	**MTD 200 related compounds**	
BZO 100 related compounds		Methadone	200
Oxazepam	100	(-)-alpha-methadol	1,500
Alprazolam	42	Doxylamine	3,500
Bromazepam	208	LAAM HCl	6,500
Chlordiazepoxide	833	Alpha Methadol	1,500
Clobazam	21	EMDP	>100,000
Clonazepam	833	EDDP	>100,000
Clorazepate	1,110	**OPI 2000 related compounds**	
Desalkflurazepam	83	Morphine	2,000
Diazepam	83	Acetylcodeine	1,563
Estazolam	1,667	Buprenorphine	25,000
Fentanyl	>100,000	Codeine	2,000
Flunitrazepam	125	Diacetylmorphine (Heroin)	5,000
Flurazepam	>100,000	Dihydrocodeine	1,563
Lorazepam	417	Ethylmorphine	250
Lormetazepam	417	Hydromorphone	25,000
Medazepam	>100,000	Hydrocodone	50,000
Midazolam	>100,000	Merperidine	>100,000
Nitrazepam	8,333	6-Monoacetylmorphine (6-MAM)	4,000
Norchlordiazepoxide	83	Morphine-3-β-d-glucuronide	12,500
Nordiazepam	167	Nalorphine Hydrochloride	>100,000
Prazepam	>100,000	Oxycodone	>100,000
Temazepam	21	Oxymorphone	>100,000
Triazolam	1,667	Rifampicine	>100,000
COC 300 related compounds		Thebaine	50,000
Benzoylecgonine	300	**OPI 1000 related compounds**	
Cocaine	1,000	Morphine	1,000

Ecgonine	100,000	Acetylcodeine	1,000
Ecgonine Methyl Ester	>100,000	Buprenorphine	>10000
COC 200 related compounds		Codeine	1,000
Benzoylecgonine	200	Diacetylmorphine (Heroin)	3,000
Cocaine	125	Dihydrocodeine	1,000
Ecgonine	5,000	Ethylmorphine	200
Ecgonine Methyl Ester	>100,000	Hydromorphone	25,000
COC 150 related compounds		Hydrocodone	50,000
Benzoylecgonine	150	Merperidine	>100,000
Cocaine	125	6-Monoacetylmorphine (6-MAM)	3,000
Ecgonine	10,000	Morphine-3-β-d-glucuronide	10,000
Ecgonine Methyl Ester	>10,000	Nalorphine Hydrochloride	>100,000
COC 100 related compounds		Oxycodone	>100,000
Benzoylecgonine	100	Oxymorphone	>100,000
COT 600 related compounds		Rifampicine	>100,000
(-)-Cotinine	600	Thebaine	50,000
COT 300 related compounds		**OXY 300 related compounds**	
(-)-Cotinine	300	Oxycodone	300
(-)-Nicotine	9,375	Hydrocodone	75,000
COT 200 related compounds		Hydromorphone	>100,000
(-)-Cotinine	200	Naloxone	>100,000
(-)-Nicotine	6,250	Oxymorphone	750
EDDP 300 related compounds		**OXY 100 related compounds**	
EDDP	300	Oxycodone	100
Meperidine	>100,000	Hydrocodone	6,250
Methadone	>100,000	Hydromorphone	50,000
Norfentanyl	>100,000	Naloxone	50,000
Phencyclidine	>100,000	Oxymorphone	250
Promazine	80,000	**PCP 25 related compounds**	
Promethazine	75,000	Phencyclidine	25
Prothipendyl	80,000	Hydrocodone	>100,000
Prozine	37,500	Hydromorphone	>100,000
EDDP 100 related compounds		4-hydroxyphencyclidine	75
EDDP	100	**PPX 300 related compounds**	
Meperidine	>100,000	D-Propoxyphene	300
Methadone	>100,000	D-Norpropoxyphene	5,000
Norfentanyl	>100,000	**TCA 1000 related compounds**	
Phencyclidine	>100,000	Nortriptyline HCl	1,000
Promazine	50,000	Amitriptyline	1,500
Promethazine	25,000	Clomipramine	>100,000
Prothipendyl	50,000	Cyclobenzaprine	12,500
Prozine	12,500	Desipramine	188
ETG 500 related compounds		Doxepin	2,000
Ethyl Glucuronide	500	Imipramine	2,500
Ethanol	>100,000	Maprotiline	750
D-Glucuronic Acid	>100,000	Nordoxepin	500
Morphine-3-D-glucuronide	>100,000	Opipramol	1,563
FYL 20 related compounds		Promazine	1,000
Fentanyl and Fentanyl metabolites	20	Promethazine	6,250
Fentanyl	200	Prothipendyl	25,000
Norfentanyl	>10,000	Protryptyline	6,250
FYL 10 related compounds		Prozine	1,250
Fentanyl and Fentanyl metabolites	10	Trimipramine	>100,000
Fentanyl	100	**THC 300 related compounds**	
Norfentanyl	>10,000	11-nor-Δ^9-THC-9-COOH	300
HMO 250 related compounds		11-nor-Δ^8-THC-9-COOH	300
Hydromorphone	250	Δ^8-Tetrahydrocannabinol	>50,000
Acetylcodeine	4,000	Δ^9-Tetrahydrocannabinol	>50,000
Buprenorphine	>10,000	Cannabinol	>100,000
Codeine	3,000	**THC 200 related compounds**	
Diacetyl Morphin	3,000	11-nor-Δ9-THC-9-COOH	200
Dihydrocodeine	4,000	**THC 150 related compounds**	
Ethylmorphine	4,000	11-nor-Δ9-THC-9-COOH	150

Hydrocodone	300	11-nor-Δ8-THC-9-COOH	90
Morphine	2,500	Δ8-Tetrahydrocannabinol	45,000
6-Monoacetylmorphine	3,000	Δ9-Tetrahydrocannabinol	45,000
Morphine-3-glucuronid	2,500	Cannabinol	60,000
Nalorphine	12,500	**THC 50 related compounds**	
Thebaine	>20,000	11-nor-Δ9-THC-9-COOH	50
Methadone	>100,000	11-nor-Δ8-THC-9-COOH	50
Oxazepam	>100,000	11-hydroxy-Δ9-Tetrahydrocannabinol	50
Oxycodone	100,000	Δ8-Tetrahydrocannabinol	15,000
EDDP	>100,000	Δ9-Tetrahydrocannabinol	15,000
K2 50 related compounds		Cannabinol	20,000
JWH-018-5-Pentanoic acid	50	Cannabidiol	>100,000
JWH-073-4-Butanoic acid	50	**THC 25 related compounds**	
KET 1000 related compounds		11-nor-Δ9-THC-9-COOH	25
Ketamine	1,000	11-nor-Δ8-THC-9-COOH	15
Norketamine	1,000	Δ8-Tetrahydrocannabinol	7,500
Dextromethorphan	>100,000	Δ9-Tetrahydrocannabinol	7,500
Dextrorphan tartrate	>100,000	Cannabinol	10,000
D-Norpropoxyphene	31,250	**TML 300 related compounds**	
EDDP	>100,000	Tramadol	300
Meperidine	12,500	**TML 100 related compounds**	
Mephentermine hemisulfate salt	50,000	Tramadol	100
Methadone	12,500	(+/-)Chlorpheniramine	50,000
D-Methamphetamine	12,500	Dimenhydrinate	50,000
3,4-Methylenedioxyethylamphetamine	25,000	Diphenhydramine	50,000
Nordoxepin hydrochloride	25,000	Phencyclidine	50,000
Phencyclidine	5,000	(+)-Chlorpheniramine	>100,000
Promazine	8,000	**ZOL 50 related compounds**	
Promethazine	25,000	Zolpidem Phenyl-4-carboxylic	50
		Zolpidem	>10,000

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations at 100 μg/ml.

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen	Dopamine	L-Phenylephrine
Acetone	Erythromycin	Procaine
Albumin	Ethanol	Protonix
Amitriptyline	Furosemide	Pseudoephedrine
Ampicillin	Glucose	Quinidine
Aspartame	Guaiacol Glyceryl Ether	Ranitidine
Aspirin	Hemoglobin	Sertraline
Atropine	Ibuprofen	Tyramine
Benzocaine	Imipramine	Vitamin C (Ascorbic Acid)
Bilirubin	(+/-)-Isoproterenol	Trimeprazine
b-Phenylethyl-amine	Lidocaine	Venlafaxine
Caffeine	Methadone	Ibuprofen
Chloroquine	N-Methyl-Ephedrine	

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GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

Dia Sure

μ

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