DRUGSMART Cup®

Instructions

FOR IN VITRO DIAGNOSTIC USE ONLY

DrugSmart Cup® Multi-Panel DOA Tests

It is an in vitro diagnostic device and rapid lateral flow immunoassay for the qualitative detection of drugs in human urine. The test cut-off concentrations and calibrators are listed below:

Analyte	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	300 ng/mL
Amphetamine (AMP)	d-Amphetamine	500 ng/mL
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL
Barbiturates (BAR)	Secobarbital /Pentobarbital	200 ng/mL
Barbiturates (BAR)	Secobarbital /Pentobarbital	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	200 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	150 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Ecstasy (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Norfentanyl (FYL)	Norfentanyl	5 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50 ng/mL
Methamphetamine (MET)	d-Methamphetamine	300 ng/mL
Methamphetamine (MET)	d-Methamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL
Tramadol (TML)	Tramadol	100 ng/mL

The multi-panel tests can consist of any combination of the drug analytes listed above. Only one cut-off concentration will be included per analyte per device. The test is intended for healthcare professional use.

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

The test is not intended to differentiate between drugs of abuse and prescription use of Amphetamine, Benzodiazepines, Barbiturates, Buprenorphine, Cocaine, Ecstasy, Fentanyl, Marijuana, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Methadone, Propoxyphene, Tricyclic Antidepressants (TCA) and Tramadol. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Test Instructions

Do not use the test if it is expired. Do not open pouches until ready to do the test.

1. Remove the test from the pouch and use it as soon as possible.
2. Collect the urine into the Cup. The urine must meet the minimum level as shown on the side of the Cup.
3. Screw the lid back on and place the cup on a flat surface. Start the timer and wait for the colored line(s) to appear.
4. Remove the Peel-Off Label.
5. Negative result(s) can be read as early as 1 minute, as long as the "C" line appears. Confirm the result(s) at 5 minutes. The result(s) remain stable for 30 minutes.

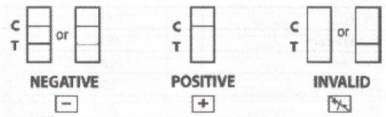
Preliminary positive test results must be confirmed by another test method.

Read Results

Negative: A "C" line appears in the "C" region and a colored line appears in the "T" region. This negative result indicates that the drug is below the cut-off level. The line intensity for the drug may be weaker or stronger than that of the "C" line.

Preliminary Positive: "C" line(s) appears in the "C" region and no colored line in the "T" region shows a preliminary positive result.

Invalid: No line appears in the "C" region. A preliminary positive sample should not be determined until the "C" line forms. If the "C" line does not form, the test result is invalid and should be repeated with a new test.



Kit Contents

Each Test Kit contains one (1) test instruction and 25 test devices.

Quality Control

If you work in a laboratory, quality control testing should be performed and you should read this section. A procedural control is included in the test by the "C" region on each test strip. This "C" line should always appear, if the control line does not appear, the test should be discarded. This "C" line confirms that enough volume was added and proper flow was obtained.

Good Laboratory Practice recommends that quality control testing be performed with each new lot, each new shipment and every thirty days to check storage. External controls are available from commercial sources. It is recommended that positive and negative controls be used to verify proper test performance.

Limitation and Precautions

- For healthcare professional and for *In Vitro* Diagnostic use Only.
- The pouch containing the device should be sealed. Discard the test device if package is ripped or torn.
- Urine specimens may be potentially hazardous and should be handled in the same manner an infectious agent.
- Avoid cross-contamination of urine samples by using a new container for a different urine sample. Do not reuse the container for different urine sample collection.

Performance Characteristics – Accuracy Study Data

Qualitative Accuracy study data in comparison with LC/MS assay values:

Drug Test/ Cutoff (ng/mL)	Result	Range of LC-MS/MS Data				
		Negative	Near cutoff (50% to the C/O)	Near cutoff (Cutoff to 150% of the C/O)	High positive (≥ 150% of the C/O)	% Agreement
FYL 5	(+)	1	2	6	26	100%
	(-)	51	7	0	0	95%
TML 100	(+)	0	0	8	23	100%
	(-)	40	12	0	0	100%

Discordant Results

(ng/mL)	Analyte assay (+/-)	Drug	LC/MS Value (ng/mL)
FYI 5	+	Norfentanyl	3.38
	+	Norfentanyl	4.94
	+	Norfentanyl	2.03*

Two (2) of the discordant results were at or near the norfentanyl cut off level of 5 ng/mL. One FY sample with a * mark contains a norfentanyl concentration of 2.03 ng/mL and Fentanyl concentratio of 15.43 ng/ml yielded a positive result. Further analysis indicated that the cross-reactive level Fentanyl is 10 ng/ml. So the positive result was caused by the high concentration of Fentanyl.

OTC Lay-User Accuracy and Usability Studies

140 OTC lay-users from three sites performed the test with spiked urine samples. See table below.

Drug Test		(-)			(+)		% Agreement
		Negative	LC/MS Negative (50% of the C/O)	Near cutoff Negative (75% of the C/O)	Near cutoff Positive (125% of the C/O)	Positive (150% of the C/O)	
AMP1000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
AMP500	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
AMP300	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
BAR300	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
BAR200	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
BUP 10	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
BZO300	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
BZO200	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
COC300	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
COC150	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
FYL 5	(+)	0	0	0	22	23	100%
	(-)	93	25	24	0	0	100%
MDMA500	(+)	0	0	1	24	22	100%
	(-)	93	23	22	0	0	99.3%
MET 1000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MET 500	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
MET 300	(+)	0	0	1	23	23	100%
	(-)	47	23	22	0	0	98.9%
MTD 300	(+)	0	0	0	22	23	97.8%
	(-)	93	23	23	1	0	100%
MOR 300	(+)	0	0	0	23	23	100%
	(-)	37	23	23	0	0	100%
OPI 2000	(+)	0	0	0	23	23	100%
	(-)	37	23	23	0	0	100%
OXY 100	(+)	0	0	1	23	23	100%
	(-)	93	23	22	0	0	99.3%
PCP 25	(+)	0	0	1	23	23	100%
	(-)	93	23	22	0	0	99.3%
PPX 300	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
TCA 1000	(+)	0	0	0	22	23	97.8%
	(-)	93	23	23	1	0	100%
THC 50	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
TML 100	(+)	0	0	0	24	23	100%
	(-)	93	24	23	0	0	100%

Discordant Results

Drug Test and Cutoff (ng/mL)	Test Result (+/-)	Drug	LC/MS Conc. (ng/mL)
MET 300	+	d-Methamphetamine	258
MTD 300	-	Methadone	367
MDMA 500	+	MDMA	433
OXY 100	+	Oxycodone	78
TCA 1000	-	Tricyclic Antidepressants	1272
PCP 25	+	Phencyclidine	14

Precision and Reproducibility

The urine controls listed below were tested by 3 operators with three lots in five (5) consecutive days. The data is shown below:

FYL Test (cut off 5 ng/mL):

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10 + / 0-	10 + / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	9 +/ 1-	10 + / 0-	10 + / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	8+ / 2-	10 + / 0-	10 + / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**26+ / 4-**	**30+ / 0-**	**30+ / 0-**

TML Test (cut off 100 ng/mL):

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	7+ / 3-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	8+ / 2-	10+ / 0-	10+ / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**24+ / 6-**	**30+ / 0-**	**30+ / 0-**

The Precision/Reproducibility and method comparison study data for Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Ecstasy, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants were reported in k153192

Specificity

The following compounds were found to produce positive results when tested at the concentrations listed below:

AMP 1000:

Substances	ng/ml	% Cross Reactivity
d-Amphetamine	1,000	100
d,l-Amphetamine	1,600	62.5
l-Amphetamine	>100,000	< 1
S-(+) Amphetamine	1,000	100
d-Methamphetamine	>100,000	< 1
l- Methamphetamine	>100,000	< 1
d,l-MDMA	>100,000	< 1
Ephedrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
d,l-MDA	1,000	100
Phentermine	7,000	14
MDEA	>100,000	< 1
d,l-Methamphetamine	>100,000	< 1
Phenylephrine	>100,000	< 1
PMA	1,000	100
Tyramine	>100,000	< 1

AMP 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Amphetamine	500	100
d,l-Amphetamine	800	62.5
l-Amphetamine	>50,000	< 1
S-(+) Amphetamine	500	100
d-Methamphetamine	>50,000	< 1
l-Methamphetamine	>50,000	< 1
d,l-Methamphetamine	>50,000	< 1
d,l-MDMA	>50,000	< 1
Ephedrine	>50,000	< 1
Pseudoephedrine	>50,000	< 1
d,l-MDA	800	62.5
Phentermine	5,000	10
MDEA	>50,000	< 1
d,l-Phenylpropanolamine	>50,000	< 1
Phenylephrine	>50,000	< 1
Phenylethlylamine	>50,000	< 1
PMA	500	100
Tyramine	>50,000	< 1

AMP 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Amphetamine	300	100
d,l-Amphetamine	600	50
l-Amphetamine	>30,000	< 1
S-(+) Amphetamine	300	100
d-Methamphetamine	>30,000	< 1
l-Methamphetamine	>30,000	< 1
d,l-Methamphetamine	>30,000	< 1
d,l-MDMA	>30,000	< 1
Ephedrine	>30,000	< 1
Pseudoephedrine	>30,000	< 1
d,l-MDA	300	100
Phentermine	4,000	7.5
MDEA	>30,000	< 1
d,l-Phenylpropanolamine	>30,000	< 1
Phenylephrine	>30,000	< 1
Phenylethlylamine	>30,000	< 1
PMA	300	100
Tyramine	>30,000	< 1

BAR 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	300	100
Pentobarbital	300	100
Alphenal	500	60
Amobarbital	600	50
Aprobarbital	500	60
Barbital	10,000	3
Butabarbital	500	60
Butalbital	2,000	15
Cyclopentobarbital	500	60
Phenobarbital	2,000	15

BAR 200:

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	200	100
Pentobarbital	200	100
Alphenal	300	67
Amobarbital	400	50
Aprobarbital	400	50
Barbital	6,000	3.3
Butabarbital Butisol	300	67
Butalbital	1,000	20
Cyclopentobarbital	240	83
Phenobarbital	1,200	16.7

BZO 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	300	100
Alprazolam	300	100
Alpha-Hydroxyalprazolam	300	100
Bromazepam	300	100
Chlordiazepoxide	600	50
Clobazam	800	37.5
Clonazepam	30,000	<1
Clorazepate	2,000	15
Desalkylflurazepam	1,000	30
Demoxepam	3,000	10
Diazepam	500	60
Estazolam	300	100
Flunitrazepam	4,800	6.3
Flurazepam	300	100
Lorazepam	800	37.5
Lormetazepam	3,600	8.3
Midazolam	10,000	3
Nitrazepam	1,000	30
Nordiazepam	8,000	3.8
Temazepam	600	50
Triazolam	1,800	16.7

BZO 200:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	200	100
Alprazolam	200	100
Hydroxyalprazolam	200	100
Bromazepam	200	100
Chlordiazepoxide	400	50
Clobazam	600	33
Clonazepam	20,000	< 1
Clorazepate	1,800	11
Desalkylflurazepam	800	25
Demoxepam	3,000	6.7
Diazepam	300	67
Estazolam	200	100
Flunitrazepam	4,600	4.4
Flurazepam	200	100
Lorazepam	600	33.3
Lormetazepam	2,800	7
Midazolam	8,000	2.5
Nitrazepam	800	25
Nordiazepam	5,200	3.9
Temazepam	400	50
Triazolam	1,200	16.7

BUP 10:

Substances	Concentration (ng/mL)	% Cross Reactivity
Buprenorphine	10	100
Norbuprenorphine	10	100
Morphine	1,000	< 1
Codeine	1,000	< 1

COC 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	300	100
Cocaine	300	100
Cocaethylene	300	100
Ecgonine Hcl	>30,000	< 1
Ecgonine Methylester	>30,000	< 1

COC 150:

Substances	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	150	100
Cocaine	180	83
Cocaethylene	150	100
Ecgonine Hcl	>15,000	< 1
Ecgonine Methylester	>15,000	< 1

FYL 5:

Substances	Concentration (ng/mL)	% Cross Reactivity
Norfentanyl	5	100
Fentanyl	10	50
4-Fluoro-isobutyryl Fentanyl	>20,000	<1
9-HydroxyRisperidone	10,000	<1
Acetyl Fentanyl	200	2.5
(±)-β -Hydroxythiofentanyl Hcl	20	25
Acetyl Norfentanyl	200	2.5
Acryl Fentanyl	30	16.7
Alfentanil	1,000	<1
Butyryl Fentanyl	15	33.3
Carfentanil Oxalate	>10,000	<1
Cis-d, l 3-Methylfentanyl	70	7.1
Despropionylfentanyl (4-ANPP)	>20,000	<1
Furanyl Fentanyl	80	6.25
Isobutyryl Fentanyl	5,000	<1
Labetalol Hydrochloride	>100,000	<1
MT-45	7,500	<1
Norcarfentanil Oxalate	>20,000	<1
Ocfentanil	1,000	<1
Para-fluoro butyrl Fentanyl (P-FBF)	20	25
para-Fluorofentanyl	10	50
Remifentanil	>20,000	<1
Risperidone	10,000	<1
Sufentanil	3,000	<1
Thienyl Fentanyl	40	12.5
Trans-d, l 3-Methylfentanyl	30	16.7
Trazodone	>100,000	<1
U-47700	>100,000	<1

Note: The cross-reactivity of ω-1-Hydroxyfentanyl was not tested in this product and may be a source of false positive results.

MDMA 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d,l MDMA	500	100
MDA	15,000	3.3
MDEA	1,000	50
d-Methamphetamine	50,000	< 1
d-Amphetamine	50,000	< 1

MET 1000:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	1,000	100
d,l-Methamphetamine	5,000	20
d-Amphetamine	>100,000	<1
l-Amphetamine	>100,000	< 1
Ephedrine	>100,000	< 1
Phenylephrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
d,l-MDMA	3,000	33
d,l-MDEA	30,000	3.3
d,l-MDA	>100,000	< 1
d,l- Amphetamine	>100,000	< 1
Phentermine	>100,000	< 1

MET 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	500	100
d,l-Methamphetamine	2,000	25
l-Methamphetamine	2,500	20
d-Amphetamine	>50,000	< 1
l-Amphetamine	>50,000	< 1
d,l-Amphetamine	>50,000	< 1
Ephedrine	>50,000	< 1
Phenylephrine	>50,000	< 1
Phenylethlylamine	>50,000	< 1
Pseudoephedrine	>50,000	< 1
d,l-MDMA	2,600	19
d,l-MDEA	25,000	2
d,l-MDA	>50,000	< 1
Phentermine	>50,000	< 1

MET 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	300	100
d,l-Methamphetamine	1,600	18.8
l-Methamphetamine	2,000	15
d-Amphetamine	>30,000	< 1
l-Amphetamine	>30,000	< 1
d,l-Amphetamine	>30,000	< 1
Ephedrine	>30,000	< 1
Phenylephrine	>30,000	< 1
Phenylethlylamine	>30,000	< 1
Pseudoephedrine	>30,000	< 1
d,l-MDMA	2,000	15
d,l-MDEA	20,000	1.5
d,l-MDA	>30,000	< 1
Phentermine	>30,000	< 1

MTD 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Methadone	300	100
Doxylamine	30,000	< 1
EDDP	30,000	< 1
Pheniramine	30,000	< 1

MOR 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	300	100
Codeine	300	100
6- Acetylcodeine	300	100
6-Acetylmorphine	500	60
Heroin	2,000	15
Hydrocodone	5,000	6
Hydromorphone	5,000	6
Oxycodone	30,000	< 1
Oxymorphone	30,000	< 1
Procaine	30,000	< 1

OPI 2000:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	2000	100
Codeine	2000	100
6- Acetylcodeine	2,000	100
6-Acetylmorphine	1,500	133.3
Diacetyl morphin (Heroin)	2,000	100
Hydrocodone	50,000	4
Hydromorphone	50,000	4
Oxycodone	100,000	2
Oxymorphone	100,000	2
Acetominophen	100,000	2
Normorphine	100,000	2
Ethylmorphine	1,500	133.3
Norcodeine	100,000	2

OXY 100:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxycodone	100	100
Codeine	10,000	< 1
Hydrocodone	10,000	< 1
Oxymorphone	100	100

PCP 25:

Substances	Concentration (ng/mL)	% Cross Reactivity
Phencyclidine	25	100
Pheniramine	2,500	< 1

PPX 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Propoxyphene	300	100
d-Norpropoxyphene	300	100

TCA 1000:

Substances	Concentration (ng/mL)	% Cross Reactivity
Nortriptyline	1000	100
Amitriptyline	1000	100
Desipramine	300	333
Doxepin HCl	2,000	50
Imipramine	50	2000
Protriptyline	4750	21.1
Trimipramine	2,000	50

TML 100:

Substances	Concentration (ng/mL)	% Cross Reactivity
Tramadol	100	100
n-Desmethyl Tramadol	400	25
o-Desmethyl Tramadol	1,000	10
Venlafaxine	>100,000	<1
o-Desmethyl Venlafaxine	>10,000	<1

THC 50:

Substances	Concentration (ng/mL)	% Cross Reactivity
11-nor-Δ^9-THC-9-COOH	50	100
11-nor-Δ^8-THC-9-COOH	30	167
Δ^9-Tetrahydrocannabinol	5,000	< 1
11-nor-9-Carboxy THC	1,000	5
Cannabidol	5,000	< 1
Cannabinol	5,000	< 1

Interference

The following compounds did not interfere when tested at concentrations of 100 µg/mL in above and below 25% of the drug cut-off.

Endogenous Compounds:

Albumin	Creatinine	r-Globulin	Octopamine
Acetone	Dopamine	Hemoglobin	Riboflavin
Ascorbic Acid	Ethanol	Human serum Albumin	Sodium Chloride
Atropine	Galactose	B-Hydroxybutyric Acid(F)	Uric Acid
Bilirubin	Glucose	Oxalic Acid	Urea
Cholesterol			

Structurally Unrelated Compounds:

Amlodipine Besylate	l-Erythromycin,	Norethindrone
7-Aminonitrazepam	Estradiol	Noscapine
Amoxicillin	Estrone	Octopamine
Ampicillin	Fenfluramine	Papaverine
Apomorphine	Fenofibrate	Penicillin-G
Aspirin	Fluphenazine(F)	Pentazocine
Aspartame	Fotemustine	Perphenazine
Baclofen	Furosemide	Phenelzine
Benzocaine	Gemfibrozil	Phenylethylamine
Benzylpiperiazine	Guaiacolglyceryl ether	Phenterminr
Benzoic Acid	Gentisic acid	Prednisone
4-Bromo-2,5,Dimethoxyphenethylamine	Hexobarbital	Promazine
Carisoprodol	Hydralazine	Promethazine
Clomipramine	Hydrocortisone	Propoxyphene
Cetirizine	3-Hydroxytyramine	Propranolol
Chloramphenicol	β-Hydroxybutyric Acid	Pyridoxine
Chlordiazepoxide	Ibuprofen	Pyrilamine
Chlorpheniramine	d,l-Isoproterenol	Pyrogallol
Chlorpromazine	Ketamine	Norpropoxyphene
Clofibrate	Lamotrigine	Quinidine
Clonidine	Lisinopril	Quinine
Cortisone	Loratidine	Quinolinic Acid
l-Cotinine	Maprotiline	Ranitidine
Creatine Hydrate	Meprobamate	Salicylic Acid
Cyclobenzaprine	Metoprolol	Sodium Azide
Cyclodextrin-r	Methapyrilene	Sulfamethazine
Cyproheptadine	Methylphenidate	Sulindac
Demoxepam	Nalidixic Acid	Tetracycline
Deoxycorticosterone	Naloxone	Tetrahydrozoline
Dextromethorphan	Naltrexone	Thiamine
Diclofenac	Naproxen	Thioridazine
Diflunisal	Niacinamide	Trifluoromethylphenyl-piperazine
Dimethyl-aminoantipyrine	N-desmethylapentadol	Trifluoperazine
Diphenhydramine	Nicotinic Acid	Tryptamine
Diphenylhydantoin	Nifedipine	Tyramine
		Zolpidem

The following compounds showed no interference at the concentrations below:

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Acetylsalicylic Acid	500,000	Metformin	25,000
7-Aminoflunitrazepam	25,000	Norpseudoephedrine	25,000
Bupropion	25,000	Oxazepam Glucuronide	25,000
Caffeine	500,000	Sufentanil Citrate	25,000
Carbamazepine	25,000	11-nor-9 carboxy THC	50,000
Lorazepam Glucuronide	50,000	L-thyroxine	25,000
LSD	50,000	Zolpidem Tartrate	50,000

In addition, further testing with the following opioids compounds /drugs at a concentration of 100 µg/mL in ±25% of the cutoff drug urine controls confirm that no interference or cross-reactivity was observed with the Drug Screen FYL/TML Tests.

6-Acetylmorphine	Hydrocodone	Norcodeine
Amphetamine	Hydromorphone	Norketamine
Buprenorphine	Levorphanol	Normorphine
Codeine	Methadone	Noroxycodone
Dihydrocodeine	Naloxone	Oxycodone
EDDP	Norbuprenorphine	Oxymorphone
Fluoxetine	Morphine	Pentazocine (Talwin)
Heroin	Morphine-3-glucuronide	Tramadol

The following opioids compounds /drugs do not interfere or cross-react at a concentration of 10 µg/mL in ±25% of the cutoff drug urine controls:

Meperidine	Normeperidine	Risperidone

Effect of Urine pH

The pH ranges 2.0 to 9.0 were prepared by adjusting the drug urine controls at ±25% of the drug cut-off levels. The test results show that the ranges of urine pH do not affect the test results.

Effect of Urine Specific Gravity (SG)

The SG ranges of 1.010, 1.015, 1.020, 1.025 and 1.030 were prepared by adjusting the drug urin controls at ±25% of the drug cut-off levels, respectively. The results demonstrate that the rang urine SG do not affect the test results.

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Symbols Used in the Labels with Adjacent Explanatory Text

SYMBOL	EXPLANATORY TEXT
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.
REF	Indicates the manufacturer's catalog number and the medical device can be ide
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identifie
	Indicates the temperature limits to which the medical device can be safely expo
	Indicates the need for user to consult the instructions for use.
IVD	Indicates the device that is intended to be used "For In Vitro Diagnostic Use Only
	Indicates the total number of tests in each kit box.
	Indicates the device that is intended for single use only. Do not reuse!

MANUFACTURED FOR:

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Toll-free: 1-(888)-847-9977
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Part Number: 66205-DS; Revision: 0