Instructions FOR IN VITRO DIAGNOSTIC USE ONLY

Performance Characteristics – Accuracy Study Data Qualitative Accuracy study data in comparison with LC/MS assay values

Multi-Panel Drug Screen Cup Tests

This is a CLIA Waived test. You need a CLIA certificate of waiver to perform the test in waived settings. Go to <u>http://www.cms.hhs.gov/CLIA/</u> for more information. It is an in vitro diagnostic device and rapid lateral flow immunoassay for the qualitative detection of drugs in human winter.

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-∆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.

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. Store at room temperature (2°C to 30°C). **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 In Vitro Diagnostic use and for healthcare professional use. 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 as 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.

Quantanierier					•	
			Range of LC-MS/MS Data			
Drug Test/Cutoff (ng/mL)	Result	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
EVI 5	(+)	1	2	6	26	100%
FILS	(-)	51	7	0	0	95%
TML 100	(+)	0	0	8	23	100%
TNL 100	(-)	40	12	0	0	100%
_			Discordan	t Results		
(ng/mL)		Analyte assay (+/-)		Drug	LC/MS V	/alue (ng/mL)
		+		Norfentanyl		3.38
FYL	5	+		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 FYL sample with a * mark contains a norfentanyl concentration of 2.03 ng/mL and Fentanyl concentration of 15.43 ng/ml yielded a positive result. Further analysis indicated that the cross-reactive level of Fentanyl is 10 ng/ml. So the positive result was caused by the high concentration of Fentanyl.

2.03*

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

OTC Lay-User Accuracy and Usability Studies

140 OTC lay from three sites performed the test with spiked urine

		(-)		(+)	
		LC/MS	Near cutoff	Near cutoff	Positive	0/0
Drug Test	Negative	Negative	Negative	Positive	(150% of	Agreement
	inegutive	(50% of the	(75% of	(125% of the	the C/O)	
		C/O)	the C/O)	C/O)	,	1000/
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%
EVI 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 200 (+)	-1/	0	1	23	23	100%
IVIL I 300 (1)	47	23	22	0	25	08.0%
MTD 300 (+)	-17	0	0	22	23	97.8%
WIID 500 (1)	02	22	22	1	25	100%
(-) MOR 300 (+)	93	23	23	23	23	100%
WOK 500 (1)	27	22	22	0	25	100%
(-) OPI 2000 (+)	0	0	25	22	22	100%
OF12000 (1)	27	22	22	23	23	100%
(-)	37	23	25	0	22	100%
UAT 100 (+)	0	22	1	25	25	100%
(-) DCD 25 (1)	93	23	1	0	0	99.3%
PCP 23 (+)	0	0	1	23	25	100%
(-)	93	23	22	22	22	99.5%
rPA 300 (+)	02	0	0	23	23	100%
(-)	93	23	23	0	0	100%
1 CA 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%

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

Discordant Results

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+	$26 \pm / 4 =$	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 study data for Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Ecstasy, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants were reported in k153192

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
1- 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
1-Amphetamine	>50,000	< 1
S-(+) Amphetamine	500	100
d-Methamphetamine	>50.000	< 1
1-Methamphetamine	>50.000	< 1
d.l-Methamphetamine	>50.000	< 1
d.I-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
AMD 200.		
AMP 300:	1	
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 1 Mathamphatamina	>20,000	<1
d 1 MDMA	>30,000	< 1
Enhedrine	>30,000	<1
Decude enhancing	>20,000	<1
d 1 MDA	>30,000	100
Dhentormina	300	7.5
MDEA	>20.000	/.5
d 1 Dhonylpromoto lamino	>20,000	
Dhonylarhaina	>20,000	1
Phenylephrme Dhanylathlylamina	>20,000	<1
Phenyletniylamine	>30,000	< I 100
rMA Transmission	500	100
1 yramine	~30,000	×1

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	300	100
Pentobarbital	300	100
Amobarbital	600	50
Aprobarbital	500	60
Barbital	10,000	3
Butabarbital	500	60
Butalbital	2,000	15
Phenobarbital	2,000	15
AR 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	20
Cvclopentobarbital	240	83
Phenobarbital	1,200	16.7
ZO 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
Nitrazenam	1 000	30
Nordiazenam	8,000	3.8
Temazepam	600	50
Triazolam	1,800	16.7
ZO 200:	<u>г</u>	
Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	200	100
Hydroxyalprazolam	200	100
Bromazenam	200	100
Chlordiazepoxide	400	50
Clobazam	600	33
Clonazepam	20,000	< 1
Clorazepate	1,800	11
Desalkylflurazepam	800	25
I have a line and	2 000	17
Diagona	3,000	6.7
Diazepam Estazolarr	3,000 300 200	6.7 67
Estazolam Flunitrazenam	3,000 300 200 4,600	6.7 67 100 4.4
Democepann Diazepann Estazolann Flunitrazepann Flurazepann	3,000 300 200 4,600 200	6.7 67 100 4.4 100
Democepann Diazepann Estazolam Flunitrazepann Flurazepann Lorazepann	3,000 300 200 4,600 200 600	6.7 67 100 4.4 100 33.3
Demokepan Diazepam Estazolam Flunitrazepam Flurazepam Lorazepam Lormetazepam	3,000 300 200 4,600 200 600 2,800	6.7 67 100 4.4 100 33.3 7
Denocepam Diazepam Estazolam Flunitrazepam Flurazepam Lorazepam Lormetazepam Midazolam	3,000 300 200 4,600 200 600 2,800 8,000	6.7 67 100 4.4 100 33.3 7 2.5
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lorrazepam Midazolam Nitrazepam	3,000 300 200 4,600 200 600 2,800 8,000 800 500	6.7 67 100 4.4 100 33.3 7 2.5 25 25
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lormetazepam Midazolam Nitrazepam Nordiazepam	3,000 300 200 4,600 200 600 2,800 8,000 800 5,200 400	$ \begin{array}{r} 6.7 \\ 67 \\ 100 \\ 4.4 \\ 100 \\ 33.3 \\ 7 \\ 2.5 \\ 25 \\ 3.9 \\ 50 \\ \end{array} $
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lormetazepam Midazolam Nitrazepam Nordiazepam Temazepam	3,000 300 200 4,600 200 600 2,800 8,000 800 5,200 400 1,200	$ \begin{array}{r} 6.7 \\ 67 \\ 100 \\ 4.4 \\ 100 \\ 33.3 \\ 7 \\ 2.5 \\ 25 \\ 3.9 \\ 50 \\ 16 \\ 7 \end{array} $
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lormetazepam Midazolam Nitrazepam Nordiazepam Temazepam Triazolam UP 10:	3,000 300 200 4,600 200 600 2,800 8,000 800 5,200 400 1,200	$ \begin{array}{r} 6.7 \\ 67 \\ 100 \\ 4.4 \\ 100 \\ 33.3 \\ 7 \\ 2.5 \\ 25 \\ 3.9 \\ 50 \\ 16.7 \\ \end{array} $
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lormetazepam Midazolam Nitrazepam Nordiazepam Temazepam Triazolam <u>UP 10:</u> Substances	3,000 300 200 4,600 200 600 2,800 8,000 800 5,200 400 1,200 Concentration (ng/mL)	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lormetazepam Midazolam Nitrazepam Tremazepam Triazolam <u>UP 10:</u> Substances Buprenorphine	3,000 300 200 4,600 200 600 2,800 8,000 5,200 400 1,200	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lorretazepam Midazolam Nitrazepam Triazepam Triazolam UP 10: Substances Buprenorphine Norbuprenorphine	3,000 300 200 4,600 200 600 2,800 8,000 5,200 400 1,200 Concentration (ng/mL) 10	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100
Denoxepam Diazepam Estazolam Flunitrazepam Lorazepam Lorratezepam Midazolam Nitrazepam Trinazepam Trinazepam <u>Trinazepam</u> UP 10: Substances Buprenorphine Norbuprenorphine Norbuprenorphine	3,000 300 200 4,600 200 600 2,800 8,000 5,200 400 1,200 0 1,00 10	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100 < 1
Denoxepam Diazepam Estazolam Flunitrazepam Flurazepam Lorazepam Lorrazepam Midazolam Nitrazepam Triazolam <u>UP 10:</u> Substances Buprenorphine Norbuprenorphine Morphine Codeine	3,000 300 200 4,600 200 600 2,800 8,000 5,200 400 1,200 0 1,200 1,200 10 10 1,000 1,000	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100 < 1 < 1
Denoxepan Diazepam Estazolam Flunitrazepam Flurazepam Lorrazepam Uzerazepam Nordiazepam Tremazepam Triazolam UP 10: Substances Buprenorphine Norbuprenorphine Morphine Codeine OC 300:	3,000 300 200 4,600 200 600 2,800 8,000 8,000 5,200 400 1,200 Concentration (ng/mL) 10 1,000 1,000	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100 <1 <1 <1 % Cross Pagativity
Denovepan Diazepam Estazolam Flunitrazepam Flurazepam Lorrazepam Lorrazepam Midazolam Nitrazepam Temazepam Triazolam UP 10: Substances Buprenorphine Morphine Codeine DC 300: Substances Benzovlocoonine	3,000 300 200 4,600 200 600 2,800 8,000 800 5,200 400 1,200 Concentration (ng/mL) 10 10 1,000 1,000 300	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100 < 1 < 1 % Cross Reactivity 100
Denovepam Diazepam Estazolam Flunitrazepam Flurazepam Lorrazepam Midazolam Nitrazepam Nordiazepam Temazepam Trinazolam UP 10: Substances Buprenorphine Norbuprenorphine Morphine Codeine OC 300: Substances Benzoylecgonine Cocaine	3,000 300 200 4,600 200 600 2,800 8,000 8,000 1,200 Concentration (ng/mL) 10 1,000 1,000 Concentration (ng/mL) 300 300	6.7 67 100 4.4 100 33.3 7 2.5 25 3.9 50 16.7 % Cross Reactivity 100 100 < 1 < 1 % Cross Reactivity 100

>30,000

>30,000

< 1

Ecgonine Hcl

Ecgonine Methylester

Substances	Concentration (ng/mL)	% Cross Reactivity
Cocaine	150	83
Cocaethylene	150	100
Ecgonine Hcl	>15,000	<1
Ecgonine Methylester	>15,000	< 1
<u>YL 5:</u>		
Substances Norfentanyl	Concentration (ng/ml	2) % Cross Reactivit
Fentanyl	10	50
4-Fluoro-isobutyryl Fentanyl	>20,000	<1
9-HydroxyRisperidone	10,000	<1
Acetyl Fentanyl	200	2.5
(\pm) - β -Hydroxythiofentanyl Hcl	20	25
Acetyl Norfentanyl	200	2.5
Acryl Fentanyl	30	16.7
Alfentanil	1,000	<1
Butyryl Fentanyl	15	33.3
Cis d L3 Mathylfontanyl	>10,000	<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
Remitentanil	>20,000	<1
Kisperidone Sufentanil	3,000	<1
Thienvl Fentanvl	40	12.5
Trans-d. I 3-Methylfentanyl	30	16.7
Trazodone	>100,000	<1
U-47700	>100,000	<1
Jote: The cross-reactivity of ω-1-Hydroxyfentanyl was esults.	s not tested in this product and may	be a source of false positive
MDMA 500:		
Substances	Concentration (ng/mL)	% Cross Reactivity
d,1 MDMA	500	100
MDA	15,000	3.3
MDEA d Mathamphatamina	1,000	50
d-Amphetamine	50,000	<1
ATD 300:	50,000	~ 1
Substances	Concentration (ng/mL)	% Cross Reactivity
Methadone	300	100
Doxylamine	30,000	<1
EDDP	30,000	<1
THC 50:	30,000	<1 <1
Substances	Concentration (ng/mL)	% Cross Reactivity
11-nor-∆9-THC-9-COOH	50	100
11-nor-∆ ⁸ -THC-9-COOH	30	167
Δ^9 -Tetrahydrocannabinol	5,000	< 1
11-nor-9-Carboxy THC	1,000	5
Cannabidol	5,000	< 1
MET 1000:	5,000	~1
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
rnenyiepnrine Pseudoenhedrine	>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 AET 500:	>100,000	< 1
<u>Substances</u>	Concentration (ng/mL)	% Cross Boastinite
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
Phenvlethlvlamine	>50,000	<1
Pseudoephedrine	>50,000	< 1
d,l-MDMA	2,600	19
d.l-Amphetamine Ephedrine Phenylephrine Phenylethlylamine Pseudoephedrine d,l-MDMA	>50,000 >50,000 >50,000 >50,000 >50,000 >50,000 2,600	<1 <1 <1 <1 <1 <1 <1 <1 19

d,l-MDEA		25,000		2	
d,l-MDA		>50,000		< 1	
Phentermine MET 300		>50,000		< 1	
Substances		Concentration (n	g/mL)	% Cross Reac	tivity
d-Methamphetan	nine	300		100	
d,l-Methampheta	mine	1,600	1,600		
d-Amphetam	nne	>30.000		15	
l-Amphetamin	ie	>30,000		< 1	
d,l-Amphetami	ne	>30,000		< 1	
Ephedrine		>30,000		< 1	
Phenylephrine	ine	>30,000		< 1	
Pseudoephedrin	ne	>30,000		< 1	
d,l-MDMA		2,000		15	
d,l-MDEA		20,000		1.5	
d,I-MDA Phentermine		>30,000		< 1	
MOR 300:		- 50,000		- 1	
Substances		Concentration (n	g/mL)	% Cross Reac	tivity
Morphine		300		100	
Codeine		300		100	
6- Acetylcodei	ne	300		100	
6-Acetylmorphi Heroip	ne	2 000		60	
Hydrocodone		5,000		6	
Hydromorphor	ne	5,000		6	
Oxycodone		30,000		< 1	
Procaine	3	30,000		< 1	
OPI 2000:				~ 1	
Substances		Concentration (n	g/mL)	% Cross Reac	tivity
Morphine		2000		100	
Codeine		2000	2000		
6- Acetylcodei	ne	2,000		100	
6-Acetylmorphi Disastul marrhin (I	ne Lensin)	1,500		133.3	
Hvdrocodone	eroin)	50,000		4	
Hydromorphor	ne	50,000		4	
Oxycodone		100,000		2	
Oxymorphon	Oxymorphone			2	
Acetominophen		100,000		2	
Ethylmorphin	e	1,500		133.3	
Norcodeine	Norcodeine			2	
OXY 100:			(
Oxycodone		Concentration (n	g/mL)	% Cross Reac	tivity
Codeine		10,000		< 1	
Hydrocodone		10,000		< 1	
Oxymorphone	2	100		100	
PCP 25:		1			
Bhonovaliding		Concentration (n	g/mL)	% Cross Reac	tivity
Pheniramine	-	2,500		< 1	
PPX 300:		, , ,			
Substances		Concentration (n	g/mL)	% Cross Reac	tivity
d-Propoxypher	ne	300		100	
d-Norpropoxyph	ene	300		100	
TCA 1000:			(• • >		
Substances		Concentration (n 1000	g/mL)	% Cross Reac	uvity
Amitriptyline)	1000		100	
Desipramine		300		333	_
Doxepin HC	1	2,000		50	
Impramine		50		2000	
Trimipramine	•	2,000		50	
TML 100:					
Substances	Concent	ration (ng/mL)		% Cross Reactivit	у
Tramadol		100		100	
n-Desmethyl Tramadol		400		25	
Venlafaxine	>	100,000		<10	
o-Desmethyl Venlafaxine	>	10,000		<1	
The following compounds did below 25% of the drug cut-off	In not interfere wh	nterference en tested at concentra	ations of	100 μg/mL in abo	ve and
Endogenous Compounds:					
Albumin	Creatinine	r-Globulin		Octopan D:L-f	ine in
Accorbic Acid	Ethanol	Human seru	ı ım Albuı	nin Sodium	nı Chlorid
Atropine	Galactose	B-Hydroxybu	tyric Acid	(F) Uric Aci	d
Bilirubin Chalaster-1	Glucose	Oxalic Acid	l	Urea	
Cholesterol					

Structurally Unrelated Compounds:		
Amlodipine Besylate	I-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
I-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

Symbols Used in the Labels with Adjacent Explanatory Text

SYMBOL	EXPLANATORY TEXT
<u>m</u>	Indicates the medical device manufacturer.
~	Indicates the date when the medical device was manufactured.
8	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 identified.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
X	Indicates the temperature limits to which the medical device can be safely exposed.
Ĩ	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".
T	Indicates the total number of tests in each kit box.
\otimes	Indicates the device that is intended for single use only. Do not reuse!

MANUFACTURER:

50,000

Chemtron Biotech, Inc.

9245 Brown Deer Road, Suite B, San Diego, CA 92121, USA

2 (858) 450-0044

Email address: support@uschemtronbio.com

Part Number: 66205-G; Revision: 01172024

8 1			
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

The following compounds showed no interference at the concentrations below:

50,000 Zolpidem Tartrate 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	Morphine	Oxycodone	
EDDP	Morphine-3-glucuronide	Oxymorphone	
Fluoxetine	Naloxone	Pentazocine (Talwin)	
Heroin	Norbuprenorphine	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 $\pm 25\%$ 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 urine controls at $\pm 25\%$ of the drug cut-off levels, respectively. The results demonstrate that the ranges of urine SG do not affect the test results.

Bibliography:

LSD

- 1. Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications and Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications. Document issued on November 14, 2000.
- Reference: 510(k) k153192 2.
- Draft Guidance for Industry and FDA Staff Premarket Submission and Labeling Recommendations 3. for Drugs of Abuse Screening Tests. Document issued on December 3, 2003.
- 4. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
- 5. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73 1986
- 6. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
- McBay, A.J. Clin. Chem. 33, 33B-40B, 1987.
- Gilman, A.G., and Goodman, L.S. The Pharmacological Basis of Therapeutics, eds. MacMillan 8. Publishing, New York, NY, 1980.
- 9. Karch S.B., Drug Abuse Handbook, CRC Press, 1998