



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY**

**I Background Information:**

**A 510(k) Number**

K232736

**B Applicant**

Chemtron Biotech, Inc.

**C Proprietary and Established Names**

Chemtrue® Drug Screen Fentanyl/Tramadol Cup Test, Chemtrue® Drug Screen Fentanyl/Tramadol Dip Card Test, Chemtrue® Multi-Panel Drug Screen Cup Test, Chemtrue® Multi-Panel Drug Screen Dip Card Test.

**D Regulatory Information**

<b>Product Code(s)</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology

LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
LAF	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
DNK	Class II	21 CFR 862.3640 - Morphine test system	TX - Clinical Toxicology
LCM	Unclassified		
LFG	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology

## II Submission/Device Overview:

### A Purpose for Submission:

New device

### B Measurand:

d-Amphetamine, Secobarbital/Pentobarbital, Oxazepam, Buprenorphine, Benzoylcegonine, d,l-Methylenedioxy methamphetamine, Norfentanyl, d-Methamphetamine, 11-nor- $\Delta^9$ -THC-9-COOH, Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Tramadol

### C Type of Test:

Qualitative

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Test is a rapid lateral flow immunoassay for the qualitative detection of Norfentanyl (FYL) 5 and Tramadol (TML) 100 drugs in human urine. It is an in vitro diagnostic device. The test cut-off concentrations and calibrators are listed below:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
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Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

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 Fentanyl/ Tramadol. The test is for in vitro diagnostic use only.

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Test is a rapid lateral flow immunoassay for the qualitative detection of Norfentanyl (FYL) 5 and Tramadol (TML) 100 drugs in human urine. It is an in vitro diagnostic device. The test cut-off concentrations and calibrators are listed below:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

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 Fentanyl/ Tramadol. The test is for in vitro diagnostic use only.

The Chemtrue® Multi-Panel Drug Screen Dip Card Test is a rapid lateral flow immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ecstasy, Norfentanyl, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylcegonine	150
Cocaine	COC	Benzoylcegonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

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 any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants.

The Chemtrue® Multi-Panel Drug Screen Cup Test is a rapid lateral flow immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ecstasy, Norfentanyl, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50

Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

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 any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants.

**C Special Conditions for Use Statement(s):**

OTC - Over The Counter

**D Special Instrument Requirements:**

Not applicable

**IV Device/System Characteristics:**

**A Device Description:**

The devices are colloidal gold-based lateral flow immunoassays for the rapid, qualitative detection of drugs of abuse in human urine. The tests are single-use, in vitro diagnostic devices, which come in Dip Card or Cup formats, as indicated by the test name.

**B Principle of Operation:**

These devices are rapid lateral flow immunoassays in which chemically modified drugs (drug-protein conjugates) compete with drugs that may be present in urine. On each test strip, a drug-protein conjugate is striped on the test band of the membrane - known as the test region (T) and

the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result.

A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Chemtrue® Multi-Panel Drug Screen Cup/Dip Card Tests

**B Predicate 510(k) Number(s):**

K153192

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K232736</u>	<u>K153192</u>
Device Trade Name	Chemtrue® Drug Screen Fentanyl/Tramadol Cup/Dip Card Tests  Chemtrue® Multi-Panel Drug Screen Cup/ Dip Card Tests	Chemtrue® Multi-Panel Drug Screen Cup/Dip Card Tests
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	Same	Drugs of abuse testing in human urine
<b>General Device Characteristic Differences</b>		
Analytes	Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine,	Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana,

	Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene, Tricyclic Antidepressants (TCA), Norfentanyl, and Tramadol	Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene and Tricyclic Antidepressants (TCA)
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**VI Standards/Guidance Documents Referenced:**

Not applicable

**VII Performance Characteristics (if/when applicable):**

**A Analytical Performance:**

1. Precision/Reproducibility:

Precision/reproducibility studies were carried out for Norfentanyl- and Tramadol-spiked urine controls with LC/MS confirmed concentrations of 0%, -50%, -25%, 100%, +25% and +50% of the drug cutoff. The samples were blind coded and randomly assigned to 3 operators over 5 days of testing.

Precision performance for the remaining drugs (d-Amphetamine, Secobarbital/Pentobarbital, Oxazepam, Buprenorphine, Benzoylcegonine, d,l-Methylenedioxy methamphetamine, d-Methamphetamine, 11-nor- $\Delta^9$ -THC-9-COOH, Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline) was established in k142396 and k153192.

**Dip Card Format**

Test	Concentration Tested	Lot 1 Neg/Pos	Lot 2 Neg/Pos	Lot 3 Neg/Pos	Total Neg/Pos
FYL	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	2/8	1/9	2/8	5/25
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
TML	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	1/9	3/7	1/9	5/25
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

## Cup Format

Test	Concentration Tested	Lot 1 Neg/Pos	Lot 2 Neg/Pos	Lot 3 Neg/Pos	Total Neg/Pos
FYL	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	1/9	1/9	2/8	4/26
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
TML	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	1/9	3/7	2/8	6/24
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

### 2. Linearity:

Not applicable. These devices are intended for qualitative use only.

### 3. Analytical Specificity/Interference:

For each drug and cutoff, specificity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross reactivity of those compounds is listed below (if no cross reactivity was observed, the highest concentration tested is shown as <1%):

#### Norfentanyl-related compounds:

Substances	Concentration ng/mL	% Cross Reactivity
Norfentanyl	5	100
Fentanyl	10	100
4-Fluoro-isobutyryl Fentanyl	>20,000	<1
9-HydroxyRisperidone	10,000	<1
Acetyl Fentanyl	200	2.5
Acetyl Norfentanyl	200	2.5
(±)-β-Hydroxythiofentanyl Hcl	20	25
Acryl Fentanyl	30	16.7
Alfentanil	1,000	<1
Butyryl Fentanyl	15	33.3
Carfentanil Oxalate	>10,000	<1
Cis-d, I 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
Norcarfentail 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 Fentnayl	40	12.5
Trans-d, I 3-Methylfentanyl	30	16.7
Trazodone	>100,000	<1
U-47700	>100,000	<1
Valeryl Fentanyl	>100,000	<1

Tramadol related compounds:

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

The sponsor also evaluated the potential for positive and negative interference from non-structurally related compounds, endogenous compounds, pH, and specific gravity using samples containing drugs at  $\pm 25\%$  of the respective drug cutoff concentrations.

The following endogenous compounds showed no interference when tested at 100  $\mu\text{g/mL}$ :

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			

The following structurally unrelated compounds showed no interference when tested at 100  $\mu\text{g/mL}$ :

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 <sup>6</sup>	Gemfibrozil	Phenylethylamine
Benzylpiperiazine	Guaiacolglyceryl ether	Phentermine
Benzoic Acid	Gentisic acid	Prednisone
4-Bromo-2,5-Dimethoxyphenethylamine	Hexobarbital	Promazine
Carisoprodol	Hydralazine	Promethazine
Clomipramine	Hydrocortisone	Propoxyphene
Cetirizine	3-Hydroxytyramine	Propranolol
Chloramphenicol	$\beta$ -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-desmethyapentadol	Trifluoperazine
Diphenhydramine	Nicotinic Acid	Tryptamine
Diphenylhydantoin	Nifedipine	Tyramine
		Zolpidem

The following compounds showed no interference to the detection of Norfentanyl/Tramadol when tested at the following concentrations:

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

The following opioids showed no interference when tested at 100  $\mu$ g/mL:

6-Acetylmorphine	Hydromorphone	Norcodeine
Amphetamine	Levorphanol	Norketamine

Buprenorphine	Methadone	Normorphine
Codeine	Morphine	Noroxycodone
Dihydrocodeine	Morphine-3-glucuronide	Oxycodone
EDDP	Naloxone	Oxymorphone
Fluoxetine	norbuprenorphine	Pentazocine (Talwin)
Heroin	Morphine	Tramadol
Hydrocodone	Morphine-3-glucuronide	

The following opioid compounds/drugs showed no interference when tested at 10 µg/mL:

Meperidine	Normeperidine	Risperidone
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To evaluate the effect of pH value on the test results, urine controls at ± 25% of the cutoff value were used. Each control level was adjusted by either 1N NaOH solution or 1N HCl to pH levels of 2.0, 3.0, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 and 9.0. Each test sample was tested in duplicate.

To evaluate the effect of specific gravity, urine controls at ± 25% of the cutoff values were spiked with deionized water or sugar to obtain specific gravities of 1.001, 1.010, 1.015, 1.020, 1.025, and 1.030. Each test sample was tested in duplicate.

The results demonstrated that pH and specific gravity do not affect the results from the device at the conditions tested.

The analytical specificity performance for the remaining drugs (d-Amphetamine, Secobarbital/Pentobarbital, Oxazepam, Buprenorphine, Benzoylcegonine, d,l-Methylenedioxy methamphetamine, d-Methamphetamine, 11-nor-Δ9-THC-9-COOH, Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline) was established in k142396 and k153192.

4. Assay Reportable Range:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section VII.A.1 above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

All drug calibrators of the device are traceable to available commercial reference materials.

6. Detection Limit:

Characterization of how the device performs at low concentrations appears in the precision section, VII.A.1, above.

7. Assay Cut-Off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, VII.A.1, above.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

The sponsor performed a method comparison study comparing the performance of the test strips to the LC/MS reference method. The results are summarized below:

Chemtrue® Drug Screen Dip Card	Concentration By LC/MS (ng/mL)				
	No drug present	(-)		(+)	
		Negative		Near cutoff positive (Cutoff to 150% of the cutoff)	Positive (>150% of the cutoff)
< 50% of the cutoff	50% of the cutoff to the cutoff				
FYL 5 (+)	0	1*	3	6	26
(-)	22	29	6	0	0
TML100 (+)	0	0	0	8	23
(-)	20	20	12	0	0

Chemtrue® Drug Screen Cup	Concentration By LC/MS (ng/mL)				
	No drug present	(-)		(+)	
		Negative		Near cutoff positive (Cutoff to 150% of the cutoff)	Positive (>150% of the cutoff)
< 50% of the cutoff	50% of the cutoff to the cutoff				
FYL 5 (+)	0	1*	2	6	26
(-)	22	29	7	0	0
TML100 (+)	0	0	0	8	23
(-)	20	20	12	0	0

\*This sample was found to contain fentanyl at concentrations that contributed to the observed positive result.

The analytical accuracy of the remaining drugs (d-Amphetamine, Secobarbital/Pentobarbital, Oxazepam, Buprenorphine, Benzoylcegonine, d,l-Methylenedioxy methamphetamine, d-Methamphetamine, 11-nor-Δ<sup>9</sup>-THC-9-COOH, Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline) was established in k142396 and k153192.

2. Matrix Comparison:

Not applicable. These devices are for use with urine samples only.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A consumer study was performed for all analytes to evaluate the ability of untrained users to interpret the devices properly when given only the labeling (package insert) provided with the devices. Lay-users (140) participated in this study from 3 intended user sites with LC/MS confirmed urine samples in the following concentration ranges: negative, 50%, 75%, 125% and 150% of the cutoff. Samples were created by spiking drugs into drug-free urine pool. Each sample was aliquoted into an individual blind-labeled container. Each lay-user was provided with a package insert in English only, 2 blind-coded samples, and one each of the test devices (Cup/Dip Card format). The results are summarized below:

Chemtrue® Drug Screen Dip Card		LC/MS Negative			LC/MS Positive		% Agreement with LC/MS values
		No Drug Present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	
AMP1000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
AMP500	(+)	0	0	0	23	23	100%
	(-)	47	22	23	0	0	100%
AMP300	(+)	0	0	0	23	22	100%
	(-)	47	24	22	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%
BUP10	(+)	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%
FYL5	(+)	0	0	0	24	23	100%
	(-)	93	23	23	0	0	100%
MDMA500	(+)	0	0	1	24	22	100%
	(-)	93	23	21	0	0	99%
MET1000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%

MET500	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
MET300	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
MTD300	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
MOR300	(+)	0	0	0	23	22	100%
	(-)	37	24	23	0	0	100%
OXY100	(+)	0	0	1	23	23	100%
	(-)	93	23	22	0	0	99%
OPI2000	(+)	0	0	0	23	23	100%
	(-)	37	23	23	0	0	100%
PCP25	(+)	0	0	0	22	23	98%
	(-)	93	23	23	1	0	100%
PPX300	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
TCA1000	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
THC50	(+)	0	0	0	22	23	98%
	(-)	93	23	23	1	0	100%
TML100	(+)	0	0	0	23	23	100%
	(-)	93	24	24	0	0	100%

Chemtrue® Drug Screen Cup		LC/MS Negative			LC/MS Positive		% Agreement with LC/MS values
		No Drug Present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	
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%
BUP10	(+)	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%
FYL5	(+)	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%
MET1000	(+)	0	0	0	10	10	100%
	(-)	60	10	10	0	0	100%
MET500	(+)	0	0	0	23	23	100%
	(-)	47	23	23	0	0	100%
MET300	(+)	0	0	1	23	23	100%
	(-)	47	23	22	0	0	99%
MTD300	(+)	0	0	0	22	23	98%
	(-)	93	23	23	1	0	100%
MOR300	(+)	0	0	0	23	22	100%
	(-)	37	24	23	0	0	100%
OXY100	(+)	0	0	1	23	23	100%
	(-)	0	23	22	0	0	99%
OPI2000	(+)	0	0	0	23	23	100%
	(-)	37	23	23	0	0	100%
PCP25	(+)	0	0	1	23	23	100%
	(-)	93	23	22	0	0	99%
PPX300	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
TCA1000	(+)	0	0	0	22	23	98%
	(-)	93	23	23	1	0	100%
THC50	(+)	0	0	0	23	23	100%
	(-)	93	23	23	0	0	100%
TML100	(+)	0	0	0	24	23	100%
	(-)	93	24	23	0	0	100%

**D Clinical Cut-Off:**

Not applicable.

**E Expected Values/Reference Range:**

Not applicable.

**VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

## **IX Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.