

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

**A. 510(k) Number:**

k102203

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Amphetamine, Cocaine, Methamphetamine, Morphine (OPI 300), Phencyclidine, Marijuana

**D. Type of Test:**

Qualitative lateral flow chromatographic immunoassay

**E. Applicant:**

Chemtron Biotech, Inc.

**F. Proprietary and Established Names:**

Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
DKZ	Class II	21 CFR §862.3100: Amphetamine Test System	Toxicology (91)
DIO	Class II	21 CFR §862.3250: Cocaine and Cocaine Metabolites Test System	Toxicology (91)
DJC	Class II	21 CFR §862.3610: Methamphetamine Test System	Toxicology (91)
DNK	Class II	21 CFR §862.3640: Morphine Test System	Toxicology (91)
LCM	Class II	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology (91)
LDJ	Class II	21 CFR §862.3870: Cannabinoids Test System	Toxicology (91)

## H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are rapid chromatographic immunoassays for the qualitative detection of up to six of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

<b>Analyte Concentration</b>	<b>Abbreviation</b>	<b>Calibrator</b>	<b>Cutoff</b>
Amphetamine	AMP	Amphetamine	1000 ng/ml
Cocaine	COC	Benzoyllecgonine	300 ng/ml
Marijuana	THC	11-nor- $\Delta^9$ -THC9-COOH	50 ng/ml
Methamphetamine	MET	Methamphetamine	1000 ng/ml
Opiates	OPI/MOR	Morphine	300 ng/ml
Phencyclidine	PCP	Phencyclidine	25 ng/ml

The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card are intended for qualitative detection of drugs of abuse for health care professionals, *in vitro* diagnostic use and prescription use ONLY. It is not intended for point-of-care settings or over the counter use.

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 methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

3. Special conditions for use statement(s):

For prescription use only. Not for Point-of-Care use

4. Special instrument requirements:

Not applicable, as the devices are visually-read single-use devices.

**I. Device Description:**

Chemtrue® Single/Multi Drug Screen DOA test kits has two formats: cassette and dipstick. Each kit contains 25 or 50 devices and each device contains the reagent strip(s) housed in a separate strip channel in the plastic holder. These devices are used to obtain visual qualitative results for the following analytes: amphetamine, cocaine, methamphetamine, Opiates (morphine 300) Phencyclidine, and THC.

Materials Required But Not Provided: Specimen collection container, timer, external urine controls

**J. Substantial Equivalence Information:**

**1. Predicate Device Name:** ACON (INNOVACON) One Step Drug Screen Test

**2. Predicate 510(k) Number(s):** k020771

<b>SIMILARITIES</b>			
<b>Item</b>	<b>Chemtrue® Device</b>	<b>Predicate Kit</b>	
<b>Intended Use/Indications for use</b>	Qualitative detection of drugs-of- abuse in urine for Professional, Prescription, <i>In Vitro</i> Diagnostic Use Only	Same	
<b>Specimen</b>	Urine	Same	
<b>Technological Characteristics and Principle</b>	One-Step lateral flow competitive Immunoassay	Same	
<b>Device Design/ Performance</b>	<b>Positive result</b>	1 colored line	Same
	<b>Negative result</b>	2 colored lines	Same
	<b>Detection reagent</b>	Colloidal gold	Same
	<b>Accuracy Assessment</b>	Confirm with GC/MS reference method	Same
<b>Cut-off</b>	Amphetamine 1000 ng/ml Methamphetamine 1000 ng/ml Cocaine 300 ng/ml Marijuana (THC) 50 ng/ml Phencyclidine 25 ng/ml Opiates(Morphine) 300 ng/ml	Same Same Same Same Same Same	
<b>Safety and Precaution</b>	All urine specimens should be considered potentially hazardous and handled in the same manner as infectious agent.	Same	

<b>Read time</b>	5 minutes	Same
<b>Storage</b>	2 – 30 °C (36 – 86°F)	Same
<b>DIFFERENCES</b>		
<b>Item</b>	<b>Chemtrue® Device</b>	<b>Predicate Kit</b>
<b>Pre-treatment for urine specimen</b>	Does not require pre-treatment for urine specimen.	Urine specimen needs to be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
<b>Time Frame of Result Stabilization</b>	Do not read after 8 minutes.	Results remain stable for up to 4 hours after test initiation.

**K. Standard/Guidance Document Referenced (if applicable):**

None were referenced.

**L. Test Principle:**

Chemtron Biotech’s Chemtrue® Single/Multi Drug Screen tests are a one-step lateral flow immunoassay containing a conjugate pad with colloidal gold conjugate with anti-drug antibodies, a nitrocellulose membrane with a test line (T) and a control line (C). The T line is coated with drug antigen bound to bovine protein and the C line is coated with goat anti-rabbit IgG antibodies. The test is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of sample is applied the sample migrates through the test device by capillary action. If the concentration of drug is below the cutoff level, the anti-drug antibodies in the colloidal gold particles will bind to the drug antigens coated in the test zone producing a band which indicates a negative result. If the drug concentration is at the cutoff level or higher no band will form in the test zone indicating a preliminary positive. A band should form in the control region regardless of the presence of drug or drug metabolite in the sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

The precision study was conducted by three operators. Three different lots were tested for all 6 analytes performed for 10 devices/lot at each control level of Negative, -50%, -25%, cut-off, +25%, and +50% of the cut-off. The study was conducted in non-consecutive 10 days using GC/MS confirmed commercial urine controls. The controls were blinded according to a random table and then evenly distributed to three operators. Each device was tested and interpreted by the same operator. The total of ten days run data were grouped into three sets: 3-day, 3-day, and 4 day. Summaries are presented in

the following tables:

Chemtrue® Drug Screen Dip Card Test:

<b>AMP 1000</b>	No. tested	3-day		3-day		4-day		<b>Total</b>	
		<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>
Negative	30	0	8	0	13	0	9	<b>0</b>	<b>30</b>
-50% cutoff	30	0	12	0	5	0	13	<b>0</b>	<b>30</b>
-25% cutoff	30	1	11	0	10	0	8	<b>1</b>	<b>29</b>
Cutoff	30	4	2	3	7	7	7	<b>14</b>	<b>16</b>
+25% cutoff	30	7	0	8	1	13	1	<b>28</b>	<b>2</b>
+50% cutoff	30	9	0	7	0	14	0	<b>30</b>	<b>0</b>

Chemtrue® Drug Screen Cassette Test:

<b>AMP 1000</b>	No. tested	3-day		3-day		4-day		<b>Total</b>	
		<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>
Negative	30	0	11	0	6	0	13	<b>0</b>	<b>30</b>
-50% cutoff	30	0	6	0	9	0	15	<b>0</b>	<b>30</b>
-25% cutoff	30	0	9	0	9	0	12	<b>0</b>	<b>30</b>
Cutoff	30	2	8	3	4	7	6	<b>12</b>	<b>18</b>
+25% cutoff	30	8	0	14	0	7	1	<b>29</b>	<b>1</b>
+50% cutoff	30	10	0	9	0	11	0	<b>30</b>	<b>0</b>

Chemtrue® Drug Screen Dip Card Test:

<b>COC 300</b>	No. tested	3-day		3-day		4-day		<b>Total</b>	
		<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>
Negative	30	0	10	0	9	0	11	<b>0</b>	<b>30</b>
-50% cutoff	30	0	11	0	8	0	11	<b>0</b>	<b>30</b>
-25% cutoff	30	0	10	0	7	0	13	<b>0</b>	<b>30</b>
Cutoff	30	4	6	4	4	4	8	<b>12</b>	<b>18</b>
+25% cutoff	30	3	0	13	1	10	3	<b>26</b>	<b>4</b>
+50% cutoff	30	10	0	8	0	12	0	<b>30</b>	<b>0</b>

Chemtrue® Drug Screen Cassette Test:

<b>COC 300</b>	No. tested	3-day		3-day		4-day		<b>Total</b>	
		<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>	<b>+</b>	<b>-</b>
Negative	30	0	8	0	10	0	12	<b>0</b>	<b>30</b>
-50% cutoff	30	0	9	0	9	0	12	<b>0</b>	<b>30</b>
-25% cutoff	30	0	10	0	9	0	11	<b>0</b>	<b>30</b>
Cutoff	30	5	4	2	5	7	7	<b>14</b>	<b>16</b>
+25% cutoff	30	7	1	6	0	13	3	<b>26</b>	<b>4</b>
+50% cutoff	30	10	0	13	0	7	0	<b>30</b>	<b>0</b>

Chemtrue® Drug Screen Dip Card Test:

<b>MET 1000</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	8	0	11	0	11	0	30
-50% cutoff	30	0	11	0	8	0	11	0	30
-25% cutoff	30	0	10	1	9	0	10	1	29
Cutoff	30	6	6	3	4	4	7	13	17
+25% cutoff	30	6	0	7	0	16	1	29	1
+50% cutoff	30	7	0	11	0	12	0	30	0

Chemtrue® Drug Screen Cassette Test:

<b>MET 1000</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	11	0	10	0	9	0	30
-50% cutoff	30	0	5	0	14	0	11	0	30
-25% cutoff	30	0	13	0	5	1	11	1	29
Cutoff	30	7	7	0	3	8	5	15	15
+25% cutoff	30	8	1	8	1	12	0	28	2
+50% cutoff	30	2	0	13	0	15	0	30	0

Chemtrue® Drug Screen Dip Card Test:

<b>OPI/MOR 300</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	11	0	7	0	12	0	30
-50% cutoff	30	0	12	0	11	0	7	0	30
-25% cutoff	30	0	4	0	8	1	17	1	29
Cutoff	30	5	6	3	2	7	7	15	15
+25% cutoff	30	7	1	11	0	10	1	28	2
+50% cutoff	30	8	0	12	0	10	0	30	0

Chemtrue® Drug Screen Cassette Test:

<b>OPI/MOR 300</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	9	0	9	0	12	0	30
-50% cutoff	30	0	8	0	10	0	12	0	30
-25% cutoff	30	0	11	0	8	0	11	0	30
Cutoff	30	4	4	1	6	9	6	14	16
+25% cutoff	30	9	0	10	0	10	1	29	1
+50% cutoff	30	9	0	10	0	11	0	30	0

Chemtrue® Drug Screen Dip Card Test:

<b>PCP 25</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	8	0	9	0	13	0	30
-50% cutoff	30	0	13	0	7	0	10	0	30
-25% cutoff	30	0	9	0	10	0	11	0	30
Cutoff	30	4	7	7	4	3	5	14	16
+25% cutoff	30	8	1	7	0	14	0	29	1
+50% cutoff	30	4	0	10	0	16	0	30	0

Chemtrue® Drug Screen Cassette Test:

<b>PCP 25</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	9	0	8	0	13	0	30
-50% cutoff	30	0	10	0	6	0	14	0	30
-25% cutoff	30	0	7	1	12	0	10	1	29
Cutoff	30	7	4	3	6	4	6	14	16
+25% cutoff	30	9	1	7	0	13	0	29	1
+50% cutoff	30	7	0	11	0	12	0	30	0

Chemtrue® Drug Screen Dip Card Test:

<b>THC 50</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	3	0	10	0	17	0	30
-50% cutoff	30	0	7	0	12	0	11	0	30
-25% cutoff	30	0	9	0	6	0	15	0	30
Cutoff	30	3	7	4	2	5	9	12	18
+25% cutoff	30	13	1	12	1	2	1	27	3
+50% cutoff	30	11	0	7	0	12	0	30	0

Chemtrue® Drug Screen Cassette Test:

<b>THC 50</b>	No. tested	3-day		3-day		4-day		Total	
		+	-	+	-	+	-	+	-
Negative	30	0	9	0	10	0	11	0	30
-50% cutoff	30	0	9	0	7	0	14	0	30
-25% cutoff	30	0	9	0	9	0	12	0	30
Cutoff	30	4	7	6	5	3	5	13	17
+25% cutoff	30	7	0	7	1	13	2	27	3
+50% cutoff	30	9	0	9	0	12	0	30	0

b. Linearity/assay reportable range:

Not applicable, the assay is intended for qualitative use.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

This device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Control standards are not supplied with this device; however it is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

d. *Detection limit:*

Analytical performance of the device around the cutoff is described in Section f. (Assay cut-off) below.

e. *Analytical specificity:*

A prescreen test was conducted by diluting all structurally related compounds with the negative urine pool to give a final concentration of 0.1 mg/ml and tested in 2 duplicates with test devices. For all compounds which give positive test results were retested with a 1 to 10 serially diluted solution (10µg/ml, 1µg/ml, 0.1µg/ml, etc.) to find out a rough cutoff range. The serially diluted samples were tested until the operator observes a negative result. The following compounds were tested for cross-reactivity in the drug strip:

The following compounds were found to produce positive results when tested at levels greater than the concentrations (ng/ml) listed below:

Amphetamine

Compounds	Concentration (ng/mL)
d-amphetamine	1000
d-methamphetamine	>10000
l-methamphetamine	>10000
MDMA	>10000
Ephedrine	>10000
Pseudoephedrine	>10000
d,l-amphetamine	2500
l-amphetamine	100000
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	3000
Phentermine	5000

Cocaine

Compound	Concentration (ng/mL)
Benzoylecgonine	300
Cocaine	1000
Cocaethylene	20000

Methamphetamine

Compound	Concentration (ng/mL)
d-methamphetamine	1000
d,l-methamphetamine	5000
d-amphetamine	>10000
l-amphetamine	>10000
Ephedrine	>10000
Phenylephrine	>10000
Pseudoephedrine	>10000
(+/-)-3,4-Methylenedioxymethamphetamine (d,l MDMA)	5000
d,l-MDEA (Methylenedioxyethylamphetamine)	100000
d,l-MDA (3,4-Methylenedioxyamphetamine)	100000

Opiates

Compound	Concentration (ng/mL)
Morphine	300
Codeine	300
Diacetyl morphine (Heroin)	1000
Hydrocodone	50000
Hydromorphone	5000
Oxycodone	50000
6-acetlmorphine	500
Procaine	20000
Thebaine	2000
Oxymorphone	19000

PCP

Compounds	Concentration (ng/mL)
Phencyclidine	25
Pheniramine	30000
Morpholine	>10000

THC

Compounds	Concentration (ng/mL)
11-nor- $\Delta^9$ -THC-9-COOH	50
11-nor- $\Delta^8$ -THC-9-COOH	30

$\Delta$ 9-Tetrahydrocannabinol	12000
Cannabidiol	>10000
Cannabinol	>10000

#### Interference Studies:

Interference studies were performed using the dip card and cassette tests using urine controls at +/-25% and +/-50% of each analyte cut-off concentration. Potential interferences to the Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests were evaluated by adding various drugs, drug metabolites, and other compounds (structurally unrelated and endogenous compounds) that are commonly found in the urine which may interfere with testing results. All potential interferents were tested at concentrations of 100 µg/mL. Any false positive or negative results using the +/-25% cut-off urine analyte concentrations were then retested at +/-50% of the cut-off. No interferences were observed at the +/-50% of the cut-off analyte concentration. The following compounds were found not to cross react when tested at concentrations of 100µg/mL.

#### Endogenous Compounds:

Albumin, Bilirubin, Cholesterol, Creatinine, Glucose, Hemoglobin, Riboflavin

Sodium Chloride, Uric Acid

#### Structurally unrelated compounds:

Acetaminophen	Dopamine	Oxazepam
Acetylsalicylic Acid	Doxylamine	Papaverine
Amobarbital	(-)-ephedrine	Perphenazine
Amoxicillin	l-Erythromycin	Phenelzine
R(-)-Apomorphine	Estradiol	Pheniramine
L-Ascorbic Acid	Estrone	Phenobarbital
Atropine	Ethanol	L-Phenylephrine
Baclofen	Fenofibrate	Phenylethylamine
Barbital	Fentanyl	Phenylproanolamine
Benzocaine	Fotemustine	Prednisone
Benzoic Acid	Furosemide	Promazine
Buprenorphine	Gemfibrozil	Promethazine
Cannabidiol	Guaiacol glyceryl ether	d-Propoxyphen
Carisoprodol	Gentisic acid	d,l Propranolol
chloral hydrate	Hydralazine	D-Pseudoephedrine
chloramphenicol	Hydrocortisone	Pyridoxal-5-phosphate

chlordiazepoxide	3-Hydroxytyramine	Pyridoxine
(+)-chlorpheniramine	(+/-)-Isoproterenol	Pyrilamine
Chlorpromazine	Ketamine	Pyrogallol
Chlorprothizene	Lorazepam	Quinidine
Clofibrate	Meprobamate	Quinine
Clonazepam	Methapyrilene	Quinolinic Acid
Clonidine	Methylphenidate	Salicylic Acid
		Secobarbital Sodium
Cortisone	Nalidixic Acid	Sulfamethazine
(-)-Cotinine	Naloxone	Sulindac
Creatine hydrate	Naltrexone	Tetracycline
Cyclobenzaprine	(+)-Naproxen	Tetrahydrozoline
Cyclodextrin-r	Niacinamide	Thiamine
Cyproheptadine	Nicotinic Acid	Thioridazine
Deoxycorticosterone	Nifedipine	Tramadol
Dextromethorphan	Nitrazepam	Triazolam
Diazepam	19-Norethindrone	Trifluoperazine
Diclofenac	Norpropoxyphene	Tryptamine
Diflunisal	Nortriptyline	Tyramine
4-Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine	Octopamine	
5,5-Diphenylhydantoin	Oxalic Acid	

Evaluation of SG and pH on test results:

To evaluate the effect of pH value on the test results, urine controls at 50% and 150% of the cutoff value were used. Each control level was adjusted by either 1N NaOH solution or 1N HCl to the pH levels at 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 and 8.5. Each test sample was tested in duplicates.

To evaluate the effect of specific gravity, urine controls at +/-25% and +/-50% of the cut-off values were spiked with DI water or sugar to obtain specific gravities of 1.002, 1.010, 1.015, 1.020, 1.025, and 1.030.

The testing results demonstrate that varying specific gravities and pH's do not affect urine testing results around each analyte cut-off.

*f. Assay cut-off:*

The assay cut-off for the six analytes (AMP, COC, MET, OPI/MOR 300, PCP

and THC) was determined through a reproducibility (precision) study that was performed with three lots of each product format (dip card and cassette) in ten non-consecutive days by three operators using blind coded commercial controls at negative, 50% below the cut-off, 25% below the cut-off, cut-off, 25% above the cut-off, and 50% above the cut-off levels.

Results are summarized in the following tables:

Testing Results of Chemtrue® Drug Screen Test Cassette:

Control Level	n	AMP		COC		THC	
		+	-	+	-	+	-
0	30	0	30	0	30	0	30
-50% of the cutoff	30	0	30	0	30	0	30
-25% of the cutoff	30	0	30	0	30	0	30
Cut-off	30	12	18	14	16	13	17
+25% of the cutoff	30	29	1	26	4	27	3
+50% of the cutoff	30	30	0	30	0	30	0

Control Level	n	MAMP		PCP		OPI (MOR) 300	
		+	-	+	-	+	-
0	30	0	30	0	30	0	30
-50% of the cutoff	30	0	30	0	30	0	30
-25% of the cutoff	30	1	29	1	29	0	30
Cut-off	30	15	15	16	14	14	16
+25% of the cutoff	30	28	2	29	1	29	1
+50% of the cutoff	30	30	0	30	0	30	0

Testing Results of Chemtrue® Drug Screen Dip card:

Control Level	n	AMP		COC		THC	
		+	-	+	-	+	-
0	30	0	30	0	30	0	30
-50% of the cutoff	30	0	30	0	30	0	30
-25% of the cutoff	30	1	29	0	30	0	30

Cut-off	30	14	16	12	18	12	18
+25% of the cutoff	30	28	2	27	3	29	1
+50% of the cutoff	30	30	0	30	0	30	0

Control Level	n	MAMP		PCP		OPI (MOR) 300	
		+	-	+	-	+	-
0	30	0	30	0	30	0	30
-50% of the cutoff	30	0	30	0	30	0	30
-25% of the cutoff	30	1	29	0	30	1	29
Cut-off	30	13	17	16	14	15	15
+25% of the cutoff	30	29	1	27	3	28	2
+50% of the cutoff	30	30	0	30	0	30	0

## 2. Comparison studies:

### a. *Method comparison with predicate device:*

Performance of the Chemtron Biotech's Chemtrue® 6-panel Drug Screen Dip Card and Cassette was established by comparing the results of unaltered clinical urine samples against GC/MS. Both the cassette and dipstick versions of the test were evaluated. The correlation between testing results of Chemtrue® products and the confirmed GC/MS values of the clinical specimens were evaluated and summarized below:

#### Chemtrue® Drug Screen Dip card:

**Amphetamine** (The GC/MS values contributed to the total amount of amphetamine in the specimens tested): In this study, one hundred-thirty five (135) negative and positive urine samples (0 to 63,378 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 100% and Negative Agreement: 98.4%

Chemtrue® Drug Screen Test	(-)		(+)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between -50% and cutoff)	Near cutoff (Between cutoff to +50%)	High positive (> +50% cutoff)	
(+)	0	1	9	63	100 %

(-)	48	14	0	0	98.4 %
Total	48	15	9	63	99.3 %

One discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Amphetamine 1,000	+	AMP	996

The concentration of this discordant result was confirmed at the cutoff level.

Chemtrue® Drug Screen Test Cassette:

**Amphetamine** (The GC/MS values contributed to the total amount of amphetamine in the specimens tested): In this study, one hundred-thirteen (113) negative and positive urine samples (0 to 63,378 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 100% and Negative Agreement: 98.2%

Chemtrue® Drug Screen Test	(-)		(+) High positive (> +50% cutoff)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between -50% and cutoff)	Near cutoff (Between cutoff to +50%)		
(+)	0	1	5	52	100 %
(-)	44	11	0	0	98.2 %
Total	44	12	5	52	99.1 %

One discordant result is listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Amphetamine 1,000	+	AMP	996

The concentration of this discordant result was confirmed at the cutoff level.

Chemtrue® Drug Screen Dip card:

**Cocaine** (The GC/MS values contributed to the total amount of benzoylecgonine in the specimens tested): In this study, one hundred-fifteen (115) negative and positive urine samples (0 to 59818 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 100% and Negative Agreement: 100%

Chemtrue® Drug Screen Test	(-)		(+)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)	High positive (> +50% cutoff)	
(+)	0	0	10	51	100%
(-)	44	10	0	0	100%
Total	44	10	10	51	100%

Chemtrue® Drug Screen Test Cassette:

**Cocaine:** Same results as obtained from the dipcard method – see description above

Chemtrue® Drug Screen Dip card:

**Methamphetamine** (The GC/MS values contributed to the total amount of methamphetamine in the specimens tested): In this study, one hundred-thirteen (113) negative and positive urine samples (0 to >50,000 ng/mL), were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 96.8% and Negative Agreement: 100%

Chemtrue® Drug Screen Test	(-)		(+)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)	High positive (> +50% cutoff)	
(+)	0	0	14	46	96.8%
(-)	39	12	1	1	100%
Total	39	12	15	47	98.2%

The two (2) discordant results are listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Methamphetamine 1000	-	MAMP	1050
Methamphetamine 1000	-	MAMP	3471

The two (2) discrepant specimens were confirmed with GC/MS. The result for one specimen was close to the cutoff value. The result for the second specimen was confirmed negative using a commercially available predicate test device.

Chemtrue® Drug Screen Test Cassette:

**Methamphetamine** (The GC/MS values contributed to the total amount of methamphetamine in the specimens tested): In this study, one hundred-six (106) negative

and positive urine samples (0 to >50,000 ng/mL), were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 96.4% and Negative Agreement: 100%

Chemtrue <sup>®</sup> Drug Screen Test	(-)		(+) High positive (> +50% cutoff)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)		
(+)	0	0	9	45	96.4%
(-)	39	11	1	1	100%
Total	39	11	10	46	98.1%

The two (2) discordant results are listed below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/ Metabolite	GC/MS Value (ng/mL)
Methamphetamine 1000	-	MAMP	1050
Methamphetamine 1000	-	MAMP	3471

The two (2) discrepant specimens were confirmed with GC/MS. The result for one specimen was close to the cutoff value. The result for the second specimen was confirmed negative using a commercially available predicate test device.

Chemtrue<sup>®</sup> Drug Screen Dip card:

**Opiates** (Morphine)300 (The GC/MS values contributed to the total amount of morphine or codeine in the specimens tested): In this study, one hundred-nineteen (119) negative and positive urine samples (0 to 25,606 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 98.2% and Negative Agreement: 98.4%

Chemtrue <sup>®</sup> Drug Screen Test	(-)		(+) High positive (> +50% cutoff)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)		
(+)	0	1	14	41	98.2%
(-)	40	22	1	0	98.4%
Total	40	23	15	41	98.3%

The two (2) discordant results were summarized below:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/	GC/MS Value

		Metabolite	(ng/mL)
Morphine/Opiates 300	+	MOR	288
Morphine/Opiates 300	-	MOR	367

The concentration of two discrepant specimens was confirmed with GC/MS to be close to the cutoff value.

Chemtrue® Drug Screen Test Cassette:

**Opiates** (Morphine)300: Same results as obtained from the dipcard method – see description above

Chemtrue® Drug Screen Dip card:

**PCP** (The GC/MS values contributed to the total amount of phencyclidine in the specimens tested): In this study, one hundred-fourteen (114) negative and GC/MS confirmed positive urine samples (0 to >2,000 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 98.4% and Negative Agreement: 100%

Chemtrue® Drug Screen Test	(-)		(+) High positive (> +50% cutoff)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)		
(+)	0	0	7	45	100 %
(-)	53	9	0	0	100 %
Total	53	9	7	45	100 %

Chemtrue® Drug Screen Test Cassette:

**PCP**: Same results as obtained from the dipcard method – see description above

Chemtrue® Drug Screen Dip card:

**THC** (The GC/MS values contributed to the total amount of 11-nor- $\Delta^9$ -THC-9-COOH in the specimens tested): In this study, one hundred-six (106) negative and positive urine samples (0 to 588 ng/mL) were tested and compared with GC/MS. The results are summarized below:

Positive Agreement: 100% and Negative Agreement: 100%

Chemtrue® Drug Screen Test	(-)		(+) High positive (> +50% cutoff)		% Agreement with GC/MS
	Low Negative by GC/MS (< -50%)	Near cutoff (Between - 50% and cutoff)	Near cutoff (Between cutoff to +50%)		
(+)	0	0	10	46	100%

(-)	25	25	0	0	100%
Total	25	25	10	46	100%

Chemtrue® Drug Screen Test Cassette:

**THC:** Same results as obtained from the dipcard method – see description above

3. Clinical studies:

a. *Clinical Sensitivity:*

Not Applicable.

b. *Clinical specificity:*

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

Not Applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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