DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2015

CHEMTRON BIOTECH, INC.
JANE ZHANG
DIRECTOR OF QA/RA
9245 BROWN DEER ROAD
SAN DIEGO CA 92121

Re: K143599
Trade/Device Name: Chemtrue® Drug Screen Cup Tests
Chemtrue® Drug Screen Cup Tests With OPI 2000
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, LFG, DKZ, DIO, LDJ, DNK, LAF, LCM, JXM, DIS, DJC, DJR
Dated: April 9, 2015
Received: April 13, 2015

Dear Ms. Jane Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143599

Device Name
Chemtrue Drug Screen Cup Tests

Indications for Use *(Describe)*
The Chemtrue® Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine 300, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants 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)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ9-THC9 COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Drug Screen Cup Tests panel can consist of any combination of the above listed drug analytes.

The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide 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 and Tricyclic Antidepressants. There are no uniformly recognized cutoff concentration levels for these drugs in urine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143599

Device Name
Chemtrue Drug Screen Cup Tests with OPI 2000

Indications for Use *(Describe)*
The Chemtrue Drug Screen Cup Tests with OPI 2000 are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants 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)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP	d-Methamphetamine	1000
Opiates 2000	MOR	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ9-THC9 COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue Drug Screen Cup Tests with OPI 2000 panel can consist of any combination of the above listed drug analytes.

The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide 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 and Tricyclic Antidepressants. There are no uniformly recognized cutoff concentration levels for these drugs in urine.

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510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

A. SUBMITTER: Chemtron Biotech, Inc. 9245 Brown Deer Road, Suite B, San Diego, CA 92121.
TEL: 858-450-0044;
FAX: 858-450-0046

Contact Person: Jane Zhang, Director of QA/RA
Official FDA Correspondent
9245 Brown Deer Road, Suite B
San Diego, CA 92121
Office: (858) 450-0044; FAX: (858) 450-0046
Email: jane@uschemtronbio.com

Date Prepared: April 15, 2015

B. DEVICE

Trade or Proprietary Name: Chemtrue® Drug Screen Cup Tests
Chemtrue® Drug Screen Cup Tests with OPI 2000

Common Name: Multi-Drug Urine Test Panel

Regulatory Class: Class II

Regulatory Information:

Drug of Abuse	Product Code	Panel	Regulation Section
Amphetamine	DKZ	Toxicology 91	21CFR 862.3100, Amphetamine Test System
Cocaine	DIO	Toxicology 91	21 CFR 862.3250, Cocaine and metabolites Test System
Methamphetamine	LAF	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Morphine	DNK	Toxicology 91	21 CFR 862.3640, Morphine Test System
Opiates	DJG	Toxicology 91	21 CFR 862.3650 Opiates Test System
Phencyclidine	LCM	Toxicology 91	Unclassified, Enzyme immunoassay Phencyclidine
Marijuana (THC)	LDJ	Toxicology 91	21 CFR 862.3870, Cannabinoids Test System
Benzodiazepines	JXM	Toxicology 91	21 CFR 862.3170, Benzodiazepines Test System
Barbiturates	DIS	Toxicology 91	21 CFR 862.3150, Barbiturates Test System
Ecstasy (MDMA)	DJC	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Methadone	DJR	Toxicology 91	21 CFR 862.3620, Methadone Test System
Oxycodone	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System

In addition, previously FDA cleared Chemtrue® BUP/TCA Drug Screen Cup Tests (k142396/CR140334):

Drug of Abuse	Product Code	Panel	Regulation Section
Buprenorphine (BUP)	DJG	Toxicology 91	21CFR 862.3650
Tricyclic Antidepressants (TCA)	LFG	Toxicology 91	21 CFR 862.3910

C. PREDICATE DEVICE

C-1. k061718

INNOVACON® Integrated E-Z Cup, submitter: INNOVACON Laboratories, Inc.

C-2. k060896

OnSite CupKit™, submitter: Varian, Inc.

D. INDICATIONS FOR USE:

Device Name: Chemtrue® Drug Screen Cup Tests

Chemtrue® Drug Screen Cup Tests with OPI 2000

Indications for Use:

Chemtrue® Drug Screen Cup Tests:

The Chemtrue® Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine 300, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

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Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ^9-THC-9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Drug Screen Cup Tests panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide 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 and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Drug Screen Cup Tests with OPI 2000:

The Chemtrue® Drug Screen Cup Tests with OPI 2000 are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants 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)
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Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Opiates 2000	OPI	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ^9-THC-9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Drug Screen Cup Tests with OPI 2000 panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide 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 and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

E. DEVICE DESCRIPTION

The Chemtrue® Drug Screen Cup Tests 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 the Cup format, as indicated by the test name.

F. SUBSTANTIAL EQUIVALENCE INFORMATION:

Comparison with the predicate devices is outlined below:

Similarities and Differences		
Item	**Candidate Devices**	**Predicate** (k061718 and k060896)
Intended Use	Same	For qualitative detection of drugs of abuse in human urine
Results	Same	Qualitative
Methodology	Same	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry.
Storage	2 – 30°C until the expiration date	k061718: 2 – 30°C until the expiration date; k060896: 15 – 30°C.
Intended Users	Prescription and Over-the-Counter (OTC) users	k061718:Prescription users, including point-of-care; k060896:Prescription users
Analytes and Cut Offs (ng/mL)	Buprenorphine – same Barbiturates – same Tricyclic Antidepressants – same Opiates 2000 – same MDMA – same Methadone – same Oxycodone – same Propoxyphene – not included in the device Amphetamine – 1000 Benzodiazepines – 300 Cocaine – 300 Methamphetamine – 1000 Morphine – 300 Phencyclidine – same Marijuana – same	<u>k061718</u> Buprenorphine – 10 Barbiturates – 300 Tricyclic Antidepressants – 1000 Opiates 2000 – 2000 MDMA – 500 Methadone – 300 Oxycodone – 100 Propoxyphene – 300 <u>k061718 and k060896</u> Amphetamine – 1000 / 300 Benzodiazepines – 300 / 200 Cocaine – 300 / 150 Methamphetamine – 1000 /500 / 300 Morphine – 300 / 2000 Phencyclidine – 25 Marijuana – 50
Format	Cup only	K061718-Cup and Dipcard; k060896-Cup

G. TEST PRINCIPLE

The Chemtrue® Drug Screen Tests 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.

Monoclonal anti-drug antibodies are used on the BUP/AMP/COC/MET/MOR/OPI2000/PCP/THC/ BAR/MDMA/MTD/OXY Test devices which are derived from mouse. The polyclonal anti-drug antibodies are used on TCA/BZO Test devices which are derived from sheep/mouse.

H. PERFORMANCE CHARACTERISTICS

Performance data is only provided for AMP, COC, MAMP, OPI2000, MOR300, PCP, THC, BZO, BAR, MDMA, MTD, and OXY, as the new analytes. BUP/TCA analytes of the candidate devices were previously cleared under k142396/CR140334.

1. Reproducibility (Precision) Studies:

   The precision study was conducted by three (3) Operators with three (3) lots in replicates of 10 devices/lot at each concentration level of Negative, 50%, 75%, cut-off, 125% and 150% of the cutoff which are GC/MS confirmed drug spiked urine controls. The study was conducted over a ten (10) nonconsecutive days. The samples were blind coded according to a random table and randomly distributed to three operators by the project Manager. The data is analyzed and summarized in the tables below:

   Table 1a. **AMP Cup Test:** Cutoff: 1000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**16**	**14**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1b. **BAR Cup Test:** Cutoff: 300 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**16**	**14**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1c. **BZO Cup Test:** Cutoff: 300 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**15**	**15**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1d. **COC Cup Test:** Cutoff: 300 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**18**	**12**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1e. **MDMA Cup Test:** Cutoff: 500 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**17**	**13**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1f. **MET Cup Test:** Cutoff: 1000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**16**	**14**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1g. **MTD Cup Test:** Cutoff: 300 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**13**	**17**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1h. **MOR 300 Cup Test:** Cutoff: 300 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**16**	**14**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1i. **OPI 2000 Cup Test:** Cutoff: 2000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**18**	**12**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1j. **OXY Cup Test:** Cutoff: 100 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**16**	**14**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1k. **PCP Cup Test:** Cutoff: 25 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**18**	**12**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1L. **THC Cup Test:** Cutoff: 50 ng/mL

Concentration Level	n	TOTAL	
		+	-
Negative	210	**0**	**210**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**15**	**15**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

2. Specificity Study: These studies were conducted by adding various drugs, drug metabolites, and other structurally-similar compounds likely to be present in the actual urine specimen.
   The following structurally-related compounds were tested for cross-reactivity and found to be positive if the levels were greater than the following listed concentrations:

Amphetamine related compounds:

Substances	**Conc.** (ng/mL)	**% Cross Reactivity**
d-Amphetamine	1,000	100
d,l-Amphetamine	2,500	40
l-Amphetamine	>100,000	< 1
d-Methamphetamine	>100,000	< 1
l- Methamphetamine	>100,000	< 1
(d,l)-MDMA [(d,l)-3,4-Methylenedioxymethamphetamine]	>100,000	< 1
Ephedrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
(d,l)3,4-Methylenedioxyamphetamine (MDA)	3,000	33.3
Phentermine	5,000	20
MDEA	>100,000	< 1
d,l-Methamphetamine	>100,000	< 1
Phenylephrine	>100,000	< 1

Barbiturates related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Secobarbital	300	100
Pentobarbital	300	100
Alphenal	500	60
Amobarbital	800	37.5
Aprobarbital	500	60
Barbital	10,000	3
Butabarbital	500	60
Butalbital	3,000	10
Cyclopentobarbital	750	40
Phenobarbital	2,000	15

Benzodiazepines related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Oxazepam	300	100
Alprazolam	300	100
α-Hydroxyalprazolam	100	300
Bromazepam	500	60
Chlordiazepoxide	2,500	12
Clobazam	200	150
Clonazepam	10,000	3
Clorazepate	350	85.7
Desalkylflurazepam	65	462
Diazepam	200	150
Estazolam	500	60
Flunitrazepam	375	80

Flurazepam	90	333
Lorazepam	600	50
Lormetazepam	7,500	4
Midazolam	900	33.3
Nitrazepam	200	150
Nordiazepam	150	200
Temazepam	350	85.7
Triazolam	1,000	30

Cocaine related compounds:

Substances	**Concentration (**ng/mL)	**% Cross Reactivity**
Benzoylecgonine	300	100
Cocaine	500	60
Cocaethylene	20000	1.5

MDMA (Methylenedioxymethamphetamine) related compounds:

Substances	**Conc.** (ng/mL)	**% Cross Reactivity**
d,l-(3,4)-Methylenedioxymethamphetamine (MDMA)	500	100
3,4-Methylenedioxyamphetamine (MDA)	15,000	3.3
3,4-Methylenedioxyethylamphentamine (MDEA)	1,000	50
d-Methamphetamine	100,000	0.5
d-Amphetamine	100,000	0.5
l-Methamphetamine	>100,000	< 0.5
Ephedrine	>100,000	< 0.5
Pseudoephedrine	>100,000	< 0.5
d,l- Amphetamine	>100,000	< 0.5
l-Amphetamine	>100,000	< 0.5
Phentermine	>100,000	< 0.5
d,l- Methamphetamine	>100,000	< 0.5
Phenylephrine	>100,000	< 0.5

Methamphetamine related compounds:

Substances	**Conc.** (ng/mL)	**% Cross Reactivity**
d-Methamphetamine	1,000	100
d,l-Methamphetamine	5,000	20
d-Amphetamine	10,000	10
l- Amphetamine	> 100,000	< 1
Ephedrine	> 100,000	< 1
(*R*)-(−)-Phenylephrine	10,000	10
Pseudoephedrine	> 100,000	< 1
d,l-MDMA (3,4- Methylenedioxymethamphetamine)	5,000	20
d,l-MDEA (Methylenedioxyethylamphetamine)	100,000	1
d,l-MDA (3,4- Methylenedioxyamphetamine)	>100,000	< 1
l-Methamphetamine	>100,000	< 1
d,l- Amphetamine	>100,000	< 1
Phentermine	>100,000	< 1

Methadone related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Methadone	300	100
Doxylamine	100,000	0.3
EDDP	>100,000	< 0.3
Pheniramine	>100,000	< 0.3

Morphine 300 related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Morphine	300	100
Codeine	300	100
6-Acetylmorphine	500	60
Diacetyl morphin (Heroin)	2,000	15
Hydrocodone	50,000	0.6
Hydromorphone	5,000	6
Oxycodone	50,000	0.6
Oxymorphone	>100,000	< 0.3
Procaine	>100,000	< 0.3

Opiates 2000 related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Morphine	2000	100
Codeine	2000	100
6-Acetylmorphine	1500	133.3
Diacetyl morphin (Heroin)	2000	100
Ethylmorphine	1500	133.3
Hydrocodone	50,000	4
Hydromorphone	50,000	4
Norcodeine	100,000	2
Normorphine	100,000	2
Oxycodone	100,000	2
Oxymorphone	100,000	2
Paracetamol (or Acetaminophen)	100,000	2
Thebaine	100,000	2

Oxycodone related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Oxycodone	100	100
Codeine	100,000	0.1
Hydrocodone	100,000	0.1
Oxymorphone	100	100

PCP related compounds:

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Phencyclidine	25	100
Pheniramine	>100,000	0.025

THC related compounds:

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	12,000	0.4
Cannabidol	>100,000	0.05
Cannabinol	>100,000	0.05

3. Interference:

3-1. Over one hundred of potential interferents were tested and found not to cross-react when tested at concentrations of 100 μg/mL at ±25% of the drug cut-off concentrations.

Table 3. The following compounds do not interfere with the tests:

Endogenous Compounds:

Albumin	Creatinine	Riboflavin
Bilirubin	Glucose	Sodium Chloride
Cholesterol	Hemoglobin	Uric Acid

Un-structurally related compound:

Acetaminophen	5, 5-Diphenylhydantoin	Octopamine
Acetone	Dopamine	Oxalic Acid
Acetylsalicylic Acid	1-Erythromycin,	Papaverine
Amoxicillin	Estradiol	Penicillin-G
Ampicillin	Estrone	Perphenazine
R-(-)-Apomorphine	Ethanol	Phenelzine
L-Ascorbic Acid	Fenofibrate	Phenylethylamine
Aspirin	Fentanyl	Prednisone
Aspartame	Fotemustine	Promazine
Atropine	Furosemide	Promethazine
Baclofen	Gemfibrozil	d-Propoxyphene
Benzocaine	Guaiacolglyceryl ether	d,l-Propranolol
Benzoic Acid	Gentisic acid	Pyridoxine
Carisoprodol	Hydralazine	Pyrilamine
Chloramphenicol	Hydrocortisone	Pyrogallol
Chlordiazepoxide	3-Hydroxytyramine	Quinidine
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Quinine
Chlorpromazine	Ketamine	Quinolinic Acid
Clofibrate	Meprobamate	Ranitidine
Clonidine	Methapyrilene	Salicylic Acid
Cortisone	Methylphenidate	Sulfamethazine
(-)-Cotinine	Nalidixic Acid	Sulindac
Creatine Hydrate	Naloxone	Tetracycline
Cyclobenzaprine	Naltrexone	Tetrahydrozoline
Cyclodextrin-r	(+)-Naproxen	Thiamine
Cyproheptadine	Niacinamide	Thioridazine
Deoxycorticosterone	Nicotinic Acid	Tramadol
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	19-Norethindrone	Tryptamine
Diflunisal	Norpropoxyphene	Tyramine
4-Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine		

Additional interference study: In addition to the cross-reactivity and interference studies presented in this submission, all the drug tests were tested with each of the 14 drugs at 150% and 50% of the drug cut-off urine samples. The results confirmed that there is no interference or cross-reactivity among these drug tests.

Effect of Urine pH and Specific Gravity Studies: The testing results demonstrate that the urine pH ranges from 2.0 to 9.0 at ±50% of the drug cut-off concentrations do not affect the test performance. The specific gravity (SG) ranges of 1.001, 1.010, 1.015, 1.020, 1.025 and 1.030 at ±50% of the drug cut-off concentrations do not affect the test results.

4. Stability Study: To establish and support the shelf life and expiration date, stability studies were conducted under accelerated temperature (at 60°C and 40°C), and real time (25°C±2°C) with three (3) lots of each device format. The stability study results support two (2) years shelf-life of the products at (2 to 30°C). The real time stability study is still on-going.

5. Method Comparison Studies:

Chemtrue® Drug Screen Cup Tests were compared to the GC/MS Reference Method. The accuracy of the Chemtrue® Test devices were evaluated against the confirmed GC/MS values in this blind-labeled clinical specimen correlation study (On average of 85 clinical specimens for each drug test and a total of 586 samples were tested). Three operators performed the testing. Each blind labeled sample was randomly distributed to each operator by the Clinical Research Cooperator. The results are summarized in the tables below:

Table 5a. Summary from method comparison (Accuracy) study of Chemtrue® Drug Screen Cup Test results versus GC/MS

Chemtrue® Drug Screen Cup		**Concentrations by GC/MS** (ng/mL)				**% Agreement**
		(-)		**(+)**		
		Negative (<50% of the C/O)	Near cutoff negative (50% of the C/O to the cutoff)	Near cutoff positive (Cutoff to 150% of the C/O)	Positive (≥150% of the cutoff)	
AMP	**(+)**	0	0	16	25	97.6%
	(-)	67	25	1	0	100%
BAR	**(+)**	0	0	12	28	100%
	(-)	44	11	0	0	100%
BZO	**(+)**	0	1	15	25	100%
	(-)	40	9	0	0	98%
COC	**(+)**	0	1	15	25	100%
	(-)	40	9	0	0	98%
MDMA	**(+)**	0	1	12	28	100%
	(-)	42	14	0	0	98.3%
MET	**(+)**	0	0	15	25	100%
	(-)	40	10	0	0	100%
MTD	**(+)**	0	0	14	26	100%
	(-)	40	10	0	0	100%
MOR_{300}	**(+)**	0	0	16	74	100%
	(-)	40	10	0	0	100%
OPI_{2000}	**(+)**	0	1	14	27	100%
	(-)	40	9	0	0	98%

OXY (+)	0	0	9	31	100%
(-)	40	10	0	0	100%
PCP (+)	0	1	16	24	100%
(-)	40	10	0	0	98%
THC (+)	0	0	15	25	100%
(-)	40	11	0	0	100%

Table 5b. DISCORDANT RESULTS: There are six (6) discordant results in total of all the 12-drug tests:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug Analyte	GC/MS Value (ng/mL)
Amphetamine 1000	-	Amphetamine	1,061
Cocaine 300	+	Benzoylecgonine	292
MDMA 500	+	MDMA	498
PCP 25	+	Phencyclidine	24.6
BZO 300	+	Oxazepam	253
OPI 2000	+	Morphine and Codeine	1,701

The discordant results were confirmed at the drug cutoff level with the GC/MS concentrations.

6. OTC Lay-user Accuracy and Usability Studies:

This study demonstrates OTC accuracy and usability with AMP/BAR/BZO/COC/MDMA/MET/ MTD/MOR/OPI2000/OXY/PCP/THC and previously cleared BUP/TCA Tests (k142396). One hundred (100) intended lay-users participated in this OTC accuracy and usability study from three (3) intended user sites with GC/MS confirmed urine samples at the following concentrations: negative, 50%, 75%, 125% and 150% of the cutoff by spiking drugs into drug-free urine pool. Each sample was aliquot into an individual blind-labeled container. Each lay-user was provided with a package insert in English only, one blind labeled sample and one test device. The results are summarized below:

Table 6a. Chemtrue® Drug Screen Cup Test *vs* GC/MS Value Analysis

Drug Analyte	**Cut Off** (ng/mL)	**Results**	**Drug Concentrations (Per GC/MS Values)**				
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff
AMP	1000	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
BAR	300	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
BZO	300	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%

BUP	10	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
COC	300	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
MDMA	500	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
MET	1000	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
MTD	300	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
MOR	300	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
OPI	2000	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
OXY	100	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
PCP	25	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
TCA	1000	# of positive	0	0	0	10	10
		# of Negative	60	10	10	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	100%	100%	100%
THC	50	# of positive	0	0	1	10	10
		# of Negative	60	10	9	0	0
		Total	60	10	10	10	10
		Agreement	100%	100%	90%	100%	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. ≥ 98% of the lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

I. CONCLUSION:

Based on the test principle and performance characteristics of the proposed device, it is concluded that the candidate devices are substantially equivalent to the predicate device.