



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

April 18, 2016

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

Re: K153192

Trade/Device Name: Chemtrue Multi-Panel Drug Screen Dip Card/Cup Tests, Chemtrue  
Multi-Panel Drug Screen Dip Card/Cup with OPI 2000 Tests

Regulation Number: 21 CFR 862.3650

Regulation Name: Opiate test system

Regulatory Class: II

Product Code: DJG, JXN, DKZ, LFG, DIO, LDJ, DNK, LAF, LCM, JXM, DIS, DJC, DJR

Dated: April 1, 2016

Received: April 4, 2016

Dear Ms. 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,

  
**Courtney H. Lias -S**

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

## Indications for Use

510(k) Number (if known)  
k153192

Device Name  
Chemtrue® Multi-Panel Drug Screen Cup with OPI 2000 Tests

### Indications for Use (Describe)

The Chemtrue® Multi-Panel Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene 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	1000
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
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Opiates	OPI	Morphine	2000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off 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)

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**Indications for Use**

510(k) Number (if known)  
k153192

Device Name  
Chemtrue® Multi-Panel Drug Screen Dip Card Tests

Indications for Use (Describe)

The Chemtrue® Drug Screen Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene 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	1000
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
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off 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)

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## Indications for Use

510(k) Number (if known)  
k153192

Device Name  
Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

### Indications for Use (Describe)

The Chemtrue® Drug Screen Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene 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	1000
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
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Opiates	OPI	Morphine	2000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off 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)

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**Indications for Use**

510(k) Number (if known)  
k153192

Device Name  
Chemtrue® Multi-Panel Drug Screen Cup Tests

Indications for Use (Describe)

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

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Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylcegonine	150
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Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off 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)

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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](mailto:jane@uschemtronbio.com)

**Date Prepared:** April 12, 2016

**B. DEVICE**

**Trade or Proprietary Name:** Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup with OPI2000 Tests, Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests

**Common Name:** Single/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
Benzodiazepines	JXM	Toxicology 91	21 CFR 862.3170, Benzodiazepines Test System
Barbiturates	DIS	Toxicology 91	21 CFR 862.3150, Barbiturates 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
Propoxyphene	JXN	Toxicology 91	21 CFR 862.3700 Propoxyphene test system

These devices also incorporate the assays previously cleared under 510(k) numbers k142396 and k143599, which consist of any combinations of the following drug tests:

Drug of Abuse	Product Code	Panel	Regulation Section
Buprenorphine (BUP)	DJG	Toxicology 91	21CFR 862.3650, Opiate 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
Morphine	DNK	Toxicology 91	21 CFR 862.3640, Morphine Test System
Opiates	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Oxycodone	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Phencyclidine	LCM	Toxicology 91	Unclassified, Enzyme immunoassay Phencyclidine
Marijuana	LDJ	Toxicology 91	21 CFR 862.3870, Cannabinoids Test System
Tricyclic Antidepressants (TCA)	LFG	Toxicology 91	21 CFR 862.3910, Tricyclic antidepressant drugs test system.

## C. PREDICATE DEVICES

**C-1. k061718:** Innovacon Spectrum II Test Card with Integrated Cups, applicant: Innovacon Laboratories, Inc.

**C-2. k10329:** QuickScreen™ Test. The applicant: Phamatech, Inc.

**C-3. k060896:** ONSite CupKit™. The applicant: Variance, Inc.

## D. INDICATIONS FOR USE:

### Chemtrue® Multi-Panel Drug Screen Cup with OPI 2000 Tests

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

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Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

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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. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

### **Chemtrue® Multi-Panel Drug Screen Cup Tests**

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

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The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

**Chemtrue® Multi-Panel Drug Screen Dip Card with OPI2000 Tests**

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

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Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1000
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Methadone	MTD	Methadone	300
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Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic

Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

### **Chemtrue® Multi-Panel Drug Screen Dip Card Tests**

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

<b>Analyte</b>	<b>Abbreviation</b>	<b>Calibrator</b>	<b>Cutoff Concentration (ng/mL)</b>
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1000
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
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1000
Marijuana	THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. 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, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

### E. DEVICE DESCRIPTION

The Chemtrue<sup>®</sup> Drug Screen 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 Dip Card or Cup formats, as indicated by the test name.

### F. SUBSTANTIAL EQUIVALENCE INFORMATION:

Comparison with the predicate devices is outlined below:

Item	Similarities and Differences	
	Candidate Devices	Predicate Devices (k061718, k103295 and k060896)
Indication(s) for use	Same	For qualitative detection of drugs of abuse in human urine
Specimen Type	Same	Human urine
Methodology/Technological Characteristics	Same	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry.
Results	Same	Qualitative
Cut Off	Propoxyphene – Same Cocaine – 150 Amphetamine – 500 / 300 Methamphetamine – 500 / 300  Methamphetamine – Same Barbiturates – Same Benzodiazepines – Same  Methamphetamine 300 – Same	<u>K061718</u> Propoxyphene – 300 Cocaine – 150 /300 Amphetamine – 300 /1000 Methamphetamine – 500 /1000  <u>k103295</u> Methamphetamine – 500 Barbiturates – 200 Benzodiazepines – 200  <u>K060896</u> Methamphetamine – 300
Configurations	Dip Card and Cup	<u>K061718</u> Dip Card and Cup  <u>K103295</u> Dipcard and Cassette  <u>K060896</u> Cup Only
Intended Use	Same	Prescription / OTC Use

### G. TEST PRINCIPLE

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.

Monoclonal anti-drug antibodies are used on the AMP/ BAR/COC/MET/PPX Test devices which are derived from mouse. The polyclonal and monoclonal anti-drug antibodies which are used on BZO Test devices are derived from sheep/mouse.

## H. PERFORMANCE CHARACTERISTICS

Performance data is only provided for AMP300/500, BAR200/BZO200, COC150, MET300/500 and PPX as the new analytes in this submission. AMP1000, BAR3000, BZO300, BUP, COC300, MET1000, MOR, PCP, THC, MDMA, MTD, OPI2000, OXY and TCA analytes were previously cleared under k143599 and k142396.

### 1. Reproducibility (Precision) Studies:

The precision study was conducted by three (3) Operators with three (3) lots in replicates of 10 devices/lot of each device format 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 research coordinator. The data is analyzed and summarized in the tables below:

**Table 1a. AMP Dip Card Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	0	30
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. AMP Dip Card Test: Cutoff: 500 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	0	30

50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>14</b>	<b>16</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1c. BAR Dip Card Test: Cutoff: 200 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>14</b>	<b>16</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1d. BZO Dip Card Test: Cutoff: 200 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>16</b>	<b>14</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1e. COC Dip Card Test: Cutoff: 150 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>16</b>	<b>14</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1f. MET Dip Card Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>14</b>	<b>16</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1g. MET Dip Card Test: Cutoff: 500 ng/mL**

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

**Table 1h. Propoxyphene Dip Card Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	0	30
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 1i. AMP Cup Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	0	30
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 1j. AMP Cup Test: Cutoff: 500 ng/mL**

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

**Table 1k. BAR Cup Test: Cutoff: 200 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	0	30
50% of cutoff	30	0	30
75% of cutoff	30	0	30

Cutoff	30	<b>15</b>	<b>15</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 11. BZO Cup Test: Cutoff: 200 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>15</b>	<b>15</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1m. COC Cup Test: Cutoff: 150 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>17</b>	<b>13</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1n. MET Cup Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>15</b>	<b>15</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1o. MET Cup Test: Cutoff: 500 ng/mL**

Concentration Level	n	TOTAL	
		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>17</b>	<b>13</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

**Table 1p. Propoxyphene Cup Test: Cutoff: 300 ng/mL**

Concentration Level	n	TOTAL	
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		+	-
Negative	30	<b>0</b>	<b>30</b>
50% of cutoff	30	<b>0</b>	<b>30</b>
75% of cutoff	30	<b>0</b>	<b>30</b>
Cutoff	30	<b>15</b>	<b>15</b>
125% of cutoff	30	<b>30</b>	<b>0</b>
150% of cutoff	30	<b>30</b>	<b>0</b>

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 500 related compounds:

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

Amphetamine 300 related compounds:

<b>Substances</b>	<b>Concentration (ng/mL)</b>	<b>% Cross Reactivity</b>
d-Amphetamine	300	100
d,l-Amphetamine	600	50
l-Amphetamine	>30,000	<1
d-Methamphetamine	>30,000	<1
l-Methamphetamine	>30,000	<1
d,l-Methamphetamine	>30,000	<1
d,l-MDMA	>30,000	<1
Ephedrine	>30,000	<1

Pseudoephedrine	>30,000	<1
(d,l)-(MDA)	300	100
Phentermine	4,000	7.5
MDEA	>30,000	<1
d,l-Phenylpropanolamine	>30,000	<1
Phenylephrine	>30,000	<1
Phenylethylamine	>30,000	<1
Tyramine	>30,000	<1

Barbiturates 200 related compounds:

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

Benzodiazepines 200 related compounds:

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

Cocaine 150 related compounds:

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

Methamphetamine 300 related compounds:

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

Methamphetamine 500 related compounds:

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

Propoxyphene 300 related compounds:

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

### 3. Interference:

One hundred and three (103) potential interferents were tested with one lot each of the test device format. It was 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

#### Non-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
d-Chlorpheniramine	d,l-Isoproterenol	Quinine
Chlorpromazine	Ketamine	Quinolinic Acid
Clofibrate	Meprobamate	Ranitidine
Clonidine	Methapyrilene	Salicylic Acid
Cortisone	Methylphenidate	Sulfamethazine
l-Cotinine	Nalidixic Acid	Sulindac
Creatine Hydrate	Naloxone	Tetracycline
Cyclobenzaprine	Naltrexone	Tetrahydrozoline
Cyclodextrin-r	d-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, the drug tests were tested with each of all the drug analytes at 150% and 50% of the drug cut-off urine samples. The results confirmed that the no interference or cross-reactivity among these drug tests and the Chemtrue® Drug Screen Tests are safe and equivalent to the similar test devices that were FDA cleared.

4. **Effect of Urine pH and Specific Gravity Studies:** The testing results demonstrate that the urine pH ranges from 2.0 to 9.0 at  $\pm 25\%$  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  $\pm 25\%$  of the drug cut-off concentrations do not affect the test results.
5. **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 (2°C to 30°C) with three (3) lots of each device format. The stability study results support two (2) years shelf-life of the products at (2°C to 30°C). The real time stability study is still on going.
6. **Method Comparison (Accuracy) Studies:**  
Chemtrue® DOA Low Cutoff with PPX Drug Screen 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 685 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:

**6-1. Test Result Summary:**

**Table 6a.** Method comparison study summary: Chemtrue® Drug Screen Dip Card Test results vs GC/MS

Chemtrue® Drug Screen Dip Card	Concentration By GC/MS (ng/mL)				% Agreement
	(-)		(+)		
	No drug present	Near cutoff negative (50% of the C/O to cutoff)	Near cutoff positive (Cutoff to 150% of the C/O)	GC/MS Positive (>150% of the cutoff)	
AMP <sub>300</sub> (+)	0	0	14	27	100%
(-)	31	11	0	0	100%
BAR <sub>200</sub> (+)	0	1	26	14	100%
(-)	34	9	0	0	98.2%
BZO <sub>200</sub> (+)	0	0	26	14	100%
(-)	31	16	0	0	100%
COC <sub>150</sub> (+)	0	0	15	28	100%
(-)	31	10	0	0	100%
MET <sub>300</sub> (+)	0	1	14	34	100%
(-)	31	9	0	0	97.6%
PPX (+)	0	0	12	33	100%
(-)	31	10	0	0	100%
AMP <sub>500</sub> (+)	0	0	12	31	100%
(-)	31	14	0	0	100%

MET <sub>500</sub> (+)	0	1	11	30	100%
(-)	31	11	0	0	97.8%

**Table 6b.** Method comparison study summary - Chemtrue<sup>®</sup> Drug Screen Cup Test results vs GC/MS

Chemtrue <sup>®</sup> Drug Screen Cup	Concentration By GC/MS (ng/mL)				% Agreement
	(-)		(+)		
	No drug present	Near cutoff negative (75% of the C/O to cutoff)	Near cutoff positive (Cutoff to 125% of the C/O)	GC/MS Positive (≥150% of the cutoff)	
AMP <sub>300</sub> (+)	0	1	14	27	100%
(-)	31	10	0	0	97.6%
BAR <sub>200</sub> (+)	0	1	26	14	100%
(-)	34	9	0	0	97.7%
BZO <sub>200</sub> (+)	0	0	26	14	100%
(-)	31	16	0	0	100%
COC <sub>150</sub> (+)	0	0	15	28	100%
(-)	31	10	0	0	100%
MET <sub>300</sub> (+)	0	1	14	34	100%
(-)	31	9	0	0	97.6%
PPX (+)	0	0	12	33	100%
(-)	31	10	0	0	100%
AMP <sub>500</sub> (+)	0	1	11	31	97.7%
(-)	31	13	1	0	97.8%
MET <sub>500</sub> (+)	0	0	11	30	100%
(-)	31	12	0	0	100%

**6-2. DISCORDANT RESULTS:**

**Table 6c. Dip Card Tests:**

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug Analyte	GC/MS Value (ng/mL)
Methamphetamine 300	+	Methamphetamine	296
Methamphetamine 500	+	Methamphetamine	494
Barbiturates 200	+	Pentobarbital	185

**Table 6d. Cup Tests:**

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug Analyte	GC/MS Value (ng/mL)
Amphetamine 300	+	Amphetamine	229
Amphetamine 500	-	Amphetamine	510
Amphetamine 500	+	Amphetamine	441
Methamphetamine 300	+	Methamphetamine	296
Barbiturates 200	+	Pentobarbital	185

All these eight (8) discordant results were confirmed at the drug cutoff level with the GC/MS concentrations.

**7. OTC Lay-user Accuracy Studies:**

One hundred (130) intended lay-users participated in the evaluation for each of the device format (Dip Card and Cup) for OTC accuracy and usability study from three (3) intended user sites with

GC/MS confirmed urine samples. The sample concentrations are consisted of negative (0), 50%, 75%, 125%, 150% and 200% 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 and up to two (2) random blind labeled samples with the tests of each device format. The results are summarized below:

**Table 7a.** OTC Accuracy study summary between the Chemtrue® Dip Card Tests and the GC/MS values

Chemtrue® Drug Screen Dip Card Test	Concentrations By GC/MS (mL)					% Agreement
	(-)			(+)		
	< 50% of the C/O	GC/MS Negative (50% of the C/O)	Near cutoff negative (75% of the C/O)	Near cutoff positive (C/O to 125% of the C/O)	Positive (≥150% of the C/O)	
AMP500 (+)	0	0	0	28	21	100%
(-)	54	39	41	0	0	100%
BAR200 (+)	0	0	0	43	22	100%
(-)	194	26	22	0	0	100%
BZO200 (+)	0	0	0	21	25	100%
(-)	184	37	40	0	0	100%
COC150 (+)	0	0	0	37	40	100%
(-)	183	25	22	0	0	100%
MET500 (+)	0	0	0	22	36	100%
(-)	55	44	26	0	0	100%
PPX (+)	0	0	0	38	40	100%
(-)	185	22	22	0	0	100%
AMP 300 (+)	0	0	1	24	46	100%
(-)	53	21	23	0	0	99%
MET 300 (+)	0	0	1	24	43	100%
(-)	57	20	23	0	0	99%

**Table 7b.** OTC Accuracy study summary between the Chemtrue® Cup Tests and the GC/MS values

Chemtrue® Drug Screen Cup Test	Concentrations By GC/MS (mL)					% Agreement
	(-)			(+)		
	< 50% of the C/O	GC/MS Negative (50% of the C/O)	Near cutoff negative (75% of the C/O)	Near cutoff positive (C/O to 125% of the C/O)	Positive (≥150% of the C/O)	
AMP500 (+)	0	0	0	26	21	100%
(-)	60	23	39	0	0	100%
BAR200 (+)	0	0	0	43	22	100%
(-)	194	26	22	0	0	100%
BZO200 (+)	0	0	0	22	24	100%
(-)	184	37	40	0	0	100%
COC150 (+)	0	0	0	37	41	100%
(-)	182	25	22	0	0	100%
MET500 (+)	0	0	0	26	22	100%

	(-)	55	41	25	0	0	100%
PPX	(+)	0	0	1	38	40	100%
	(-)	185	22	21	0	0	99.6%
AMP 300	(+)	0	0	0	23	48	100%
	(-)	51	21	25	0	0	100%
MET 300	(+)	0	0	0	23	42	100%
	(-)	56	22	25	0	0	100%

The results demonstrate that the agreement between the Chemtrue<sup>®</sup> Drug Screen test device and GC/MS values is  $\geq 99\%$ .

These lay-users were also given surveys on the ease of understanding the package insert instructions. The results demonstrate that  $\geq 96\%$  of the lay users can easily follow the instructions to perform the test and interpret the results. A Flesch-Kincaid reading analysis supports a 7<sup>th</sup> grade reading level.

#### **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.