



February 28, 2018

Hangzhou Clongene Biotech Co.,Ltd.  
% Jesse Xia  
Manager  
LSI International  
504 E Diamond Ave., Suite I  
Gaithersburg, MD 20877

Re: k180255

Trade/Device Name: CLUNGENE Multi-Drug Test Dip Card  
CLUNGENE Multi-Drug Test Easy Cup

Regulation Number: 21 CFR 862.3150

Regulation Name: Barbiturate Test System

Regulatory Class: Class II

Product Code: PTH, PTG, NGL, NGG, NFT, NFW, NFY, NFV

Dated: January 25, 2018

Received: January 30, 2018

Dear Jesse Xia:

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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Kellie B. Kelm -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

## Indications for Use

510(k) Number (if known)  
k180255

### Device Name

CLUNGENE® Multi-Drug Test Dip Card  
CLUNGENE® Multi-Drug Test Easy Cup

### Indications for Use (Describe)

CLUNGENE® Multi-Drug Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug(Identifier)	Calibrator	Cut-off level
Amphetamine	d-Amphetamine	1000 ng/mL
Oxazepam	Oxazepam	300 ng/mL
Cocaine	Benzoylcegonine	300 ng/mL
Marijuana	11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH	50 ng/mL
Methamphetamine	d-Methamphetamine	1000 ng/mL
Morphine	Morphine	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Secobarbital	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL

Configuration of the CLUNGENE® Multi-Drug Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. For in vitro diagnostic use only.

CLUNGENE® Multi-Drug Test Easy Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug(Identifier)	Calibrator	Cut-off level
Amphetamine	d-Amphetamine	1000 ng/mL
Oxazepam	Oxazepam	300 ng/mL
Cocaine	Benzoylcegonine	300 ng/mL
Marijuana	11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH	50 ng/mL
Methamphetamine	d-Methamphetamine	1000 ng/mL
Morphine	Morphine	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Secobarbital	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL

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Configuration of the CLUNGENE® Multi-Drug Test Easy Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. For in vitro diagnostic use only.

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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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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) SUMMARY

k180255

1. Date: February 28, 2018
2. Submitter: Hangzhou Clongene Biotech Co., Ltd.  
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Hangzhou 311121, China
3. Contact person: Zheng Shujian  
Hangzhou Clongene Biotech Co., Ltd.  
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Hangzhou 311121, China  
Telephone: 86 571 88262120  
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4. Device Name: CLUNGENE Multi-Drug Test Dip Card  
CLUNGENE Multi-Drug Test Easy Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGL Morphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended Use

CLUNGENE® Multi-Drug Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone in human urine at the cutoff concentrations of:

<u>Drug(Identifier)</u>	<u>Calibrator</u>	<u>Cut-off level</u>
Amphetamine	d-Amphetamine	1000 ng/mL

Oxazepam	Oxazepam	300 ng/mL
Cocaine	Benzoyllecgonine	300 ng/mL
Marijuana	11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH	50 ng/mL
Methamphetamine	d-Methamphetamine	1000 ng/mL
Morphine	Morphine	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Secobarbital	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL

Configuration of the CLUNGENE® Multi-Drug Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

CLUNGENE® Multi-Drug Test Easy Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone in human urine at the cutoff concentrations of:

<u>Drug(Identifier)</u>	<u>Calibrator</u>	<u>Cut-off level</u>
Amphetamine	d-Amphetamine	1000 ng/mL
Oxazepam	Oxazepam	300 ng/mL
Cocaine	Benzoyllecgonine	300 ng/mL
Marijuana	11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH	50 ng/mL
Methamphetamine	d-Methamphetamine	1000 ng/mL
Morphine	Morphine	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Secobarbital	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL

Configuration of the CLUNGENE® Multi-Drug Test Easy Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

## 7. Device Description

The CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of

Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone (target analytes) in human urine. The products are single-use in vitro diagnostic devices. The CLUNGENE Multi-Drug Test Dip Card kit contains a Dip Card device, a package insert and a urine cup for sample collection. The CLUNGENE Multi-Drug Test Easy Cup kit contains a Cup device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup and the predicate devices is provided in following tables.

**Table 1: Features Comparison of CLUNGENE Multi-Drug Test Dip Card and the Predicate Devices**

Item	Device	Predicate - K142396
<b>Indication(s) for Use</b>	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
<b>Calibrator and Cut-Off Values</b>	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml 11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Type of Test</b>	Qualitative	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Intended Use</b>	For over-the-counter	Same
<b>Configurations</b>	Dip Card	Same

**Table 2: Features Comparison of CLUNGENE Multi-Drug Test Easy Cup Tests and the Predicate Devices**

Item	Device	Predicate - K142396
<b>Indication(s) for Use</b>	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)

<b>Calibrator and Cut-Off Values</b>	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml 11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Type of Test</b>	Qualitative	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Intended Use</b>	For over-the-counter	Same
<b>Configurations</b>	Cup	Dip Card

## 9. Test Principle

The CLUNGENE Multi-Drug Test Dip Card, and CLUNGENE Multi-Drug Test Easy Cup are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital and Methadone in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

## 10. Performance Characteristics

### 1. Analytical Performance

#### a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the



following tables for Secobarbital, Methadone and Oxycodone. The data for Methamphetamine, Morphine and Marijuana were reported in k153741; and the data for Amphetamine, Oxazepam and Cocaine were reported in k161251.

### Secobarbital

#### CLUNGENE Multi-Drug Test Dip Card

Lot Number	Concentration by LC/MS (ng/mL)	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
		0	69	147	226	286	370	457	510	559
Lot 1		50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2		50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3		50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

#### CLUNGENE Multi-Drug Test Easy Cup

Lot Number	Concentration by LC/MS (ng/mL)	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
		0	69	147	226	286	370	457	510	559
Lot 1		50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2		50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3		50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-

### Methadone

#### CLUNGENE Multi-Drug Test Dip Card

Lot Number	Concentration by LC/MS (ng/mL)	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
		0	76	140	235	297	377	431	507	631
Lot 1		50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2		50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3		50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

#### CLUNGENE Multi-Drug Test Easy Cup

Lot Number	Concentration by LC/MS (ng/mL)	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
		0	76	140	235	297	377	431	507	631
Lot 1		50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2		50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3		50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

### Oxycodone

#### CLUNGENE Multi-Drug Test Dip Card

Lot Number	Concentration by LC/MS (ng/mL)	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
		0	25	48	72	101	119	142	164	187
Lot 1		50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

Concentration by LC/MS (ng/mL)  Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
	0	25	48	72	101	119	142	164	187
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

**CLUNGENE Multi-Drug Test Easy Cup**

Concentration by LC/MS (ng/mL)  Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
	0	25	48	72	101	119	142	164	187
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

The following cut-off values are verified.

Drug(Identifier)	Cut-off level
Secobarbital (BAR)	300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C. Real time stability studies are ongoing.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences observed between the CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup.

Acetaminophen (4-Acetamidophenol)	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	EMDP	Oxalic acid
N-Acetylprocainamide	Erythromycin	Oxolinic acid
Acetylsalicylic acid	β-Estradiol	Oxymetazoline
Albumin	Fenopropfen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol

Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid
Bilirubin	D,L-Isoproterenol	Serotonin (5- Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac
Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-( $\beta$ -Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Maprotiline	Thiamine
Cortisone	Meperidine	Thioridazine
(-) Cotinine	Meprobamate	Triamterene
Creatinine	Methoxyphenamine	DL-Tyrosine
Deoxycorticosterone	Nalidixic acid	Trifluoperazine
Dextromethorphan	Naloxone	Trimethoprim
Diclofenac	Naltrexone	D L-Tryptophan
Diffunisal	Naproxen	Tyramine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nifedipine	Verapamil
Disopyramide	Norethindrone	Zomepirac
EDDP	Noscapine	

To demonstrate that there are no interference from each of the nine drug analytes on the other eight drug strips, devices in both CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup were tested using standard drug urine solutions at three fold cut-off drug concentrations of each drug analyte. Tests showed positive result only for each target drug and negative result for other drugs.

#### e. Specificity

To test specificity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Secobarbital, Methadone and Oxycodone. The data for Methamphetamine, Morphine and Marijuana were reported in k153741; and the data for Amphetamine, Oxazepam and Cocaine were reported in k161251. There were no differences observed between the CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup.

<b>Secobarbital (Cut-off=300 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
Secobarbital	300	100%
Amobarbital	300	100%
Alphenol	150	200%
Aprobarbital	200	150%
Butobarbital	75	400%
Butathal	100	300%
Butalbital	2500	12%
Cyclopentobarbital	600	50%
Pentobarbital	300	100%
Phenobarbital	100	300%

<b>Methadone (Cut-off=300 ng/mL)</b>	<b>Result Positive at(ng/ml)</b>	<b>% Cross-Reactivity</b>

Methadone	300	100%
Doxylamine	5000	6%
LAAM HCl	>100000	<0.3%
Alpha Methadol	>100000	<0.3%
EDDP	>100000	<0.3%
EMDP	>100000	<0.3%

Oxycodone (Cut-off=100 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Oxycodone	100	100%
Codeine	50000	0.2%
Dihydrocodeine	12500	0.8%
Ethylmorphine	25000	0.4%
Hydrocodone	1562	6.4%
Hydromorphone	12500	0.8%
Oxymorphone	1562	6.4%
Thebaine	50000	0.2%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed between the CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup.

2. Comparison Studies

Method comparison studies for the CLUNGENE Multi-Drug Test Dip Card and the CLUNGENE Multi-Drug Test Easy Cup were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below for Secobarbital, Methadone and Oxycodone. The data for Methamphetamine, Morphine and Marijuana were reported in k153741; and the data for Amphetamine, Oxazepam and Cocaine were reported in k161251.

**Secobarbital**

CLUNGENE Multi-Drug Test Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	15	15	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

**Discordant Results**

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer A	BAR79	298	Positive
Viewer C	BAR29	294	Positive
Viewer A	BAR14	316	Negative

CLUNGENE Multi-Drug Test Easy Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer B	Positive	0	0	2	18	20
	Negative	10	15	13	2	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	15	14	1	0

#### Discordant Results

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	BAR79	298	Positive
Viewer B	BAR30	296	Positive
Viewer B	BAR79	298	Positive
Viewer C	BAR29	294	Positive
Viewer A	BAR33	330	Negative
Viewer B	BAR14	316	Negative
Viewer B	BAR35	349	Negative
Viewer C	BAR14	316	Negative

#### Methodone

CLUNGENE Multi-Drug Test Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	19	20
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

#### Discordant Results

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer B	MTD28	297	Positive
Viewer C	MTD14	292	Positive
Viewer A	MTD29	308	Negative

CLUNGENE Multi-Drug Test Easy Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	20
	Negative	10	15	13	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	15	14	1	0

#### Discordant Results

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	MTD14	292	Positive
Viewer A	MTD28	297	Positive
Viewer B	MTD28	297	Positive
Viewer C	MTD14	292	Positive
Viewer A	MTD29	308	Negative
Viewer C	MTD76	313	Negative

#### Oxycodone

CLUNGENE Multi-Drug Test Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	20	20
	Negative	10	15	15	0	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	15	15	1	0

#### Discordant Results

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer B	OXY66	92	Positive

<b>Viewer B</b>	OXY39	101	Negative
<b>Viewer C</b>	OXY30	102	Negative

CLUNGENE Multi-Drug Test Easy Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
	Viewer A	Positive	0	0	0	19
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	15	15	1	0

#### Discordant Results

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
<b>Viewer B</b>	OXY66	92	Positive
<b>Viewer A</b>	OXY39	101	Negative
<b>Viewer C</b>	OXY30	102	Negative

#### Lay-user study

A lay user study was performed at three intended user sites with 300 lay persons for each device format. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Results are shown below.

#### CLUNGENE Multi-Drug Test Dip Card

Drugs	% of Cut-off	Number of samples	Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
				No. of Positive	No. of Negative	
AMP	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	250	0	20	100
	-50% Cut-off	160	500	0	160	100
	-25% Cut-off	20	750	1	19	95
	+25% Cut-off	20	1250	19	1	95
	+50% Cut-off	40	1500	40	0	100
	+75% Cut-off	20	1750	20	0	100
BAR	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	18	2	90

	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
COC	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	1	19	95
	+25% Cut-off	20	375	19	1	95
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
BZO	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	19	1	95
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
MET	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	250	0	20	100
	-50% Cut-off	160	500	0	160	100
	-25% Cut-off	20	750	1	19	95
	+25% Cut-off	20	1250	20	0	100
	+50% Cut-off	40	1500	40	0	100
	+75% Cut-off	20	1750	20	0	100
MTD	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	18	2	90
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
MOP	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	2	18	90
	+25% Cut-off	20	375	20	0	100
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
OXY	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	25	0	20	100
	-50% Cut-off	160	50	0	160	100
	-25% Cut-off	20	75	1	19	95
	+25% Cut-off	20	125	20	0	100
	+50% Cut-off	40	150	40	0	100
	+75% Cut-off	20	175	20	0	100
THC	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	12.5	0	20	100
	-50% Cut-off	160	25	0	160	100
	-25% Cut-off	20	37.5	0	20	100
	+25% Cut-off	20	62.5	18	2	90
	+50% Cut-off	40	75	40	0	100
	+75% Cut-off	20	87.5	20	0	100

**CLUNGENE Multi-Drug Test Easy Cup**



Drugs	% of Cut-off	Number of samples	Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
				No. of Positive	No. of Negative	
AMP	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	250	0	20	100
	-50% Cut-off	160	500	0	160	100
	-25% Cut-off	20	750	1	19	95
	+25% Cut-off	20	1250	18	2	90
	+50% Cut-off	40	1500	40	0	100
	+75% Cut-off	20	1750	20	0	100
BAR	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	18	2	90
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
COC	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	19	1	95
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
BZO	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	1	19	95
	+25% Cut-off	20	375	19	1	95
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
MET	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	250	0	20	100
	-50% Cut-off	160	500	0	160	100
	-25% Cut-off	20	750	2	18	90
	+25% Cut-off	20	1250	20	0	100
	+50% Cut-off	40	1500	40	0	100
	+75% Cut-off	20	1750	20	0	100
MTD	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	0	20	100
	+25% Cut-off	20	375	19	1	95
	+50% Cut-off	40	450	40	0	100
	+75% Cut-off	20	525	20	0	100
MOP	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	75	0	20	100
	-50% Cut-off	160	150	0	160	100
	-25% Cut-off	20	225	1	19	95
	+25% Cut-off	20	375	20	0	100
	+50% Cut-off	40	450	40	0	100

	+75% Cut-off	20	525	20	0	100
OXY	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	25	0	20	100
	-50% Cut-off	160	50	0	160	100
	-25% Cut-off	20	75	1	19	95
	+25% Cut-off	20	125	20	0	100
	+50% Cut-off	40	150	40	0	100
	+75% Cut-off	20	175	20	0	100
THC	-100% Cut-off	20	0	0	20	100
	-75% Cut-off	20	12.5	0	20	100
	-50% Cut-off	160	25	0	160	100
	-25% Cut-off	20	37.5	0	20	100
	+25% Cut-off	20	62.5	19	1	95
	+50% Cut-off	40	75	40	0	100
	+75% Cut-off	20	87.5	20	0	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

### 3. Clinical Studies

Not applicable.

### 11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the CLUNGENE Multi-Drug Test Dip Card and CLUNGENE Multi-Drug Test Easy Cup are substantially equivalent to the predicate.