



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

March 18, 2016

HANGZHOU CLONGENE BIOTECH CO., LTD.  
C/O JOE SHIA  
MANAGER  
504 E DIAMOND AVE., SUITE I  
GAITHERSBURG MD 20877

Re: K153741

Trade/Device Name: Clungene Methamphetamine Test, Clungene Morphine Test, Clungene Marijuana Test

Regulation Number: 21 CFR 862.3870

Regulation Name: Cannabinoid test system

Regulatory Class: II

Product Code: LDJ, DJC, DJG

Dated: December 19, 2015

Received: December 28, 2015

Dear Mr. Shia:

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)  
k153741

### Device Name

Clungene Methamphetamine Tests  
Clungene Marijuana Tests  
Clungene Morphine Tests

### Indications for Use (Describe)

Clungene Methamphetamine Tests are immunochromatographic assays for the qualitative determination of d-methamphetamine in human urine at cut-off concentration of 1000 ng/mL. The calibrator is d-methamphetamine. The tests are available in a Cassette format, a Easy Cup format, a Split Key Cup format and a Dip Card format. The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling. For in vitro diagnostic use only.

Clungene Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH in human urine at cut-off concentration of 50 ng/mL. The calibrator is 11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH. The tests are available in a Cassette format, a Easy Cup format, a Split Key Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling. For in vitro diagnostic use only.

Clungene Morphine Tests are immunochromatographic assays for the qualitative determination of Morphine in human urine at cut-off concentration of 300 ng/mL. The calibrator is Morphine. The tests are available in a Cassette format, a Easy Cup format, a Split Key Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling. For in vitro diagnostic use only.

### 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.**

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510(k) SUMMARY

1. Date: February 22, 2016
2. Submitter: Hangzhou Clongene Biotech Co., Ltd.  
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4. Device Name: CLUNGENE Methamphetamine Tests  
CLUNGENE Morphine Tests  
CLUNGENE Marijuana Tests

Classification:

Product Code	CFR	Panel
DJC	21 CFR, 862.3610 Methamphetamine Test	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices: K052115

The FIRST CHECK MULTI DRUG CUP Urine Test

6. Intended Use

Clungene Methamphetamine Tests are immunochromatographic assays for the qualitative determination of d-methamphetamine in human urine at cut-off concentration of 1000 ng/mL. The calibrator is d-methamphetamine. The tests are available in a Cassette format, an Easy Cup format, a Split Key Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

For in vitro diagnostic use only.

Clungene Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH in human urine at cut-off concentration of 50 ng/mL. The calibrator is 11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH. The tests are available in a Cassette format, an Easy Cup format, a Split Key Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must

be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.  
For in vitro diagnostic use only.

Clungene Morphine Tests are immunochromatographic assays for the qualitative determination of Morphine in human urine at cut-off concentration of 300 ng/mL. The calibrator is Morphine. The tests are available in a Cassette format, an Easy Cup format, a Split Key Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.  
For in vitro diagnostic use only.

7. Device Description

The CLUNGENE Methamphetamine Tests, CLUNGENE Morphine Tests, and CLUNGENE Marijuana Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Methamphetamine, Morphine and 11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH (target analytes) in human urine. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

A summary comparison of features of the CLUNGENE Methamphetamine Tests, CLUNGENE Morphine Tests and CLUNGENE Marijuana Tests and the predicate devices is provided in following tables.

**Table 1: Features Comparison of CLUNGENE Methamphetamine Tests and the Predicate Devices**

<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<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</b>	d-Methamphetamine	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>Cut-Off Values</b>	1000 ng/mL	Same
<b>Intended Use</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cassette, Dip Card and Cups	Cup

**Table 2: Features Comparison of CLUNGENE Morphine Tests and the Predicate Devices**

<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<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</b>	Morphine	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>Cut-Off Values</b>	300 ng/mL	Same
<b>Intended Use</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cassette, Dip Card and Cups	Cup

**Table 3: Features Comparison of CLUNGENE Marijuana Tests and the Predicate Devices**

<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<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</b>	11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH	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>Cut-Off Values</b>	50 ng/mL	Same
<b>Intended Use</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cassette, Dip Card and Cups	Cup

## 9. Test Principle

The CLUNGENE Methamphetamine Tests, CLUNGENE Morphine Tests, and CLUNGENE Marijuana Tests are rapid tests for the qualitative detection of d-Methamphetamine, Morphine and 11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH 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, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/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.

#### **CLUNGENE Methamphetamine Tests**

##### Cassette

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
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+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

##### Dip Card

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

##### Split-Key Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
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+	17-/33+	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-

##### Easy Cup



Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	17-/33+	50+/0-	50+/0-	50+/0-	50+/0-

### CLUNGENE Morphine Tests

#### Cassette

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	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+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

#### Dip Card

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
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+	27-/23+	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-

#### Split-Key Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	32-/18+	50+/0-	50+/0-	50+/0-	50+/0-

#### Easy Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	31-/19+	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+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

### CLUNGENE Marijuana Tests

#### Cassette

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

#### Dip Card

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

#### Split-Key Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	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+	31-/19+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

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 and real time stability determination at both 4 °C and 30 °C.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Morphine and Marijuana.

The following cut-off values for the candidate devices have been verified.

Calibrator	Cut-off (ng/mL)
d-Methamphetamine	1000
Morphine	300
11-Nor- $\Delta$ 9-Tetrahydrocannabinol-9-COOH	50

e. 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 batches of each device. Compounds that showed no interference at a concentration of 100 $\mu$ g/mL are summarized in the following tables. There were no differences observed for different devices.

**Methamphetamine:**

4-Acetamidophenol	(-) Y Ephedrine	Penicillin-G
Acetophenetidin	Erythromycin	Pentazocaine
N-Acetylprocainamide	$\beta$ -Estradiol	Pentobarbital
Acetylsalicylic acid	Estrone-3-sulfate	Perphenazine
Aminopyrine	Ethyl-p-aminobenzoate	Phencyclidine

Amitriptyline	Fenfluramine	Phenelzine
Amobarbital	Fenoprofen	Phendimetrazine
Amoxicillin	Furosemide	Phenobarbital
Ampicillin	Gentisic acid	Phetoin
Ascorbic acid	Hemoglobin	L-Phenylephrine
Apomorphine	Hydralazine	$\beta$ -Phenylethylamine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine	Hydrocodone	Prednisolone
Benzilic acid	Hydrocortisone	Prednisone
Benzoic acid	O-Hydroxyhippuric acid	Procaine
Benzoyllecgonine	3-Hydroxytyramine	Promazine
Bilirubin	Ibuprofen	Promethazine
Brompheniramine	Imipramine	D,L-Propranolol
Caffeine	(-) Isoproterenol	Propiomazine
Cannabidiol	Isoxsuprine	D-Propoxyphene
Cannabinol	Ketamine	Quinidine
Chloralhydrate	Ketoprofen	Quinine
Chloramphenicol	Labetalol	Ranitidine
Chlordiazepoxide	Levorphanol	Salicylic acid
Chlorothiazide	Loperamide	Secobarbital
( $\pm$ ) Chlorpheniramine	Maprotiline	Serotonin
Chlorpromazine	Meperidine	Sulfamethazine
Chlorquine	Meprobamate	Sulindac
Cholesterol	Methadone	Temazepam
Clomipramine	Methylphenidate	Tetracycline
Clonidine	Morphine-3-Dglucuronide	Tetrahydrocortisone
Cocaine hydrochloride	Nalidixic acid	Tetrahydrozoline
Codeine	Naloxone	$\Delta^9$ -THC-COOH
Cortisone	Naltrexone	Thebaine
(-) Cotinine	Naproxen	Thiamine
Creatinine	Niacinamide	Thioridazine
Deoxycorticosterone	Nifedipine	D,L-Thyroxine
Dextromethorphan	Norcodein	Tolbutamine
Diazepam	Norethindrone	Triamterene
Diclofenac	D-Norpropoxyphene	Trifluoperazine
Diflunisal	Noscapine	Trimethoprim
Digoxin	D,L-Octopamine	Trimipramine
Diphenhydramine	Oxalic acid	Tryptamine
Doxylamine	Oxazepam	D, L-Tyrosine
Ecgonine hydrochloride	Oxolinic acid	Uric acid
Ecgonine methylester	Oxycodone	Verapamil
(1R,2S)-(-)-Ephedrine	Oxymetazoline	Zomepirac
L-Ephedrine	Papaverine	

## Morphine

Acebutolol	(-) Y Ephedrine	Hydroxymethamphetamine
Acetopromazine - d6	Erythromycin	Papaverine
4-Acetamidophenol	$\beta$ -Estradiol	Penicillin-G
Acetophenetidin	Estrone-3-sulfate	Pentazocaine
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Pentobarbital
Acetylsalicylic acid	Fenoprofen	Perphenazine
D,L-Amphetamine	Furosemide	Phencyclidine
L-Amphetamine	Gentisic acid	Phenelzine
Aminopyrine	Hemoglobin	Phenobarbital
Amitriptyline	Hydralazine	Phentermine
Amobarbital	Hydrochlorothiazide	$\beta$ -Phenylethylamine
Amoxicillin	Hydrocortisone	L-Phenylephrine
Ampicillin	O-Hydroxyhippuric acid	$\beta$ -Phenylethylamine
Ascorbic acid	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Promazine
Benzilic acid	(-) Isoproterenol	Promethazine
Benzoic acid	Isoxsuprine	D,L-Propranolol
Benzoyllecgonine	Ketamine	D-Propoxyphene
Benzphetamine	Ketoprofen	D-Pseudoephedrine
Bilirubin	Labetalol	Quinidine
Brompheniramine	Loperamide	Quinine
Caffeine	Maprotiline	Salicylic acid
Chloramphenicol	Meprobamate	Secobarbital
Chlordiazepoxide	Methoxyphenamine	Serotonin
Chlorothiazide	Methylenedioxyamphetamine	Sulfamethazine
( $\pm$ ) Chlorpheniramine	Methylenedioxymethamphetamine	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methylphenidate	Tetracycline
Cholesterol	Methyprylon	Tetrahydrozoline
Clomipramine	Nalorphine	Tetrahydrocortisone
Clonidine	Nalidixic acid	Tetrahydrocortisone-(5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Thiamine
Cortisone	Naltrexone	Thioridazine
(-) Cotinine	Naproxen	D,L-Thyroxine
Creatinine	Niacinamide	Tolbutamine
Deoxycorticosterone	Nifedipine	Triamterene
Dextromethorphan	Norcodein	Trifluoperazine

Diazepam	Norethindrone	Trimethoprim
Diclofenac	D-Norpropoxyphene	Trimipramine
Diflunisal	Noscapine	Tryptamine
Digoxin	D,L-Octopamine	D, L-Tyrosine
Diphenhydramine	Oxalic acid	Uric acid
Doxylamine	Oxazepam	Verapamil
Ecgonine	Oxolinic acid	Zomepirac
Ecgonine methylester	Oxymetazoline	

### **Marijuana**

4-Acetamidophenol	Estrone-3-sulfate	Penicillin-G
Acetophenetidin	Ethyl-p-aminobenzoate	Pentazocine
N-Acetylprocainamide	Fenoprofen	Pentobarbital
Acetylsalicylic acid	Furosemide	Perphenazine
Aminopyrine	Gentisic acid	Phencyclidine
Amitriptyline	Hemoglobin	Phenelzine
Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
Ascorbic acid	Hydrocortisone	$\beta$ -Phenylethylamine
D,L-Amphetamine	O-Hydroxyhippuric acid	$\beta$ -Phenylethylamine
L-Amphetamine	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Procaine
Benzilic acid	(-) Isoproterenol	Promazine
Benzoic acid	Isoxsuprine	Promethazine
Benzoylecgonine	Ketamine	D,L-Propranolol
Benzphetamine	Ketoprofen	D-Propoxyphene
Bilirubin	Labetalol	D-Pseudoephedrine
Brompheniramine	Levorphanol	Quinidine
Caffeine	Loperamide	Quinine
Chloralhydrate	Maprotiline	Ranitidine
Chloramphenicol	Meprobamate	Salicylic acid
Chlordiazepoxide	Methadone	Secobarbital
Chlorothiazide	Methoxyphenamine	Serotonin (5-
( $\pm$ ) Chlorpheniramine	(+) 3,4-	Sulfamethazine
Chlorpromazine	(+)3,4-	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methyprylon	Tetracycline
Clomipramine	Morphine-3- $\beta$ -Dglucuronide	Tetrahydrocortisone, 3

Clonidine	Nalorphine	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diffunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	D, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-) Y Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac
β-Estradiol	Papaverine	

#### f. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below. There were no differences observed for different devices.

<b>Methamphetamine (Cut-off=1000 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross- Reactivity</b>
D - Methamphetamine	1000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20000	5%
D/L-Methamphetamine	3000	33%
p-Hydroxymethamphetamine	30000	3.3%
L-Methamphetamine	8000	12.5%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	20000	5%
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	Negative at 100000	<1%
D-Amphetamine	Negative at 100000	<1%
L-Amphetamine	Negative at 100000	<1%

<b>Morphine (Cut-off=300 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactvity</b>
Morphine	300	100%

O6-Acetylmorphine	300	100%
Codeine	300	100%
EthylMorphine	6000	5%
Heroin	300	100%
Hydromorphone	3000	10%
Hydrocodone	50000	0.6%
Levorphanol	1500	20%
Oxycodone	30000	1%
Procaine	15000	2%
Thebaine	6000	5%
Morphine-3-glucuronide	>100000	<0.3%

<b>Marijuana (Cut-off=50 ng/mL)</b>	<b>Result Positive at(ng/mL)</b>	<b>% Cross-Reactivity</b>
11-Nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy- $\Delta^9$ -Tetrahydrocannabinol	5000	1%
11-Nor- $\Delta^8$ -Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.3%
$\Delta^8$ -Tetrahydrocannabinol	10000	0.5%
$\Delta^9$ -Tetrahydrocannabinol	10000	0.5%
Cannabidiol	20000	0.3%
11-Nor- $\Delta^9$ -THC-carboxy glucuronide	2500	2%
(-)-11-nor-9-carboxy- $\Delta^9$ -THC	2500	2%

g. 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 for different devices.

2. Comparison Studies

Method comparison studies for the CLUNGENE Methamphetamine Tests, the CLUNGENE Morphine Tests and the CLUNGENE Marijuana Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

**Methamphetamine**

Cassette	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	18	21
	Negative	14	12	13	1	0
Viewer B	Positive	0	0	1	17	21
	Negative	14	12	13	2	0
Viewer C	Positive	0	0	1	17	21
	Negative	14	12	13	2	0

**Discordant Results of Methamphetamine Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
<b>Viewer A</b>	MET09	936	Positive
<b>Viewer B</b>	MET60	963	Positive
<b>Viewer C</b>	MET60	963	Positive
<b>Viewer A</b>	MET15	1010	Negative
<b>Viewer B</b>	MET15	1010	Negative
<b>Viewer B</b>	MET69	1100	Negative
<b>Viewer C</b>	MET15	1010	Negative
<b>Viewer C</b>	MET69	1100	Negative

Panel Dip		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	18	21
	Negative	14	12	13	1	0
Viewer B	Positive	0	0	1	18	21
	Negative	14	12	13	1	0
Viewer C	Positive	0	0	1	19	21
	Negative	14	12	13	0	0

**Discordant Results of Methamphetamine Panel Dip**

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
<b>Viewer A</b>	MET60	963	Positive
<b>Viewer B</b>	MET60	963	Positive
<b>Viewer C</b>	MET60	963	Positive
<b>Viewer A</b>	MET69	1100	Negative
<b>Viewer B</b>	MET15	1010	Negative

Split-Key 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%)
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Viewer A	Positive	0	0	2	19	21
	Negative	14	12	12	0	0
Viewer B	Positive	0	0	1	18	21
	Negative	14	12	13	1	0
Viewer C	Positive	0	0	1	18	21
	Negative	14	12	13	1	0

**Discordant Results of Methamphetamine Split-Key Cup**

Viewer	Sample Number	GC/MS Result	Split-Key Cup Viewer Results
Viewer A	MET05	947	Positive
Viewer A	MET60	963	Positive
Viewer B	MET60	963	Positive
Viewer C	MET60	963	Positive
Viewer B	MET15	1010	Negative
Viewer C	MET15	1010	Negative

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	16	21
	Negative	14	12	14	3	0
Viewer B	Positive	0	0	0	17	21
	Negative	14	12	14	2	0
Viewer C	Positive	0	0	0	18	21
	Negative	14	12	14	1	0

**Discordant Results of Methamphetamine Easy Cup**

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	MET65	1065	Negative
Viewer A	MET69	1100	Negative
Viewer A	MET15	1010	Negative
Viewer B	MET69	1100	Negative
Viewer B	MET15	1010	Negative
Viewer C	MET69	1100	Negative

**Morphine**

Cassette		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	16	23
	Negative	9	19	12	1	0
Viewer B	Positive	0	0	2	17	23
	Negative	9	19	10	0	0
Viewer C	Positive	0	0	2	17	23
	Negative	9	19	10	0	0

**Discordant Results of Morphine Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
Viewer B	MOP53	274	Positive
Viewer B	MOP01	297	Positive
Viewer C	MOP53	274	Positive
Viewer C	MOP01	297	Positive
Viewer A	MOP43	314	Negative

Panel Dip		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	16	23
	Negative	9	19	12	1	0
Viewer B	Positive	0	0	0	16	23
	Negative	9	19	12	1	0
Viewer C	Positive	0	0	0	17	23
	Negative	9	19	12	0	0

**Discordant Results of Morphine Panel Dip**

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	MOP43	314	Negative
Viewer B	MOP43	314	Negative

Split-Key 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	16	23
	Negative	9	19	11	1	0
Viewer B	Positive	0	0	1	17	23
	Negative	9	19	11	0	0
Viewer C	Positive	0	0	0	17	23
	Negative	9	19	12	0	0

### Discordant Results of Morphine Split-Key Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	MOP01	297	Positive
Viewer B	MOP01	297	Positive
Viewer A	MOP43	314	Negative

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	17	23
	Negative	9	19	10	0	0
Viewer B	Positive	0	0	2	17	23
	Negative	9	19	10	0	0
Viewer C	Positive	0	0	1	16	23
	Negative	9	19	11	1	0

### Discordant Results of Morphine Easy Cup

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	MOP53	274	Positive
Viewer A	MOP01	297	Positive
Viewer B	MOP53	274	Positive
Viewer B	MOP01	297	Positive
Viewer C	MOP01	297	Positive
Viewer C	MOP43	314	Negative

### Marijuana

Cassette		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	24	16
	Negative	8	18	12	0	0
Viewer B	Positive	0	0	1	23	16
	Negative	8	18	13	1	0
Viewer	Positive	0	0	2	24	16

C	Negative	8	18	12	0	0
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**Discordant Results of Marijuana Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
Viewer A	THC05	49	Positive
Viewer A	THC67	47	Positive
Viewer B	THC05	49	Positive
Viewer C	THC05	49	Positive
Viewer C	THC67	47	Positive
Viewer B	THC79	51	Negative

Panel Dip		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	22	16
	Negative	8	18	14	2	0
Viewer B	Positive	0	0	0	22	16
	Negative	8	18	14	2	0
Viewer C	Positive	0	0	0	20	16
	Negative	8	18	14	4	0

**Discordant Results of Marijuana Panel Dip**

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	THC66	52	Negative
Viewer A	THC79	51	Negative
Viewer B	THC66	52	Negative
Viewer B	THC79	51	Negative
Viewer C	THC04	53	Negative
Viewer C	THC66	52	Negative
Viewer C	THC68	52	Negative
Viewer C	THC79	51	Negative

Split-Key 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	22	16
	Negative	8	18	13	2	0
Viewer B	Positive	0	0	1	23	16
	Negative	8	18	13	1	0
Viewer	Positive	0	0	0	23	16

C	Negative	8	18	14	1	0
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**Discordant Results of Marijuana Split-Key Cup**

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	THC05	49	Positive
Viewer B	THC05	49	Positive
Viewer A	THC68	52	Negative
Viewer A	THC79	51	Negative
Viewer B	THC68	52	Negative
Viewer C	THC68	52	Negative

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	23	16
	Negative	8	18	14	1	0
Viewer B	Positive	0	0	0	21	16
	Negative	8	18	14	3	0
Viewer C	Positive	0	0	0	23	16
	Negative	8	18	14	1	0

**Discordant Results of Marijuana Easy Cup**

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	THC66	52	Negative
Viewer B	THC04	53	Negative
Viewer B	THC66	52	Negative
Viewer B	THC79	51	Negative
Viewer C	THC16	53	Negative

**Lay-user study**

A lay user study was performed at three intended user sites with 1680 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/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.

**Comparison between GC/MS and Lay Person Results for Methamphetamine Cassette**

			<b>Lay person results</b>	<b>The</b>
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% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	25	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	1	19	95
+25% Cutoff	20	1,250	19	1	95
+50% Cutoff	20	1,500	20	0	100
+75% Cutoff	20	1,750	20	0	100

**Comparison between GC/MS and Lay Person Results for Methamphetamine Dip Card**

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	25	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	1	19	95
+25% Cutoff	20	1,250	18	2	90
+50% Cutoff	20	1,500	20	0	100
+75% Cutoff	20	1,750	20	0	100

**Comparison between GC/MS and Lay Person Results for Methamphetamine Split-Key Cup**

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	25	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	1	19	95
+25% Cutoff	20	1,250	18	2	90
+50% Cutoff	20	1,500	20	0	100
+75% Cutoff	20	1,750	20	0	100

**Comparison between GC/MS and Lay Person Results for Methamphetamine Easy Cup**

% of Cutoff	Number of samples	d-Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	25	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	2	18	90
+25% Cutoff	20	1,250	19	1	95

<b>+50% Cutoff</b>	20	1,500	20	0	100
<b>+75% Cutoff</b>	20	1,750	20	0	100

**Comparison between GC/MS and Lay Person Results for Morphine Cassette**

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	1	19	95
<b>+25% Cutoff</b>	20	375	19	1	95
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results for Morphine Dip Card**

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	1	19	95
<b>+25% Cutoff</b>	20	375	19	1	95
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results for Morphine Split-Key Cup**

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	2	18	90
<b>+25% Cutoff</b>	20	375	18	2	90
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results for Morphine Easy Cup**

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	20	150	0	20	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	375	19	1	95
+50% Cutoff	20	450	20	0	100
+75% Cutoff	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results for Marijuana Cassette**

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.5	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37.5	1	19	95
+25% Cutoff	20	62.5	19	1	95
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

**Comparison between GC/MS and Lay Person Results for Marijuana Dip Card**

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.5	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37.5	0	20	10
+25% Cutoff	20	62.5	18	2	90
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

**Comparison between GC/MS and Lay Person Results for Marijuana Split-Key Cup**

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100



<b>-75% Cutoff</b>	20	12.5	0	20	100
<b>-50% Cutoff</b>	20	25	0	20	100
<b>-25% Cutoff</b>	20	37.5	1	19	95
<b>+25% Cutoff</b>	20	62.5	19	1	95
<b>+50% Cutoff</b>	20	75	20	0	100
<b>+75% Cutoff</b>	20	87.5	20	0	100

**Comparison between GC/MS and Lay Person Results for Marijuana Easy Cup**

% of Cutoff	Number of samples	Marijuana Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	12.5	0	20	100
<b>-50% Cutoff</b>	20	25	0	20	100
<b>-25% Cutoff</b>	20	37.5	1	19	95
<b>+25% Cutoff</b>	20	62.5	20	0	100
<b>+50% Cutoff</b>	20	75	20	0	100
<b>+75% Cutoff</b>	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 Methamphetamine Tests, CLUNGENE Morphine Tests and CLUNGENE Marijuana Tests are substantially equivalent to the predicate.