



Food and Drug Administration  
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August 30, 2016

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

Re: k161251

Trade/Device Name: Clungene Amphetamine Tests, Clungene Cocaine Tests, Clungene Oxazepam Tests  
Regulation Number: 21 CFR 862.3100  
Regulation Name: Amphetamine test system  
Regulatory Class: II  
Product Code: DKZ, DIO, JXM  
Dated: July 22, 2016  
Received: July 27, 2016

Dear Mr. 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 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)  
k161251

Device Name

Clungene Amphetamine Tests  
Clungene Cocaine Tests  
Clungene Oxazepam Tests

Indications for Use (Describe)

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

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

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

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

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

The test may yield preliminary positive results even when prescription drug Oxazepam is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxazepam in urine. 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.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

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: August 29, 2016
- 2. Submitter: Hangzhou Clongene Biotech Co., Ltd.  
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- 4. Device Name: CLUNGENE Amphetamine Tests  
CLUNGENE Cocaine Tests  
CLUNGENE Oxazepam Tests

Classification:

Product Code	CFR #	Panel
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
JXM	21 CFR, 862.3170 Benzodiazepine Test System	Toxicology
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology

- 5. Predicate Devices: K052115

The FIRST CHECK MULTI DRUG CUP Urine Test

- 6. Intended Use

CLUNGENE Amphetamine Tests are immunochromatographic assays for the qualitative determination of d-Amphetamine in human urine at cut-off concentration of 1000 ng/mL. The tests are available in a Cassette format, a Cup format, a Dip Card format, and a Split Key Cup 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. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

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

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

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

The test may yield preliminary positive results even when prescription drug Oxazepam is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxazepam in urine. 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. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

7. Device Description

The CLUNGENE Amphetamine Tests, CLUNGENE Cocaine Tests, and CLUNGENE Oxazepam Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Amphetamine, Cocaine and Oxazepam (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 Amphetamine Tests, CLUNGENE Cocaine Tests and CLUNGENE Oxazepam Tests and the predicate devices is provided in following tables.

**Table 1: Features Comparison of CLUNGENE Amphetamine 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-Amphetamine	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 Cocaine 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>	Cocaine	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 Oxazepam 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>	Oxazepam	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

### 9. Test Principle

The CLUNGENE Amphetamine Tests, CLUNGENE Cocaine Tests, and CLUNGENE Oxazepam Tests are rapid tests for the qualitative detection of d-Amphetamine, Cocaine and Oxazepam 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 Amphetamine 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+	28-/22+	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+	20-/30+	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+	29-/21+	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-

##### 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+	27-/23+	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+	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+	28-/22+	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+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-

#### **CLUNGENE Cocaine 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+	28-/22+	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+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

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+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	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+	24-/26+	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+	29-/21+	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+	21-/29+	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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	31-/19+	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-

**CLUNGENE Oxazepam 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+	24-/26+	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-

**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+	24-/26+	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-

**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+	30-/20+	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-

**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+	28-/22+	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+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
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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 Amphetamine, Cocaine and Oxazepam.

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

Calibrator	Cut-off (ng/mL)
d-Amphetamine	1000
Cocaine	300
Oxazepam	300

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 100µg/mL are summarized in the following tables. There were no differences observed for different devices.

**Amphetamine:**

4-Acetamidophenol	Diazepam	O-Hydroxyhippuric acid
(-)-Cotinine	Diclofenac	Oxalic acid
(-)-Isoproterenol	Diflunisal	Oxazepam
(-)-Y-Ephedrine	Digoxin	Oxolinic acid
(±)-Chlorpheniramine	Diphenhydramine	Oxycodone
(IR,2S)-(-)-Ephedrine	Doxylamine	Oxymetazoline
3-Hydroxytyramine	Ecgonine hydrochloride	Papaverine
Acetophenetidin	Ecgonine methylester	Penicillin-G
Acetylsalicylic acid	Erythromycin	Pentazocaine
Aminopyrine	Estrone-3-sulfate	Pentobarbital
Amitriptyline	Ethyl-p-aminobenzoate	Perphenazine
Amobarbital	Fenfluramine	Phencyclidine
Amoxicillin	Fenoprofen	Phenelzine
Ampicillin	Furosemide	Phenobarbital

Ascorbic acid	Gentisic acid	Phenylpropanolamine
Aspartame	Hemoglobin	Prednisolone
Atropine	Hydralazine	Prednisone
Benzilic acid	Hydrochlorothiazide	Procaine
Benzoic acid	Hydrocodone	Promazine
Benzoylcegonine	Hydrocortisone	Promethazine
Bilirubin	Ibuprofen	Quinidine
Brompheniramine	Imipramine	Quinine
Caffeine	Isoxsuprine	Ranitidine
Cannabidiol	Ketamine	Salicylic acid
Cannabinol	Ketoprofen	Secobarbital
Chloralhydrate	L-Ephedrine	Sulfamethazine
Chloramphenicol	L-Phenylephrine	Sulindac
Chlordiazepoxide	Labetalol	Temazepam
Chloroquine	Levorphanol	Tetracycline
Chlorothiazide	Loperamide	Tetrahydrocortisone
Chlorpromazine	Maprotiline	Tetrahydrozoline
Cholesterol	Meperidine	Thebaine
Clomipramine	Meprobamate	Thiamine
Clonidine	Methadone	Thioridazine
Cocaine hydrochloride	Methylphenidate	Tolbutamine
Codeine	Morphine-3-D-glucuronide	Triamterene
Cortisone	N-Acetylprocainamide	Trifluoperazine
Creatinine	Nalidixic acid	Trimethoprim
D-Norpropoxyphene	Naloxone	Trimipramine
D-Propoxyphene	Naltrexone	Tryptamine
D/L-Octopamine	Naproxen	Uric acid
D/L-Propranolol	Niacinamide	Verapamil
D/L-Thyroxine	Nifedipine	Zomepirac
D/L-Tyrosine	Norcodeine	$\beta$ -Estradiol
Deoxycorticosterone	Norethindrone	$\Delta^9$ -THC-COOH
Dextromethorphan	Noscapine	

## Cocaine

Acetaminophen	Diffunisal	Oxazepam
(-)-Cotinine	Digoxin	Oxolinic acid
(-)- $\Psi$ -Ephedrine	Diphenhydramine	Oxycodone

(±)-3,4-Methylene dioxymphetamine	Doxylamine	Oxymetazoline
(±)-Brompheniramine	Ecgonine methylester	p-Hydroxymethamphetamine
(±)-Chlorpheniramine	Erythromycin	Papaverine
(±)-Isoproterenol	Estrone-3-sulfate	Penicillin-G
3-Hydroxytyramine	Ethyl-p-aminobenzoate	Pentobarbital
Acetophenetidin	Fenoprofen	Perphenazine
Acetylsalicylic acid	Furosemide	Phencyclidine
Aminopyrine	Gentisic acid	Phenelzine
Amitriptyline	Hemoglobin	Phenobarbital
Amobarbital	Hydralazine	Phentermine
Amoxicillin	hydrochloride	Phenylpropanolamine
Ampicillin	hydrochloride(±)-3,4-Methylene-dioxymphetamine	Prednisolone
Apomorphine	Hydrochlorothiazide	Prednisone
Aspartame	Hydrocodone	Procaine
Atropine	Hydrocortisone	Promazine
Benzilic acid	Ibuprofen	Promethazine
Benzoic acid	Imipramine	Quinidine
Benzphetamine	Iproniazid	Quinine
Caffeine	Isoxsuprine	Ranitidine
Cannabidiol	Ketamine	Salicylic acid
Cannabinol	Ketoprofen	Secobarbital
Chloralhydrate	L-Ascorbic acid	Serotonin
Chloramphenicol	L-Phenylephrine	Sulfamethazine
Chlordiazepoxide	Labetalol	Sulindac
Chloroquine	Levorphanol	Temazepam
Chlorothiazide	Loperamide	Tetracycline
Chlorpromazine	Maprotiline	Tetrahydrocortisone 3 (β-D-glucuronide)
Cholesterol	Meperidine	Tetrahydrozoline
Clomipramine	Meprobamate	Thebaine
Clonidine	Methadone	Thiamine
Codeine	Methoxyphenamine	Thioridazine
Cortisone	Morphine Sulfate	Tolbutamide
Creatinine	Morphine-3-β-D-glucuronide	Triamterene
D-Norpropoxyphene	N-Acetylprocainamide	Trifluoperazine
D-Propoxyphene	Nalidixic acid	Trimethoprim
D-Pseudoephedrine	Naloxone	Trimipramine

D/L-Amphetamine Sulfate	Naltrexone	Tryptamine
D/L-Octopamine	Naproxen	Tyramine
D/L-Propranolol	Niacinamide	Uric acid
D/L-Tryptophan	Nifedipine	Verapamil
D/L-Tyrosine	Norcodeine	Zomepirac
Deoxycorticosterone	Norethindrone	$\beta$ -Estradiol
Dextromethorphan	Noscapine	$\beta$ -Phenylethylamine
Diazepam	O-Hydroxyhippuric acid	
Diclofenac	Oxalic acid	

### Oxazepam

4-Acetamidophenol	D-Propoxyphene	Naproxen
(-)-cotinine	D-Pseudoephedrine	Niacinamide
(-)-Y-Ephedrine	D/L-Amphetamine	Nifedipine
(+)-3,4-Methylenedioxy-amphetamine	D/L-Octopamine	Norethindrone
(+)-3,4-Methylenedioxy-methamphetamine	D/L-Propranolol	Noscapine
( $\pm$ )-Chlorpheniramine	D/L-Tryptophan	O-Hydroxyhippuric acid
( $\pm$ )-Chlorpheniramine	D/L-Tyrosine	Oxalic acid
( $\pm$ )-Isoproterenol	Dextromethorphan	Oxolinic acid
3-Hydroxytyramine	Diclofenac	p-Hydroxy- methamphetamine
Acetophenetidin	Diflunisal	Pentobarbital
Acetylsalicylic acid	Digoxin	Perphenazine
Aminopyrine	Diphenhydramine	Phencyclidine
Amitriptyline	Doxylamine	Phenelzine
Amorbarbital	Ecgonine hydrochloride	Phenobarbital
Amoxicillin	Ecgonine methylester	Phterminate
Ampicillin	Fenoprofen	Phenylpropanolamine
Apomorphine	Furosemide	Prednisone
Aspartame	Gentisic acid	Quinine
Atropine	Hemoglobin	Ranitidine
Benzillic acid	Hydrocortisone	Salicylic acid
Benzoic acid	Ibuprofen	Secobarbital
Benzoyllecgonine	Imipramine	Serotonin (5-Hydroxytyramine)

Benzphetamine	Iproniazid	Sertraline
Bilirubin	Isoxsuprine	Sulfamethazine
Brompheniramine	Ketamine	Sulindac
Caffeine	Ketoprofen	Tetrahydrocortisone 3 ( $\beta$ -D-glucuronide)
Caffeine	l-Ascorbic Acid	Tetrahydrozoline
Cannabidiol	L-Phenylephrine	Thiamine
Chloralhydrate	Labetalol	Thioridazine
Chloramphenicol	Loperamide	Tolbutamide
Chloroquine	Maprotiline	Triamterene
Chlorothiazide	Meperidine	Trifluoperazine
Chlorpromazine	Meprobamate	Trimethoprim
Cholesterol	Methadone	Tryptamine
Clomipramine	Methoxyphenamine	Tyramine
Clonidine	N-Acetylprocainamide	Uric acid
Cocaine hydrochloride	Nalidixic acid	Verapamil
Cortisone	Nalorphine	Zomepirac
Creatinine	Naloxone	$\beta$ -Phenylethylamine
D-Norpropoxyphene	Naltrexone	

#### 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.

#### AMP

Drugs	Concentration (ng/ml)	% Cross Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	50000	2%
D/L – Amphetamine	3000	33%
Phentermine	3000	33%
Hydroxyamphetamine	5000	20%
Methylenedioxyamphetamine (MDA)	5000	20%
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	< 1%
Methylenedioxyethylamphetamine (MDE)	Negative at 100000	< 1%
D-methamphetamine	Negative at 100000	< 1%

L-methamphetamine	Negative at 100000	< 1%
Ephedrine	Negative at 100000	< 1%
Pseudoephedrine	Negative at 100000	< 1%

## COC

Cocaine (COC)	Concentration(ng/ml)	% Cross-Reactivity
Benzoylcegonine	300	100
Cocaine HCl	780	38.5
Cocaethylene	12,500	2.4
Ecgonine HCl	32,000	0.9
Norcocaine	100,000	0.3

## BZO

Drugs	Concentration (ng/ml)	% Cross Reactivity
Oxazepam	300	100%
Alprazolam	200	150%
a-Hydroxyalprazolam	1250	24%
Bromazepam	1500	20%
Chlordiazepoxide	1500	20%
Clobazam	100	300%
Clonazepam	800	37%
Clorazepate dipotassium	200	150%
Delorazepam	1500	20%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2500	12%
Flunitrazepam	400	75%
Midazolam	12500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%

Nordiazepam	400	75%
Temazepam	100	300%
Triazolam	2500	12%
D/L-Lorazepam	1500	20%

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 Amphetamine Tests, the CLUNGENE Cocaine Tests and the CLUNGENE Oxazepam 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:

**Amphetamine**

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	20	20
	Negative	10	15	14	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	15	15	2	0

**Discordant Results of Amphetamine Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
Viewer A	AMP30	963	Positive
Viewer B	AMP59	1005	Negative
Viewer C	AMP59	1005	Negative
Viewer C	AMP78	1037	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	19	20
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

#### Discordant Results of Amphetamine Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer C	AMP30	963	Positive
Viewer A	AMP59	1005	Negative
Viewer B	AMP59	1005	Negative
Viewer B	AMP78	1037	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	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 of Amphetamine Split-Key Cup

Viewer	Sample Number	GC/MS Result	Split-Key Cup Viewer Results
Viewer B	AMP30	963	Positive
Viewer B	AMP59	1005	Negative
Viewer C	AMP59	1005	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	18	20
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	15	13	0	0

#### Discordant Results of Amphetamine Easy Cup

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer B	AMP30	963	Positive
Viewer C	AMP30	963	Positive
Viewer C	AMP18	952	Positive
Viewer A	AMP59	1005	Negative
Viewer A	AMP78	1037	Negative
Viewer B	AMP59	1005	Negative

#### Cocaine

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	20	20
	Negative	10	15	14	0	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	15	15	0	0

#### Discordant Results of Cocaine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
Viewer A	COC45	284	Positive
Viewer B	COC45	284	Positive
Viewer B	COC66	307	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	2	20	20
	Negative	10	15	13	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	15	15	1	0

**Discordant Results of Cocaine Panel Dip**

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
<b>Viewer B</b>	COC35	311	Negative
<b>Viewer C</b>	COC35	311	Negative
<b>Viewer A</b>	COC16	296	Positive
<b>Viewer A</b>	COC45	284	Positive

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	0	20	20
	Negative	10	15	15	0	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

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

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
<b>Viewer C</b>	COC45	284	Positive
<b>Viewer B</b>	COC35	311	Negative
<b>Viewer B</b>	COC66	307	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	18
	Negative	10	15	15	2	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 of Cocaine Easy Cup**

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
<b>Viewer B</b>	COC45	284	Positive
<b>Viewer A</b>	COC35	311	Negative
<b>Viewer A</b>	COC66	307	Negative
<b>Viewer B</b>	COC66	307	Negative
<b>Viewer C</b>	COC35	311	Negative

**Oxazepam**

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	19
	Negative	10	15	15	1	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 of Oxazepam Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Viewer Results
<b>Viewer B</b>	BZO77	291	Positive
<b>Viewer A</b>	BZO13	309	Negative
<b>Viewer B</b>	BZO26	311	Negative
<b>Viewer C</b>	BZO61	308	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	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 of Oxazepam Panel Dip**

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
<b>Viewer A</b>	BZO77	291	Positive
<b>Viewer C</b>	BZO57	298	Positive
<b>Viewer A</b>	BZO61	308	Negative

Split-Key Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and	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	20
	Negative	10	15	14	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	15	14	2	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	15	15	1	0

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

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
<b>Viewer A</b>	BZO57	298	Positive
<b>Viewer B</b>	BZO77	291	Positive
<b>Viewer A</b>	BZO26	311	Negative
<b>Viewer A</b>	BZO13	309	Negative
<b>Viewer B</b>	BZO26	311	Negative
<b>Viewer B</b>	BZO21	323	Negative
<b>Viewer C</b>	BZO61	308	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	1	18	20
	Negative	10	15	14	2	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 of Oxazepam Easy Cup

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer A	BZO57	298	Positive
Viewer B	BZO57	298	Positive
Viewer B	BZO77	291	Positive
Viewer B	BZO26	311	Negative
Viewer A	BZO61	308	Negative
Viewer A	BZO13	309	Negative
Viewer B	BZO13	309	Negative
Viewer C	BZO77	291	Positive
Viewer C	BZO26	311	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 Amphetamine Cassette

% of Cutoff	Number of samples	d-Amphetamine 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	0	20	100%
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

#### Comparison between GC/MS and Lay Person Results for Amphetamine Dip Card

% of Cutoff	Number of samples	d-Amphetamine 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	250	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	1	19	95
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100
+75% Cutoff	20	1750	20	0	100

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

% of Cutoff	Number of samples	d-Amphetamine 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%
+25% Cutoff	20	1250	18	2	90%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	d-Amphetamine 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	1	19	95%
+25% Cutoff	20	1250	18	2	90%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	Cocaine 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 Cocaine Dip Card**

% of Cutoff	Number of samples	Cocaine 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 Cocaine Split-Key Cup**

% of Cutoff	Number of samples	Cocaine 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 Cocaine Easy Cup**

% of Cutoff	Number of samples	Cocaine 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
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**Comparison between GC/MS and Lay Person Results for Oxazepam Cassette**

% of Cutoff	Number of samples	Oxazepam 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	0	20	100
<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 Oxazepam Dip Card**

% of Cutoff	Number of samples	Oxazepam 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	20	0	100
<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 Oxazepam Split-Key Cup**

% of Cutoff	Number of samples	Oxazepam 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	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 Oxazepam Easy Cup**

% of Cutoff	Number of samples	Oxazepam 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	18	2	90
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	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 Amphetamine Tests, CLUNGENE Cocaine Tests and CLUNGENE Oxazepam Tests are substantially equivalent to the predicate.