

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k153741

B. Purpose for Submission:

New Device

C. Measurand:

Methamphetamine, Marijuana and Morphine

D. Type of Test:

Qualitative Lateral Flow chromatographic immunoassay

E. Applicant:

Hangzhou Clongene Biotech Co., Ltd.

F. Proprietary and Established Names:

CLUNGENE Methamphetamine Tests
CLUNGENE Morphine Tests
CLUNGENE Marijuana Tests

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
DJC	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
LDJ	Class II	21 CFR 862.3870, Cannabinoids Test System	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below.

2. Indication(s) for 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- Δ 9-Tetrahydrocannabinol-9-COOH in human urine at cut-off concentration of 50 ng/mL. The calibrator is 11-Nor- Δ 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.

3. Special conditions for use statement(s):

For in vitro diagnostic use only, for over-the-counter use and for prescription use

4. Special instrument requirements:

Not applicable, the devices are visually-read single-use devices.

I. 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- Δ^9 -Tetrahydrocannabinol-9-COOH (target analytes) in human urine. The tests are available in cassette, dip card, easy cup and split key cup formats. Each test and format is available separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

The First Check Multi Drug Cup Urine Test

2. Predicate 510(k) number(s):

k052115

3. Comparison with predicate

Comparison of CLUNGENE Methamphetamine Tests and the Predicate Device

Item	Device - CLUNGENE Methamphetamine Tests	Predicate - K052115 First Check Multi Drug Cup Urine Test
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	d-Methamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Cassette, Dip Card, Easy Cup and Split Key Cup	Cup

Comparison of CLUNGENE Morphine Tests and the Predicate Device

Item	Device - CLUNGENE Morphine Tests	Predicate - K052115 First Check Multi Drug Cup Urine Test
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	Morphine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Cassette, Dip Card, Easy Cup and Split Key Cup	Cup

Comparison of CLUNGENE Marijuana Tests and the Predicate Device

Item	Device - CLUNGENE Marijuana Tests	Predicate - K052115 First Check Multi Drug Cup Urine Test
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator	11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Cassette, Dip Card, Easy Cup and Split Key Cup	Cup

K. Standard/Guidance Document Referenced (if applicable):

In Vitro Diagnostic Devices; Guidance for the Preparation of 510(k) Submission, HHS Publication FDA 97-4224

L. 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- Δ 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

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 this person did not take part in the sample testing. For each concentration, tests were performed by 12 operators in 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/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Device stability has been evaluated through accelerated and real-time studies. A transport simulation study was performed to test extreme shipping temperatures. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims that the devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45°C, real time stability determination at both 4°C and 30°C and transport simulation conditions at -20°C and 40°C.

This device has internal process controls. A colored line appearing in the control region confirms that sufficient sample volume and that the correct technique has been used. Users are informed not to interpret the test if a colored line failed to appear in the control region. External control materials are not supplied with these devices; however the labeling provides information on how to obtain quality control materials.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

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 for different devices.

CLUNGENE Methamphetamine Tests

4-Acetamidophenol	(-) Y Ephedrine	Penicillin-G
Acetophenetidin	Erythromycin	Pentazocaine
N-Acetylprocainamide	β -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	β -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	Δ^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	

CLUNGENE Morphine Tests

Acebutolol	(-) Y Ephedrine	Hydroxymethamphetamine
Acetopromazined-d-6	Erythromycin	Papaverine
4-Acetamidophenol	β -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	β -Phenyllethylamine
Amoxicillin	Hydrocortisone	L-Phenylephrine
Ampicillin	O-Hydroxyhippuric acid	β -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
(±) Chlorpheniramine	Methylenedioxymethamphetamine	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methylphenidate	Tetracycline
Cholesterol	Methyprylon	Tetrahydrozoline
Clomipramine	Nalorphine	Tetrahydrocortisone
Clonidine	Nalidixic acid	Tetrahydrocortisone-(5-D-glucuronide)
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	

CLUNGENE Marijuana Tests

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	Phenterrmine
Ampicillin	Hydrocodone	L-Phenylephrine
Ascorbic acid	Hydrocortisone	β-Phenylethylamine
D,L-Amphetamine	O-Hydroxyhippuric acid	β-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-Hydroxytyramine)
(±) Chlorpheniramine	(+/-) 3,4Methylenedioxyamphetamine	Sulfamethazine
Chlorpromazine	(+) 3,4 Methylenedioxymethamphetamine	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methyprylon	Tetracycline
Clomipramine	Morphine-3-β-D-glucuronide	Tetrahydrocortisone, 3
Clonidine	Nalorphine	Tetrahydrocortisone3 (5- D-glucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	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	

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

CLUNGENE Methamphetamine Tests (Cut-off=1000 ng/mL)	Result Positive at (ng/mL)	% Cross- Reactivity
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%

CLUNGENE Morphine Tests (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross- Reactivity
Morphine	300	100%
6-Acetylmorphine	300	100%
Codeine	300	100%
Ethylmorphine	6000	5%
Heroin	300	100%
Hydromorphone	3000	10%
Hydrocodone	5000	0.6%
Levorphanol	1500	20%
Oxycodone	3000	1%
Procaine	1500	2%
Thebaine	6000	5%
Morphine-3-glucuronide	>100000	<0.3%

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

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 (1.000, 1.003, 1.008, 1.014, 1.018, 1.020, 1.022, 1.025, 1.028, 1.030, 1.032, and 1.035) and urine samples with pH 4 to 9 (4.0, 5.0, 6.0, 7.0, 8.0, and 9.0) 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 and the sponsor claims that pH and specific gravity do not affect the results of the device.

f. Assay 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 Tests. This study supports the following claimed cut-off values for the devices.

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

2. Comparison studies:

a. Method comparison with predicate device:

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

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 (ng/mL)	Cassette Viewer Results
Viewer A	MET09	936	Positive
Viewer B	MET60	963	Positive
Viewer C	MET60	963	Positive
Viewer A	MET15	1010	Negative
Viewer B	MET15	1010	Negative
Viewer B	MET69	1100	Negative
Viewer C	MET15	1010	Negative
Viewer C	MET69	1100	Negative

Methamphetamine Panel Dip

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 (ng/mL)	Panel Dip Viewer Results
Viewer A	MET60	963	Positive
Viewer B	MET60	963	Positive
Viewer C	MET60	963	Positive
Viewer A	MET69	1100	Negative
Viewer B	MET15	1010	Negative

Methamphetamine Split-Key Cup

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	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 (ng/mL)	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

Methamphetamine Easy Cup

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 (ng/mL)	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

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 (ng/mL)	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

Morphine Panel Dip

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 (ng/mL)	Panel Dip Viewer Results
Viewer A	MOP43	314	Negative
Viewer B	MOP43	314	Negative

Morphine Split-Key Cup

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 (ng/mL)	Split Cup Viewer Results
Viewer A	MOP01	297	Positive
Viewer B	MOP01	297	Positive
Viewer A	MOP43	314	Negative

Morphine Easy Cup

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 (ng/mL)	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

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 C	Positive	0	0	2	24	16
	Negative	8	18	12	0	0

Discordant Results of Marijuana Cassette

Viewer	Sample Number	GC/MS Result (ng/mL)	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

Marijuana Panel Dip

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 (ng/mL)	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

Marijuana Split-Key Cup

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 C	Positive	0	0	0	23	16
	Negative	8	18	14	1	0

Discordant Results of Marijuana Split-Key Cup

Viewer	Sample Number	GC/MS Result (ng/mL)	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

Marijuana Easy Cup

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 (ng/mL)	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

b. Matrix comparison:

Not applicable. This device is for use with urine samples only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

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 in English only, 1 blind labeled sample and a device. Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions could be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

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

% 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	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 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	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 Methamphetamine Split-KeyCup

% 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	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 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	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 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	
-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	1	19	95
+25% Cutoff	20	375	1	1	95
+50% Cutoff	20	450	2	0	10
+75% Cutoff	20	525	2	0	10

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	
-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	1	19	95
+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 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	
-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	18	2	90
+50% Cutoff	20	450	20	0	100
+75% Cutoff	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	
-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
-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 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	
-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	20	0	100
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.