

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k161251

B. Purpose for Submission:

New device

C. Measurand:

Amphetamines, Cocaine, and Oxazepam in urine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Hangzhou Clongene Biotech Co., Ltd.

F. Proprietary and Established Names:

Clungene Oxazepam Tests

Clungene Amphetamine Tests

Clungene Cocaine Tests

G. Regulatory Information:

1. Regulation section:

21 CFR, 862.3170 Benzodiazepine Test System

21 CFR, 862.3100 Amphetamine Test System

21 CFR, 862.3250 Cocaine Test System

2. Classification:

All Class II

3. Product codes:

JXM, DKZ, DIO

4. Panel:

91- Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for use below

2. Indication(s) for 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.

3. Special conditions for use statement(s):

For Over-The-Counter (OTC) use.

For In Vitro Diagnostic Use only.

4. Special instrument requirements:

Not applicable, as the device is a visually-read single use device

I. 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 available in Cassette, Dip Card, Cup, and Split Key Cup formats. 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.

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:

Similarities		
Item	Predicate (k052115)	Candidate Device
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine	Same (but the number of drugs detected is different)
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
Cutoff	AMP 1000 ng/mL, COC 300 ng/mL, BZO 300 ng/mL	Same
Intended Users	Lay Users (Over the Counter)	Same
Differences		
Item	Predicate (k052115)	Candidate Device
Format	Cup	Cup, cassette, dip card
Analytes	Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, Phencyclidine, Benzodiazepines, Barbiturates, Methadone, Tricyclic Antidepressants, and Oxycodone	Amphetamines, cocaine, oxazepam

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

None referenced

L. Test Principle:

The CLUNGENE Amphetamine Tests, CLUNGENE Cocaine Tests, and CLUNGENE Oxazepam Tests utilize lateral flow immunochromatographic technology based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level,

will not saturate the binding sites of antibody coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control that appears in the control line region indicating that the sample has migrated properly on the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision study samples were prepared from negative urine samples spiked to nine different concentrations: +100%, +75%, +50%, +25%, cut off, -25%, -50%, -75% and -100% of the drug cutoff concentration for each drug. All sample concentrations were confirmed by GC/MS. All aliquots for testing were blind labeled by the same person who prepared the samples but who did not take part in sample testing. For each combination of analyte and format, three operators read 50 results at each of the nine concentrations, for a total of 1350 results per analyte per format. Results are summarized below.

Cassette Format

AMP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
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 Format

AMP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
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-

**Easy Cup
Format**

AMP	-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-

**Split Key
Cup**

AMP	-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-

**Cassette
Format**

COC	-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+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

**Dip card
Format**

COC	-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-

**Easy Cup
Format**

COC	-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-

**Split Key
Cup
Format**

COC	-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-

**Cassette
Format**

OXAZ	-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
Format**

OXAZ	-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-

**Easy Cup
Format**

OXAZ	-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-

Split Key Cup Format

OXAZ	-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-

b. Linearity/assay reportable range:

Not applicable. These devices are for qualitative use only.

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

Procedural controls are included in the test strip and device. A colored line appearing in the control zone is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with these tests; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow local, state, and federal guidelines to run the external controls.

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.

d. Detection limit:

See Precision/Reproducibility section in M.1.a above.

e. Analytical specificity:

Cross reactivity was evaluated by spiking the structurally similar compounds shown

below into drug free urine. The concentrations specified below represent the lowest concentration tested that produced a positive result. Testing was performed as instructed in the package insert and three lots of each device were evaluated. No differences were seen between formats. Results are summarized below.

Amphetamine

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	50000	2%
D/L – Amphetamine	3000	33%
Phentermine	3000	33%
Hydroxyamphetamine	5000	20%
MDA	5000	20%
MDMA	Negative at 100000	< 1%
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%

Cocaine

Potential cross-reactant	Highest Concentration producing a negative result (ng/ml)	% Cross Reactivity
Benzoylcegonine	300	100
Cocaine HCl	780	38.5
Cocaethylene	12500	2.4
Ecgonine HCl	32000	0.9
Norcocaine	100000	0.3

Oxazepam

Potential cross-reactant	Highest Concentration producing a negative result (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%

Potential interfering substances were evaluated by spiking the compounds below into drug free urine and urine with drug concentrations at +/-25% of the cutoff. Each compound was spiked at 100,000 ng/mL and tested on three lots of each device. No interference was detected.

Amphetamine		
4-Acetamidophenol	Diazepam	O-Hydroxyhippuric acid
(-)-Cotinine	Diclofenac	Oxalic acid
(-)-Isoproterenol	Diffunisal	Oxazepam
(-)-Y-Ephedrine	Digoxin	Oxolinic acid
(±)-Chlorpheniramine	Diphenhydramine	Oxycodone
(1R,2S)-(-)-Ephedrine	Doxylamine	Oxymetazoline

Amphetamine		
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
Benzoyllecgonine	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-Propanolol	Niacinamide	Verapamil

Amphetamine		
D/L-Thyroxine	Nifedipine	Zomepirac
D/L-Tyrosine	Norcodeine	β -Estradiol
Deoxycorticosterone	Norethindrone	Δ^9 -THC-COOH
Dextromethorphan	Noscapine	

Cocaine		
Acetaminophen	Diffunisal	Oxazepam
(-)-Cotinine	Digoxin	Oxolinic acid
(-)- Ψ -Ephedrine	Diphenhydramine	Oxycodone
($\pm$)-3,4-Methylene dioxymphetamine	Doxylamine	Oxymetazoline
($\pm$)-Brompheniramine	Ecgonine methylester	p-Hydroxymethamphetamine
($\pm$)-Chlorpheniramine	Erythromycin	Papaverine
($\pm$)-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($\pm$)-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

Cocaine		
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	β -Estradiol
Dextromethorphan	Noscapine	β -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

Oxazepam		
Amobarbital	Ecgonine hydrochloride	Phenobarbital
Amoxicillin	Ecgonine methylester	Phentermine
Ampicillin	Fenoprofen	Phenylpropanolamine
Apomorphine	Furosemide	Prednisone
Aspartame	Gentisic acid	Quinine
Atropine	Hemoglobin	Ranitidine
Benzilic 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
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	β-Phenylethylamine
D-Norpropoxyphene	Naltrexone	

To evaluate the effect of specific gravity, twelve drug free urine samples with specific gravities ranging from 1.000-1.035 were spiked with each drug to $\pm 25\%$ of the cutoff values. Three lots of each device were used to test all samples.

To evaluate the effects of pH, a negative urine pool was aliquoted and the pH of each aliquot was adjusted to 4.00 to 9.00, in increments of 1 pH unit. Three lots of each device were used to test all samples. The aliquots were then spiked with amphetamine, cocaine, or Oxazepam to concentrations 25% below and 25% above the cutoff concentrations.

The pH and specific gravity ranges tested did not affect the results from the device.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison samples consisted of 80 clinical samples (40 negative and 40 positive) for each drug. The samples were masked and randomized by a person who prepared the samples and who didn't take part in the sample testing. Operators were blinded to the sample identity. Each sample concentration of the drug was confirmed by GC-MS. The drug concentration ranges tested were as follows: drug-free, $\leq 50\%$ cut-off, -50% cut-off to cut-off, Cut-off to +50% cut-off, and $\geq 50\%$ cut-off, for each drug.

The above samples were tested using one lot of each format of the devices. Twelve (three for each format) laboratory assistants performed the test following the instructions for use. The obtained results were compared to the GC/MS results. The results are summarized 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 with Amphetamine Cassette

Viewer	GC/MS Result	Cassette Viewer Results
Viewer A	963	Positive
Viewer B	1005	Negative
Viewer C	1005	Negative
Viewer C	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 with Amphetamine Panel Dip

Viewer	GC/MS Result	Panel Dip Viewer Results
Viewer C	963	Positive
Viewer A	1005	Negative
Viewer B	1005	Negative
Viewer B	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	1	15	15	0	0
Viewer B	Positive	0	0	1	19	20
	Negative	1	15	14	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	1	15	15	1	0

Discordant Results with Amphetamine Split-Key Cup

Viewer	GC/MS Result	Split-Key Cup Viewer Results
Viewer B	963	Positive
Viewer B	1005	Negative
Viewer C	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 with Amphetamine Easy Cup

Viewer	GC/MS Result	Easy Cup Viewer Results
Viewer B	963	Positive
Viewer C	963	Positive
Viewer C	952	Positive
Viewer A	1005	Negative
Viewer A	1037	Negative
Viewer B	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 with Cocaine Cassette

Viewer	GC/MS Result	Cassette Viewer Results
Viewer A	284	Positive
Viewer B	284	Positive
Viewer B	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 with Cocaine Panel Dip

Viewer	GC/MS Result	Panel Dip Viewer Results
Viewer B	311	Negative
Viewer C	311	Negative
Viewer A	296	Positive
Viewer A	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 with Cocaine Split-Key Cup

Viewer	GC/MS Result	Split Cup Viewer Results
Viewer C	284	Positive
Viewer B	311	Negative
Viewer B	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	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	0	19	20
	Negative	10	15	15	1	0

Discordant Results with Cocaine Easy Cup

Viewer	Sample Number	GC/MS Result	Easy Cup Viewer Results
Viewer B	COC45	284	Positive
Viewer A	COC35	311	Negative
Viewer A	COC66	307	Negative
Viewer B	COC66	307	Negative
Viewer C	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	20
	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 with Oxazepam Cassette

Viewer	GC/MS Result	Cassette Viewer Results
Viewer B	291	Positive
Viewer A	309	Negative
Viewer B	311	Negative
Viewer C	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 with Oxazepam Panel Dip

Viewer	GC/MS Result	Panel Dip Viewer Results
Viewer A	291	Positive
Viewer C	298	Positive
Viewer A	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 with Oxazepam Split-Key Cup

Viewer	GC/MS Result	Split Cup Viewer Results
Viewer A	298	Positive
Viewer B	291	Positive
Viewer A	311	Negative
Viewer A	309	Negative
Viewer B	311	Negative
Viewer B	323	Negative
Viewer C	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 for Oxazepam Easy Cup

Viewer	GC/MS result	Easy Cup Viewer Results
Viewer A	298	Positive
Viewer B	298	Positive
Viewer B	291	Positive
Viewer B	311	Negative
Viewer A	308	Negative
Viewer A	309	Negative
Viewer B	309	Negative
Viewer C	291	Positive
Viewer C	311	Negative

b. Matrix comparison:

Not applicable

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 consumer study was performed at three testing sites with a total of 1680 test subjects, with diverse educational backgrounds representative of U.S. demographics. A total of 140 users tested each format of each analyte. The study was performed by spiking drug free urine sample pools with drug at concentrations of 0%, 25%, 50%, 75%, 125%, 150%, and 175% of each drug cutoff. Each participant received one blinded sample, one test device format, and one English language package insert for the device they were to test. The only instructions provided to users were the package inserts for the device being tested. Participants ranged in age from 21 to greater than 50 years of age. None of the participants had experience using drug testing products before.

Each person performed the test and filled out a questionnaire to evaluate the ease of use of the device. All of the users correctly answered the questions on the questionnaire and rated the clarity of the package insert as either “very clear” or “clear”. The participant test results were compared to GC/MS results and are summarized below.

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		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		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		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		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		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 Cocaine Dip Card

% of Cutoff	Number of samples	Cocaine Concentration by GC/MS (ng/mL)	Lay person results		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 Cocaine Split-Key Cup

% of Cutoff	Number of samples	Cocaine Concentration by GC/MS (ng/mL)	Lay person results		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 Cocaine Easy Cup

% of Cutoff	Number of samples	Cocaine Concentration by GC/MS (ng/mL)	Lay person results		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 Oxazepam Cassette

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		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	0	20	100
+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 Oxazepam Dip Card

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		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	20	0	100
+50% Cutoff	20	450	20	0	100
+75% Cutoff	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		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 Oxazepam Easy Cup

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		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	18	2	90
+50% Cutoff	20	450	20	0	100
+75% Cutoff	20	525	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.

R. Conclusion:

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