



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

September 25, 2014

POLYMED THERAPEUTICS, INC.
C/O JOE SHIA
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE., SUITE F
GAITHERSBURG MD 20877

Re: K142408

Trade/Device Name: FaStep Marijuana Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup);
FaStep Methamphetamine Test (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)

Regulation Number: 21 CFR 862.3870

Regulation Name: Cannabinoid test system

Regulatory Class: II

Product Code: LDJ, LAF

Dated: August 25, 2014

Received: August 28, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k142408

Device Name

FaStep Marijuana Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)

FaStep Methamphetamine Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)

Indications for Use (Describe)

FaStep Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-nor- Δ^9 -THC-9-COOH in human urine at a cut-off concentration of 50ng/mL. The test is available in a Strip format, a Panel Dip format, a Quick Cup format and a Turn-Key Split Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS 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. It is intended for over-the-counter and for prescription use.

FaStep Methamphetamine Tests are immunochromatographic assays for the qualitative determination of methamphetamine in human urine at a cut-off concentration of 1000 ng/mL. The test is available in a Strip format, a Panel Dip format, a Quick Cup format and a Turn-Key Split Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS 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. It is 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: September 23, 2014
2. Submitter: POLYMED THERAPEUTICS, INC
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4. Device Name: FaStep Marijuana Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)
FaStep Methamphetamine Tests (Strip, Panel Dip, Quick Cup, Turn-Key Split Cup)

Classification: Class II

Product Code	CFR #	Panel
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology
LAF	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

5. Predicate Devices: k052115
FIRST CHECK DIAGNOSTICS LLC

6. Intended Use:
FaStep Marijuana Tests are immunochromatographic assays for the qualitative determination of 11-nor- Δ^9 -THC-9-COOH in human urine at a cut-off concentration of 50ng/mL. The test is available in a Strip format, a Panel Dip format, a Quick Cup format and a Turn-Key Split Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS 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. It is intended for over-the-counter and for prescription use.

FaStep Methamphetamine Tests are immunochromatographic assays for the qualitative determination of methamphetamine in human urine at a cut-off

concentration of 1000 ng/mL. The test is available in a Strip format, a Panel Dip format, a Quick Cup format and a Turn-Key Split Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS 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. It is intended for over-the-counter and for prescription use.

7. Device Description:

Immunochromatographic assays for Marijuana and Methamphetamine Urine Tests use a lateral flow system for the qualitative detection of 11-nor- Δ^9 -THC-9-COOH and Methamphetamine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information:

A summary comparison of features of the FaStep Marijuana Test and FaStep Methamphetamine Test and the predicate devices is provided in Table 1 & Table 2.

Table 1: Features Comparison of FaStep Marijuana Test and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of 11-nor- Δ^9 -THC-9-COOH in human urine.	Same (but the number of drugs detected is different)
Calibrator	11-nor- Δ^9 -THC-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Panel Dip, Cup, and Turn-Key Split Cup	Cup

Table 2: Features Comparison of FaStep Methamphetamine Test and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of Methamphetamine in human urine.	Same (but the number of drugs detected is different)
Calibrator	Methamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Panel Dip, Cup, and Turn-Key Split Cup	Cup

9. Test Principle

These are rapid tests for the qualitative detection of 11-nor- Δ^9 -THC-9-COOH or Methamphetamine in urine samples. These are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific 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 cut-off-concentration because it will saturate all the binding sites of the antibody coated on the particles. A line should form in the control region of the test devices regardless of the presence of drug in the sample.

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 blind-labeled and randomized. For each concentration,

tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

THC Strip Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: THC1304001	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: THC1304002	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: THC1304003	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

THC Panel Dip Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSD1305001	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSD1305002	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSD1305003	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

THC Turn-Key Split Cup Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSCP1305004	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305005	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305006	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

THC Quick Cup Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSCP1305007	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305008	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305009	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

MET Strip Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MET1303001	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MET1303002	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MET1303003	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

MET Panel Dip Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSD1305001	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSD1305002	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSD1305003	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

MET Turn-Key Split Cup Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSCP1305004	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305005	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305006	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

MET Quick CUP Format

Result Drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot: MSCP1305007	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305008	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MSCP1305009	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 18 months based on the accelerated stability study at 50 °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 all Marijuana and Methamphetamine tests. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
FaStep Marijuana Test	11-nor- Δ^9 -THC-9-COOH	50
FaStep Methamphetamine Test	Methamphetamine	1000

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and to urine containing target drugs (11-nor- Δ^9 -THC-9-COOH or Methamphetamine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences observed for different formats.

THC:

4-Acetamidophenol	Erythromycin	Papaverine
Acetone	β-Estradiol	Penicillin-G
Acetophenetidin	Estrone-3-sulfate	Pentazocine
N-Acetylprocainamide	Ethanol	Pentobarbital
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Perphenazine
Albumin	Fenoprofen	Phencyclidine
Aminopyrine	Furosemide	Phenelzine
Amitriptyline	Gentisic acid	Pheniramine
Amobarbital	Glucose	Phenobarbital
Amoxicillin	Guaicol Glyceryl Ether	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
Ascorbic acid	Hydralazine	β-Phenylethylamine
D,L-Amphetamine	Hydrochlorothiazide	β-Phenyllethylamine
L-Amphetamine	Hydrocodone	Phenylpropanolamine
Apomorphine	Hydrocortisone	Prednisolone
Aspartame	O-Hydroxyhippuric acid	Prednisone
Atropine	3-Hydroxytyramine	Procaine
Benzilic acid	Ibuprofen	Promazine
Benzocaine	Imipramine	Promethazine
Benzoic acid	Iproniazid	D,L-Propanolol
Benzoylcegonine	(-) Isoproterenol	D-Propoxyphene
Benzphetamine	Isoxsuprine	D-Pseudoephedrine
Bilirubin	Ketamine	Quinidine
Brompheniramine	Ketoprofen	Quinine
Caffeine	Labetalol	Ranitidine
Chloralhydrate	Levorphanol	Riboflavin
Chloramphenicol	Loperamide	Salicylic acid
Chlordiazepoxide	Maprotiline	Secobarbital
Chlorothiazide	Meprobamate	Serotonin (5-Hydroxytyramine)
(+) Chlorpheniramine	Methadone	Sodium Chloride
(±) Chlorpheniramine	Methoxyphenamine	Sulfamethazine
Chlorpromazine	(+) 3,4-Methylenedioxyampheta mine	Sulindac
Chlorquine	(+)3,4-Methylenedioxymetha mphetamine	Temazepam
Cholesterol	Methylphenidate	Tetracycline
Clomipramine	Methypylon	Tetrahydrocortisone, 3 Acetate

Clonidine	Morphine-3-β-Dglucuronide	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Nalorphine	Tetrahydrozoline
Codeine	Naloxone	Thebaine
Cortisone	Nalidixic acid	Theophylline
(-) Cotinine	Naltrexone	Thiamine
Creatine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nicotine	Tolbutamine
Dexbrompheniramine	Nifedipine	Triamterene
Dextromethorphan	Norcodein	Trifluoperazine
Diazepam	(+)-Norephedrine	Trimethoprim
Diclofenac	Norethindrone	Trimipramine
Diffunisal	D-Norpropoxyphene	Tryptamine
Digoxin	Noscapine	D, L-Tryptophan
4-Dimethylaminoantipyrine	D,L-Octopamine	Tyramine
Diphenhydramine	Oxalic acid	D, L-Tyrosine
Dopamine	Oxazepam	Uric acid
Doxylamine	Oxolinic acid	Verapamil
Ecgonine hydrochloride	Oxycodone	Zomepirac
Ecgonine methylester	Oxymetazoline	
(-) Y Ephedrine	p-Hydroxymethamphetamine	

MET

4-Acetamidophenol	(1R,2S)-(-)-Ephedrine	Papaverine
Acetone	L-Ephedrine	Penicillin-G
Acetophenetidin	(-) Y Ephedrine	Pentazocaine
N-Acetylprocainamide	Erythromycin	Pentobarbital
Acetylsalicylic acid	β-Estradiol	Perphenazine
Albumin	Estrone-3-sulfate	Phencyclidine
Aminopyrine	Ethanol	Phenelzine
Amitriptyline	Ethyl-p-aminobenzoate	Phendimetrazine
Amobarbital	Fenfluramine	Pheniramine
Amoxicillin	Fenoprofen	Phenobarbital
Ampicillin	Furosemide	Phetoin
Ascorbic acid	Gentisic acid	L-Phenylephrine
Apomorphine	Glucose	β-Phenylethylamine
Aspartame	Guaiacol Glyceryl Ether	Phenylpropanolamine
Atropine	Hemoglobin	Prednisolone
Benzilic acid	Hydralazine	Prednisone
Benzocaine	Hydrochlorothiazide	Procaine
Benzoic acid	Hydrocodone	Promazine
Benzoyllecgonine	Hydrocortisone	Promethazine
Bilirubin	O-Hydroxyhippuric acid	D,L-Propanolol

Brompheniramine	3-Hydroxytyramine	Propiomazine
Caffeine	Ibuprofen	D-Propoxyphene
Cannabidiol	Imipramine	Quinidine
Cannabinol	(-) Isoproterenol	Quinine
Chloralhydrate	Isoxsuprine	Ranitidine
Chloramphenicol	Ketamine	Riboflavin
Chlordiazepoxide	Ketoprofen	Salicylic acid
Chlorothiazide	Labetalol	Secobarbital
(+)-Chlorpheniramine	Levorphanol	Serotonin
(±) Chlorpheniramine	Loperamide	Sodium Chloride
Chlorpromazine	Maprotiline	Sulfamethazine
Chlorquine	Meperidine	Sulindac
Cholesterol	Meprobamate	Temazepam
Clomipramine	Methadone	Tetracycline
Clonidine	Methylphenidate	Tetrahydrocortisone
Cocaine hydrochloride	Morphine-3-Dglucuronide	Tetrahydrozoline
Codeine	Nalidixic acid	Δ9-THC-COOH
Cortisone	Naloxone	Thebaine
(-) Cotinine	Naltrexone	Theophylline
Creatine	Naproxen	Thiamine
Creatinine	Niacinamide	Thioridazine
Deoxycorticosterone	Nicotine	D,L-Thyroxine
Dexbrompheniramine	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	(+)-Norephedrine	Trifluoperazine
Diclofenac	Norethindrone	Trimethoprim
Diflunisal	D-Norpropoxyphene	Trimipramine
Digoxin	Noscapine	Tryptamine
4-Dimethylaminoantipyrine	D,L-Octopamine	Tyramine
Diphenhydramine	Oxalic acid	D, L-Tyrosine
Dopamine	Oxazepam	Uric acid
Doxylamine	Oxolinic acid	Verapamil
Ecgonine hydrochloride	Oxycodone	Zomepirac
Ecgonine methylester	Oxymetazoline	

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 for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

THC (11-nor- Δ^9 -THC-9-COOH, Cut-off=50 ng/mL)	Result Positive at 50 ng/mL	% Cross-Reactivity 100%
11-nor- Δ^8 -THC-9-COOH	Positive at 30 ng/mL	167%
11-hydroxy- Δ^9 -Tetrahydrocannabinol	Positive at 50 ng/mL	100%
Δ^8 - Tetrahydrocannabinol	Positive at 15000 ng/mL	0.3%
Δ^9 - Tetrahydrocannabinol	Positive at 15000 ng/mL	0.3%
Cannabinol	Positive at 20000 ng/mL	0.25%
Cannabidiol	Positive at 100000 ng/mL	0.05%
11-nor- Δ^9 -THC-carboxy glucuronide	Positive at 25000 ng/mL	0.2%
(-)-11-nor-9-carboxy- Δ^9 -THC	Positive at 30 ng/mL	167%

MET (D-Methamphetamine, Cut-off=1000 ng/mL)	Result Positive at 1000 ng/mL	% Cross-Reactivity 100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	Positive at 10,000 ng/mL	10%
Procaine (Novocaine)	Positive at 60,000 ng/mL	1.7%
Trimethobenzamide	Positive at 20,000 ng/mL	5%
L-Methamphetamine	Positive at 10000 ng/mL	10%
Ranitidine (Zantac)	Positive at 50,000 ng/mL	2%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	Positive at 500 ng/mL	200%
Chloroquine	Positive at 50,000 ng/mL	2%
Ephedrine	Positive at 4,000 ng/mL	25%
Fenfluramine	Positive at 20,000 ng/mL	5%
p-Hydroxymethamphetamine	Positive at 10,000 ng/mL	10%
D-Amphetamine	>100000	Not detected

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 the cut-off level. These samples were tested using three batches of each device for all formats. 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 formats.

2. Comparison Studies

The method comparison studies for the FaStep Marijuana Test, and the FaStep Methamphetamine Test was performed in-house with three laboratory assistants for each format of the 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:

THC

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of THC Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	83698	46	Positive
Viewer B	83698	46	Positive
Viewer C	83698	46	Positive

Panel Dip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Viewer C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Discordant Results of THC Panel Dip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	83698	46	Positive
Viewer A	18881	53	Negative
Viewer B	83698	46	Positive

Turn-Key Split Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of THC Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	83698	46	Positive
Viewer B	18881	53	Negative
Viewer C	83698	46	Positive

Quick Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of THC Quick Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer B	37144	54	Negative
Viewer C	83698	46	Positive

MET

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of MET Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	17448	949	Positive
Viewer A	13563	1099	Negative
Viewer B	17448	949	Positive
Viewer B	90196	1002	Negative
Viewer C	17448	949	Positive

Panel Dip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Discordant Results of MET Panel Dip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	17448	949	Positive
Viewer A	90196	1002	Negative
Viewer B	17448	949	Positive
Viewer B	90196	1002	Negative

Turn-Key Split format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of MET Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	17448	949	Positive
Viewer A	90196	1002	Negative
Viewer B	17448	949	Positive
Viewer C	17448	949	Positive
Viewer C	90196	1002	Negative

Quick Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and cut-off)	Near Cut-off Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	0	14	25
	Negative	10	20	10	1	0

Discordant Results of MET Quick Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer B	17448	949	Positive
Viewer C	90196	1002	Negative

Lay-user study

A lay user study was performed at three intended user sites with 147 lay persons. They had diverse educational and professional backgrounds and ranged in age from 18 to >50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cut-off by spiking drugs 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. The results are summarized below:

Comparison of GC/MS and Lay Person Results for THC and MET Strip Formats

% Cut-off	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		11-nor- Δ^9 -THC-9-COOH	Methamphetamine	THC	MET	THC	MET
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	12	250	0+/21-	0+/21-	100	100
-50%	21	25	500	0+/21-	0+/21-	100	100
-25%	21	37	750	2+/19-	1+/20-	90.5	95.2
+25%	21	63	1250	21+/0-	20+/1-	100	95.2
+50%	21	75	1500	21+/0-	21+/0-	100	100
+75%	21	88	1750	21+/0-	21+/0-	100	100

Comparison of GC/MS and Lay Person Results for THC and MET Panel Dip Formats

% Cut-off	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		11-nor- Δ^9 -THC-9-COOH	Methamphetamine	THC	MET	THC	MET
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	12	250	0+/21-	0+/21-	100	100
-50%	21	25	500	0+/21-	0+/21-	100	100
-25%	21	37	750	2+/19-	1+/20-	90.5	95.2
+25%	21	63	1250	21+/0-	21+/0-	100	100
+50%	21	75	1500	21+/0-	21+/0-	100	100
+75%	21	88	1750	21+/0-	21+/0-	100	100

Comparison of GC/MS and Lay Person Results for THC and MET Turn-Key Split Cup Formats

% Cut-off	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		11-nor- Δ^9 -THC-9-COOH	Methamphetamine	THC	MET	THC	MET
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	12	250	0+/21-	0+/21-	100	100
-50%	21	25	500	0+/21-	0+/21-	100	100
-25%	21	37	750	1+/20-	1+/20-	95.2	95.2
+25%	21	63	1250	21+/0-	21+/0-	100	100
+50%	21	75	1500	21+/0-	21+/0-	100	100
+75%	21	88	1750	21+/0-	21+/0-	100	100

Comparison of GC/MS and Lay Person Results for THC and MET Quick Cup Formats

% Cut-off	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		11-nor- Δ^9 -THC-9-COOH	Methamphetamine	THC	MET	THC	MET
-100%	21	0	0	0+/21-	0+/21-	100	100

-75%	21	12	250	0+/21-	0+/21-	100	100
-50%	21	25	500	0+/21-	0+/21-	100	100
-25%	21	37	750	2+/19-	1+/20-	90.2	95.2
+25%	21	63	1250	21+/0-	21+/0-	100	100
+50%	21	75	1500	21+/0-	21+/0-	100	100
+75%	21	88	1750	21+/0-	21+/0-	100	100

Lay-users were also given surveys on the ease of understanding of 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 and method comparison of the devices, it's concluded that the FaStep Marijuana Test, and the FaStep Methamphetamine Test are substantially equivalent to the predicate.