July 17, 2026

Assure Tech., LLC
% Jenny Xia
Director
LSI International, Inc.
504e Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K261984
Trade/Device Name: AssureTech Quick Cup Tests;AssureTech Multi-drug Urine Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NFW , NGL , NFY , NFV , PTH , NGG , NGM , PTG , QAW , QBF
Dated: June 12, 2026
Received: June 12, 2026

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S
Digitally signed by JOSEPH A. KOTAREK -S
Date: 2026.07.17 13:46:03 -04'00'

Joseph Kotarek
Branch Chief for Toxicology
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261984

Device Name
AssureTech Quick Cup Tests
AssureTech Multi-drug Urine Test Cup

Indications for Use *(Describe)*
The AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL or 500 ng/mL or 300 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine(BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine(COC)	300 ng/mL or 150 ng/mL
EDDP	300 ng/mL
Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
Propoxyphene (PPX)	300 ng/mL
Morphine (MOR)	2000 ng/mL or 300 ng/mL
Methadone(MTD)	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Oxycodone (OXY)	100 ng/mL
Norfentanyl (NFYL)	5 ng/mL
Methamphetamine(MET)	1000 ng/mL or 500 ng/mL or 300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL
Tramadol (TML)	100 ng/mL
Marijuana (THC)	50 ng/mL or 20 ng/mL

The single or multi-test cup can include any combination of the analytes listed above. However, only one cut-off concentration can be included per analyte per device.
The test may yield positive results for the prescription drugs above when taken at or above prescribed doses. 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 or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

The AssureTech Multi-drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off level
Amphetamine(AMP)	d-Amphetamine	1000 ng/mL or 500 ng/mL or 300 ng/mL
Secobarbital (BAR)	Secobarbital	300 ng/mL
Buprenorphine(BUP)	BUP-3-D-Glucuronide	10 ng/mL
Oxazepam (BZO)	Oxazepam	300 ng/mL

Cocaine(COC)	Benzoylecgonine	300 ng/mL or 150 ng/mL
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Fentanyl (FYL)	Fentanyl	1 ng/mL
Ecstasy (MDMA)	3,4-Methylenediioxy-MET	500 ng/mL
Propoxyphene (PPX)	D-Propoxyphene	300 ng/mL
Morphine (MOR)	Morphine	2000 ng/mL or 300 ng/mL
Methadone(MTD)	Methadone	300 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Norfentanyl (NFYL)	Norfentanyl	5 ng/mL
Methamphetamine(MET)	Methamphetamine	1000 ng/mL or 500 ng/mL or 300 ng/mL
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL
Tramadol (TML)	Cis-Tramadol	100 ng/mL
Marijuana (THC)	11-nor-9-THC-9-COOH	50 ng/mL or 20 ng/mL

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device. It is for in vitro diagnostic use only.

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 or LC/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.

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

K261984

1. Date: July 12, 2026

2. Submitter: Assure Tech. LLC.
1521 Concord Pike, Suite 201
Wilmington, DE 19803

3. Contact person: Jenny Xia
LSI International Inc.
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

4. Device Name: AssureTech Quick Cup Tests
AssureTech Multi-drug Urine Test Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL 6-Monoacetylmorphine Buprenorphine Fentanyl Morphine Norfentanyl Oxycodone Tramadol	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methamphetamine Methylenedioxy-methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test	Toxicology (91)

		System	
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K252259

   AssureTech Quick Cup Tests

6. Indications for Use

   The AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

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Oxazepam (BZO)	300 ng/mL
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Marijuana (THC)	50 ng/mL or 20 ng/mL

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   The test may yield positive results for the prescription drugs above when taken at or above prescribed doses. 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 or LC/MS is the preferred confirmatory method.

   For in vitro diagnostic use only.

The AssureTech Multi-drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Calibrator**	**Cut-off level**
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EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Fentanyl (FYL)	Fentanyl	1 ng/mL
Ecstasy (MDMA)	3,4-Methylenediioxy-MET	500 ng/mL
Propoxyphene (PPX)	D-Propoxyphene	300 ng/mL
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Methamphetamine(MET)	Methamphetamine	1000 ng/mL or 500 ng/mL or 300 ng/mL
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL
Tramadol (TML)	Cis-Tramadol	100 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50 ng/mL or 20 ng/mL

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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 or LC/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.

7. Device Description

The AssureTech Quick Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana (target analytes) in human urine. The products are single-use in vitro diagnostic devices. Each test kit contains a Test Device and a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the AssureTech Quick Cup Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AssureTech Quick Cup Tests and the Predicate Devices

Item	Device	Predicate – K252259
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 and Cut-Off Values	Amphetamine (AMP): 500 ng/ml or 300 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 150 ng/ml Marijuana (THC):50 ng/ml or 20 ng/ml Methamphetamine (MET): 500 ng/ml or 300 ng/ml Morphine (MOR): 2000 ng/ml or 300ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml Fentanyl (FYL): 1ng/ml Norfentanyl (NFYL): 5ng/ml 6-Monoacetylmorphine (6-MAM): 10 ng/ml Tramadol (TML): 100 ng/ml	Same except that No AMP 1000, MET 1000, and COC 300
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
Intended Use	For over-the-counter	Same
Configurations	Cup	Same

9. Test Principle

The AssureTech Quick Cup Tests are rapid tests for the qualitative detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

The precision data were reported in the k180349 and k252259.

b. Stability

The devices are stable at 2-30 °C for 36 months based on the real time stability study at 2-30 °C.

c. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 50% below and 50% 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 or specified concentrations are summarized in the following table.

11-nor-9 carboxy THC (except for THC)	Hydrocortisone	Tetrahydrocortisone 3-acetate
3-Hydroxytyramine	Hydroxytyramine	Tetrahydrocortisone3-(β-Dglucuronide)
4-Bromo-2,5,Dimethoxyphenethylamine	Ibuprofen	Tetrahydrozoline
7-Aminoflunitrazepam	I-Cotinine	Thiamine
7-Aminonitrazepam	I-Erythromycin	Thioridazine
Acetaminophen	Imipramine (except for TCA)	Triamterene
Acetone (1000 mg/dL)	Isoproterenol	Trifluoperazine
Acetophenetidin	Isoxsuprine	Trifluoromethylphenyl- piperazine
Acetylsalicylic Acid (500 µg/mL)	Ketamine	Trimethoprim
Albumin (100 mg/dL)	Ketoprofen	Tryptamine
Albuterol	Labetalol	Tyramine
Aminopyrine	Lamotrigine	Urea (2000 mg/dL)
Amitriptyline (except for TCA)	Lidocaine	Uric Acid
Amlodipine besylate	Lisinopril	Valproic acid (250 µg/mL)
Amobarbital (except for BAR)	Loperamide	Venlafaxine
Amoxicillin	Loratidine	Verapamil
Ampicillin	Lorazepam (except for BZO)	Zolpidem
Apomorphine	LSD	Zolpidem Tartrate
Ascorbic Acid	L-thyroxine	Zomepirac
Aspartame	Maprotiline (except for TCA)	β-Estradiol

Aspirin	Meperidine	β-Hydroxybutyric Acid
Atropine	Meprobamate	Alpha Methadol (except for MTD)
Baclofen	Metformin	Cannabidiol
Benzilic acid	Methapyrilene	Carfentanil (except for FYL/NFYL)
Benzocaine	Methaqualone	Chloroquine (except for MET)
Benzoic Acid	Methoxyphenamine (except for AMP/MET)	Disopyramide (except for EDDP)
Benzoylecgonine (except for COC)	Methylphenidate	Doxylamine (except for MTD)
Benzylpiperiazine	Metoprolol	Procaine
Bilirubin	Metronidazole (300 µg/mL)	LAAM HCl (except for MTD)
Boric Acid (1%)	N-Acetylprocainamide	Trimethobenzamide (except for MET)
Bupropion	NaCl (40000 µg/mL)	Phenylpropanolamine
Caffeine (500 µg/mL)	Nalidixic Acid	L-phenylephrine
Carbamazepine	Naloxone (except for OXY)	THC (except for THC)
Carisoprodol	Naltrexone	Theophylline
Cetirizine	Naproxen	Rifampicin
Chloral hydrate	N-desmethyl Tapentadol	Magnesium
Chloramphenicol	Niacinamide	Desloratadine
Chlordiazepoxide (except for BZO)	Nicotine	Zaleplon
Chlorothiazide	Pentazocaine	Mifepristone
Chlorpheniramine	Ethyl-p-aminobenzoate	D,L-Epinephrine
Chlorpromazine	4-Acetamidophenol	L-Epinephrine
Cholesterol	Phenytoin	Levonorgestrel
Clofibrate	Prednisolone	Vitamin B2
Clomipramine (except for TCA)	Ethyl-p-aminobenzoate	Delorazepam (except for BZO)
Clonidine	Nicotinic Acid	Levothyroxine Sodium
Cortisone	Nifedipine	Quetiapine
Cotinine	Norethindrone	Telmisartan
Creatine Hydrate	Norpropoxyphene (except for PPX)	Loratadine
Creatinine	Norpseudoephedrine	Sertraline
Cyclobenzaprine (except for TCA)	Nortriptyline (except for TCA)	Pregablin
Cyclodextrin-r	Noscapine	Sildenafil Citrate
Cyproheptadine	Octopamine	Gabapentin
d,l-Isoproterenol	O-Hydroxyhippuric acid	Levofloxacin Hydrochloride
Demoxepam	Oxalic Acid (100 mg/dL)	Simvastatin
Deoxycorticosterone	Oxazepam (except for BZO)	Trazodone Hydrochloride
Desipramine (except for TCA)	Oxolinic acid	Fluoxetine Hydrochloride
Dextromethorphan	Oxymetazoline	Paliperidone
Diclofenac	Papaverine	Esomeprazole Magnesium
Diflunisal	Penicillin-G	PenicillinV Potassium
Digoxin	Pentazocine	Gatifloxacin
Dimethyl-aminoantipyrine	Perphenazine	Oxalinic acid
Diphenhydramine (except for TML)	Phencyclidine (except for PCP/TML)	Duloxetine
Diphenylhydantoin	Phenelzine	Omeprazole
DL-Tryptophan	Phenobarbital (except for BAR)	Aripiprazole
DL-Tyrosine	Phentermine (except for AMP)	Aminophylline
Dopamine	Phenylethylamine (except for MET)	Acyclovir
Doxepin (except for TCA)	Prednisone	7-Aminoclonazepam
Ecgonine methyl ester	Promazine (except for TCA/EDDP)	Atomoxetine
Ephedrine (except for MET)	Promethazine (except for BZO/EDDP/TCA)	Atorvastatin Calcium
Erythromycin	Propoxyphene (except for PPX)	Azithromycin
Estradiol	Propranolol	Benzphetamine
Estrone	Pseudoephedrine	Cefradine
Ethanol (1%)	Pyridoxine	Cephalexin
Fenfluramine (except for MET)	Pyrilamine	Ciprofloxacin Hydrochloride
Fenofibrate	Pyrogallol	Citalopram
Fenoprofen	Quinidine	Clarithromycin

Fluphenazine	Quinine	Clozapine
Fotemustine	Quinolinic Acid	Conjugated Estrogens
Furosemide	Ranitidine	Nitroglycerin
Galactose	r-Globulin	Olanzapine
Gamma Globulin (500 mg/dL)	Riboflavin	Captopril
Gemfibrozil	Salicylic Acid	D,L-Propanolol
Gentisic acid	Secobarbital (except for BAR)	Chloralhydrate
Glucose (3000 mg/dL)	Serotonin(5-Hydroxytyramine)	Deoxycorticosterone
Guaiacolglyceryl ether	Sodium Azide	Tolbutamide
Hemoglobin	Sufentanil Citrate	Iproniazid
Hexobarbital	Sulfamethazine	Loxapine succinate
Hydralazine	Sulindac	
Hydrochlorothiazide	Tetracycline	

d.Specificity

The specificity data were reported in the k180349 and k252259.

e. Effect of Urine Specific Gravity and Urine pH

The urine specific gravity and urine pH data were reported in the k180349 and k252259.

2. Comparison Studies

The method comparison data were reported in the k180349 and k252259

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons. 68 male and 72 female tested AssureTech Quick Cup Tests. They 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 drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/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.

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	1000	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
BAR	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BUP	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BZO	300	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90%	100%	100%
COC	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
EDDP	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
FYL	1	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MDMA	500	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
PPX	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MOP	2000	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
MTD	300	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90%	100%	100%
PCP	25	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OXY	100	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	100%	100%	100%
NFYL	5	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MET	1000	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
TCA	1000	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
6-MAM	10	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90%	100%	100%
TML	100	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
THC	50	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the device, it's concluded that the AssureTech Quick Cup Tests and AssureTech Multi-drug Urine Test Cup are substantially equivalent to the predicate.