



August 15, 2025

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

Re: K252259

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, NFF, PTH, NGG, NGM, PTG, QAW, QBF

Dated: July 18, 2025

Received: July 21, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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Date: 2025.08.15 08:03:32
-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

510(k) Number (if known)
K252259

Device Name

Assure Tech Quick Cup Tests;
Assure Tech 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)	500 ng/mL or 300 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
EDDP	300ng/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)	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

Configuration of the AssureTech Quick Cup Tests can consist of any combination of the above listed drug analytes. The test may yield positive results for the prescription drugs above when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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	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)	Benzoyllecgonine	150 ng/mL
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300ng/ml
Fentanyl (FYL)	Fentanyl	1 ng/mL
Ecstasy (MDMA)	3,4-Methylenedioxy-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	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

Configuration of the AssureTech Multi-drug Urine Test Cup can consist of any combination of the above listed drug analytes. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
K252259

1. Date: August 6, 2025
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 System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K243996

AssureTech Panel Dip Tests and 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:

Drug (Identifier)	Cut-off level
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Fentanyl (FYL)	1 ng/mL
Ecstasy (MDMA)	500 ng/mL
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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)	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

Configuration of the AssureTech Quick Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs above when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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	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)	Benzoyllecgonine	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-Methylenedioxy-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	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

Configuration of the AssureTech Multi-drug Urine Test Cup can consist of any combination of the above listed drug analytes. 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.

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 Panel Dip Tests and 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 – K243996
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 6-MAM and TML; No AMP 300, MET300, THC 20 and MOR2000
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	Dip Card and Cup

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

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 LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables only for Amphetamine (AMP300), Methamphetamine (MET300) and Tramadol (TML100). Data for Fentanyl (FYL) and Norfentanyl (NFYL) was reported in K243996. Data for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20) was reported in K201630. Data for Amphetamine (AMP500), Cocaine (COC150), and Methamphetamine (MET500) was reported in K181768. Data for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP300), Propoxyphene (PPX300), and Nortriptyline (TCA1000) was reported in K180349. Data for Oxazepam (BZO300), Methylenedioxy-methamphetamine (MDMA500), and Morphine (MOR300) was reported in K170049. Data for Phencyclidine (PCP25) and Marijuana (THC50) was reported in K161044. Data for Morphine (MOR2000) was reported in K153465. Data for Buprenorphine (BUP10) and Methadone (MTD300) was reported in K152025. Data for Secobarbital (BAR300) and Oxycodone (OXY100) was reported in K151211.

AMP300

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	30+/20-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	32+/18-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	34+/16-	50+/0-	50+/0-	50+/0-	50+/0-

MET300

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	35+/15-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	33+/17-	50+/0-	50+/0-	50+/0-	50+/0-

Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	36+/14-	50+/0-	50+/0-	50+/0-	50+/0-
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TML100

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	36+/14-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	34+/16-	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-

b. Stability

The devices are stable at 2-30 °C for 36 months based on the accelerated stability study at 55 °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. There were no differences observed for different devices.

11-nor-9 carboxy THC (Except for THC)	Diphenylhydantoin	Norpropoxyphene (except for PPX)
3-Hydroxytyramine	Disopyramide (except for EDDP)	Norpseudoephedrine
4-Bromo- 2,5,Dimethoxyphenethylamine	DL-Tryptophan	Nortriptyline (except for TCA)
7-Aminoclonazepam	DL-Tyrosine	Noscapine
7-Aminoflunitrazepam	Dopamine	O-Hydroxyhippuric acid
7-Aminonitrazepam	Doxepin (except for TCA)	Octopamine
Acetaminophen	Doxylamine (except for MTD)	Olanzapine
Acetone (1000 mg/dL)	Duloxetine	Omeprazole
Acetophenetidin	Ecgonine methyl ester	Oxalic Acid (100mg/dL)
Acetylsalicylic Acid (500 µg/mL)	Ephedrine (except for MET)	Oxalinic acid
Acyclovir	Erythromycin	Oxazepam (except for BZO)
Albumin(100 mg/dL)	Esomeprazole Magnesium	Oxolinic acid
Albuterol	Estradiol	Oxymetazoline
Alpha Methadol (except for MTD)	Estrone	Paliperidone
Aminophylline	Ethanol (1%)	Papaverine
Aminopyrine	Fenfluramine (except for MET)	Penicillin-G
Amitriptyline (except for TCA)	Fenofibrate	PenicillinV Potassium
Amlodipine besylate	Fenoprofen	Pentazocine
Amobarbital (except for BAR)	Fluoxetine Hydrochloride	Perphenazine
Amoxicillin	Fluphenazine	Phencyclidine (except for PCP/TML)
Ampicillin	Fotemustine	Phenelzine
Apomorphine	Furosemide	Phenobarbital (except for BAR)
Aripiprazole	Gabapentin	Phentermine (except for AMP)
Ascorbic Acid	Galactose	Phenylethylamine (except for MET)
Aspartame	Gamma Globulin (500mg/dL)	Phenylpropanolamine
Aspirin	Gatifloxacin	Prednisone
Atomoxetine	Gemfibrozil	Pregablin
Atorvastatin Calcium	Gentisic acid	Procaine
Atropine	Glucose (3000 mg/dL)	Promazine (except for TCA/EDDP)
Azithromycin	Guaiacolglyceryl ether	Promethazine (except for BZO/EDDP/TCA)
Baclofen	Hemoglobin	Propoxyphene (except for PPX)
Benzilic acid	Hexobarbital	Propranolol
Benzocaine	Hydralazine	Pseudoephedrine
Benzoic Acid	Hydrochlorothiazide	Pyridoxine
Benzoylecgonine (except for COC)	Hydrocortisone	Pyrilamine
Benzphetamine	Hydroxytyramine	Pyrogallol
Benzylpiperiazine	I-Cotinine	Quetiapine
Bilirubin	I-Erythromycin	Quinidine
Boric Acid (1%)	Ibuprofen	Quinine
Bupropion	Imipramine (except for TCA)	Quinolinic Acid
Caffeine (500 µg/mL)	Isoproterenol	r-Globulin

Cannabidiol	Isoxsuprine	Ranitidine
Captopril	Ketamine	Riboflavin
Carbamazepine	Ketoprofen	Rifampicin
Carfentanil (except for FYL/NFYL)	L-Epinephrine	Salicylic Acid
Carisoprodol	L-phenylephrine	Secobarbital (except for BAR)
Cefradine	L-thyroxine	Serotonin(5-Hydroxytyramine)
Cephalexin	LAAM HCl (except for MTD)	Sertraline
Cetirizine	Labetalol	Sildenafil Citrate
Chloral hydrate	Lamotrigine	Simvastatin
Chloramphenicol	Levofloxacin Hydrochloride	Sodium Azide
Chlordiazepoxide (except for BZO)	Levonorgestrel	Sufentanil Citrate
Chloroquine (except for MET)	Levothyroxine Sodium	Sulfamethazine
Chlorothiazide	Lidocaine	Sulindac
Chlorpheniramine	Lisinopril	Telmisartan
Chlorpromazine	Loperamide	Tetracycline
Cholesterol	Loratadine	Tetrahydrocortisone 3-acetate
Ciprofloxacin Hydrochloride	Loratidine	Tetrahydrocortisone3-(β -Dglucuronide)
Citalopram	Lorazepam (except for BZO)	Tetrahydrozoline
Clarithromycin	LSD	THC
Clofibrate	Magnesium	Theophylline
Clomipramine (except for TCA)	Maprotiline (except for TCA)	Thiamine
Clonidine	Meperidine	Thioridazine
Clozapine	Meprobamate	Trazodone Hydrochloride
Conjugated Estrogens	Metformin	Triamterene
Cortisone	Methapyrilene	Trifluoperazine
Cotinine	Methaqualone	Trifluoromethylphenyl- piperazine
Creatine Hydrate	Methoxyphenamine (except for AMP/MET)	Trimethobenzamide (except for MET)
Creatinine	Methylphenidate	Trimethoprim
Cyclobenzaprine (except for TCA)	Metoprolol	Tryptamine
Cyclodextrin-r	Metronidazole (300 ug/mL)	Tyramine
Cyproheptadine	Mifepristone	Urea (2000 mg/dL)
D,L-Epinephrine	N-Acetylprocainamide	Uric Acid
d,l-Isoproterenol	N-desmethyl Tapentadol	Valproic acid (250 ug/mL)
Delorazepam (except for BZO)	NaCl (40000 ug/mL)	Venlafaxine
Demoxepam	Nalidixic Acid	Verapamil
Deoxycorticosterone	Naloxone (except for OXY)	Vitamin B2
Desipramine (except for TCA)	Naltrexone	Zaleplon
Desloratadine	Naproxen	Zolpidem
Dextromethorphan	Niacinamide	Zolpidem Tartrate
Diclofenac	Nicotine	Zomepirac
Diflunisal	Nicotinic Acid	β -Estradiol
Digoxin	Nifedipine	β -Hydroxybutyric Acid
Dimethyl-aminoantipyrine	Nitroglycerin	
Diphenhydramine (except for TLM)	Norethindrone	

d. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Amphetamine (AMP300), Methamphetamine (MET300) and Tramadol (TML100). Data for Fentanyl (FYL) and Norfentanyl (NFYL) was reported in K243996. Data for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20) was reported in K201630. Data for Amphetamine (AMP500), Cocaine (COC150), and Methamphetamine (MET500) was reported in K181768. Data for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP300), Propoxyphene (PPX300), and Nortriptyline (TCA1000) was reported in K180349. Data for Oxazepam (BZO300), Methylenedioxy-methamphetamine (MDMA500), and Morphine (MOR300) was reported in K170049. Data for Phencyclidine (PCP25) and Marijuana (THC50) was reported in K161044. Data for Morphine (MOR2000) was reported in K153465. Data for Buprenorphine (BUP10) and Methadone (MTD300) was reported in K152025. Data for Secobarbital (BAR300) and Oxycodone (OXY100) was reported in K151211.

Amphetamine (Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
d-Amphetamine	300	100
l-Amphetamine	50000	0.6
Mephentermine hemisulfate salt	100000	0.3
3,4-Methylenedioxyamphetamine (MDA)	625	48
Phentermine	625	48
Paramethoxyamphetamine (PMA)	625	48
Paramethoxymethamphetamine (PMMA)	100000	0.3
Tyramine	100000	0.3
d,l-Amphetamine	600	50
d,l-Methamphetamine	>100000	<0.3
Pseudoephedrine	>100000	<0.3
Phenylephrine	>100000	<0.3
Phenylethylamine	>100000	<0.3
Hydroxyamphetamine	2000	15
β -Phenylethylamine	>100000	<0.3
p-Hydroxynorephedrine	>100000	<0.3
D,L-Norephedrine	>100000	<0.3
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	>100000	<0.3
d-Methamphetamine	>100000	<0.3
l-Methamphetamine	>100000	<0.3
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100000	<0.3
Ephedrine hydrochloride	>100000	<0.3
Phenylpropanolamine	>100000	<0.3
Benzphetamine	>100000	<0.3
L-Epinephrine	>100000	<0.3
D,L-Epinephrine	>100000	<0.3

Methamphetamine (Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
d-Methamphetamine	300	100
Chloroquine	7,500	4
(-)-Ephedrine	2,000	15
Fenfluramine	12,500	2.4
l-Methamphetamine	1,000	30
Mephentermine hemisulfate salt	31,250	0.96
MDEA	50,000	0.6
MDMA	313	95.85
PMMA	625	48
d,l-Methamphetamine	1250	24
p-Hydroxymethamphetamine	4000	7.5
(+/-)-Ephedrine	2000	15

d-Amphetamine	>100000	<0.3
d,l-Amphetamine	>100000	<0.3
l-Amphetamine	>100000	<0.3
Phenylephrine	>100000	<0.3
Phenylethylamine	>100000	<0.3
Pseudoephedrine	>100000	<0.3
d,l-(MDA)	>100000	<0.3
Phentermine	>100000	<0.3
Methoxyphenamine hydrochloride	2500	12
Trimethobenzamide	>100000	<0.3
Procaine hydrochloride	>100000	<0.3

Tramadol (Cutoff=100ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Tramadol	100	100
(+/-)Chlorpheniramine	50000	0.2
Dimenhydrinate	50000	0.2
Diphenhydramine	50000	0.2
Phencyclidine	50000	0.2
(+)-Chlorpheniramine	>100000	<0.1
Tramadol-N-Desmethyl	300	33.33
Tramadol-O-Desmethyl	5,000	2
Venlafaxine	>100000	<0.1
o-Desmethyl Venlafaxine	>100000	<0.1

e. 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 Amphetamine (AMP300), Methamphetamine (MET300) and Tramadol (TML100) at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off. There were no differences observed for different devices. Data for Fentanyl (FYL) and Norfentanyl (NFYL) was reported in K243996. Data for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20) was reported in K201630. Data for Amphetamine (AMP500), Cocaine (COC150), and Methamphetamine (MET500) was reported in K181768. Data for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP300), Propoxyphene (PPX300), and Nortriptyline (TCA1000) was reported in K180349. Data for Oxazepam (BZO300), Methylendioxy-methamphetamine (MDMA500), and Morphine (MOR300) was reported in K170049. Data for Phencyclidine (PCP25) and Marijuana (THC50) was reported in K161044. Data for Morphine (MOR2000) was reported in K153465. Data for Buprenorphine (BUP10) and Methadone (MTD300) was reported in K152025. Data for Secobarbital (BAR300) and Oxycodone (OXY100) was reported in K151211.

2. Comparison Studies

Method comparison studies for the AssureTech Quick Cup Tests were performed in-house with three laboratory assistants for the device. Operators ran unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Amphetamine (AMP300), Methamphetamine (MET300) and Tramadol

(TML100). Data for Fentanyl (FYL) and Norfentanyl (NFYL) was reported in K243996. Data for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20) was reported in K201630. Data for Amphetamine (AMP500), Cocaine (COC150), and Methamphetamine (MET500) was reported in K181768. Data for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP300), Propoxyphene (PPX300), and Nortriptyline (TCA1000) was reported in K180349. Data for Oxazepam (BZO300), Methylenedioxy-methamphetamine (MDMA500), and Morphine (MOR300) was reported in K170049. Data for Phencyclidine (PCP25) and Marijuana (THC50) was reported in K161044. Data for Morphine (MOR2000) was reported in K153465. Data for Buprenorphine (BUP10) and Methadone (MTD300) was reported in K152025. Data for Secobarbital (BAR300) and Oxycodone (OXY100) was reported in K151211.

AMP300		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Positive	0	0	1	24	16
	Negative	5	15	19	0	0
Operator 2	Positive	0	0	2	24	16
	Negative	5	15	18	0	0
Operator 3	Positive	0	0	1	23	16
	Negative	5	15	19	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 2	226	287.658	+
Operator 2, 3	173	292.420	+
Operator 3	054	300.145	-

MET300		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Positive	0	0	0	20	20
	Negative	4	13	23	0	0
Operator 2	Positive	0	0	2	18	20
	Negative	4	13	21	2	0
Operator 3	Positive	0	0	1	19	20
	Negative	4	13	22	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 2	084	263.912	+
Operator 2, 3	233	290.852	+

Operator 2, 3	072	300.124	-
Operator 2	139	306.361	-

TML100		Negative	Low	Near Cutoff	Near Cutoff	High Positive
			Negative by LC/MS (less than -50%)	Negative by LC/MS (Between -50% and cutoff)	Positive by LC/MS (Between the cutoff and +50%)	by LC/MS (greater than +50%)
Operator 1	Positive	0	0	2	19	20
	Negative	2	18	18	1	0
Operator 2	Positive	0	0	1	19	20
	Negative	2	18	19	1	0
Operator 3	Positive	0	0	0	19	20
	Negative	2	18	20	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	006	94.451	+
Operator 1, 2	109	98.345	+
Operator 1, 3	218	102.172	-
Operator 2	265	106.333	-

Lay-user study

A lay user study was performed at three intended user sites with 280 lay persons. 66 male and 74 female tested AssureTech Quick Cup Tests configuration 1; 87 male and 53 female tested AssureTech Quick Cup Tests configuration 2. 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.

The results summary for Configuration 1:

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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%
BAR	300	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%
BUP	10	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%
BZO	300	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%
COC	150	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%
EDDP	300	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%
FYL	1	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%
MDMA	500	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%
PPX	300	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%
MOP	2000	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%
MTD	300	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%
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	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%
NFYL	5	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%
MET	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%
TCA	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%
6-MAM	10	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%
TML	100	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%
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%

The results summary for Configuration 2:

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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%
BAR	300	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%
BUP	10	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%
BZO	300	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%
COC	150	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	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%
FYL	1	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%
MDMA	500	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%
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	300	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%
MTD	300	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%
PCP	25	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%
OXY	100	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%
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	300	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	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%
6-MAM	10	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%
TML	100	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%
THC	20	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	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.