

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

A. 510(k) Number:

k180349

B. Purpose for Submission:

Addition of EDDP, Nortriptyline, and d-Propoxyphene devices to a previously cleared device

C. Measurand:

Amphetamine, Marijuana, Cocaine, Methamphetamine, Morphine, Oxazepam, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, and d-Propoxyphene.

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Assure Tech. Co, Ltd.

F. Proprietary and Established Names:

AssureTech Panel Dip Tests

AssureTech Quick Cup Tests

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|----------------|--|-----------------|
| NFT | II | 21 CFR 862.3100, Amphetamine Test System | Toxicology (91) |
| NFW | II | 21 CFR 862.3870, Cannabinoids Test System | Toxicology (91) |
| NFY | II | 21 CFR 862.3250, Cocaine and Cocaine Metabolites Test System | Toxicology (91) |
| NGG | II | 21 CFR 862.3610, Methamphetamine Test System | Toxicology (91) |

| | | | |
|-----|--------------|---|--------------------|
| NFV | II | 21 CFR 862.3170, Benzodiazepine Test System | Toxicology (91) |
| PTH | II | 21 CFR 862.3150, Barbiturate Test System | Toxicology (91) |
| NGL | II | 21 CFR 862.3650, Opiate Test System | Toxicology (91) |
| NGM | unclassified | Enzyme Immunoassay Phencyclidine | Toxicology (91) |
| PTG | II | 21 CFR 862.3620, Methadone Test System | Toxicology (91) |
| QAW | II | 21 CFR 862.3910 Tricyclic Antidepressant Drugs Test System | Toxicology (91) |
| QBF | II | 21 CFR 862.3700 Propoxyphene Test System | Toxicology (91) |

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, and d-Propoxyphene in human urine at the cutoff concentrations of:

| <u>Drug (Identifier)</u> | <u>Cut-off level</u> |
|--------------------------------|-------------------------|
| Amphetamine | 1000 ng/mL |
| Oxazepam | 300 ng/mL |
| Cocaine | 300 ng/mL |
| Marijuana | 50 ng/mL |
| Methamphetamine | 1000 ng/mL |
| Morphine | 300 ng/mL or 2000 ng/mL |
| Oxycodone | 100 ng/mL |
| Secobarbital | 300 ng/mL |
| Buprenorphine | 10 ng/mL |
| Methylenedioxy-methamphetamine | 500 ng/mL |
| Phencyclidine | 25 ng/mL |
| Methadone | 300 ng/mL |
| EDDP | 300 ng/mL |
| Nortriptyline | 1000 ng/mL |
| d-Propoxyphene | 300 ng/mL |

Configuration of the AssureTech Panel Dip Tests and 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 Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone 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.

3. Special conditions for use statement(s):

For over-the-counter use.

4. Special instrument requirements:

Not applicable; this is a visually read single use device.

I. Device Description:

The AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline, and Propoxyphene (target analytes) in human urine. The tests are the first step in a two-step process. The test strips used in the AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are identical.

The AssureTech Panel Dip Tests comprise two items, a urine collection cup and the dip card with a plastic casing as the lateral flow device. The AssureTech Quick Cup Tests comprise a urine collection cup and a quick cup test with a lateral flow device that will start when the cap is screwed onto cup. Each test device is sealed with a desiccant in an aluminum pouch.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Rapid Single/multi-drug Test Cup, Rapid Single/multi-drug Test Dipcard

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

k153050

3. Comparison with predicate:

| Item | Candidate Devices: AssureTech Panel Dip Tests and Assure Tech Quick Cup Tests (k180349) | Predicate Device: Rapid Single/multi-drug Test Cup, Rapid Single/multi-drug Test Dipcard (k153050) |
|--|--|---|
| Indication(s) for Use | For the qualitative determination of drugs of abuse in human urine. | Same |
| Analyte and Cut- Off Values | Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO): 300 ng/ml Cocaine (COC): 300 ng/ml Marijuana (THC): 50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/mL or 2000 ng/ml Oxycodone (OXY): 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxymethamphetamine(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 | Same |
| Methodology | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same |
| Type of Test | Qualitative | Same |
| Specimen Type | Human Urine | Same |
| Intended Use | For over-the-counter use | Same |
| Configurations | Dip Card, Cup | Dip Card, Cup |

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

None referenced.

L. Test Principle:

The AssureTech Panel Dip Tests and AssureTech Quick Cup Tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If a target drug present in the urine specimen is below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on gold particles. The antibody-coated particles will then be captured by immobilized drug-conjugate in the test line region 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 (coated with anti-mouse antibodies) regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. The samples used in the precision studies were prepared by spiking drug into negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and who did not 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 for 2-ethylidene-1, 5-dimethyl, 3-diphenylpyrrolidine (EDDP), Nortriptyline (TCA), and Propoxyphene (PPX). The precision data for the remaining drugs of abuse devices were reported in k153465, k151211, k152025, k161044, and k170049.

EDDP

AssureTech Panel Dip Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 10-/40+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

AssureTech Quick Cup Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 10-/40+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

Nortriptyline

AssureTech Panel Dip Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 10-/40+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 10-/40+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

AssureTech Quick Cup Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 8-/42+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 8-/42+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

Propoxyphene

AssureTech Panel Dip Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 12-/38+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 11-/39+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

AssureTech Quick Cup Tests

| Lot Number | -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 1 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 8-/42+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 9-/41+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

b. Linearity/assay reportable range:

Not applicable, these devices are intended for qualitative use only.

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

The devices are stable at 4 - 30°C for 24 months based on accelerated and real-time stability studies. Real time stability studies are ongoing.

d. Detection limit:

Not applicable.

e. Analytical specificity:

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. For each target drug, drug metabolites and other related compounds were added to drug-free urine at different concentration levels, and the lowest concentration that resulted in a positive result was determined. The cross-reactivity result for each compound is listed below for EDDP, Nortriptyline, and Propoxyphene. The data for the remaining drugs of abuse devices were reported in k153465, k151211, k152025, k161044, and k170049. There were no differences in cross-reactivity observed for the AssureTech Panel Dip Tests and

AssureTech Quick Cup Tests, and the results are summarized in the below table.

| EDDP (Cut-off = 300 ng/mL) | Result Positive at (ng/mL) | % Cross-Reactivity |
|---------------------------------------|---------------------------------------|---------------------------|
| EDDP | 300 | 100% |
| EMDP | >100000 | <0.3% |
| Disopyramide | 75 | 400% |
| Methadone | >100000 | <0.3% |
| LAAM HCl | >100000 | <0.3% |
| Alpha Methadol | >100000 | <0.3% |
| Doxylamine | >100000 | <0.3% |

| Nortriptyline (Cut-off = 1000 ng/mL) | Result Positive at (ng/ml) | % Cross-Reactivity |
|---|---|---------------------------|
| Nortriptyline | 1000 | 100% |
| Amitriptyline | 750 | 133.3% |
| Clomipramine | 10000 | 10% |
| Desipramine | 200 | 500% |
| Doxepin | 1250 | 80% |
| Imipramine | 625 | 160% |
| Maprotiline | 2000 | 50% |
| Nordoxepin | 1000 | 100% |
| Promazine | 1500 | 66.7% |
| Promethazine | 25000 | 4% |
| Trimipramine | 3000 | 33.3% |
| Cyclobenzaprine Hydrochloride | 5000 | 20% |
| Norclomipramine | 3000 | 33.3% |

| Propoxyphene (Cut-off = 300 ng/mL) | Result Positive at (ng/ml) | % Cross-Reactivity |
|---|---------------------------------------|---------------------------|
| d-Propoxyphene | 300 | 100% |
| Norpropoxyphene | 333 | 90.1% |

Interference:

Potential interfering substances were added to drug-free urine and urine with target drug concentrations at 25% below and 25% above cut-off levels. These urine samples were tested using three lots of each device. The compounds in the following table were tested at a concentration of 100 µg/mL (albumin was tested at 100 mg/dL), and did not show positive or negative interference. There were no differences in interferences observed for the AssureTech Panel Dip Tests and AssureTech Quick Cup Tests, and the results are summarized in the below table.

| | | |
|----------------------|------------------------|---|
| Acetaminophen | Ecgonine methyl ester | D,L-Octopamine |
| Acetophenetidin | Erythromycin | Oxalic acid |
| N-Acetylprocainamide | β -Estradiol | Oxalinic acid |
| Albumin (100 mg/dL) | Fenoprofen | Oxymetazoline |
| Acetylsalicylic acid | Furosemide | Papaverine |
| Aminopyrine | Gentisic acid | Penicillin-G |
| Amoxicillin | Hemoglobin | Perphenazine |
| Ampicillin | Hydralazine | Phenelzine |
| Ascorbic Acid | Hydrochlorothiazide | Prednisone |
| Apomorphine | Hydrocortisone | DL-Propranolol |
| Aspartame | O-Hydroxyhippuric acid | D-Pseudoephedrine |
| Atropine | 3-Hydroxytyramine | Quinine |
| Benzylic acid | Ibuprofen | Ranitidine |
| Benzoic acid | Isoproterenol | Salicylic acid |
| Bilirubin | Isoxsuprine | Serotonin (5- Hydroxytyramine) |
| Chloralhydrate | Ketamine | Sulfamethazine |
| Chloramphenicol | Ketoprofen | Sulindac |
| Chlorothiazide | Labetalol | Tetrahydrocortisone, 3-acetate |
| Chlorpromazine | Loperamide | Tetrahydrocortisone 3-(β -D glucuronide) |
| Cholesterol | Maprotiline | Tetrahydrozoline |
| Clonidine | Meperidine | Thiamine |
| Cortisone | Meprobamate | Thioridazine |
| (-) Cotinine | Methoxyphenamine | Triamterene |
| Creatinine | Nalidixic acid | DL-Tyrosine |
| Deoxycorticosterone | Naloxone | Trifluoperazine |
| Dextromethorphan | Naltrexone | Trimethoprim |
| Diclofenac | Naproxen | D L-Tryptophan |
| Diffunisal | Niacinamide | Tyramine |
| Digoxin | Nifedipine | Uric acid |
| Diphenhydramine | Norethindrone | Verapamil |
| Disopyramide | Noscapine | Zomepirac |

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 (tested in increments of 1 pH unit) were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three lots of each device. For all devices, results were all positive for samples at 25% above cut-off and all negative for samples at 25% below cut-off. There were no differences in performance observed for the AssureTech Panel Dip Tests and AssureTech Quick Cup Tests.

f. Assay cut-off:

Please see section M.1.a. above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies for the AssureTech Panel Dip Tests and the AssureTech Quick Cup Tests were performed with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug per device. The samples were blind labeled and compared to LC/MS results. The results from each of the three operators for each format are presented in the tables below for EDDP, Nortriptyline, and Propoxyphene. The data for the remaining drugs of abuse were reported in k153465, k151211, k152025, k161044, and k170049.

EDDP AssureTech Panel Dip Tests

| Panel Dip | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cut-off) | Near Cutoff Positive by LC/MS (Between the cut-off and +50%) | High Positive by LC/MS (greater than +50%) |
|-----------|----------|----------|--|--|--|--|
| Viewer A | Positive | 0 | 0 | 2 | 14 | 25 |
| | Negative | 10 | 20 | 8 | 1 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 15 | 25 |
| | Negative | 10 | 20 | 10 | 0 | 0 |
| Viewer C | Positive | 0 | 0 | 1 | 14 | 25 |
| | Negative | 10 | 20 | 9 | 1 | 0 |

Discordant Results of EDDP AssureTech Panel Dip Tests

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|----------|---------------|--------------|-------------------------|
| Viewer A | 86905 | 295 | Positive |
| Viewer A | 36355 | 290 | Positive |
| Viewer C | 63254 | 295 | Positive |
| Viewer A | 24973 | 308 | Negative |
| Viewer C | 24082 | 307 | Negative |

EDDP AssureTech Quick Cup Tests

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

Discordant Results of EDDP AssureTech Quick Cup Tests

| Viewer | Sample Number | LC/MS Result | Quick Cup Viewer Results |
|----------|---------------|--------------|--------------------------|
| Viewer A | 47796 | 296 | Positive |
| Viewer B | 63254 | 295 | Positive |
| Viewer C | 36355 | 290 | Positive |
| Viewer B | 24082 | 307 | Negative |
| Viewer C | 24973 | 308 | Negative |

Nortriptyline AssureTech Panel Dip Tests

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

Discordant Results for Nortriptyline AssureTech Panel Dip Tests

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|----------|---------------|--------------|-------------------------|
| Viewer B | 50313 | 942 | Positive |
| Viewer B | 77063 | 1081 | Negative |

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|----------|---------------|--------------|-------------------------|
| Viewer C | 77063 | 1081 | Negative |

Nortriptyline AssureTech Quick Cup Tests

| Quick Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cut-off) | Near Cutoff Positive by LC/MS (Between the cut-off and +50%) | High Positive by LC/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 Nortriptyline AssureTech Quick Cup Tests

| Viewer | Sample Number | LC/MS Result | Quick Cup Viewer Results |
|----------|---------------|--------------|--------------------------|
| Viewer C | 50313 | 942 | Positive |
| Viewer A | 77063 | 1081 | Negative |
| Viewer B | 54803 | 1130 | Negative |

Propoxyphene AssureTech Panel Dip Tests

| Panel Dip | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cut-off) | Near Cutoff Positive by LC/MS (Between the cut-off and +50%) | High Positive by LC/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 | 0 | 15 | 25 |
| | Negative | 10 | 20 | 10 | 0 | 0 |

Discordant Results for AssureTech Propoxyphene Panel Dip Tests

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|----------|---------------|--------------|-------------------------|
| Viewer A | 31727 | 294 | Positive |
| Viewer B | 34150 | 298 | Positive |

Propoxyphene AssureTech Quick Cup Tests

| Quick Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cut-off) | Near Cutoff Positive by LC/MS (Between the cut-off and +50%) | High Positive by LC/MS (greater than +50%) |
|-----------|----------|----------|--|--|--|--|
| Viewer A | Positive | 0 | 0 | 0 | 14 | 25 |
| | Negative | 10 | 20 | 10 | 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 for Propoxyphene AssureTech Quick Cup Tests

| Viewer | Sample Number | LC/MS Result | Quick Cup Viewer Results |
|----------|---------------|--------------|--------------------------|
| Viewer B | 66995 | 287 | Positive |
| Viewer C | 34150 | 298 | Positive |
| Viewer A | 27051 | 359 | Negative |
| Viewer C | 27051 | 359 | Negative |

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

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

Lay-user Study

A lay user study was performed at three intended user sites with 310 lay persons using each device (AssureTech Panel Dip Tests and AssureTech Quick Cup Tests). The lay users 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 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. Each device containing test strips for all 15 drug analytes was tested. Results were similar between the AssureTech Panel Dip Tests and AssureTech Quick Cup Tests, and representative results are provided for the AssureTech Panel Dip Tests in the table below.

Comparison between LC/MS and Lay Person Results for Amphetamine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 248 | 0 | 20 |
| -50% Cut-off | 140 | 508 | 0 | 140 |
| -25% Cut-off | 20 | 752 | 1 | 19 |
| +25% Cut-off | 20 | 1255 | 19 | 1 |
| +50% Cut-off | 40 | 1506 | 40 | 0 |
| +75% Cut-off | 20 | 1748 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Barbiturates:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 73 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|--------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -50% Cut-off | 140 | 151 | 0 | 140 |
| -25% Cut-off | 20 | 223 | 1 | 19 |
| +25% Cut-off | 20 | 378 | 20 | 0 |
| +50% Cut-off | 40 | 456 | 40 | 0 |
| +75% Cut-off | 20 | 521 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Cocaine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 76 | 0 | 20 |
| -50% Cut-off | 140 | 154 | 0 | 140 |
| -25% Cut-off | 20 | 222 | 1 | 19 |
| +25% Cut-off | 20 | 377 | 20 | 0 |
| +50% Cut-off | 40 | 452 | 40 | 0 |
| +75% Cut-off | 20 | 528 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Buprenorphine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 2.6 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|--------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -50% Cut-off | 140 | 4.8 | 0 | 140 |
| -25% Cut-off | 20 | 7.2 | 2 | 18 |
| +25% Cut-off | 20 | 12.6 | 20 | 0 |
| +50% Cut-off | 40 | 15.4 | 40 | 0 |
| +75% Cut-off | 20 | 17.3 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Methamphetamine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 255 | 0 | 20 |
| -50% Cut-off | 140 | 496 | 0 | 140 |
| -25% Cut-off | 20 | 757 | 1 | 19 |
| +25% Cut-off | 20 | 1258 | 20 | 0 |
| +50% Cut-off | 40 | 1504 | 40 | 0 |
| +75% Cut-off | 20 | 1744 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Methadone:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | |
|---------------|-------------------|------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 73 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | |
|--------------|-------------------|------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -50% Cut-off | 140 | 155 | 0 | 140 |
| -25% Cut-off | 20 | 228 | 0 | 20 |
| +25% Cut-off | 20 | 377 | 19 | 1 |
| +50% Cut-off | 40 | 454 | 40 | 0 |
| +75% Cut-off | 20 | 528 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Morphine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 77 | 0 | 20 |
| -50% Cut-off | 140 | 155 | 0 | 140 |
| -25% Cut-off | 20 | 227 | 1 | 19 |
| +25% Cut-off | 20 | 371 | 20 | 0 |
| +50% Cut-off | 40 | 447 | 40 | 0 |
| +75% Cut-off | 20 | 521 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Oxycodone:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 20 | 0 |
| -75% Cut-off | 20 | 23 | 20 | 0 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|--------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -50% Cut-off | 140 | 53 | 0 | 140 |
| -25% Cut-off | 20 | 72 | 1 | 19 |
| +25% Cut-off | 20 | 128 | 19 | 1 |
| +50% Cut-off | 40 | 154 | 40 | 0 |
| +75% Cut-off | 20 | 171 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Phencyclidine:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 7 | 0 | 20 |
| -50% Cut-off | 140 | 11 | 0 | 140 |
| -25% Cut-off | 20 | 18 | 2 | 18 |
| +25% Cut-off | 20 | 32 | 20 | 0 |
| +50% Cut-off | 40 | 39 | 40 | 0 |
| +75% Cut-off | 20 | 44 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Marijuana:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 13 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|--------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -50% Cut-off | 140 | 24 | 0 | 140 |
| -25% Cut-off | 20 | 38 | 1 | 19 |
| +25% Cut-off | 20 | 64 | 19 | 1 |
| +50% Cut-off | 40 | 77 | 40 | 0 |
| +75% Cut-off | 20 | 86 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Benzodiazepines:

| % of Cut-off | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | |
|---------------|-------------------|------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 73 | 0 | 20 |
| -50% Cut-off | 140 | 146 | 0 | 140 |
| -25% Cut-off | 20 | 228 | 1 | 19 |
| +25% Cut-off | 20 | 377 | 20 | 0 |
| +50% Cut-off | 40 | 452 | 40 | 0 |
| +75% Cut-off | 20 | 519 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Methylenedioxymethamphetamine (MDMA):

| % of Cut-off | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | |
|---------------|-------------------|------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut- | 20 | 121 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | |
|--------------|-------------------|------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| off | | | | |
| -50% Cut-off | 140 | 253 | 0 | 140 |
| -25% Cut-off | 20 | 371 | 0 | 20 |
| +25% Cut-off | 20 | 628 | 19 | 1 |
| +50% Cut-off | 40 | 756 | 40 | 0 |
| +75% Cut-off | 20 | 879 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for EDDP

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 73 | 0 | 20 |
| -50% Cut-off | 170 | 148 | 0 | 170 |
| -25% Cut-off | 20 | 228 | 1 | 19 |
| +25% Cut-off | 20 | 373 | 19 | 1 |
| +50% Cut-off | 40 | 254 | 40 | 0 |
| +75% Cut-off | 20 | 523 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Nortriptyline

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut- | 20 | 254 | 0 | 20 |

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|--------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| off | | | | |
| -50% Cut-off | 170 | 505 | 0 | 170 |
| -25% Cut-off | 20 | 755 | 1 | 19 |
| +25% Cut-off | 20 | 1258 | 18 | 2 |
| +50% Cut-off | 40 | 1508 | 40 | 0 |
| +75% Cut-off | 20 | 1745 | 20 | 0 |

Comparison between LC/MS and Lay Person Results for Propoxyphene

| % of Cut-off | Number of samples | Drug Concentration by LC/MS (ng/mL) | Lay person Results | |
|---------------|-------------------|-------------------------------------|--------------------|-----------------|
| | | | No. of Positive | No. of Negative |
| -100% Cut-off | 20 | 0 | 0 | 20 |
| -75% Cut-off | 20 | 73 | 0 | 20 |
| -50% Cut-off | 170 | 154 | 0 | 170 |
| -25% Cut-off | 20 | 228 | 0 | 20 |
| +25% Cut-off | 20 | 378 | 19 | 1 |
| +50% Cut-off | 40 | 453 | 40 | 0 |
| +75% Cut-off | 20 | 523 | 20 | 0 |

Lay-users were also given surveys on the ease of understanding the package insert instructions and device use, and the results were found to be acceptable. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

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

O. Conclusion:

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