



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

July 16, 2015

NANTONG EGENS BIOTECHNOLOGY CO., LTD.
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG MD 20878

Re: K151557

Trade/Device Name: EGENS Urine Test Cup Morphine - Methamphetamine,
EGENS Urine Test DipCard Morphine - Methamphetamine

Regulation Number: 21 CFR 862.3640

Regulation Name: Morphine test system

Regulatory Class: II

Product Code: DNK, LAF

Dated: June 3, 2015

Received: June 10, 2015

Dear Joe Shia:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

Courtney H. Lias -S

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

Enclosure

Indications for Use

510(k) Number (if known)

k151557

Device Name

EGENS Urine Test Cup Morphine - Methamphetamine

Indications for Use (Describe)

The EGENS Urine Test Cup Morphine - Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively.

EGENS Urine Test Cup Morphine - Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in-vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

510(k) Number (if known)
k151557

Device Name
EGENS Urine Test DipCard Morphine - Methamphetamine

Indications for Use (Describe)

The EGENS Urine Test DipCard Morphine - Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively.

EGENS Urine Test DipCard Morphine - Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

~~For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.~~

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

1. Date: July 9, 2015
- Submitter: NANTONG EGENS BIOTECHNOLOGY, LTD.
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2. Contact person: Yan Cao
NANTONG EGENS BIOTECHNOLOGY, LTD.
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Nantong 226010, China
Phone: 86-0513-85920700
Email: cyhfhn@163.com
3. Device Name: EGENS Urine Test Cup Morphine – Methamphetamine
EGENS Urine Test DipCard Morphine – Methamphetamine
Classification: Class II

| Product Code | CFR # | Panel |
|--------------|--|------------|
| DNK | 21 CFR, 862.3640 Morphine Test System | Toxicology |
| LAF | 21 CFR, 862.3610 Methamphetamine Test System | Toxicology |

4. Predicate Devices: K142580
Chemtrue Multi-Panel DOA DipCard Tests

5. Intended Use:

The EGENS Urine Test Cup Morphine - Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively.

EGENS Urine Test Cup Morphine - Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

The EGENS Urine Test DipCard Morphine - Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively.

EGENS Urine Test DipCard Morphine - Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.

GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

6. Device Description:

EGENS Urine Test Morphine–Methamphetamine test uses immunochromatographic assays for Morphine and Methamphetamine. The test is a lateral flow system for the qualitative detection of Morphine and Methamphetamine in human urine. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

7. Substantial Equivalence Information

| Item | Device | Predicate – K142580 |
|-----------------------|--|---------------------------------------|
| Indication(s) for use | For the qualitative determination of drugs of abuse in human urine | Same |
| Methodology | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same |
| Results | Qualitative | Same |
| Specimen Type | Human urine | Same |
| Cut Off Values | Morphine: 300ng/ml Methamphetamine: 1000ng/ml | Same for Morphine and Methamphetamine |
| Configurations | Cup and Dipcard | Dipcard |
| Conditions for Use | Over-the-Counter & Prescription Use | Same |

8. Test Principle

The EGENS Urine Test Morphine–Methamphetamine test is a rapid test for the qualitative detection of Morphine and Methamphetamine 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 below its 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.

9. 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, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. For each concentration, tests were performed two runs per day by three operators for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Morphine (MOP) DipCard

| Result MOP | -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+ | 33+/17- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 31+/19- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 32+/18- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

B. For Methamphetamine (MET) DipCard

| Result MET | -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+ | 32+/18- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 30+/20- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 31+/19- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

C. For Morphine (MOP) Cup

| Result MOP | -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+ | 31+/19- | 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+ | 33+/17- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

D. For Methamphetamine (MET) Cup

| | | | | | | | | | |
|-----------------------------|------------------|-----------------|-----------------|-----------------|---------|-----------------|-----------------|-----------------|------------------|
| Result MET | -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+ | 30+/20- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 2 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 31+/19- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| Lot 3 | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 30+/20- | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

b. Linearity

Not applicable.

c. Stability

The EGENS Urine Test Morphine–Methamphetamine is stable at 4-30°C for 24 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

Cut-off studies were conducted using a total of 125 morphine samples and 125 methamphetamine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both morphine and methamphetamine. The following cut-off values for the test devices have been verified.

| Test | Calibrator | Cut-off (ng/ml) |
|-----------------------|-------------------|----------------------------|
| Morphine (MOP) | Morphine | 300 |
| Methamphetamine (MET) | D–Methamphetamine | 1000 |

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to urine containing target drugs (morphine or methamphetamine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the EGENS Urine Test DipCard (or Cup) Morphine–Methamphetamine by three different operators. There were no differences observed for different formats. Compounds that showed no interference at a concentration of 100µg/mL are summarized below:

Morphine

| | | |
|-----------------------|---------------------------------------|--|
| 4-Acetamidophenol | Ecgonine methylester | Oxolinic acid |
| Acetaminophen | (-)-Y-Ephedrine | Oxycodone |
| Acetophenetidin | Erythromycin | Oxymetazoline |
| N-Acetyprocainamide | Fenoprofen | Penicillin-G |
| Acetylsalicylate | Furosemide | Pentobarbital |
| Aminopyrine | Gentisic acid | Perphenazine |
| Amitypyline | Hemoglobin | Phencyclidine |
| Amorbarbital | Hydralazine | Phenelzine |
| Amoxicillin | Hydrochlorothiazide | Phenobarbital |
| Ampicillin | Hydrocortisone | L-Phenylephrine |
| l-Ascorbic Acid | O-Hydroxyhippuric acid | b-Phenylethylamine |
| Apormorphine | p-Hydroxy-methamphetamine | Phenylpropanotamine |
| Aspartame | 3-Hydroxytyramine | Prednisone |
| Atropine | Ibuprofen | Prednisolone |
| Benzilic acid | Imipramine | Procaine |
| Benzoic acid | (±)Isoproterenol | D.L-Propranolol |
| Benzoyllecgonine | Isoxsuprine | D-Propoxyphene |
| Bilirubin | Ketamine | D-Pseudoephedrine |
| Caffeine | Ketoprofen | Quinine |
| Cannabidiol | Labetalol | Ranitidine |
| Chloralhydrate | Loperamide | Salicylic acid |
| Chloramphenicol | Loxapine succinate | Secobarbital |
| Chlordiazepoxide | Maprotiline | Serotonin (5-Hydroxytyramine) |
| Chlorothiazide | Meperidine | Sulfamethazine |
| Chlorpromazine | Meprobamate | Sulindac |
| Chlorquine | Methadone | Temazepam |
| Cholesterol | Methoxyphenamine | Tetracycline |
| Clomipramine | (+)3,4-Methylenedioxy-amphetamine | Tetrahydrocortisone,3 Acetate |
| Clonidine | (+)3,4-Methylenedioxy-methamphetamine | Tetrahydrocortisone 3 (β-D glucuronide) |
| Cocaine hydrochloride | Nalidixic acid | Tetrahydrozoline |
| (-)cotinine | Nalorphine | Thiamine |
| Creatinine | Naloxone | Thioridazine |
| Dextromethlorphan | Naltrexone | D.L-Tyrosine |
| Deoxycorticosterone | Naproxen | Tolbutamide |
| Diazepam | Niacinamide | Triamterene |

| | | |
|------------------------|-------------------|-----------------|
| Diclofenac | Nifedipine | Trifluoperazine |
| Diflunisal | Norethindrone | Trimethoprim |
| Diaoxin | D-Norpropoxyphene | Tryptamine |
| Diphenhydramine | Noscapine | D.L-Tryptophan |
| Doxylamine | D.L-Octopamine | Tyramine |
| Ecgonine hydrochloride | Oxalic acid | Uric acid |
| β -Estradiol | Oxazepam | Verapamil |
| Estrone-3-sulfate | Papaverine | Zomepirac |

Methamphetamine

| | | |
|---------------------|-----------------------------------|--|
| 4-Acetamidophenol | Estrone-3-sulfate | Oxycodone |
| Acetaminophen | Erythromycin | Papaverine |
| Acetophenetidin | Fenoprofen | Penicillin-G |
| N-Acetyprocainamide | Furosemide | Pentobarbital |
| Acetylsalicylate | Gentisic acid | Perphenazine |
| Aminopyrine | Hemoglobin | Phencyclidine |
| Amitypyline | Hydralazine | Phenelzine |
| Amorbarbital | Hydrochlorothiazide | Phenobarbital |
| Amoxicillin | Hydrocodone | L-Phenylephrine |
| Ampicillin | Hydrocortisone | Phenylpropanotamine |
| l-Ascorbic Acid | O-Hydroxyhippuric acid | Prednisone |
| Apomorphine | 3-Hydroxytyramine | Prednisolone |
| Aspartame | Ibuprofen | Procaine |
| Atropine | Imipramine | D.L-Propranolol |
| Benzilic acid | (\pm)Isoproterenol | D-Propoxyphene |
| Benzoic acid | Isoxsuprine | D-Pseudoephedrine |
| Benzoyllecgonine | Ketamine | Quinine |
| Bilirubin | Ketoprofen | Ranitidine |
| Caffeine | Labetalol | Salicylic acid |
| Cannabidiol | Loperamide | Secobarbital |
| Chloralhydrate | Loxapine succinate | Serotonin (5-Hydroxytyramine) |
| Chloramphenicol | Maprotiline | Sulfamethazine |
| Chlordiazepoxide | Meperidine | Sulindac |
| Chlorothiazide | Meprobamate | Temazepam |
| Chlorpromazine | Methadone | Tetracycline |
| Cholesterol | Methoxyphenamine | Tetrahydrocortisone,3 Acetate |
| Clomipramine | Morphine-3- β -Dglucuronide | Tetrahydrocortisone 3 (β -D glucuronide) |
| Clonidine | Nalidixic acid | Tetrahydrozoline |

| | | |
|------------------------|-------------------|-----------------|
| Cocaine hydrochloride | Nalorphine | Thebaine |
| Codeine | Naloxone | Thiamine |
| (-)-cotinine | Naltrexone | Thioridazine |
| Creatinine | Naproxen | D.L-Tyrosine |
| Dextromethlorphan | Niacinamide | Tolbutamide |
| Deoxycorticosterone | Nifedipine | Triamterene |
| Diazepam | Norethindrone | Trifluoperazine |
| Diclofenac | D-Norpropoxyphene | Trimethoprim |
| Diflunisal | Noscapine | Triptamine |
| Diaoxin | D.L-Octopamine | D.L-Tryptophan |
| Diphenhydramine | Oxalic acid | Tyramine |
| Doxylamine | Oxazepam | Uric acid |
| Ecgonine hydrochloride | Oxolinic acid | Verapamil |
| β-Estradiol | Oxymetazoline | Zomepirac |
| Ecgonine methylester | | |

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (Morphine or Methamphetamine), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the EGENS Urine Test DipCard (or Cup) Morphine–Methamphetamine by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables. There were no differences observed for different formats.

| MOP (Morphine, Cut-off=300 ng/mL) | Result | % Cross-Reactivity |
|--|--------------------------|-------------------------------|
| Morphine | Positive at 300 ng/mL | 100% |
| Normorphine | Positive at 300 ng/mL | 100% |
| 6-Monoacetylmorphine | Positive at 300 ng/mL | 100% |
| Codeine | Positive at 300 ng/mL | 100% |
| Ethyl Morphine | Positive at 300 ng/mL | 100% |
| Heroin | Positive at 300 ng/mL | 100% |
| Hydrocodone | Positive at 3,000 ng/mL | 10% |
| Hydromorphone | Positive at 4,000 ng/mL | 8% |
| Morphine-3-β-d-glucuronide | Positive at 1,000 ng/mL | 30% |
| Thebaine | Positive at 15,000 ng/mL | 2% |

| | | |
|-------------|---------------------------|-------|
| Oxycodone | Negative at 100,000 ng/mL | <0.3% |
| Oxymorphone | Negative at 100,000 ng/mL | <0.3% |

| MET (D-Methamphetamine, Cut-off=1000 ng/mL) | Result | % Cross-Reactivity |
|--|--------------------------|-------------------------------|
| D-Methamphetamine | Positive at 1,000 ng/mL | 100% |
| (+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA) | Positive at 1,000 ng/mL | 100% |
| D/L-Methamphetamine | Positive at 1,000 ng/mL | 100% |
| p-Hydroxymethamphetamine | Positive at 1,000 ng/mL | 100% |
| D-Amphetamine | Positive at 50,000 ng/mL | 2% |
| L-Amphetamine | Positive at 50,000 ng/mL | 2% |
| Chloroquine | Positive at 50,000 ng/mL | 2% |
| (+/-)-Ephedrine | Positive at 20,000 ng/mL | 5% |
| L-Methamphetamine | Positive at 20,000 ng/mL | 5% |
| (+/-)3,4-Methylenedioxyamphetamine (MDA) | Positive at 1,000 ng/mL | 100% |
| (+/-)3,4-methylenedioxymethamphetamine(MDMA) | Positive at 2,000 ng/mL | 50% |
| β -Phenylethylamine | Positive at 34,000 ng/mL | 3% |
| Trimethobenzamide | Positive at 8,300 ng/mL | 12% |

g. Effect of Specific Gravity and Urine pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with either Morphine or Methamphetamine at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the EGENS Urine Test DipCard (or Cup) Morphine-Methamphetamine by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Morphine or Methamphetamine at 25% below and 25% above the corresponding cut-off levels. These samples were tested using three batches of the EGENS Urine Test DipCard (or Cup) Morphine - Methamphetamine by three different operators.

The device performance was found to not be affected by varying specific gravity and pH. There were no differences observed for different formats.

2. Comparison Studies

The method comparison for the EGENS Urine Test DipCard (Cup) Morphine - Methamphetamine was performed in-house with three laboratory assistants for each format. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results were compared to GC/MS results. The results are presented in the table below:

Morphine DipCard

| Group Operators | | Negative | Low Negative by GC/MS (less than -50%) | Near Cutoff Negative by GC/MS (Between -50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) |
|--------------------|----------|----------|--|---|---|--|
| | | | | | | |
| Viewer A | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |

Discordant table:

| Viewer | Sample number | GC/MS result | Viewer result |
|----------|---------------|--------------|---------------|
| Viewer A | 1019 | 308 | negative |
| Viewer A | 1040 | 305 | negative |
| Viewer B | 1019 | 308 | negative |
| Viewer B | 1040 | 305 | negative |
| Viewer C | 1019 | 308 | negative |
| Viewer C | 1040 | 305 | negative |

Morphine Cup

| Group Operators | | Negative | Low Negative by GC/MS (less than -50%) | Near Cutoff Negative by GC/MS (Between -50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) |
|--------------------|----------|----------|--|---|---|--|
| | | | | | | |
| Viewer A | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |

Discordant table:

| Viewer | Sample number | GC/MS result | Viewer result |
|----------|---------------|--------------|---------------|
| Viewer A | 1019 | 308 | negative |
| Viewer A | 1040 | 305 | negative |
| Viewer B | 1019 | 308 | negative |
| Viewer B | 1040 | 305 | negative |
| Viewer C | 1019 | 308 | negative |
| Viewer C | 1040 | 305 | negative |

Methamphetamine DipCard

| Group Operators | | Negative | Low Negative by GC/MS (less than -50%) | Near Cutoff Negative by GC/MS (Between -50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) |
|--------------------|----------|----------|--|---|---|--|
| | Viewer A | Positive | 0 | 0 | 0 | 12 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |

Discordant table:

| Viewer | Sample number | GC/MS result | viewer results |
|----------|---------------|--------------|----------------|
| Viewer A | 849 | 1045 | negative |
| Viewer A | 866 | 1040 | negative |
| Viewer B | 849 | 1045 | negative |
| Viewer B | 866 | 1040 | negative |
| Viewer C | 849 | 1045 | negative |
| Viewer C | 866 | 1040 | negative |

Methamphetamine Cup

| Group Operators | | Negative | Low Negative by GC/MS (less than -50%) | Near Cutoff Negative by GC/MS (Between -50% and cutoff) | Near Cutoff Positive by GC/MS (Between the cutoff and +50%) | High Positive by GC/MS (greater than +50%) |
|--------------------|----------|----------|--|---|---|--|
| | Viewer A | Positive | 0 | 0 | 0 | 12 |
| | Negative | 10 | 18 | 12 | 2 | 0 |

| | | | | | | |
|----------|----------|----|----|----|----|----|
| Viewer B | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 12 | 26 |
| | Negative | 10 | 18 | 12 | 2 | 0 |

Discordant table:

| Viewer | Sample number | GC/MS result | viewer results |
|----------|---------------|--------------|----------------|
| Viewer A | 849 | 1045 | negative |
| Viewer A | 866 | 1040 | negative |
| Viewer B | 849 | 1045 | negative |
| Viewer B | 866 | 1040 | negative |
| Viewer C | 849 | 1045 | negative |
| Viewer C | 866 | 1040 | negative |

Lay-user study

A lay user study was performed at three intended user sites with 560 lay persons, of which, 80 tested for drug-free samples, 240 for morphine samples, 240 for methamphetamine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

| DipCard format | | Number of samples | OTC user | | % Agreement With GC/MS |
|-----------------|---------------|-------------------|----------|----------|------------------------|
| Drug | Concentration | | Negative | Positive | |
| Drug -free | -100% | 20 | 20 | 0 | 100% |
| Morphine | -75% | 20 | 20 | 0 | 100% |
| | -50% | 20 | 20 | 0 | 100% |
| | -25% | 20 | 18 | 2 | 90% |
| | +25% | 20 | 2 | 18 | 90% |
| | +50% | 20 | 0 | 20 | 100% |
| | +75% | 20 | 0 | 20 | 100% |
| Drug -free | -100% | 20 | 20 | 0 | 100% |
| Methamphetamine | -75% | 20 | 20 | 0 | 100% |
| | -50% | 20 | 20 | 0 | 100% |
| | -25% | 20 | 18 | 2 | 90% |
| | +25% | 20 | 2 | 18 | 90% |
| | +50% | 20 | 0 | 20 | 100% |
| | +75% | 20 | 0 | 20 | 100% |

| Cup format | | Number of samples | OTC user | | % Agreement With GC/MS |
|-----------------|---------------|-------------------|----------|----------|------------------------|
| Drug | Concentration | | Negative | Positive | |
| Drug -free | -100% | 20 | 20 | 0 | 100% |
| Morphine | -75% | 20 | 20 | 0 | 100% |
| | -50% | 20 | 20 | 0 | 100% |
| | -25% | 20 | 18 | 2 | 85% |
| | +25% | 20 | 2 | 18 | 85% |
| | +50% | 20 | 0 | 20 | 100% |
| | +75% | 20 | 0 | 20 | 100% |
| Drug -free | -100% | 20 | 20 | 0 | 100% |
| Methamphetamine | -75% | 20 | 20 | 0 | 100% |
| | -50% | 20 | 20 | 0 | 100% |
| | -25% | 20 | 18 | 2 | 85% |
| | +25% | 20 | 2 | 18 | 85% |
| | +50% | 20 | 0 | 20 | 100% |
| | +75% | 20 | 0 | 20 | 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 the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

Not applicable.

10. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that EGENS Urine Test DipCard Morphine –Methamphetamine and EGENS Urine Test Cup Morphine – Methamphetamine are substantially equivalent to the predicate.