



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

April 15, 2016

CORETESTS, INC.  
ERIC SUN  
REGULATORY AFFAIRS SCIENTIST  
6190 YARROW DRIVE  
CARLSBAD, CA 92011

Re: K152590

Trade/Device Name: ACCU NEWS Drug Test Card/Urine Cup  
Regulation Number: 21 CFR 862.3100  
Regulation Name: Amphetamine Test System  
Regulatory Class: II  
Product Code: DKZ, DJC, DJG, DIO, and LDJ  
Dated: March 11, 2016  
Received: March 16, 2016

Dear Eric Sun:

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 regulation (21 CFR Part 801), 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" (21CFR 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)  
K152590

Device Name  
ACCU NEW® Drug Screening Test Card  
ACCU NEW® Drug Screening Urine Cup

Indications for Use (Describe)

The ACCU NEW® Drug Screening Test Card/Urine Cup are immunochromatographic assays for the qualitative determination of the drugs/drug metabolites in human urine. The test cutoff concentrations and the compounds the tests are calibrated to are as follows:

| Analyte         | Abbreviation | Calibrator          | Cutoff (ng/ml) |
|-----------------|--------------|---------------------|----------------|
| Amphetamine     | AMP          | d-Amphetamine       | 1000           |
| Methamphetamine | MET          | d-Methamphetamine   | 1000           |
| Morphine        | MOP          | Morphine            | 300            |
| Cocaine         | COC          | Benzoylcegonine     | 300            |
| Marijuana       | THC          | 11-Nor-9-THC-9-COOH | 50             |

The ACCU NEWS® Drug Screening Test Card /Urine Cup can consist of any combination of the drug analytes listed above.

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

The device provides only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be exercised for any drugs of abuse test results, particularly when preliminary results are positive.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510k Summary

### A. Submitter Information

Coretests Inc.

6190 Yarrow Drive, Carlsbad, CA 92011, USA.

Phone Number: 858-333-1122

Contact Person: Eric Sun (Regulatory Affairs Scientist)

Summary Prepared on March 11, 2016

### B. Trade Name, common name, classification name

*Trade Name:* ACCU NEWS® Drug Screening Test Card/Urine Cup containing one to five of the following drug of abuse test(s) in each device: Amphetamine, Methamphetamine, Morphine, Cocaine, & Marijuana

*Common Name:* Qualitative Lateral Flow Immunoassay

*Classification:* Class II

*Panel:* Toxicology 91

| Drug of Abuse   | Product Code | Regulation Section   |
|-----------------|--------------|--|
| Amphetamine     | DKZ          | 21 CFR 862.3100, Amphetamine Test System                     |
| Methamphetamine | DJC          | 21 CFR 862.3610, Methamphetamine Test System                 |
| Morphine        | DJG          | 21 CFR 862.3640, Morphine Test System                        |
| Cocaine         | DIO          | 21 CFR 862.3250, Cocaine and Cocaine Metabolites Test System |
| Marijuana       | LDJ          | 21 CFR 862.3870, Cannabinoids Test System                    |

### C. Predicate Device

K061718 Innovacon® Spectrum II Test Card/Test Card with Integrated Cups

### D. Device Description

ACCU NEWS® Drug Screening Test Card/Urine Cup is based on the principle of highly specific immunochemical reactions between antigens and antibodies. The devices utilize a competitive immunoassay in which a drug-protein conjugate immobilized on a nitrocellulose membrane competes with the drug target present in human urine for limited binding sites presented in colloidal gold-labeled mouse monoclonal antibody. The presence of a color band at a test region (coated with drug-protein conjugate) indicates a

negative result for that particular test. The absence of a color band at the test region indicates presumptive positive result for that particular test.

A color band at the control region, which was coated with goat anti-mouse polyclonal antibody, should always appear regardless of the presence of the drug or its metabolites. The presence of the control band during testing serves as a built-in procedural control, indicating the completion of the test and validity of the operation.

There are two formats of the test device, and both of them operate on the same basic principle. ACCU NEWS® Drug Screening Test Card device consists of individual test strips encased in a protective plastic case, and the device can detect up to 5 drugs/drug metabolites simultaneously. The ACCU NEWS® Drugs of Abuse Screening Urine Cup consists of the assembled test card integrated into a sample collection cup. Both formats are single-use, in vitro diagnostic devices.

Test results interpretation:

Negative: Two pink lines appear, one in the control region and the other in the test region. Regardless of the color intensity, any line formed in the test region, even if it is faint, the result is considered negative.

Positive: Only one pink line appears in the control region, and no line appears in the test region.

Invalid: If no line appears in the control region, the test result is invalid regardless of the absence or presence of the test line.

**E. Intended Use**

Coretests Inc.'s ACCU NEWS® Drug Screening Test Card/Urine Cup is a qualitative lateral flow for screening drugs/drug metabolites in human urine to aid detection of drugs of abuse. The test devices are for both prescription and over-the-counter (OTC) use.

**F. Summary of the technological characteristics of your device compared to the predicate device**

| <b>Similarities and Differences</b> |                          |                                       |
|-------------------------------------|--------------------------|---------------------------------------|
| <i>Feature</i>                      | <i>Candidate Devices</i> | <i>Predicate Devices</i><br>(K061718) |

|                                    |   |  |
|------------------------------------|---|--|
| <b>Intended Use</b>                | For detection of drugs/drug metabolites in human urine to screen for drugs of abuse.              | Same   |
| <b>Specimen</b>                    | Human urine   | Same   |
| <b>Results</b>                     | Qualitative   | Same   |
| <b>Methodology</b>                 | Competitive Lateral Flow Immunoassay  | Same   |
| <b>Intended Users</b>              | Prescription and over-the-counter (OTC) users   | Prescription users   |
| <b>Analytes and Cutoff (ng/ml)</b> | Amphetamine – 1000<br>Cocaine – 300<br>Methamphetamine – 1000<br>Morphine – 300<br>Marijuana – 50 | Amphetamine – 1000/300<br>Cocaine – 300/150<br>Methamphetamine – 1000/500<br>Morphine – 2000/300<br>Marijuana – 50 |
| <b>Storage Temperature</b>         | 2-30°C (36-86°F)  | Same   |
| <b>Formats</b>                     | Test Card and Urine Cup   | Same   |

## G. Non-clinical performance data

### a. Read Time Window

To determine the optimal time to interpret the test results of ACCU NEWS® Drug Screening Test Card/Urine Cup, 10 devices were tested with urine controls at the following concentration: negative, -50%, -25%, +25%, +50% and +200% of cutoff. Based on the test results, ACCU NEWS® Drug Screening Test Card/Urine Cup can be read between 3 and 8 minutes with accuracy at 95% or greater.

### b. Precision/Sensitivity

The precision study was conducted by three (3) operator with three (3) lots of testing devices using a total of 6 urine samples spiked with different drug concentrations: negative, -50%, -25%, cutoff, +25%, and +50% of cutoff concentrations. The drug concentrations in the urine samples were confirmed with GC/MS analysis. These urine samples were blind-labeled and randomly distributed by the project coordinator to the three operators. The study was conducted in six days. The results were summarized below:

Table 1: Summary of Precision/Sensitivity Data – Test Card  
AMP (cutoff: 1000 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|--------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 6-/24+ | 0-/30+         | 0-/30+         |

MET (cutoff: 1000 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff  | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|---------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 10-/20+ | 0-/30+         | 0-/30+         |

MOP (cutoff: 300 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|--------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 7-/23+ | 0-/30+         | 0-/30+         |

COC (cutoff: 300 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|--------|----------------|----------------|
| 30-/0+ | 30-/0+         | 29-/1+         | 21-/9+ | 1-/29+         | 0-/30+         |

THC (cutoff: 50 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|--------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 24-/6+ | 2-/28+         | 0-/30+         |

Table 2: Summary of Precision/Sensitivity Data – Urine Cup  
AMP (cutoff: 1000 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff  | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|---------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 16-/14+ | 0-/30+         | 0-/30+         |

MET (cutoff: 1000 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff  | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|---------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 14-/16+ | 1-/29+         | 0-/30+         |

MOP (cutoff: 300 ng/ml)

| Neg.   | -50%<br>cutoff | -25%<br>cutoff | cutoff  | +25%<br>cutoff | +50%<br>cutoff |
|--------|----------------|----------------|---------|----------------|----------------|
| 30-/0+ | 30-/0+         | 30-/0+         | 17-/13+ | 2-/28+         | 0-/30+         |

COC (cutoff: 300 ng/ml)

| Neg.   | -50% cutoff | -25% cutoff | cutoff  | +25% cutoff | +50% cutoff |
|--------|-------------|-------------|---------|-------------|-------------|
| 30-/0+ | 30-/0+      | 30-/0+      | 19-/11+ | 2-/28+      | 0-/30+      |

THC (cutoff: 50 ng/ml)

| Neg.   | -50% cutoff | -25% cutoff | cutoff | +25% cutoff | +50% cutoff |
|--------|-------------|-------------|--------|-------------|-------------|
| 30-/0+ | 30-/0+      | 30-/0+      | 23-/7+ | 0-/30+      | 0-/30+      |

**c. Interference**

**1. Chemicals**

To determine if common substances possibly found in human urine in physiological or pathological conditions would react and interfere with ACCU NEWS® Drug Screening Test Card/Urine Cup, positive urine control (+50% cutoff) and negative urine control (-50% cutoff) were spiked with individual compounds at 100,000 ng/ml. Each spiked urine control was tested with three (3) testing devices from three (3) different lots. Results showed that the ACCU NEWS® Drug Screening Test Card/Urine Cup was not interfered by the substances listed below.

Table 3: List of Compounds showing no interference

|                      |                       |                     |                   |
|----------------------|-----------------------|---------------------|-------------------|
| Acetylsalicylic Acid | Dextromethorphan      | Meprobamate         | Prednisone        |
| Aminopyrine          | Diclofenac            | Nalidixic acid      | D,L-Propranolol   |
| Amoxicillin          | Diflunisal            | Naloxone            | D-Pseudoephedrine |
| Ampicillin           | Digoxin               | Naltrexone          | Quinidine         |
| Apomorphine          | Diphenhydramine       | Methoxyphenamine    | Quinine           |
| Aspartame            | Ecgonine methyl ester | Naproxen            | Ranitidine        |
| Atropine             | L-ψ-Ephedrine         | Niacinamide         | Salicylic acid    |
| Benzilic acid        | Ethyl-p-aminobenzoate | Nifedipine          | Serotonin         |
| Benzoic acid         | Erythromycin          | Norethindrone       | Sulfamethazine    |
| Bilirubin            | β-Estradiol           | D-Norpropoxyphene   | Tetrahydrozoline  |
| Caffeine             | Fenoprofen            | Noscapine           | Thiamine          |
| Chloral hydrate      | Furosemide            | D,L-Octopamine      | Thioridazine      |
| Chloramphenicol      | Gentisic acid         | Oxalic acid         | D,L-Tyrosine      |
| Chlorothiazide       | Hemoglobin            | Oxolinic acid       | Triamterene       |
| D,L-Chlorpheniramine | Hydralazine           | Oxymetazoline       | Trifluoperazine   |
| Chlorpromazine       | Hydrochlorothiazide   | Papaverine          | Trimethoprim      |
| Chloroquine          | Hydrocortisone        | Penicillin-G        | Tyramine          |
| Cholesterol          | 3-Hydroxytyramine     | Perphenazine        | D,L-Tryptophan    |
| Clonidine            | D,L-Isoproterenol     | Phenacetin          | Uric acid         |
| Cortisone            | Isoxsuprine           | Phenelzine          | Verapamil         |
| L-Cotinine           | Ketoprofen            | L-Phenylephrine     | Zomepirac         |
| Creatinine           | Labetalol             | β-Phenylethylamine  |                   |
| Deoxycorticosterone  | Loperamide            | Phenylpropanolamine |                   |

## 2. pH

To determine if different pH values in urine would affect ACCU NEWS® Drug Screening Test Card/Urine Cup, three (3) testing devices from three (3) different lots were tested with positive (+50% cutoff) and negative (-50% cutoff) urine controls with pH adjusted to the following values: 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0.

Experimental results indicated that pH values ranging from 3.0 to 9.0 in urine do not interfere with the performance of the testing device.

## 3. Specific Gravity

To determine if different specific gravity values in urine can affect ACCU NEWS® Drug Screening Test Card/Urine Cup, positive (+50% cutoff) and negative (-50% cutoff) urine controls with the following specific gravity levels, 1.001, 1.010, 1.020, 1.030 and 1.040, were tested. Three (3) testing devices from three (3) different lots were tested with each urine control. Result showed that the testing devices functioned properly with no interference in the specific gravity value range of 1.001 to 1.040.

### d. Specificity

ACCU NEWS® Drug Screening Test Card/Urine Cup were tested for specificity and cross-reactivity by testing with structurally related compounds spiked into drug-free negative urine. Three (3) testing devices from three (3) different lots were tested for each serially diluted urine sample, and the lowest concentration producing a positive test result was determined for each structurally related compound. The compounds in the following table produced positive results when tested at or above the concentrations listed below; the results were the same for both test card and urine cup formats:

Table 4: List of Structurally Similar Compounds showing cross-reactivity

| Drug Test | Compound                                 | Conc. (ng/ml) | % Cross-reactivity |
|-----------|--|---------------|--------------------|
| AMP       | d-Amphetamine                            | 1,000         | 100                |
|           | d,l-Amphetamine                          | 3,000         | 33.3               |
|           | l-Amphetamine                            | 50,000        | 2                  |
|           | d-Methamphetamine                        | >100,000      | <1                 |
|           | l-Methamphetamine                        | >100,000      | <1                 |
|           | d-Ephedrine                              | >100,000      | <1                 |
|           | l- Ephedrine                             | >100,000      | <1                 |
|           | d-Pseudoephedrine                        | >100,000      | <1                 |
|           | l-Pseudoephedrine                        | >100,000      | <1                 |
|           | (+/-)3,4-methylenedioxyamphetamine (MDA) | 2,500         | 40                 |

|                   |   |          |     |
|-------------------|---|----------|-----|
|                   | 3,4-Methylenedioxythylamphetamine (MDEA)      | >100,000 | <1  |
|                   | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | >100,000 | <1  |
|                   | Phentermine                                   | 25,000   | 4   |
| MET               | d-Methamphetamine                             | 1,000    | 100 |
|                   | l-Methamphetamine                             | 100,000  | 1   |
|                   | d-Amphetamine                                 | >100,000 | <1  |
|                   | l-Amphetamine                                 | >100,000 | <1  |
|                   | d-Ephedrine                                   | >100,000 | <1  |
|                   | l-Ephedrine                                   | >100,000 | <1  |
|                   | d-Pseudoephedrine                             | >100,000 | <1  |
|                   | l-Pseudoephedrine                             | >100,000 | <1  |
|                   | (+/-)3,4-methylenedioxyamphetamine (MDA)      | >100,000 | <1  |
|                   | 3,4-Methylenedioxythylamphetamine (MDEA)      | 50,000   | 2   |
|                   | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 25,000   | 4   |
|                   | Chloroquine                                   | 50,000   | 2   |
|                   | $\beta$ -Phenylethylamine                     | 50,000   | 2   |
| Trimethobenzamide | 10,000  | 10       |     |
| MOP               | Morphine                                      | 300      | 100 |
|                   | Codeine                                       | 300      | 100 |
|                   | Ethylmorphine                                 | 300      | 100 |
|                   | Heroin  | 300      | 100 |
|                   | 6-Monoacetylmorphine                          | 300      | 100 |
|                   | Hydrocodone                                   | 5,000    | 6   |
|                   | Hydromorphone                                 | 5,000    | 6   |
|                   | Morphine-3- $\beta$ -glucuronide              | 1,000    | 30  |
|                   | Oxycodone                                     | >100,000 | <1  |
| COC               | Benzoylecgonine                               | 300      | 100 |
|                   | Cocaine HCl                                   | 750      | 40  |
|                   | Cocaethylene                                  | 12,500   | 2.4 |
|                   | Ecgonine                                      | 32,000   | <1  |
|                   | Norcocaine                                    | >100,000 | <1  |

|     |   |         |     |
|-----|---|---------|-----|
| THC | 11-Nor- $\Delta$ 9-Tetrahydrocannabinol carboxylic acid | 50      | 100 |
|     | 11-Hydroxy- $\Delta$ 9-Tetrahydrocannabinol             | 2,500   | 2   |
|     | $\Delta$ 8-Tetrahydrocannabinol                         | 7,500   | <1  |
|     | $\Delta$ 9 –Tetrahydrocannabinol                        | 10,000  | <1  |
|     | Cannabinol  | 10,000  | <1  |
|     | Cannabidiol   | 100,000 | <1  |

### e. Method Comparison

A total of 340 clinical urine samples were collected to be used in method comparison study. These urine were distributed and tested across three different sites with two operators from each site. The urine samples were blind-labeled for testing, and the drug concentrations were determined by GC/MS. The device results were compared to GC/MS results for the study.

Table 5: Summary of Method Comparison Data – Test Card

|     |   | No Drug Present | Near Cutoff Negative (between -50% cutoff and cutoff) | Near Cutoff Positive (between cutoff and +50% cutoff) | High Positive (> +50% cutoff) | % Agreement with GC/MS |          | Overall % Agreement with GC/MS |
|-----|---|-----------------|---|---|-------------------------------|------------------------|----------|--------------------------------|
|     |   |                 |   |   |                               | Negative               | Positive |                                |
| AMP | + | 0               | 1   | 9   | 40                            | 98.0%                  | 98.0%    | 98.0%                          |
|     | – | 40              | 9   | 1   | 0                             |                        |          |                                |
| MET | + | 0               | 1   | 8   | 40                            | 98.0%                  | 96%      | 97.0%                          |
|     | – | 40              | 9   | 2   | 0                             |                        |          |                                |
| MOP | + | 0               | 2   | 10  | 40                            | 96.0%                  | 100%     | 98.0%                          |
|     | – | 40              | 8   | 0   | 0                             |                        |          |                                |
| COC | + | 0               | 1   | 8   | 40                            | 98.0%                  | 96.0%    | 97.0%                          |
|     | – | 40              | 9   | 2   | 0                             |                        |          |                                |
| THC | + | 0               | 0   | 8   | 40                            | 100%                   | 96.0%    | 98.0%                          |
|     | – | 40              | 10  | 2   | 0                             |                        |          |                                |

Table 6: Summary of Discordant Results – Test Card

| Sample | Drug Test | Results Recorded | GC/MS Value (ng/mL) |
|--------|-----------|------------------|---------------------|
| 844591 | AMP 1000  | Positive         | 952                 |
| 545390 | AMP 1000  | Negative         | 1030                |
| 960940 | MET 1000  | Positive         | 982                 |
| 860829 | MET 1000  | Negative         | 1054                |
| 610670 | MET 1000  | Negative         | 1060                |
| 572595 | MOP 300   | Positive         | 284                 |
| 898906 | MOP 300   | Positive         | 286                 |

|        |         |          |      |
|--------|---------|----------|------|
| 699527 | COC 300 | Positive | 285  |
| 710595 | COC 300 | Negative | 322  |
| 491069 | COC 300 | Negative | 330  |
| 494372 | THC 50  | Negative | 54.3 |
| 801073 | THC 50  | Negative | 55.0 |

Table 7: Summary of Method Comparison Data – Urine Cup

|     |   | No Drug Present | Near Cutoff Negative (between -50% cutoff and cutoff) | Near Cutoff Positive (between cutoff and +50% cutoff) | High Positive (> +50% cutoff) | % Agreement with GC/MS |          | Overall % Agreement with GC/MS |
|-----|---|-----------------|---|---|-------------------------------|------------------------|----------|--------------------------------|
|     |   |                 |   |   |                               | Negative               | Positive |                                |
| AMP | + | 0               | 1   | 9   | 40                            | 98.0%                  | 98.0%    | 98.0%                          |
|     | – | 40              | 9   | 1   | 0                             |                        |          |                                |
| MET | + | 0               | 1   | 8   | 40                            | 98.0%                  | 96.0%    | 97.0%                          |
|     | – | 40              | 9   | 2   | 0                             |                        |          |                                |
| MOP | + | 0               | 2   | 10  | 40                            | 96.0%                  | 100%     | 98.0%                          |
|     | – | 40              | 8   | 0   | 0                             |                        |          |                                |
| COC | + | 0               | 0   | 8   | 40                            | 100%                   | 96.0%    | 98.0%                          |
|     | – | 40              | 10  | 2   | 0                             |                        |          |                                |
| THC | + | 0               | 0   | 8   | 40                            | 100%                   | 96.0%    | 98.0%                          |
|     | – | 40              | 10  | 2   | 0                             |                        |          |                                |

Table 8: Summary of Discordant Results – Urine Cup

| Sample | Drug Test | Results Recorded | GC/MS Value (ng/mL) |
|--------|-----------|------------------|---------------------|
| 844591 | AMP 1000  | Positive         | 952                 |
| 545390 | AMP 1000  | Negative         | 1030                |
| 960940 | MET 1000  | Positive         | 982                 |
| 860829 | MET 1000  | Negative         | 1054                |
| 610670 | MET 1000  | Negative         | 1060                |
| 572595 | MOP 300   | Positive         | 284                 |
| 898906 | MOP 300   | Positive         | 286                 |
| 710595 | COC 300   | Negative         | 322                 |
| 491069 | COC 300   | Negative         | 330                 |
| 494372 | THC 50    | Negative         | 54.3                |
| 801073 | THC 50    | Negative         | 55.0                |

## H. Clinical performance data

### a. Clinical Sensitivity:

Not Applicable

### b. Clinical Specificity:

Not Applicable

**c. Other Clinical Supportive Data:**

**OTC Lay-User Study**

A lay-user study was conducted at 3 sites with 300 lay persons. A total of 175 males and 125 females from ages of 18 to 47 with a variety of educational background participated in the study. The blind-labeled urine samples were spiked to the following concentrations: negative urine, -50% cutoff, -25% cutoff, +25% cutoff, +50% cutoff, and +100% cutoff. All the samples were verified by GC/MS, and the results of lay-user were compared to those of GC/MS.

**Table 9: Summary of Lay-User Result Data – Test Card**

| Drug | Results | Drug Concentration |      |      |      |      |       | Agreement with GC/MS |
|------|---------|--------------------|------|------|------|------|-------|----------------------|
|      |         | Negative           | -50% | -25% | +25% | +50% | +100% |                      |
| AMP  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| MET  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| MOP  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| COC  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| THC  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |

**Table 10: Summary of Lay-User Result Data – Urine Cup**

| Drug | Results | Drug Concentration |      |      |      |      |       | Agreement with GC/MS |
|------|---------|--------------------|------|------|------|------|-------|----------------------|
|      |         | Negative           | -50% | -25% | +25% | +50% | +100% |                      |
| AMP  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| MET  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| MOP  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| COC  | +       | 0                  | 0    | 0    | 20   | 40   | 20    | 100%                 |
|      | -       | 180                | 20   | 20   | 0    | 0    | 0     |                      |
| THC  | +       | 0                  | 0    | 0    | 19   | 40   | 20    | 99.7%                |
|      | -       | 180                | 20   | 20   | 1    | 0    | 0     |                      |

For both ACCU NEWS® Drug Screening Test Card/Urine Cup, Data showed above 95% agreement between lay-user results and GC/MS results. This demonstrated that the devices were easy enough to be used by untrained lay-users. In addition, each subject was given questionnaires in English to assess the readability of the labeling.

The results showed that the lay-users found the product instruction to be easy to understand and the device to be easy to use.

## **I. Conclusion**

The performance characteristics studies performed demonstrated substantial equivalency between ACCU NEWS® Drug Screening Test Card/Urine Cup and Innovacon® Spectrum II Test Card/Test Card with Integrated Cups.