

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

A. 510(k) Number:

k061005

B. Purpose for Submission:

New product

C. Measurand:

Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Morphine, Methamphetamine, Methadone, Phencyclidine, and Nortriptyline

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Applied DNA Technologies Inc.

F. Proprietary and Established Names:

ACCUSTEP Single and Multi-Strip Cassette/Dipstick DOA Screen Panels

G. Regulatory Information:

1. Regulation section:

21 CFR §862.3100: Test System, Amphetamine

21 CFR §862.3150: Test System, Barbiturate

21 CFR §862.3170: Enzyme Immunoassay, Benzodiazepine

21 CFR §862.3250: Enzyme Immunoassay, Cocaine and Cocaine Metabolites

21 CFR §862.3870: Enzyme Immunoassay, Cannabinoids

21 CFR §862.3640: Morphine test system

21 CFR §862.3610: Test System, Methamphetamine

21 CFR §862.3620: Methadone test system

21 CFR §862.3100: Test System, Amphetamine (Phencyclidine)

21 CFR §862.3910: Tricyclic Antidepressant Drugs Test System

2. Classification:

Class II

3. Product code:

DKZ, DIS, JXM, DIO, LDJ, DNK, DJC, DJR, LCM, LFG

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for Use.

2. Indication(s) for use:

The Applied DNA Technologies ACCUSTEP DOA Panels are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to ten of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

| Analyte | Abbreviation | Calibrator | Cutoff Concentration |
|-----------------|--------------|-------------------------------|----------------------|
| Amphetamine | AMP | Amphetamine | 1000 ng/ml |
| Barbiturate | BAR | Secobarbital | 300 ng/ml |
| Benzodiazepines | BZO | Benzodiazepine | 300 ng/ml |
| Cocaine | COC | Benzoyllecgonine | 300 ng/ml |
| Marijuana | THC | 11-nor- Δ^9 -THC9-COOH | 50 ng/ml |
| Methamphetamine | MET | Methamphetamine | 1000 ng/ml |
| Methadone | MTD | Methadone | 300 ng/ml |
| Morphine | MOR | Morphine | 2000 ng/ml |
| Phencyclidine | PCP | Phencyclidine | 25 ng/ml |
| Nortriptyline | NOR | Nortriptyline | 1000 ng/ml |

These test kits are intended for health care professional use only.

This assay provided only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

3. Special conditions for use statement(s):

For professional prescription use only.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS are the preferred confirmatory methods.

4. Special instrument requirements:

Not applicable, as the devices are visually-read single-use devices.

I. Device Description:

The ACCUSTEP DOA test has two formats: cassette and dipstick. These two formats are manufactured with the same formulation, components, and manufacturing processes. The Cassette contains a testing in a plastic housing with a specimen well and a window to read the test results. A specimen pipette is included with the Test Device, but a specimen collection container is not included with either test format.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ACON One Step Multi-Drug Multi-Line Screen Test Card/Device
2. Predicate 510(k) number(s):
k020313, k023946
3. Comparison with predicate:
The device is similar to or the same as to the previously cleared predicate(s) in the following ways: test principles, indication for use, cut-off concentration(s), use in a professional setting, sample matrix, endpoint, and test time.

The devices differ by manufacturer, specific monoclonal antibodies used, and the proposed device is not cleared for use in point-of-care settings.

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

None referenced by the manufacturer.

L. Test Principle:

The devices employ lateral flow immunochromatographic technology and are based on the principle of competitive binding. Drug, if present in concentrations below the cutoff level, will not saturate the binding sites of antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. A line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control. Formation of a line in the control line region indicates that the proper volume of urine has been added and membrane wicking has occurred. If a line does not form in the control region then the test is not valid and users are cautioned to repeat the test. A 'presumptive positive' is determined by the appearance of a procedural control line AND no line appearing next to the test region.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Drug-free urine was spiked with drug to concentrations of 50%, 75%, 125%, 150%, and 300% of the cutoff; test strips from one lot and cassettes from one lot were tested in duplicate for 15 or 19 days respectively (n = 30 or 38 per format; 60 or 76 total). Results were read by three observers after five minutes as 'positive' or as 'negative'. There was no significant difference in precision between the two lots or between the readers:

| Drug/Test Conc | % Correct by Reader | | | Drug/Test Conc | % Correct by Reader | | |
|----------------------------|----------------------------|-----|-----|----------------------------|----------------------------|-----|-----|
| <i>AMP (n = 60)</i> | 1 | 2 | 3 | <i>MOR (n = 60)</i> | 1 | 2 | 3 |
| Negative | 100 | 100 | 100 | Negative | 100 | 100 | 100 |
| 50% c/o | 100 | 100 | 100 | 50% c/o | 100 | 100 | 100 |
| 75% c/o | 83 | 83 | 82 | 75% c/o | 87 | 88 | 88 |
| 125% c/o | 83 | 83 | 83 | 125% c/o | 88 | 92 | 97 |
| 150% c/o | 100 | 100 | 100 | 150% c/o | 100 | 100 | 100 |
| 300% c/o | 100 | 100 | 100 | 300% c/o | 100 | 100 | 100 |
| | | | | | | | |
| <i>BAR (n = 60)</i> | 1 | 2 | 3 | <i>MTD (n = 76)</i> | 1 | 2 | 3 |
| Negative | 100 | 100 | 100 | Negative | 100 | 100 | 100 |
| 50% c/o | 100 | 100 | 100 | 50% c/o | 100 | 100 | 100 |
| 75% c/o | 88 | 88 | 87 | 75% c/o | 100 | 100 | 100 |
| 125% c/o | 82 | 80 | 82 | 125% c/o | 100 | 100 | 99 |
| 150% c/o | 100 | 100 | 100 | 150% c/o | 100 | 100 | 100 |
| 300% c/o | 100 | 100 | 100 | 300% c/o | 100 | 100 | 100 |
| | | | | | | | |
| | | | | | | | |
| <i>BZO (n = 60)</i> | 1 | 2 | 3 | <i>PCP (n = 76)</i> | 1 | 2 | 3 |
| Negative | 100 | 100 | 100 | Negative | 100 | 100 | 100 |
| 50% c/o | 100 | 100 | 100 | 50% c/o | 100 | 100 | 100 |
| 75% c/o | 85 | 87 | 85 | 75% c/o | 100 | 100 | 100 |
| 125% c/o | 83 | 83 | 85 | 125% c/o | 100 | 100 | 100 |
| 150% c/o | 100 | 100 | 100 | 150% c/o | 100 | 100 | 100 |
| 300% c/o | 100 | 100 | 100 | 300% c/o | 100 | 100 | 100 |
| | | | | | | | |
| <i>COC (n = 76)</i> | 1 | 2 | 3 | <i>NOR (n = 60)</i> | 1 | 2 | 3 |
| Negative | 100 | 100 | 100 | Negative | 100 | 100 | 100 |
| 50% c/o | 100 | 100 | 100 | 50% c/o | 100 | 100 | 100 |
| 75% c/o | 100 | 100 | 100 | 75% c/o | 88 | 88 | 85 |
| 125% c/o | 100 | 100 | 100 | 125% c/o | 85 | 85 | 85 |
| 150% c/o | 100 | 100 | 100 | 150% c/o | 100 | 100 | 100 |
| 300% c/o | 100 | 100 | 100 | 300% c/o | 100 | 100 | 100 |
| | | | | | | | |
| <i>MET (n = 76)</i> | 1 | 2 | 3 | <i>THC (n = 60)</i> | 1 | 2 | 3 |
| Negative | 100 | 100 | 100 | Negative | 100 | 100 | 100 |
| 50% c/o | 100 | 100 | 100 | 50% c/o | 100 | 100 | 100 |
| 75% c/o | 99 | 100 | 97 | 75% c/o | 85 | 85 | 85 |
| 125% c/o | 100 | 100 | 100 | 125% c/o | 87 | 83 | 87 |
| 150% c/o | 100 | 100 | 100 | 150% c/o | 100 | 100 | 100 |
| 300% c/o | 100 | 100 | 100 | 300% c/o | 100 | 100 | 100 |
| | | | | | | | |

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
This device has internal process controls. A red line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed not to interpret the test if no line forms in the control region.

Control standards are not supplied with this device; however it is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

- d. *Detection limit:*

To test the analytical sensitivity of the devices, drug-free urine was spiked with drug to concentrations of 50%, 75%, 125%, 150%, and 300% of the cutoff; 25 test strips from one lot and 25 cassettes from one lot were tested. Drug concentrations were confirmed by GC/MS:

| Amphetamine | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 7 | 18 | 72 | 9 | 16 | 64 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Barbiturates | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 5 | 20 | 80 | 6 | 19 | 76 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Benzodiazepines | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |

| Benzodiazepines | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 9 | 16 | 64 | 8 | 17 | 68 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Cocaine | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 5 | 20 | 80 | 6 | 19 | 76 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Marijuana (THC) | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 10 | 15 | 60 | 7 | 18 | 72 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Methadone | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 2 | 23 | 92 | 4 | 21 | 84 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Methamphetamine | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 11 | 14 | 56 | 12 | 13 | 52 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Morphine | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 7 | 18 | 72 | 6 | 19 | 76 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Phencyclidine | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 4 | 21 | 84 | 5 | 20 | 80 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

| Nortriptyline | | Strip | | | Cassette | | |
|-----------------|----------------|---------|-----|--------------|----------|-----|--------------|
| Conc (ng/mL) | % of Cutoff | Reading | | % Correct | Reading | | % Correct |
| | | Neg | Pos | | Neg | Pos | |
| 0 | 0 | 25 | 0 | 100 | 25 | 0 | 100 |
| 500 | 50% | 25 | 0 | 100 | 25 | 0 | 100 |
| 750 | 75% | 25 | 0 | 100 | 25 | 0 | 100 |
| 1000 | Cutoff | 4 | 21 | 84 | 5 | 20 | 80 |
| 1250 | 125% | 0 | 25 | 100 | 0 | 25 | 100 |
| 1500 | 150% | 0 | 25 | 100 | 0 | 25 | 100 |
| 3000 | 300 % | 0 | 25 | 100 | 0 | 25 | 100 |

e. *Analytical specificity:*

The drugs tested for by these devices, their known metabolites, and related compounds were spiked into drug-free urine then serially diluted and tested until the concentrations which yielded a negative result were obtained. The following tables list the lowest concentration (ng/mL) which yields a positive result for the compound being tested.

ACCUSTEP DOA Tests: Cross Reactivity of Compounds

| <i>Amphetamine - related compounds</i> | <i>Conc</i> | <i>Methamphetamine - related compounds</i> | <i>Conc</i> |
|--|--------------------|---|--------------------|
| d-Amphetamine | 1000 | d-Methamphetamine | 1000 |
| l-Amphetamine | >50,000 | d-Amphetamine | >40,000 |
| d-Methamphetamine | >20,000 | Chloroquine | 10,000 |
| l-Methamphetamine | >20,000 | (+/-) Ephedrine | >100,000 |
| 3,4-Methylenedioxyamphetamine (MDA) | 2,400 | l-Methamphetamine | 15,000 |
| 3,4-Methylenedioxy-methamphetamine (MDMA) | >20,000 | 3,4-Methylenedioxyamphetamine (MDA) | >10,000 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | >100,000 | 3,4-Methylenedioxy-methamphetamine (MDMA) | 2,000 |
| Paramethoxyamphetamine (PMA) | 1000 | 3,4-Methylenedioxyethylamphetamine (MDEA) | 20,000 |
| | | Procaine | 100,000 |
| <i>Barbiturate-related compounds</i> | | <i>Morphine-related compounds</i> | |
| Secobarbital | 300 | Morphine | 2,000 |
| Allobarbital | 5000 | Codeine | 2,000 |
| Alphenal | 625 | Diacetyl Morphin (Heroin) | 2,000 |
| Amobarbital | 600 | Ethylmorphine | 600 |
| Aprobarbital | 600 | Hydromorphone | 15,000 |
| Butabarbital | 75 | Hydrocodone | 15,000 |
| Butalbital | 3000 | Oxymorphon | >20,000 |
| Hexobarbital | >100,000 | Oxycodone | >20,000 |
| Pentobarbital | 300 | Merperidine | >100,000 |
| Phenobarbital | 300 | 6-Monoacetylmorphine | 5,000 |
| | | Morphine-3-glucuronid | 10,000 |
| | | Rifampicin | >50,000 |
| | | Thebaine | 20,000 |
| <i>Benzodiazepine - related compounds</i> | | <i>Methadone - related compounds</i> | |
| Oxazepam | 300 | Methadone | 300 |
| Alprazolam | 500 | Methadol | 1,000 |
| Bromazepam | 1,000 | Doxylamine | >40,000 |
| Chlordiazepoxide | ≥10,000 | EDDP | >40,000 |

| <i>Benzodiazepine - related compounds</i> | <i>Conc</i> | <i>PCP - related compounds</i> | <i>Conc</i> |
|--|--------------------|---------------------------------------|--------------------|
| Clobazam | 300 | Phencyclidine | 25 |
| Clonazepam | 8,000 | TCP | 3000 |
| Clorazepate | 2000 | | |
| Delorazepam | 2400 | | |
| Desalkflurazepam | 2500 | | |
| Diazepam | 300 | <i>NOR - related compounds</i> | <i>Conc</i> |
| Estazolam | 2,000 | Nortriptyline | 1000 |
| Fentanyl | >100,000 | Amitriptyline | 1000 |
| Flunitrazepam | 1,200 | Chlorpromazine | 3500 |
| Flurazepam | >10,000 | Clomipramine | 10,000 |
| α -Hydroxyalprazolam | 100,000 | Cyclobenzaprine | 1500 |
| Lorazepam | 2,000 | Desipramine | 500 |
| Lormetazepam | 1,000 | Diphenhydramine | 20,000 |
| Medazepam | >100,000 | Doxepin | 1,000 |
| Midazolam | >50,000 | Imipramine | 800 |
| Nitrazepam | >50,000 | Nordoxepine | 1000 |
| Nordiazepam | 300 | Perphenazine | 2,500 |
| Prazepam | >100,000 | Promazine | 200 |
| Temazepam | 500 | Promethazine | 40,000 |
| Triazolam | 2,000 | Protryptiline | 3000 |
| | | Trimipramine | 2500 |
| <i>Cocaine - Related Compounds</i> | <i>Conc</i> | <i>THC - related compounds</i> | <i>Conc</i> |
| Benzoylecgonine | 300 | 11-nor- Δ^9 -THC-9-COOH | 50 |
| Cocaine | 1000 | 11-nor- Δ^8 -THC-9-COOH | 50 |
| Ecgonine | 40,000 | 11-hydroxy-- Δ^9 -THC | 100,000 |
| Ecgonine methyl ester | 100,000 | Δ^8 -THC | 15,000 |
| | | Δ^9 -THC | 15,000 |
| | | Cannabinol | 20,000 |
| | | Cannabidiol | 100,000 |

The following unrelated compounds were found not to cross-react when tested spiked into drug-free urine at concentrations at 100 μ g/ml:

| | |
|------------------|-------------------------|
| Acetaminophen | Furosemide |
| Acetone | Guaiacol Glyceryl Ether |
| Albumin | Hemoglobin |
| Amitriptyline | Ibuprofen |
| Ampicillin | Imipramine |
| Aspartame | (+/-)-Isoproterenol |
| Aspirin | Lidocaine |
| Atropine | N-Methyl-Ephedrine |
| Benzocaine | (+)-Naproxen |
| Bilirubin | Oxalic Acid |
| Caffeine | Penicillin-G |
| Chloroquine | Pheniramine |
| Chlorpheniramine | Phenothiazine |

| | |
|---------------------------|--------------------|
| Creatine | L-Phenylephrine |
| Dextrophan tartrate | β-Phenylethylamine |
| 4-Dimethylaminoantipyrine | Procaine |
| Dopamine | Quinidine |
| (+/-)-Ephedrine | Ranitidine |
| (-)-Ephedrine | Sulindac |
| Erythromycin | Tyramine |
| Ethanol | Vitamin C |

The pH of an aliquoted negative urine pool was adjusted to pH 3, pH 5, pH 6.5, pH 7.5, or pH 8.5; three of the four aliquots at each pH were spiked with a drug to 75%, 125%, and 300% of the cutoff concentration. The spiked, pH-adjusted urine was tested in duplicate. Altering the pH of the urine sample did not affect the accuracy of any of the test results.

Four (4) urine samples with specific gravities of 1.00, 1.01, 1.02, and 1.03 were aliquoted into four samples each; one sample remained neat while the other three aliquots were spiked with each drug to the concentration of 75%, 125%, and 300% of the cutoff respectively. Each sample was tested in duplicate. Variations in specific gravity did not affect the accuracy of any of the test results.

f. Assay cut-off:

Analytical performance of the device around the cutoff is described in Section 1.M.d above.

2. Comparison studies:

a. Method comparison with predicate device:

The ACCUSTEP Multi-Strip Drugs of Abuse Cassette and Dipstick Card were evaluated in comparison to GC/MS and the predicate. Specimens, including at least 48 negative and 38 positive samples, were obtained from commercial reference laboratories. All samples were confirmed by GC/MS but no clinical information was available:

Agreement between Individual ACCUSTEP Tests and GC/MS

| | | Drug Concentration by GC/MS | | | | | |
|----------------|--------|-----------------------------|----------|-------------|--------------|-----------|--------------|
| ACCU STEP Drug | Result | Neg | <25% C/O | 25 % to C/O | C/O to +125% | >125% C/O | Agrmnt w/ GC |
| AMP | Pos | 0 | 0 | 0 | 5 | 41 | 98% |
| | Neg | 36 | 12 | 7 | 2 | 0 | |
| BAR | Pos | 0 | 0 | 1 | 3 | 42 | 98% |
| | Neg | 35 | 10 | 6 | 1 | 0 | |

| | | Drug Concentration by GC/MS | | | | | |
|----------------|--------|-----------------------------|----------|-------------|--------------|-----------|--------------|
| ACCU STEP Drug | Result | Neg | <25% C/O | 25 % to C/O | C/O to +125% | >125% C/O | Agrmnt w/ GC |
| BZO | Pos | 0 | 3 | 1 | 5 | 36 | 94% |
| | Neg | 35 | 12 | 5 | 2 | 0 | |
| | | | | | | | |
| COC | Pos | 0 | 0 | 1 | 4 | 51 | 98% |
| | Neg | 35 | 12 | 6 | 1 | 0 | |
| | | | | | | | |
| MTD | Pos | 0 | 0 | 0 | 4 | 45 | 98% |
| | Neg | 35 | 11 | 8 | 2 | 0 | |
| | | | | | | | |
| MET | Pos | 0 | 0 | 0 | 4 | 57 | 98% |
| | Neg | 35 | 9 | 8 | 2 | 0 | |
| | | | | | | | |
| MOR | Pos | 0 | 0 | 1 | 7 | 33 | 98% |
| | Neg | 35 | 21 | 7 | 1 | 0 | |
| | | | | | | | |
| PCP | Pos | 0 | 0 | 0 | 5 | 40 | 99% |
| | Neg | 35 | 11 | 2 | 1 | 0 | |
| | | | | | | | |
| NOR | Pos | 0 | 0 | 0 | 6 | 29 | 97% |
| | Neg | 35 | 15 | 7 | 3 | 0 | |
| | | | | | | | |
| THC | Pos | 0 | 0 | 1 | 7 | 53 | 98% |
| | Neg | 35 | 10 | 14 | 2 | 0 | |

- b. Matrix comparison:*
Not applicable; these devices are for use with urine only.
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):*
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.