**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**
k080635

**B. Purpose for Submission:**
New drugs of abuse test system for Amphetamines, Barbiturates, Benzodiazepines, Cocaine (Benzoylecgonine), Methamphetamine, Methadone, Opiates, Phencyclidine and THC (Cannabinoids).

**C. Measurand:**
Amphetamines (d-Amphetamine), Barbiturates (Butalbital), Benzodiazepines (Nordiazepam), Cocaine (Benzoylecgonine), Methamphetamine (d-Methamphetamine), Methadone (Methadone) Opiates (Morphine), Phencyclidine (Phencyclidine), and THC (11-nor-9-carboxy-Δ9-THC).

**D. Type of Test**:
Qualitative immunochromatographic tests for drugs in urine performed on a reader.

**E. Applicant:**
Medtox Diagnostics, Inc.
c/o New World Regulatory Solutions

F**. Proprietary and Established Names:**
PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

**G. Regulatory Information**:

1. Regulation section:
   862.3100, Enzyme Immunoassay, Amphetamine
   862.3150, Enzyme Immunoassay, Barbiturates
   862.3170, Enzyme Immunoassay, Benzodiazepine
   862.3870, Enzyme Immunoassay, Cannabinoids
   862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites
   862.3620, Enzyme Immunoassay, Methadone
   862.3610, Thin Layer Chromatography, Methamphetamine
   862.3650, Enzyme Immunoassay, Opiates
   Unclassified Phencyclidine

2. Classification:
   Class II – for all except PCP
   PCP- Unclassified, 510(k) required

3. Product code:
   DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LCM and JJQ

4. Panel:
   (91) Toxicology

**H. Intended Use:**

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:
   The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOXScan® Test Devices and the MEDTOXScan® Reader. The PROFILE®-V MEDTOXScan® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine and THC (Cannabinoids) or their metabolites. The PROFILE®-V MEDTOXScan® Test Devices can only be used with the MEDTOXScan® Reader. The MEDTOXScan® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOXScan® Test Device. The PROFILE®-V MEDTOXScan® Test Devices cannot be visually read.

   The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System is for in vitro diagnostic use and is intended for professional use only. It is not intended for use in point-of-care settings.

   The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:
   AMP Amphetamine (d-Amphetamine) 500 ng/mL
   BAR Barbiturates (Butalbital) 200 ng/mL
   BZO Benzodiazepines (Nordiazepam) 150 ng/mL
   COC Cocaine (Benzoylecgonine) 150 ng/mL
   MAMP Methamphetamine (d-Methamphetamine) 500 ng/mL
   MTD Methadone (Methadone) 200 ng/mL
   OPI Opiates (Morphine) 100 ng/mL
   PCP Phencyclidine (Phencyclidine) 25 ng/mL
   THC Cannabinoids (11-nor-9-carboxy-□9-THC) 50 ng/mL

   Configurations of the PROFILE®-V MEDTOXScan® Test Devices may consist of any combination of the above listed drug analytes.

   THE PROFILE®-V MEDTOXScan® Drugs of Abuse Test System provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry

(GC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is 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 obtained.

The MEDTOXScan® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOXScan® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOXScan® Reader and a contaminated contact imaging sensor (CIS) and to verify that the CIS cleaning procedure using the MEDTOXScan® Cleaning Cassette effectively removed any contamination.

3. Special conditions for use statement(s):

The device is for in vitro diagnostic prescription use.

The assay is not designated for use in point-of-care settings.

The PROFILE®-V MEDTOXScan® Test Devices cannot be visually read.

THE PROFILE®-V MEDTOXScan® Drugs of Abuse Test System provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is 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 obtained.

4. Special instrument requirements:

PROFILE®-V MEDTOXScan®

## I. Device Description:

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System includes an instrument and drugs of abuse cassettes that detect specific drugs in urine. The PROFILE®-V MEDTOXScan® Test Device includes antibody-colloidal gold, drug-conjugates and a control line. A test line will form when drug in the sample is below the detection threshold (negative result). The MEDTOXScan® Reader scans the test device and utilizes a contact imaging sensor (CIS) to capture relative line intensities. Software algorithms and barcodes are used to identify the test device, the drug tests associated with the test device and whether the presence or absence of a line is associated with a negative or positive result, respectively.

The MEDTOXScan® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOXScan® Positive and Negative QC Test.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):
   Biosite Triage Tox Drug Screen

2. Predicate 510(k) number(s):
   k060791

3. Comparison with predicate:
   Both devices are for the qualitative determination of the same analyte in the same matrix. Both devices use immunochromatographic lateral flow technology.

   The candidate device uses gold-conjugated reagents to generate the reddish-purple test and controls lines, which are read by the instrument. The predicate device uses fluorescent-conjugated reagents to generate control and test lines that are not visible and can be read only by the instrument.

   The predicate device detects Acetaminophen and Tricyclic Antidepressants in addition to the same nine drugs of abuse detected by the candidate device. The cutoff concentrations vary, with the candidate device having lower cutoffs in all but two of the assays, i.e., THC and PCP.

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

CLSI Guidance EP-12A User Protocol for the Evaluation of Qualitative Test Performance

**L. Test Principle:**

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System includes a competitive, membrane-based immunochromatographic PROFILE®-V MEDTOXScan® Test Device and the MEDTOXScan® Reader.

Antibody-Colloidal Gold: Mouse monoclonal antibodies bind to the drug being tested.

Drug-Conjugates: Each drug to be tested was individually conjugated to bovine serum albumin (BSA) or IgG. Each drug conjugate is immobilized on a test line at a designated position on the membrane strip.

Control Line: Each test strip has anti-mouse antibody immobilized at the Control (C) position of the membrane strip. The anti-mouse antibody will bind excess antibody-colloidal gold, indicating that the reagents are migrating properly. When the urine sample is placed in the sample well of a test strip, the dried antibody-colloidal gold under the sample pad dissolves and the urine wicks up the white strips carrying the reddish-purple antibody-colloidal gold with it.

Negative Samples
When no drug(s) is present in the urine sample, the reddish purple antibody-colloidal gold solutions migrate along the strip and bind to the respective drug conjugate(s) immobilized on the membrane. Each strip has up to 4 drug test lines labeled T1 – T4. The binding of the antibody-colloidal gold to the drug conjugate generates a line at the corresponding test (T) position on the strip. The MEDTOXScan® Reader will scan each test position and if a line is detected it will return "NEG" on the display screen (or print out) next to the abbreviation for the drug test, indicating a negative result.

Positive Samples
When drug(s) is present in the urine sample the antibody-colloidal gold binds to the drug(s) before it migrates along the strip. When the antibody colloidal gold binds to the drug(s) in the urine, it cannot bind to the drug conjugate immobilized on the membrane and no line is generated at the drug specific position in the result window. The MEDTOXScan® Reader will scan each test position and if no line is detected it will return "POS" on the display screen (or print out) next to the abbreviation for the drug test, indicating a preliminary positive result.

Control Line (Valid or Invalid results)
Each test strip has an internal procedural control. A line must form at the Control (C) position in the result window to indicate that sufficient sample was applied and that the reagents are migrating properly. If a Control line does not form, the test is invalid. The MEDTOXScan® Reader scans each control line and returns "VALID" to the right of the drug test result to confirm that the control line was detected. If no control line is detected it will return "INVALID" on the display screen next to the abbreviation for the invalid drug test, and no result will be given for the drug test.

## M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*
   Urine stock solutions were prepared for each of the test compounds by spiking standard solution of known concentration into commercially available negative pool urine or into an in-house negative pool prepared from fresh drug-free urines (pH 6-7, Specific Gravity 1.012-1.018). Each stock solution was assayed by GC/MS or LC/MS/MS. The average value obtained was used to make serial dilutions around the cutoff value to obtain from 150% of cutoff down to 10% of the cutoff. The stock solution was diluted with negative pool urine to obtain the serial dilutions.

| Amphetamine (d-Amphetamine) Cutoff = 500 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 100 | 45 | 0 | 45 |
| 250 | 45 | 4 | 41 |
| 375 | 45 | 8 | 37 |
| 625 | 45 | 37 | 8 |
| 750 | 45 | 45 | 0 |

| Barbiturates (Butabital) Cutoff = 200 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 100 | 45 | 0 | 45 |
| 150 | 45 | 12 | 33 |
| 250 | 45 | 45 | 0 |
| 300 | 45 | 45 | 0 |

| Benzodiazepines (Nordiazepam) Cutoff = 150 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 75 | 45 | 0 | 45 |
| 112.5 | 45 | 12 | 33 |
| 187.50 | 45 | 37 | 8 |
| 225 | 45 | 45 | 0 |

| Cocaine (Benzoylecgonine) Cutoff = 150 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 75 | 45 | 0 | 45 |
| 112.50 | 45 | 21 | 24 |
| 187.50 | 45 | 45 | 0 |
| 225 | 45 | 45 | 0 |

| Methamphetamine (d-Methamphetamine) Cutoff = 500 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 100 | 45 | 0 | 45 |
| 250 | 45 | 18 | 27 |
| 375 | 45 | 32 | 13 |
| 625 | 45 | 44 | 1 |
| 750 | 45 | 43 | 2 |

| Methadone (Methadone) Cutoff = 200 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 50 | 45 | 0 | 45 |
| 100 | 45 | 11 | 34 |
| 150 | 45 | 37 | 8 |
| 250 | 45 | 45 | 0 |
| 300 | 45 | 45 | 0 |

| Opiates (Morphine) Cutoff = 100 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 25 | 45 | 0 | 45 |
| 50 | 45 | 8 | 37 |
| 75 | 45 | 41 | 4 |
| 125 | 45 | 45 | 0 |
| 150 | 45 | 45 | 0 |

| Phencyclidine (Phencyclidine) Cutoff = 25 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 6.25 | 45 | 0 | 45 |
| 12.50 | 45 | 14 | 31 |
| 18.75 | 45 | 44 | 1 |
| 31.25 | 45 | 45 | 0 |
| 37.50 | 45 | 45 | 0 |

| Cannabinoids (11-nor-9-carboxy-$\Delta^9$-THC) Cutoff = 50 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| 0 | 45 | 0 | 45 |
| 25 | 45 | 0 | 45 |
| 37.5 | 45 | 6 | 39 |
| 62.50 | 45 | 45 | 0 |
| 75 | 45 | 45 | 0 |

*b. Linearity/assay reportable range:*
Not applicable. The assay is intended for qualitative use.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*
Profile V quality control materials are sold separately. The sponsor specifies the quality control product in the "Materials Required but Not Provided" section of the labeling.

No calibrators are required. The device is calibrated during the manufacturing process.

*d. Detection limit:*

Sensitivity of qualitative assays may be characterized by validating performance around the claimed cutoff concentration of the assay, and demonstrating the lowest concentration of drug that is capable of or consistently producing a positive result. This information appears in the precision section, 1.a., above.

*e. Analytical specificity:*

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. The tables below summarize the results of cross-reactivity studies using various common and structurally similar compounds. Results are expressed as the minimum concentration of metabolite or compound required to produce a positive test result (or, if no cross-reactivity observed, "none detected").

| Amphetamine (d-amphetamine, cutoff = 500 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| l-Amphetamine | Positive at 50,000 ng/mL | 1% |
| Fenfluramine | Positive at 10,000 ng/mL | 5% |
| MDA | Positive at 250 ng/mL | 200% |
| Phentermine | Positive at 7,500 ng/mL | 7% |
| Ephedrine | Negative at 100,000 ng/mL | None Detected |
| MDE (MDEA) | Negative at 100,000 ng/mL | None Detected |
| MDMA | Negative at 100,000 ng/mL | None Detected |
| l-Methamphetamine | Negative at 100,000 ng/mL | None Detected |
| d-Methamphetamine | Negative at 100,000 ng/mL | None Detected |
| Pseudoephedrine | Negative at 100,000 | None Detected |
| Tyramine | Negative at 100,000 ng/mL | None Detected |

| Barbiturates (Butalbital, cutoff = 200 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Allobarbital | Positive at 250 ng/mL | 80% |
| Amobarbital | Positive at 800 ng/mL | 205% |
| Barbital | Positive at 2,500 ng/mL | 8% |
| Butabarbital | Positive at 400 ng/mL | 50% |
| Cyclopentobarbital | Positive at 250 ng/mL | 80% |
| Diphenylydantion | Positive at 2,000 ng/mL | 10% |
| Pentobarbital | Positive at 300 ng/mL | 67% |
| Phenobarbital | Positive at 1,250 ng/mL | 16% |
| Secobarbital | Positive at 50 ng/mL | 400% |
| Talbutal | Positive at 50 ng/mL | 400% |

| | | |
|---|---|---|
| Barbituric Acid | Negative at 100,000 ng/mL | None Detected |
| Glutethimide | Negative at 100,000 ng/mL | None Detected |
| Hexobarbital | Negative at 100,000 ng/mL | None Detected |
| Mephobarbital | Negative at 100,000 | None Detected |
| Thiopental | Negative at 100,000 ng/mL | None Detected |

| Benzodiazepines (Nordiazepam, cutoff = 150 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Alprazolam | Positive at 100 ng/mL | 150% |
| Alprazolam, 1-Hydroxy | Positive at 25,000 ng/mL | < 1% |
| Clobazam | Positive at 75 ng/mL | 200% |
| Clonazepam | Positive at 900 ng/mL | 17% |
| Clorazepate | Positive at 200 ng/mL | 75 |
| Desalkylflurazepam | Positive at 600 ng/mL | 25% |
| Desmethyl-chlordiazepoxide | Positive at 1,000 ng/mL | 15% |
| Desmethylflunitrazepam | Positive at 75 ng/mL | 200% |
| Diazepam | Positive at 75 ng/mL | 200% |
| Flunitrazepam | Positive at 50 ng/mL | 300% |
| Lorazepam | Positive at 1,200 ng/mL | 13% |
| Lorazepam glucuronide | Positive at 1,000 ng/mL | 15% |
| Midazolam | Positive at 5,000 ng/mL | 3%. |
| Nitrazepam | Positive at 50 ng/mL | 300% |
| Oxazepam | Positive at 200 ng/mL | 75% |
| Oxazepam glucuronide | Positive at 2,500 ng/mL | 6% |
| Temazepam | Positive at 90 ng/mL | 167% |
| Temazepam glucuronide | Positive at 750 ng/mL | 20% |
| Triazolam | Positive at 750 ng/mL | 20% |
| Triazolam, 1-hydroxy | Positive at 10,000 ng/mL | 2% |
| 7-Aminoclonazepam | Negative at 100.000 ng/mL | None detected |
| 7-Aminoflunitrazepam | Negative at 100.000 ng/mL | None detected |
| Chlordiazepoxide | Negative at 100.000 ng/mL | None detected |
| Flurazepam | Negative at 100.000 ng/mL | None detected |

| Cocaine (Benzoylecgonine, cutoff = 150 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Cocaine | Positive at 250 ng/mL | 60% |
| Ecgonine | Negative at 100,000 ng/mL | None detected |
| Ecgonine Methyl Ester | Negative at 100,000 ng/mL | None detected |

| Methamphetamine (d-Methamphetamine, cutoff = 500 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Ephedrine | Positive at 2,500 ng/mL | 20% |
| Fenfluramine | Positive at 50,000 ng/mL | 1% |
| MDE (MDEA) | Positive at 7,500 ng/mL | 7% |
| MDMA | Positive at 1,150 ng/mL | 43% |
| l-Methamphetamine | Positive at 7,500 ng/mL | 7% |
| Phenethylamine | Positive at 2,500 ng/mL | 20% |
| Phenyleprhine | Positive at 25,000 ng/mL | 2% |
| Procaine | Positive at 7,500 ng/mL | 7% |
| d-Amphetamine | Negative at 100,000 ng/mL | None Detected |
| l-Amphetamine | Negative at 100, 000 ng/mL | None Detected |
| MDA | Negative at 100,000 ng/mL | None Detected |
| Phentermine | Negative at 100, 000 ng/mL | None Detected |
| Phenmetrazine | Negative at 100,000 ng/mL | None Detected |
| Pseudoephedrine | Negative at 100,000 ng/mL | None Detected |
| Tyramine | Negative at 100, 000 ng/mL | None Detected |

| Methadone (Methadone, cutoff = 200 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Buprenorphine (MTD Replacement)_ | Negative at 100,000 ng/mL | None Detected |
| EDDP (Primary Metabolite) | Negative at 100,000 ng/mL | None Detected |
| EMDP (Secondary Metabolite) | Negative at 100,000 ng/mL | None Detected |

| Opiates (Morphine, cutoff = 100 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| Codeine | Positive at 50 ng/mL | 200% |
| Diacetylmorphine | Positive at 50 ng/mL | 200% |
| Dihydrocodeine | Positive at 75 ng/mL | 133% |
| Ethylmorphine | Positive at 50 ng/mL | 200% |
| Hydrocodone | Positive at 400 ng/mL | 25% |
| Hydromorphone | Positive at 800 ng/mL | 13% |
| Levorphanol | Positive at 2,500 ng/mL | 4% |
| 6-Monoacetylmorphine | Positive at 350 ng/mL | 29% |
| Morphine 3-β-D-Glucuronide | Positive at 75 ng/mL | 133% |
| Morphine | Negative at 500 ng/mL | 20% |

| Opiates (Morphine, cutoff = 100 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| 6-β-D-Glucuronide | | |
| Nalorphine | Positive at 50,000 ng/mL | < 1% |
| Norcodeine | Positive at 10,000 ng/mL | 1% |
| Thebaine | Positive at 25,000 ng/mL | < 1% |
| Apomorphine | Negative at 100,000 ng/mL | None Detected |
| Naloxone | Negative at 100,000 ng/mL | None Detected |
| Naltrexone | Negative at 100,000 ng/mL | None Detected |
| Oxycodone | Negative at 100,000 ng/mL | None Detected |
| Oxymorphone | Negative at 100,000 ng/mL | None Detected |

| Phencyclidine (Phencyclidine, cutoff = 25 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| 4-Hydroxy-Phencyclidine | Positive at 7,500 ng/mL | <1% |

| THC (Cannabinoids) (11-nor-9-carboxy-$\Delta^9$-THC, cutoff = 50 ng/mL) | Result | % Cross-Reactivity |
|---|---|---|
| $\Delta^9$ – Tetrahydrocannabinol | Positive at 100,000 ng/mL | < 1% |
| Cannabidiol | Negative at 100,000 ng/mL | None Detected |
| Cannabinol | Negative at 100,000 ng/mL | None Detected |
| l-11-Hydroxy- $\Delta^9$-THC | Negative at 100,000 ng/mL | None Detected |
| $\Delta^9$ – Tetrahydrocannabinol | Negative at 100,000 ng/mL | None Detected |

Non Cross-reactive Endogenous Compounds

The following compounds were evaluated for reactivity with the Profile V device at 100 µg/mL (albumin was evaluated at 20 mg/mL and bilirubin was evaluated at 200 µg/mL). Samples were evaluated in triplicate by in-house operators. The listed compounds gave negative results with the Profile V device.

| | | |
|---|---|---|
| Acetaldehyde | Creatinine | Hemoglobin, Human |
| Acetone | Epinephrine | Sodium Chloride |
| Albumin, Human | β-Estradiol | Tetrahydrocortisone |
| Bilirubin | Estriol | d, 1-Thyroxine |
| Cholesterol | Glucose Std. | Uric Acid |

Unrelated Compounds, Prescription and Over-the-Counter Medications

Common compounds were evaluated for reactivity at 100 µg/mL. Samples were evaluated in triplicate by in-house operators and the list of compounds evaluated appears in the package insert.

pH and Specific Gravity:
To test for possible positive and/or negative interference from pH, the sponsor prepared two study control samples. The control samples consisted of drug free urine spiked with the calibrator drugs at negative and positive concentrations. Aliquots of the control samples were adjusted to a pH of 4.0, 7.0, and 9.0. Each sample was assayed in triplicate. No negative interference due to pH was observed.

To test for possible positive and/or negative interference from specific gravity the sponsor, prepared two study control samples. The control samples consisted of drug free urine spiked with the calibrator drugs at negative and positive concentrations. Aliquots of the control samples were altered to span the specific gravity range of 1.007 to 1.031. No positive or negative interference due to specific gravity was observed.

Common Drugs:
Drug free urine samples were spiked with the Profile V targeted drugs to the concentrations of 25% and 150% of the cutoff concentrations. 100 µg/mL of the common drugs listed below, were then added to the preparation and assayed. Evaluations were performed in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

COMMON DRUGS EVALUATED WITH MedTox Scan Drugs of Abuse Test System

| | | |
|---|---|---|
| Acetylsalicylic Acid | Chlorpheniramine | Ibuprofen |
| Acetaminophen | Cocaine-COC | Morphine-OPI |
| Brompheniramine maleate | Doxylamine | Phenobarbital |
| Caffeine | Dextromethorphan | d-Pseudoephedrine |
| Carbamazepine | Diphenylhydantoin | Salicylic Acid |

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results.

*f. Assay cut-off:*
Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, 1.a, above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Performance was evaluated by assaying a panel of masked unaltered clinical urine samples containing varying concentrations of drugs with Profile V device. Results were then compared to GC/MS or LC/MS/MS results. Samples were obtained from MedTox Laboratories. Samples less than -50% of the cutoff, near cutoff negative (between -50% and the cutoff), near cutoff positive (between cutoff and +50%) and high positive (+50%) were confirmed by GC/MS or LC/MS/MS for Benzodiazepines. Testing was performed in-house. Readings were taken at 10 minutes and reported in this table.

| Drug | Candidate Device Results | Negative | Less than half the cutoff concentration by GC/MS or LC/MS/MS | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|---|---|---|---|---|---|---|
| AMP (500) | Positive | 0 | 0 | 4 | 5 | 41 |
| | Negative | 40 | 5 | 0 | 2 | 0 |
| BAR (200) | Positive | 0 | 0 | 3 | 4 | 36 |
| | Negative | 40 | 3 | 2 | 0 | 0 |
| BZO (150) | Positive | 0 | 0 | 1 | 4 | 41 |
| | Negative | 40 | 3 | 3 | 0 | 0 |
| COC (150) | Positive | 0 | 0 | 2 | 4 | 52 |
| | Negative | 56 | 1 | 5 | 1 | 1 |
| mAMP (500) | Positive | 0 | 0 | 1 | 3 | 40 |
| | Negative | 40 | 4 | 3 | 1 | 0 |
| MTD (200) | Positive | 0 | 0 | 2 | 3 | 40 |
| | Negative | 40 | 4 | 2 | 1 | 0 |
| OPI (100) | Positive | 0 | 0 | 3 | 5 | 44 |
| | Negative | 46 | 2 | 2 | 0 | 0 |
| PCP (25) | Positive | 0 | 0 | 3 | 10 | 30 |
| | Negative | 40 | 1 | 1 | 0 | 0 |
| THC (50) | Positive | 0 | 0 | 2 | 7 | 33 |
| | Negative | 40 | 4 | 2 | 0 | 0 |

The Summary of Discordant Results is listed in the table below:

| Assay | Cutoff Value (ng/mL) | Profile V Assay Pos/Neg | GC/MS or LC/MS/MS value (ng/mL) |
|---|---|---|---|
| AMP | 500 | Positive | Total d+l Amphetamine 277 |
| AMP | 500 | Positive | Total d+l Amphetamine 352 |
| AMP | 500 | Positive | Total d+l Amphetamine 368 |
| AMP | 500 | Positive | Total d+l Amphetamine 463 |
| AMP | 500 | Negative | Total d+l Amphetamine 504 |
| AMP | 500 | Negative | Total d+l Amphetamine 667 |
| BAR | 200 | Positive | Butalbital 126 |
| BAR | 200 | Positive | Butalbital 159 |

| | | | |
|---|---|---|---|
| BAR | 200 | Positive | Butalbital 184 |
| BZO | 150 | Positive | Alprazalom 146 |
| COC | 150 | Positive | Benzoylecgonine 114 |
| COC | 150 | Positive | Benzoylecgonine 121 |
| COC | 150 | Negative | Benzoylecgonine180 |
| COC | 150 | Negative | Benzoylecgonine 278 |
| MAMP | 500 | Positive | Total d+l mAMP 483 |
| MAMP | 500 | Negative | Total d+l mAMP 554 |
| MTD | 200 | Negative | Methadone 148 |
| MTD | 200 | Negative | Methadone 176 |
| MTD | 200 | Negative | Methadone 250 |
| OPI | 100 | Positive | Morphine 51 |
| OPI | 100 | Positive | Morphine 79 |
| OPI | 100 | Positive | Morphine 92 |
| PCP | 25 | Positive | Phencyclidine 19 |
| PCP | 25 | Positive | Phencyclidine 21 |
| PCP | 25 | Positive | Phencyclidine 24 |
| THC | 50 | Positive | 11-nor-9-carboxy-Δ9-THC – 35 |
| THC | 50 | Positive | 11-nor-9-carboxy-Δ9-THC – 39 |

*b. Matrix comparison:*
Not applicable. The assay is intended for only one sample matrix, urine.

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):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
   Not applicable

**N. Instrument Name:**

MEDTOXScan® Reader

**O. System Descriptions:**

1. Modes of Operation:
   Each cassette is single use and must be replaced with a cassette for additional readings.

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____x____ or No _____

3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the cassette.

4. Specimen Sampling and Handling:
   This device is intended to be used with urine samples. The labeling provides instructions to the users how to store the samples refrigerated and frozen.

5. Calibration:
   Factory Calibrated

6. Quality Control:
   Controls are available. They are prepared from human based urine available as negative or positive (above cutoff) levels to monitor the performance of PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**
None

**Q. Proposed Labeling:**
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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