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

A. 510(k) Number:

k100023

B. Purpose for Submission:

Addition of 2 new drugs of abuse tests (buprenorphine and opiates 2000) to an already cleared reader (MEDTOX*Scan*® Reader, k080635). Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates 100, Oxycodone, Phencyclidine, Propoxyphene, THC and Tricyclics antidepressants assays were previously cleared on the reader.

C. Measurand:

Buprenorphine and Opiates 2000

D. Type of Test:

Qualitative immunochromatographic test for drugs of abuse in urine performed on a reader.

E. Applicant:

Medtox Diagnostics, Inc.

F. Proprietary and Established Names:

PROFILE®-V MEDTOXScan®

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG – Opiate Test System	II	862.3650	91- Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The PROFILE®-V MEDTOX *Scan*® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids), and Tricyclic Antidepressants or their metabolites. The PROFILE®-V MEDTOX*Scan*® Test Devices can only be used with the MEDTOX*Scan*® Reader. The MEDTOX *Scan*® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOX*Scan*® Test Device. PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read. The PROFILE®-V MEDTOX*Scan*® 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 MEDTOX*Scan*® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

AMP Amphetamine (d-Amphetamine)	500 ng/mL	OPI Opiates (Morphine)	100 ng/mL or 2000 ng/mL
BAR Barbiturates (Butalbital)	200 ng/mL	OXY Oxycodone (Oxycodone)	100 ng/mL
BUP Buprenorphine (Nordiazepam)	10 ng/mL	PCP Phencyclidine (Phencyclidine)	25 ng/mL
COC Cocaine (Benzoylecgonine	150 mg/mL	PPX Propoxyphene (Norpropoxyphene)	300 ng/mL
MAMP Methamphetamine (d-Methamphetamine)	500 ng/mL	THC (Cannabinoids 11-nor-9-carboxy-r9-THC)	50 ng/mL
MTD Methadone (Methadone)	200 ng/mL	TCA Tricyclic Antidepressants (Desipramine)	300 ng/mL

Configurations of the PROFILE®-V MEDTOX*Scan*® Test Devices may consist of any combination of the above listed and previously cleared drug. Test Devices will have an opiate cutoff of either 100 ng/mL or 2000 ng/mL. Refer to specific product labeling for the combination of drug tests included on that test device.

The PROFILE®-V MEDTOX*Scan*® DRUGS OF ABUSE TEST SYSTEM PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROMETRY (GC/MS), HIGH

PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY / TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

The MEDTOX*Scan*® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOX*Scan* ® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOX*Scan*® Reader and a contaminated contact imaging sensor (CIS), and to verify that the CIS cleaning procedure using the MEDTOX*Scan*® 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 the point-of-care settings.

The PROFILE®-V MEDTOX*Scan*® Tes devices cannot be visually read.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmation analytical result. Gas chromatography/mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The positive and negative QC test devices should not be used to replace performing QC using external liquid quality control materials.

4. Special instrument requirements:

PROFILE®-V MEDTOX*Scan*®

I. Device Description:

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System kit contains PROFILE®-V MEDTOX*Scan*® Test Devices for use with the MEDTOX*Scan*® Reader.

- Each test device has all the reagents necessary to test one urine sample for one or more drugs simultaneously on the MEDTOX*Scan*® Reader.
- Each test device holds one or more test strips composed of a membrane strip coated with drug conjugate and a pad coated with antibody-colloidal gold in a protein matrix.

  Kit Contents:
  1. Twenty-five (25) test devices in individual foil packages
  2. Twenty-five (25) disposable pipette tips
  3. One Quick Reference guide

  MEDTOX*Scan*® Reader Contents:
  1. Positive and Negative QC Test Devices
  2. Cleaning Cassette
  3. MiniPet pipettor
  4. Quick Set Up guide
  5. User Manual

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PROFILE®-V MEDTOXScan®

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

   k091454

3. Comparison with predicate:

   The device and the predicate device have the same intended use and test the same sample type (urine). The similarities and differences are presented below.

Item	Similarities/Differences Device	Predicate
Intended use	Determines qualitative positive or negative result from drug of abuse immunoassay screens.	Same
System Procedure Measurement Method Output	Sample is added to a single use test cassette, which is then read by instrument. Instrument is designed to read multiple single use test cassettes, one at a time. Scans the single-use test cassette with contact imaging sensor (CIS) to detect a single Outputs “positive,” “negative, “ and “invalid” test results on	Same

	paper printout or LCD screen; stores and uploads results.	
Analytes	Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids) and Tricyclic Antidepressants	Amphetamines, Barbiturates, Benzodiazepines, Cocaine Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids) and Tricyclic Antidepressants

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

None were referenced

L. Test Principle:

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System includes a competitive, membrane-based immunochromatographic PROFILE®-V MEDTOX*Scan*® Test Device and the MEDTOX*Scan*® 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 working 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.

The MEDTOX*Scan*® 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.

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 position on the strip. The MEDTOX*Scan*® 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 MEDTOX*Scan*® 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 MEDTOX*Scan*® 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 (or print out) next to the abbreviation for the invalid drug test, and no result will be given for that drug test.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Urine stock solutions were prepared for each test compound by spiking standard solution of known concentrations into negative pool urine. Each stock solution concentration was confirmed by GC/MS or LC/MS/MS. The stock solution was serially diluted into negative urine to obtain concentrations of 50%, 75%, 125% and 150% of the cutoff. The prepared sample concentrations were confirmed by GC/MS or LC/MS/MS. A total of 45 results (3 readers x 3 aliquots for 5 days and one strip lot) were obtained for each level. Testing was rotate between 8 operators. The results are presented in the tables below:

Buprenorphine Cutoff=10 ng/mL				
Conc. (ng/mL)	% of Cutoff	Number Tested	Positive	Negative
Negative	Negative	45	0	45
5	50%	45	0	45
7.5	75%	45	15	30
12.5	125%	45	45	0
15	150%	45	45	0

Opiate (Morphine) Cutoff = 2000 ng/mL				
Conc. (ng/mL)	% of Cutoff	Number Tested	Positive	Negative
Negative	Negative	45	0	45
1000	50%	45	0	45
1500	75%	45	14	31
2500	125%	45	45	0
3000	150%	45	45	0

b. Linearity/assay reportable range:

Not applicable. This is a qualitative test.

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

Profile V quality control materials were previously cleared and 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:

Analytical performance of the device around the cutoff is described 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. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross re-activities of those compounds are presented below:

Buprenorphine (BUP) (Buprenorphine) 10 ng/mL		
Compound	Result	% Cross Reactive
Buprenorphine-glucuronide	Positive at 20 ng/mL	50%
Norbuprenorphine	Positive at 250 ng/mL	4%
Norbuprenorphine-glucuronide	Positive at 500 ng/mL	2%
Codeine	Negative at 100,000 ng/mL	None Detected
Diacetylmorphine	Negative at 100,000 ng/mL	None Detected
Hydrocodone	Negative at 100,000 ng/mL	None Detected
Hydromorphine	Negative at 100,000 ng/mL	None Detected
Levorphanol	Negative at 100,000 ng/mL	None Detected
6-Monoacetylmorphine	Negative at 100,000 ng/mL	None Detected
Morphine	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
Thebaine	Negative at 100,000 ng/mL	None Detected

Opiates (OPI) (Morphine) 2000 ng/mL		
Compound	Result	% Cross Reactive
Codeine	Positive at 900 ng/mL	222%
Diacetylmorphine	Positive at 2500 ng/mL	80%
Dihydrocodeine	Positive at 3800 ng/mL	53%
Ethylmorphine	Positive at 600 ng/mL	333%
Hydrocodone	Positive at 1400 ng/mL	143%
Hydromorphine	Positive at 1900 ng/mL	105%
Levorphanol	Positive at 5000 ng/mL	40%
6-Monoacetylmorphine	Positive at 3800 ng/mL	53%
Morphine 3-β-D-Glucuronide	Positive at 5000 ng/mL	40%
Morphine 6- β-D-Glucuronide	Positive at 6000 ng/mL	33%
Norcodeine	Positive at 40,000 ng/mL	5%
Thebaine	Positive at 2500 ng/mL	80%
Apomorphine	Negative at 100,000 ng/mL	None Detected
Nalorphine	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

Non Cross-reactive endogenous compounds

The following compounds were evaluated for reactivity with the Profile V device at 100 ug/mL (albumin was evaluated at 20 mg/mL and bilirubin was evaluated at 200 ug/mL).Samples were evaluated in triplicate by in-house operators. None of the listed compounds affected the expected results.

Acetaldehyde	Creatinine	Hemoglobin, Human
Acetone	Epinephrine	Sodium Chloride
Albumin, Human	b-Estradiol	Tetrahydrocortisone
Bilirubin	Estriol	D, l-Thyroxine
Cholesterol	Glucose Std.	Uric Acid

Unrelated Compounds, Prescription and Over –the-Counter Medication

Common compounds were evaluated for reactivity at 100 ug/mL. Samples were evaluated in triplicate by in-house operators. The list of compounds tested can be found in the package insert.

Common Drugs

Drug free urine samples were spiked with the Profile V targeted drugs to the concentrations of 50% and 125% of the cutoff concentrations. An amount of 100,000 ng/mL of each common drug was added to the preparation and assayed. Evaluations were performed in triplicate by in-house operators. None of the common drugs listed affected the expected results.

Acetylsalicylic Acid	Chorpheniramine	Morphine – OPI, OXY
Acetaminophen	Cocaine	Phenobarbital
Brompheniramine Maleate	Dextromethorphan	Phenytoin
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

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

pH and Specific Gravity

To test for possible positive and/or negative interference drug free urine was divided into three aliquots and adjusted to the following pH

concentrations 4.0, 7.0, and 9.0. Each of these samples was spiked to 50% of the cutoff and 125% of the cutoff for each drug. 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 drug free urine samples having specific gravity from 1.003, 1.015 and 1.030 were used. Each of these samples were divided into two aliquots for each drug and spiked to 50% of the cutoff and 125% of the cutoff. No negative interference due to specific gravity was observed.

f. Assay cut-off:

Characterization of how the device performs 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 2 operators who tested a total of 172 unaltered clinical samples, 88 samples for OPI and 84 samples for BUP. The samples were compared to the GC/MS or LC/MS/MS. The results are presented in the table below:

Durg ng/mL	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)
BUP (10)	Positive	0	0	0	4	36
	Negative	40	0	4	0	0
OPI (2000)	Positive	0	0	1	4	36
	Negative	40	4	3	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)
OPI	2000	Positive	Morphine at 1375 ng/mL

b. Matrix comparison:

Not applicable. The assay is intended for use with urine samples 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):

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.