



<b>Subject</b> <b>Profile® –V Medtox Scan Reader System for Urine Procedure</b> (HealthPartners Neuroscience Center only)	<b>Attachments</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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<b>Manual</b> Clinic Laboratory Procedure Manual	<b>Last Review Date</b> <b>See Electronic File</b>
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<b>Applicable</b> Clinic Laboratory Staff	<b>Origination Date</b> <b>April 2016</b>
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<b>Review Responsibility</b> Regional Clinic Laboratory Supervisors, Laboratory Director	<b>Approval Date</b> <b>See Electronic File</b>
<b>APPROVAL(S)</b> Laboratory Medical Director	

**PURPOSE**

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 rapid, qualitative detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Methamphetamine, Opiate 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. Test Devices cannot be visually read.

The PROFILE® –V MEDTOX Scan® Drugs of Abuse System is for in vitro diagnostic use and is intended for prescription use only. It is not intended for use in point-of-care settings.

**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 to obtain a confirmed analytical result.

**PRINCIPLE OF OPERATION**

**The PROFILE®-V MEDTOX Scan® contains all the reagents necessary for the qualitative determination of metabolites of drugs of abuse in urine**

## TEST DEVICE

The PROFILE®-V MEDTOXScan® Test Device includes antibody-colloidal gold, drug-conjugates and a control line.

**ANTIBODY-COLLOIDAL GOLD** Mouse monoclonal antibodies were developed that bind specifically to the drug class being tested. The individual monoclonal antibodies were adsorbed to colloidal gold and dried onto the test device.

**DRUG-CONJUGATES** Drugs from each class to be tested were 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 © 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 on the sample pad dissolves and the urine wicks up the white strips carrying the reddish-purple antibody-colloidal gold with it. The PROFILE®-V MEDTOX Scan® Drugs of Abuse Test System will detect specific classes of drugs in urine because drug(s) in the urine and the drug(s) conjugated to the protein compete to bind to the antibody-colloidal gold. A test line will form when drug in the sample is below the detection threshold (negative result).

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. The results of the scans are displayed on the MEDTOX Scan® Reader screen or, optionally, can be printed.

### 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 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 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 (or print out) next to the abbreviation for the invalid drug test, and no result will be given for that drug test.

## **REAGENTS and MATERIALS /STORAGE CONDITIONS**

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

- Each test device has all the reagents necessary to test one urine sample for one or more drugs simultaneously on the MEDTOXScan® 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

### **Storage Conditions.**

The PROFILE-V MEDTOX Scan test device is stable while in the sealed pouch up to the expiration date printed on the pouch when stored at 2-25°C (36-77°F). Do not store the test kit at temperatures above 25°C (77°F). Do not freeze. If the test devices have been stored refrigerated, bring to ambient temperature prior to opening foil pouch

### **MEDTOXScan® Reader Contents**

1. Positive and Negative QC Test Devices
2. Cleaning Cassette
3. MiniPet pipettor
4. Quick Set Up guide
5. User Manual

### **MATERIALS REQUIRED BUT NOT PROVIDED**

1. Urine specimen collection container
2. PROFILE® –V MEDTOX Scan® Positive and Negative Control Solutions (external controls)

### **OPTIONAL MATERIALS**

1. Thermal Printer and Printer paper
2. Hand held Barcode Scanner

NOTE: Specimen containers and external control solutions are available from MEDTOX Diagnostics, Inc.

### **SPECIMEN REQUIREMENTS:**

1. Urine sample collected in a clean, dry container.
  - a. Approximately 75 uL is required for each sample well. Collection of 30 mL of urine is more than sufficient for initial and subsequent testing.
  - b. No preservatives should be added.
  - c. Urine may be tested immediately following collection, not to exceed 2 hours at room temperature or stored under refrigeration at 2 to 8°C (36-46°F) for no more than 2 days. Urine may be frozen at -20°C (-4°F) or colder. Bring to ambient temperature and mix well to assure a homogenous sample prior to testing. All urine samples tested for Medtox Drug Screens will be frozen and retained for at least 30 days, in an effort to accommodate a physician's request for confirmatory testing.

### **PROCEDURE:**

1. Open one pouch for each sample to be tested and mark the PROFILE®-V MEDTOX Scan® Test Device with the patient or sample identification (ID). Make sure you only mark along the left edge of the test device.
2. Dispense 75µL of urine into sample well (indicated by ▽ on the test device). If you notice a reddish/purple color in the sample well, this is normal.
  - a. Place a disposable yellow sample tip securely on to the end of the green Mini-Pet.
  - b. Grasp the Mini-Pet under its collar using the index finger and middle finger. With the thumb, depress the plunger completely.
  - c. Holding the Mini-Pet vertically, lower the yellow tip no more than ¼” into the urine specimen.
  - d. With tip in the urine specimen slowly and smoothly release the plunger allowing it to rise completely.

- e. Visually inspect the urine sample in the tip. Ensure there are no air bubbles and that no excess urine is on the outer surface of the tip.
  - f. Hold the pipette tip directly over sample well. Depress plunger completely to dispense the entire contents of urine into one sample well of the testing device.
3. Repeat Step 2 for all sample wells with a ▽ above them. Wipe off any spills on the device.
  4. Insert test device in the MEDTOX *Scan*® Reader cassette drawer and close the drawer immediately. The MEDTOX *Scan*® Reader will read the barcode on the test device and determine its part number and test configuration.
    - a. It will prompt the user to enter Lot#, User ID#, and Specimen ID#, which can all be entered using the MEDTOX *Scan*® Reader keypad or hand held barcode scanner.
    - b. The MEDTOX *Scan*® Reader will begin timing the assay once it detects the barcode and results will be displayed 10 minutes after the scan and analysis are complete.
  5. When the test is complete, remove the cartridge by holding your hand in front of the drawer to carefully and slowly open the cassette drawer. This prevents urine from splashing from the cassette and contaminating the MEDTOX *Scan*® Reader.
  6. Discard disposable yellow Mini-Pet sample tip.
    - a. Store the Mini-Pet in a dry, secure location at room temperature (18 – 25 °C or 64 – 77 °F). Replace the Mini-Pet if it becomes damaged or does not function properly.

### **READING AND INTERPRETATION OF THE TEST RESULTS:**

The PROFILE®-V MEDTOX*Scan*® Test Devices are labeled horizontally with the names of the test on each strip, and vertically with “C” and the symbols T1 – T4. The letter “C” represents the control lines. T1 – T4 refers to Test Position 1 to Test Position 4 from top to bottom of viewing window. The test position of each test is indicated on the label above the strip.

The MEDTOX *Scan*® Reader will automatically read the control and test lines at the correct positions and display the test results for each drug. Results may also be printed. The MEDTOX *Scan*® Reader displays the results as either “NEG” for a negative result, “\*\*\*POS\*\*\*” for a preliminary positive result, or “\*\*\*INVALID\*\*\*” for an invalid result. “VALID” will be displayed if valid results are obtained. “\*\*\*ERROR\*\*\*” will be displayed if there is a problem with the instrument or test cartridge. Positive, invalid and Error results are emphasized with asterisks (\*\*\*) on each side of the results and bold type. PROFILE®-V MEDTOX *Scan*® Test Devices cannot be visually read.

**Valid:** The control line must be present for the test to be valid.

**\*\*\*NEG\*\*\*:** A NEGATIVE test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

**\*\*\*POS\*\*\*:** A POSITIVE test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample. If Positive results do not correlate with clinical information please request confirmatory testing.

**\*\*\*INVALID\*\*\*:** The control line must be present for the test to be valid. The absence of a control line indicates the test is invalid. The urine sample should be retested on a new test device.

**\*\*\*ERROR\*\*\*:** There is an instrument or cartridge problem. Follow the instrument display or retest patient with a new test cartridge.

### **RESULTS**

**Results are interfaced.**

## **DETECTION LIMITS:**

The PROFILE®-V MEDTOX Scan® Drugs of Abuse Test System detects the following drugs at the cutoff levels listed below.

AMP Amphetamine	500 ng/mL
BAR Barbiturates (Butalbital)	200 ng/mL
BZO Benzodiazepines (Nordiazepine)	150 ng/mL
BUP Buprenorphine	10 ng/mL
COC Benzoyllecgonine	150 ng/mL
MAMP Methamphetamine	500 ng/mL
MTD Methadone	200 ng/mL
OPI Morphine	100 ng/mL
OPI2 Morphine	2000 ng/mL
OXY Oxycodone	100 ng/mL
PCP Phencyclidine	25 ng/mL
PPX Propoxyphene (Norpropoxyphene)	300 ng/mL
THC 11-nor-9-carboxy- $\Delta^9$ -THC	50 ng/mL
TCA Tricyclic Antidepressants (Desipramine)	300 ng/mL

## **CONFIRMATORY TESTING:**

The PROFILE®-V MEDTOXScan® drugs of abuse test system provides 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. If confirmation of positive results is auto-ordered, send specimen aliquot to Regions. No "legal" drug screens are to be performed via this method.

For Confirmatory testing, See Computer Order and Result Entry on page 12 for ordering instructions.

## **CALIBRATION:**

The MEDTOXScan® Reader is calibrated before shipment to the user.

## **QUALITY CONTROL AND ACCEPTABILITY OF RESULTS**

This test has an individual quality control plan (IQCP) in place. The Risk Assessment can be found on site as one component of the Profile-V MedtoxScan method validation.

## **CONTROLS:**

External controls:

1. External Controls:
  - a. Profile-V MEDTOXScan Positive Control (SP102137)
  - b. MEDTOX Negative Control (SP101183)
2. External Controls are urine based control material that contains drugs to be tested at concentrations above the cut off (positive control) or contain no drug (negative control).
3. Run external controls as if they were patient samples.
4. Run Positive and Negative Quality Control within every 7 days and with each new lot of devices. Run QC if you suspect that the reader or test device is not working properly or if you have had a repeated unexpected test result or storage problem.
5. Positive and Negative controls come frozen and are stable for 6 months or to the expiration date, whichever comes first, when stored at -10 to -20°C. Controls are stable for 31 days when tightly capped at refrigerated temperatures 2-8°C or until the expiration date, whichever comes first.

- Controls can be aliquoted and re-frozen. Make 13 aliquots of approximately 375uL each, parafilm and label each aliquot with Lot#, Neg or Pos, and expiration date. Place all aliquots along with the empty bottle in a plastic bag and store in freezer. There should be one bag for Positive QC and one bag for Negative QC.
- Thaw controls as needed, allowing controls to come to room temperature and mix before using.

#### Internal controls:

Internal Controls ensure that the test is working and that the test is being performed correctly. A control line (internal control) is included on each PROFILE®-V MEDTOXScan® test strip. Whether or not drug is present in the sample, a line must form at the Control (C) position on the test strip to show that enough sample volume was used and that the reagents are migrating properly. If a Control line does not form, the test is invalid.

#### QC Test Devices:

1. Run the QC Test Devices routinely each day of patient testing.
2. The QC Test Devices function as an optical performance system check for the MEDTOX Reader. QC Test Devices should be run if the PROFILE®-V MEDTOX Scan Reader is not working properly, if the Contact Imaging Sensor is dirty, or if the PROFILE®-V MEDTOX Scan Reader has been dropped or damaged.

#### Procedure:

- a. Remove devices from storage pouch. The Positive device has one line on each strip. The Negative device has six lines on each strip. Visually examine the devices to be sure the strips in the device window are clean (free of dust, fingerprints, smudges or discoloration/yellowing) and undamaged (scratched, torn, or bent). Do not add sample to the sample wells of the QC Test Devices.
- b. Place device in PROFILE®-V MEDTOX Scan Reader tray and close.
- c. At the prompt, enter test device Lot Number and press “OK”
- d. Enter User ID and press “OK”
- e. Scan POS or NEG barcode from pouch for Specimen ID and press “OK” (or manually enter).
- f. Test results print out when QC Test device scan is complete.
- g. Repeat steps 3-7 with second device.
- h. Verify that test results are reporting correctly. If the test results are all POS for the positive QC Test device, and all NEG for the negative QC Test device, the PROFILE®-V MEDTOX Scan Reader is reporting results correctly. Resume normal operation.
- i. Should the devices fail, perform the “Cleaning Cassette Procedure”

**MAINTENANCE:** As needed, we will clean the sensor using the Cleaning Cassette. Follow the MEDTOX Scan Sensor Cleaning Procedure on the intranet. No maintenance other than periodic external cleaning is required. Use isopropyl alcohol wipes to clean the outside of the reader and the device drawer.

#### Cleaning Cassette Procedure

1. If results are incorrect when running the QC Test device, or if the PROFILE®-V MEDTOX Scan Reader displays the “Contaminated Sensor” error message it is appropriate to run the “Cleaning Cassette Procedure”. It is effective for cleaning contamination such as dirt, dust or sample accumulated on the contact imaging sensor (CIS)
  - a. Disconnect the PROFILE®-V MEDTOX Scan Reader from the power supply.
  - b. Prepare the MEDTOXScan Cleaning Cassette by rinsing under running tap water. Apply one drop of mild liquid hand soap to the pad. Rinse thoroughly to remove any soap remnants.
  - c. Remove excess water by blotting Cleaning Cassette pad on paper towels.
  - d. Place moist cleaning cassette in PROFILE®-V MEDTOX Scan Reader drawer. While holding down the eject button, slowly move the drawer in and out 10 times. Use the “tape tail” attached to the Cleaning Cassette to pull the drawer out while holding down the eject button.

- e. If visible dirt is observed on the Cleaning Cassette pad, wash, rinse and blot the Cleaning Cassette again. Place the Cleaning Cassette in the drawer of the MEDTOX PROFILE®-V Scan Reader and repeat step d.
  - f. When finished cleaning the CIS, remove the Cleaning Cassette from the MEDTOX PROFILE®-V Scan Reader drawer.
  - g. Re-connect power supply and power on the MEDTOX PROFILE®-V Scan Reader.
  - h. If the Welcome screen appears, then run the QC Test Devices to confirm that any contamination has been removed from the sensor and the MEDTOX PROFILE®-V Scan Reader is functioning properly.
  - i. If the “Contaminated Sensor” error message displays again after the first cleaning procedure, repeat steps a-g.
  - j. If the MEDTOX PROFILE®-V Scan Reader still displays the error message after the Cleaning Cassette procedure has been conducted twice, call Technical Support. (1-800-832-3244).
2. Auto Contamination Detection of the Contact Imaging Sensor (CIS) is performed without user intervention when the instrument is turned on, and with each scan of a test device. If this fails an error message, “Contaminated Sensor” will display. Please perform Cleaning Cassette Procedure.

### **LIMITATIONS OF PROCEDURE:**

1. The test is only for use with unadulterated preservative free, human urine samples. Urine that is either extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results. If adulteration is suspected, obtain an additional specimen and re-test. Clear polystyrene containers may absorb some drugs; use of polypropylene containers is advised.
2. A positive result for any drug does not indicate the level of intoxication, administration route or concentration of that drug in the urine specimen.
3. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
4. Place PROFILE®-V MEDTOX *Scan*® Test Devices in MEDTOX *Scan*® Reader immediately after adding the sample. Once the test device has been read in the MEDTOX *Scan*® Reader, it must not be reinserted for a repeat reading, as the ten minute timing will begin again. If a repeat reading is required, rerun the sample on a fresh test cassette.
5. The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is not intended for use in point-of care settings.
6. There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false results.
7. Gas Chromatography/Mass Spectroscopy is the recommended confirmatory method for most drugs. HPLC or LC/MS/MS is the preferred confirmatory method for Tricyclic Antidepressants and Benzodiazepines. Any of the drugs being tested for in the PROFILE-V MEDTOX*Scan* Drugs of Abuse Test System may give a preliminary positive result if ingested at prescribed therapeutic doses.
8. The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System cannot distinguish between abused drugs and certain prescribed medications. A positive test may be obtained from certain foods or food supplements.
9. The PROFILE®-V MEDTOX*Scan*® Test Devices must be used only with the MEDTOX*Scan*® Reader. They cannot be visually read.

### **WARNINGS AND PRECAUTIONS:**

- PROFILE®-V MEDTOX *Scan*® Drugs of Abuse Test System is for *in vitro* diagnostic use only.
- Do not use PROFILE®-V MEDTOX *Scan*® Test Devices after the expiration date printed on the package label.
- The PROFILE®-V MEDTOX *Scan*® Test Device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.

- If PROFILE®-V MEDTOX Scan® Test Devices have been stored refrigerated, bring to ambient temperature (18-25°C/ 64-77°F) prior to opening foil pouch.
- Do not store the test kit at temperatures above 25°C (77°F). Do not freeze.
- Avoid cross-contamination of urine samples by using a new urine specimen container and a fresh pipette tip for each urine sample. Avoid polystyrene containers. Do not use preservatives.
- Do not touch test strips in large viewing window of the PROFILE®-V MEDTOX Scan® Test Device.
- Do not use PROFILE®-V MEDTOX Scan® Test Device if strips are damaged or dirty.
- Do not apply labels or tape to the PROFILE®-V MEDTOX Scan® Test Device.
- Do not write outside of the ID box on the PROFILE®-V MEDTOX Scan® Test Device top.
- Urine specimens and all materials coming in contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Avoid contact with broken skin.
- **Avoid contaminating the top of the test device with urine sample.** Clean any urine off the top of the test device using a dry wipe to prevent contamination of the MEDTOX Scan® Reader sensor.

### **Clinical Significance**

Qualitative PROFILE®-V MEDTOXScan® Test Devices utilize a one-step, solid-phase immunoassay technology. The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System includes the MEDTOXScan® Reader for a convenient automated result. This test system may be used to screen urine samples for one or more of the following drug classes prior to confirmatory testing:

- Amphetamines are a group of drugs that are central nervous system stimulants. This group includes amphetamine and methamphetamine.
- Amphetamine (d-amphetamine) is detected on the Test Device only at the (AMP) position, methamphetamine (MAMP) is detected at the (MAMP) position.
- Barbiturates (BAR) are a group of structurally related prescription drugs that are used to reduce restlessness and emotional tension, induce sleep and to treat certain convulsive disorders.
- Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.
- Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.
- Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.
- Opiates (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.
- Oxycodone (OXY) (Oxycontin®, Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release oral formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.
- Phencyclidine (PCP) is a hallucinogenic drug.
- Propoxyphene (PPX) is a narcotic analgesic. Its primary metabolite is norpropoxyphene.<sup>3</sup>
- Tricyclic Antidepressants (TCA) are a group of structurally related prescription drugs that are used to manage depression.
- Marijuana (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors can influence the time period during which drug metabolites are detected in urine. These include the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume will lower the drug concentration in the urine and may decrease the detection period. Lower detection levels may increase the detection time window. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.



<b><u>Drug</u></b>	<b><u>Detection Period</u></b>
Amphetamine Acid Conditions Alkaline Condition	1-3 days 3-10 days
Barbiturates Short-Acting Long-Acting	Up to 6 days Up to 16 days
Benzodiazepines	1-12 days
Buprenorphine	up to 3 days
Cocaine metabolite	Up to 5 days 1 to 3 days typical
Methamphetamine Acid Conditions Alkaline Conditions	1-3 days 3-10 days
Opiates Heroin Morphine Codeine	1 day 1-3 days 1-3 days
Oxycodone	1-3 days
PCP Single Use Chronic Use	1-8 days Up to 4 weeks
Propoxyphene	Up to 1 week
THC Single Use Chronic Use	1-7 days Less than 30 days typical
Tricyclic Antidepressants	1-7 days

### **Troubleshooting:**

Use the QC Test Devices provided with the MEDTOXScan® Reader 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 (dirt, dust or sample).

The QC Test Devices function as an optical performance system check for the MEDTOXScan® Reader only, not for the PROFILE®-V MEDTOXScan® Drugs of Abuse Test System, and they are not intended to replace the need for external controls. The QC Test Devices have been designed to simulate the endpoints that are generated in the PROFILE®-V MEDTOXScan® Test Device when external positive and negative QC controls are run. The QC Test Devices consist of artificial control lines and test lines (negative) or artificial control lines and no test lines (positive) printed on a membrane and placed in the PROFILE®-V MEDTOXScan® Test Device plastic housing. The QC Test Devices are not intended to evaluate all components of the test system from specimen preparation through generation of results. They are intended to function as a troubleshooting device to determine that the reader optics are functioning correctly. You should run the QC Test Devices (1) if you suspect the MEDTOXScan® Reader is not functioning properly, or (2) if you suspect the CIS (optics) is dirty, or (3) if the MEDTOXScan® Reader has been dropped or damaged.

Consult the MEDTOXScan® Reader User Manual for details on troubleshooting, cleaning procedure and explanation of MEDTOXScan® Reader error messages. Contact MEDTOX Technical Support if you need any additional help at 1-800-832-3244.

### **DEFINITIONS**

### **REVIEWERS**

MLAFROMBOISE

**COMPLIANCE**

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

**ATTACHMENTS**

**OTHER RESOURCES**

PROFILE-V MEDTOX Scan Drugs of Abuse Test System Standard Operating Procedure manual and Package Insert Manual

**ENDORSEMENT** Laboratory Administration

**Computer Order and Result Entry**  
(Health Partners Neuroscience Center only)

**RAPID PAIN MANAGEMENT PANEL**  
**EPIC: 6380**

**EPIC 6380**

This order has questions associated with it and should be answered in EPIC when the order is placed by the provider. These questions are to determine if the patient is prescribed the drug, so they need to be answered yes or no.

**Results:**

**Presumptive Positive**

**Negative: Not Detective**

**DRUGS:**

<b>THC (Marijuana) METAB SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>PHENCYCLIDINE (PCP) SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>COCAINE METABOLITE SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>METHAMPHETAMINE</b>	<b>Confirmatory testing to Regions</b>
<b>OPIATES SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>AMPHETAMINES SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>BENZODIAZEPINES SCREEN</b>	<b>Confirmatory testing to ARUP</b>
<b>TRICYCLIC SCREEN UR</b>	<b>DO NOT REPORT</b>
<b>METHADONE SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>BARBITUATES SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>OXYCODONE SCREEN</b>	<b>Confirmatory testing to Regions</b>
<b>PROPOXYPHENE, URINE</b>	<b>DO NOT REPORT</b>
<b>BUPRENORPHINE SCREEN</b>	<b>Confirmatory testing to ARUP</b>

Confirmatory testing is automatically ordered if drug is not prescribed but found in the urine in the rapid pain management screen. Confirmatory testing will be sent to Aliquot.

**Note:** Call Regions Toxicology with questions. Regions Toxicology phone number is 651-254-9637 and is staffed M-F 6:30am-5:00 pm