**CHEM.KIT.8.0 MEDTOX DRUGS OF ABUSE TEST SYSTEM**

**PRINCIPLE**

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System includes the one-step, competitive, membrane-based immunochromatographic PROFILE®-V MEDTOX*Scan*® Test Device and the MEDTOX*Scan*® Reader, which interprets and reports the test results automatically. A single urine sample can be evaluated for the presence of each of the classes of drugs specified in a single PROFILE®-V MEDTOX*Scan*® Test Device. The PROFILE®-V MEDTOX*Scan*® Test Device includes antibody-colloidal gold, drug-conjugates and a control line.

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 and can be printed with the optional thermal printer.

**OWNER**

Manager, Community East Hospital Laboratory

**SPECIMEN**

A. Patient Preparation: None.

B. Specimen collection:

1. The urine sample must be collected in a clean, dry, previously unused glass or plastic container free of preservatives.

2. Urine collected at any time of the day may be used.

3. Approximately 375 µL is required for testing. Collection of 30 mL of urine is more than sufficient for initial and subsequent testing.

4. Centrifuging an aliquot of the specimen is not necessary; however, if the urine is turbid, an aliquot of the specimen can be centrifuged for 5 minutes at 1500 RPM before testing.

C. Specimen Storage and Stability:

1. Urine samples may be stored at 2 to 8°C for up to 48 hours prior to testing in polypropylene containers.

2. For prolonged storage, samples may be frozen and stored at -20°C or colder. Frozen samples should be brought to ambient temperature and mixed well before testing.

**MATERIALS**

A. Materials provided in the test kit:

1. PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System Kit

a. Twenty-five (25) PROFILE®-V MEDTOX*Scan*® Test Devices for use with the MEDTOX*Scan*® Reader in individual foil packages

b. Twenty-five (25) disposable pipette tips

c. One Quick Reference guide

2. MEDTOX*Scan*® Reader Kit

a. Positive and Negative QC Test Devices

b. Cleaning Cassette

c. MiniPet pipettor

d. Quick Set Up guide

e. User Manual

B. Materials required, but not provided:

1. Thermal Printer and Printer paper (optional)

2. Hand held Barcode Scanner (optional)

3. Disposable tube for centrifuging specimen aliquot

4. Centrifuge

**REAGENTS**

A. 1. Composition of test devices

a. Each test device has all the reagents necessary to test one urine sample for one or more drugs simultaneously on the MEDTOX*Scan*® Reader. The number of drugs tested for depends on the configuration of the PROFILE®-V MEDTOX*Scan®* test device being used.

b. 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.

B. Storage and Stability:

1. The kit, stored in its original packaging, is stable until the expiration date on the label when stored at 2 to 25°C. Do not store the test kit at temperatures above 25°C. Do not freeze.

2. Do not use PROFILE®-V MEDTOX*Scan*® Test Devices after the expiration date printed on the package label.

3. 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.

4. If PROFILE®-V MEDTOX*Scan*® Test Devices have been stored refrigerated, bring to ambient temperature (18 to 25°C) prior to opening the foil pouch.

**INSTRUMENT MAINTENANCE**

1. Weekly Maintenance
2. Perform both Positive and Negative External liquid QC
3. Use isopropyl alcohol wipes to clean the exterior and device drawer of the MedTox.
4. Monthly Maintenance

1. Perform the MedTox Cleaning Cassette procedure as outlined in the Cleaning Cassette

Instructions to clean the internal sensor. Higher volume labs may require twice monthly cleaning.

1. After cleaning, store air dried cassette in clean, dry plastic bag.
2. After cleaning with cleaning cassette, run positive and negative QC Test Device to verify instrument function.
3. Replace Cleaning Cassette when:

* Cassette is visibly soiled
* QC failures continue to occur.

1. Annual Maintenance
2. Replacement of the MiniPet Pipettor with a new MiniPet from MedTox.

**QUALITY CONTROL**

A. Internal Quality Control:

1. A control line is included on each PROFILE®-V MEDTOX*Scan*® test strip.

2. A line must form at the Control position on the test strip to show that enough sample volume was used and that the reagents are migrating properly.

3. If a Control line does not form, the test is invalid.

4. The Control line consists of immobilized anti-mouse antibody that reacts with the antibody-colloidal gold as it passes this region of the membrane. Formation of a line detectable by the MEDTOX*Scan*® Reader verifies the Control line antibody-antigen reaction occurred.

B. QC Test Devices:

1. Positive and Negative QC Test Devices are included in the MEDTOX*Scan*® Reader Kit. These devices function as an optical performance system check for the MEDTOX*Scan*® Reader only, not for the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System, and are not intended to replace the need for the external controls.

2. The QC Test Devices have been designed to simulate the end points that are generated in the PROFILE®-V MEDTOX*Scan*® 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 MEDTOX*Scan*® Test Device plastic housing.

3. Both the Positive and Negative QC Test Devices should be used daily to verify the performance of the MEDTOX*Scan*® Reader.

C. External Quality Control:

1. QC material—must be purchased from MEDTOX Diagnostics, Inc.:

a. MEDTOX Negative Toxicology Urine Control, PN 101183

b. PROFILE®-V MEDTOX*Scan*® Positive Toxicology Control, PN 102367

2. Storage and Stability:

**NOTE: Controls can be aliquoted and frozen in polypropylene tubes.**

a. Unopened: The controls are stable until the expiration date on the label when stored at 2 to 8⁰C or -20 to -10⁰C and protected from light.

b. After opening:

1) The controls are stable for six months or until the expiration date, whichever comes first when stored at -20 to -10⁰C.

2) The controls are stable for 31 days or until the expiration date, whichever comes first when stored tightly capped at 2 to 8⁰C.

3) Thaw frozen aliquots as needed. Allow them to come to room temperature followed by gentle swirling before use. Thawed aliquots are stable for 31 days when stored tightly capped at 2 to 8⁰C.

3. Frequency:

a. Both levels of external QC should be performed at least once every 7 days.

b. Both levels of external QC should be performed with each new lot or shipment.

1. External QC can also be used to verify test performance as needed.

4. Procedure:

a. Allow the controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.

b. Perform testing of QC materials as if they were patient samples.

c. Follow QC Package insert for QC use.

5. Expected results:

a. The internal control results should be as expected to confirm the validity of the testing.

b. The results of testing of the QC material should be as expected (negative or positive, depending on the QC used).

6. Unexpected results:

a. If unexpected results are seen when running the controls, review the procedure, interpretation of results and limitations sections of this procedure and repeat the test with another device.

b. If the problem persists:

1) Consult the MEDTOX*Scan*® Reader User Manual for details on troubleshooting, cleaning procedure and explanation of MEDTOX*Scan*® Reader error messages.

2) Discontinue use of the test kit immediately and Contact MEDTOX Technical Support if you need any additional help.

**PROCEDURE**

A. Device preparation:

1. If PROFILE®-V MEDTOX*Scan*® Test Devices have been stored refrigerated, bring to ambient temperature (18 to 25°C) prior to opening the foil pouch.

2. Open one pouch 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 (labeled “ID ”).

a. Do **not** apply labels or tape to the PROFILE®-V MEDTOX*Scan*® Test Device.

b. Do **not** write outside of the ID area on the left side of the PROFILE®-V MEDTOX*Scan*® Test Device top.

3. Do not use PROFILE®-V MEDTOX*Scan*® Test Device if the strips are damaged or dirty. NOTE: You may notice a reddish-purple color in the sample well; this is normal, do not discard the test.

4. Dispense 75 µL of urine into sample well (indicated by  on the test device).

a. Place a disposable yellow sample tip securely onto the end of the green (75 µL) MiniPet™.

b. Grasp the MiniPet under its collar using the index and middle fingers. With the thumb, depress the plunger *completely*.

c. Holding the MiniPet vertically (straight up-down), 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.

g. 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.

h. Do not touch the test strips in the large viewing window of the test device.

5. Repeat Step 4 for all sample wells with a  above them.

B. Insert the device into the MEDTOX*Scan*® Reader:

1. Place the 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.

2. When prompted, enter the Lot# and Specimen ID# using the hand held barcode scanner. Enter the User ID# using the MEDTOX*Scan*® Reader keypad.

3. The MEDTOX*Scan*® Reader will begin timing the assay once it detects the barcode and results will be displayed after the scan and analysis are complete. 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.

C. Care of the Minipet:

1. Discard the disposable yellow MiniPet sample tip.

2. Store the MiniPet in a dry, secure location at room temperature (18 to 25⁰C).

3. Replace the MiniPet if it becomes damaged or does not function properly.

**INTERPRETATION OF RESULTS**

A. PROFILE®-V MEDTOX*Scan*® Test devices **cannot** be visually read.

B. Interpretation of Results:

1. 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 will also be printed by the thermal printer.

2. The MEDTOX*Scan*® Reader displays the results as either “NEG” for a negative result, “POS” for a positive result, or “INVALID” for an invalid result. “VALID” will be displayed if valid results are obtained.

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

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

c. **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.

d. **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.

**REPORTING RESULTS**

A. Expected value: Negative

B. Manual result entry:

To enter results into Sunquest manually, answer the SQ commands as follows:

FUNCTION: MEM

TECH: [Enter] to verify tech code

SHIFT: [Enter] or indicate shift 1, 2 or 3

WORKSHEET: Site Specific

TEST-1 [Enter] for all tests or enter test code DRGSC or DRCGN

WORKLOAD DATA FOR: [Enter]

ACC. NO. Enter accession number.

Enter result (POS or NEG). [Enter]

In Location result field: type “HIDE”

ACCEPT (A), MODIFY (M), **A**ccept if correct. **M**odify to add text code.

DISPLAY PRIOR (D), **D**isplay prior to compare to previous result.

PRELIM (P) OR REJECT (R)? **P**reliminary results will not be printed on patient reports. **R**eject results.

C. If the HIS or LIS system is not functional, see the Laboratory Computer Downtime Policy.

**PROCEDURE NOTES**

A. Interferences:

1. Varying ranges of specific gravity (1.003 to 1.030) do not affect the test results.

2. Varying ranges of pH (pH 4 to 9) do not affect the test results.

3. A lengthy list of compounds which do not show cross-reactivity when tested with the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is given in the package insert.

B. Limitations:

1. The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. 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.

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

3. Clear polystyrene containers may absorb some drugs; use of polypropylene containers is advised.

4. 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.

5. 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.

6. The PROFILE®-V MEDTOX*Scan*® Test Devices must be used only with the MEDTOX*Scan*® Reader. They cannot be visually read.

**CLINICAL SIGNIFICANCE**

A. Specific drugs tested for will be determined by the configuration of the PROFILE®-V MEDTOX*Scan*® Test Device being used and may include any or all of the following drugs.

1. The 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.

2. 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.

3. Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.

4. Buprenorphine (BUP) is a potent analgesic often used in the treatment of opiate abusers.

5. Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.

6. Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.

7. Opiates (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.

8. 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.

9. Phencyclidine (PCP) is a hallucinogenic drug.

10. Propoxyphene (PPX) is a narcotic analgesic. Its primary metabolite is norpropoxyphene.

11. Tricyclic Antidepressants (TCA) are a group of structurally related prescription drugs that are used to manage depression.

12. Marijuana (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

B. Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors 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. The detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism. Information on the detection period for each drug is given in the package insert.

**REFERENCES**

A. PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System Package Insert, P/N 102038, MEDTOX Diagnostics, Inc., Burlington, NC, 12/09.

B. MEDTOX® Toxicology Urine Controls Package Insert, P/N 102070, MEDTOX Diagnostics, Inc., Burlington, NC, 12/09.