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SUBJECT:	MEDTOX$_{Scan}$ DRUGS OF ABUSE	REVISION DATE:	1/16

MEDTOX$_{Scan}$ DRUG OF ABUSE TEST SYSTEM

INSTRUMENT PROFILE-V MEDTOX

METHOD This method is intended to be used for Emergency Department, Labor and Delivery patients and neonates.
Positive Drug Screens may need to be sent out for confirmation depending on patient demographics. See attached Technical Bulletin (11/5/12) for confirmation guidelines.

PRINCIPLE 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, Buprenorphine, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, TCH and Tricyclic Antidepressants or their metabolites. 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 system will detect specific classes of drugs in urine because drugs in the urine and drugs 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 MEDTOXScan reader scans the test device and utilizes a contact imaging sensor 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 MEDTOXScan Reader screen and are printed out on the optionally attached printer.

SAFETY All reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance.
Refer to Laboratory Policy and Procedure Manual Safety Section (11).

SAMPLE COLLECTION Urine should be collected in a clean, dry container. Approximately 75 microliters is required for each sample well. No preservatives should be added. (Do not use urine preservative tube). If it is necessary to store urine, store under refrigeration at 2 to 8 degrees C for no more than two days. Stored urine must be brought to ambient temperature and mixed well to assure a homogeneous sample prior to testing.

MEDTOXScan DRUG OF ABUSE TEST SYSTEM, 03-286

Continued

REAGENTS &SUPPLIES

- Test devices in individual foil packages (stored at 2-25°C)
- Disposable pipette tips
- MiniPet pipettor
- External Negative and Positive controls (stored at < -18°C) Stable for 30 days once thawed and stored at 2-8°C
- Positive and negative QC Test Devices (refer to QC Test Devices reference guide for detailed instructions)
- Cleaning Cassette (refer to Cleaning Cassette reference guide for detailed instructions)

PRECAUTIONS & LIMITATIONS

- Do not use the test devices after the expiration date printed on the package label.
- The test devices should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
- If the test devices have been stored refrigerated, bring to ambient temperature prior to opening foil pouch. Do not store test kit at temperatures above 25°C (77°F)
- Do not use urine preservatives and use a fresh pipette tip for each urine sample.
- Do not apply labels or tape to the test device
- Do not touch test strips in large viewing window of the test device.
- Once the test device has been read in the reader it must not be reinserted for a repeat reading. If repeat reading is required, rerun the sample on a fresh cassette.
- Urine samples that have been previously analyzed on the automated urinalysis analyzer (Iricell) should NOT be used for Medtox drug screen testing due to the possibility of carryover.

QUALITY CONTROL

Each test strip has an internal procedural control. A line must form at the Control 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 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 printout) next to the abbreviation for the invalid drug test, and no result will be given for that drug test.

MEDTOX positive and negative external controls will be run:

- With each **new lot number** of test devices
- **Once per day**
- If you suspect that the test devices are not performing as expected.

PROCEDURE

Step	Action
1.	Open one pouch for each sample to be tested and mark the test device with the patient or sample identification (ID). Make certain you do not mark along the left edge of the test device (labeled "ID >"). (You may note a reddish-purple color in the sample well. This is normal, do not discard the test.) Note: If device was stored refrigerated, allow it to come to room temperature (64-77°F) before opening and using.)
2.	Dispense 75 µL of urine into sample well (indicated by V on the test device). If urine was refrigerated, allow it to come to room temperature (64-77°F) and mix by swirling before use.)
3.	Repeat Step 2 for all sample wells with a V above them. Wipe off any spills on the device.
4.	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. 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. 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.
5.	Discard disposable, yellow MiniPet sample tip. Store the MiniPet in a dry, secure location at room temperature (64-77°F). Replace the MiniPet if it becomes damaged or does not function properly.

INTERPRETATIONS OF RESULTS

The test devices are labeled with a barcode that identifies which tests are present on the device being run. The test devices cannot be visually read. The Scan reader will automatically read the control and test lines at the correct test position and display the test results for each drug. The 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.

- **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 above the cutoff level.
- **POS:** A preliminary POSITIVE test result for a specific drug indicates that the sample may contain drug near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of the drug in the urine sample.
- **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.

THRESHOLD CONCENTRATION

PCP (Phencyclidine)	**25 ng/mL**
Benzodiazepines	**150 ng/mL**
Cocaine	**150 ng/mL**
Amphetamines	**500 ng/mL**
Methamphetamines	**500 ng/mL**
THC	**50 ng/mL**
Opiates	**100 ng/mL**
Barbiturates	**200 ng/mL**
TCA	**300 ng/mL**

ROUTINE MAINTENANCE & CLEANING

MEDTOX recommends isopropyl alcohol wipes for routine cleaning of the exterior of the Scan reader and the device drawer. A specialized cleaning cassette is used for cleaning the internal sensor in the event that you get incorrect results or the scan reader displays the “CONTAMINATED SENSOR” error message. The Cleaning Cassette should be used in conjunction with the MEDTOX QC Test Devices to confirm that the cleaning procedure has worked.
Refer to the Cleaning Cassette Quick Reference Guide and the QC Test Devices reference guide for more detailed instructions.

REFERENCE RANGE

Negative

REFERENCE

Profile-V MedtoxScan Drug of Abuse Test System Package Insert. Medtox Diagnostics, Inc., Rev. 3/12
http://kpnet.kp.org:81/california/scpmg/labnet/

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Imp.
New		Cindy Schwartz			
Major	Changed frequency of performing external controls to once per day.	Cindy Schwartz			1/13/16

Imp. =Implemented