PROFILE®-V MEDTOX® Scan Reader System

Quick Reference Instructions

Before performing the test, refer to the PROFILE®-V MEDTOX*Scan®* *Drugs of Abuse Test System Insert and* MEDTOX*Scan®* *User Manual for complete operating instructions and QC recommendations.*

INTENDED 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: Amphetamine, 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. The 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 prescription use only. It is not intended for use in point-of-care settings. In Canada, it is for Laboratory use only.

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		
BZO Benzodiazepines (Nordiazepam)	150 ng/mL	OXY Oxycodone (Oxycodone)	100 ng/mL
BUP Buprenorphine (Buprenorphine)	10 ng/mL	PCP Phencyclidine (Phencyclidine)	25 ng/mL
COC Cocaine (Benzoylecgonine)	150 ng/mL	PPX Propoxyphene (Norpropoxyphene)	300 ng/mL
MAMP Methamphetamine (d-Methamphetamine)	500 ng/mL	THC Cannabinoids (11-nor-9-carboxy-Δ^9-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 drug analytes. 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.

MATERIALS PROVIDED with MEDTOX*Scan®* Reader

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

Optional Materials

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

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine specimen collection container
2. PROFILE®-V MEDTOX*Scan®* Positive or High Positive and MEDTOX Negative Control Solutions

MATERIALS PROVIDED with PROFILE®-V MEDTOX*Scan®* TEST KIT

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 kit, in its original packaging, should be stored at 2-25°C (36-77°F) until the expiration date on the label.

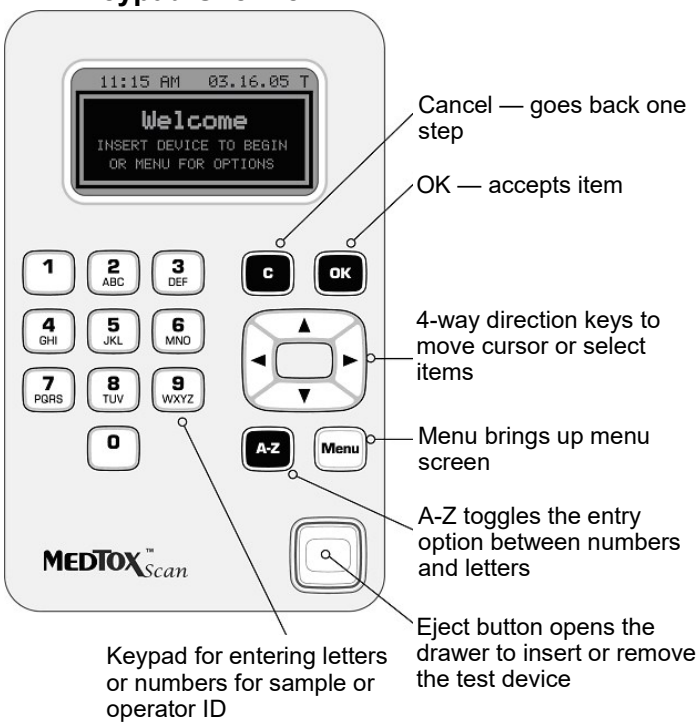
NOTE: Specimen containers and external control solutions are available from MEDTOX Diagnostics, Inc.

PRECAUTIONS

- The 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 or 64-77°F) prior to opening foil pouch. Stored urine must be brought to ambient temperature and mixed well before testing.
- 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 area on the left side of 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 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.

Operation

Keypad Overview



Use Menu / Setup to configure MEDTOX*Scan*® Reader options such as print mode, results beep, etc. See MEDTOX*Scan*® Reader User Manual for details.

Run the Test

- Power on the MEDTOX*Scan*® Reader.
- Obtain urine sample.
- Open foil pouch and remove PROFILE®-V MEDTOX*Scan*® Test Device. You may notice a reddish-purple color in the sample well-this is normal, do not discard test.
- Write the Specimen ID in the ID area (ID ▷) on the left side of the Test Device.
- Place a disposable yellow sample tip securely onto the end of the green (75µL) MiniPet pipette.
- Wait for the Reader Welcome screen.
- Add 75µL of urine to each sample well indicated by a ▽ on the Test Device. Expect to observe reddish color flowing up the strips.
- Wipe off any spills on device.
- Place the Test Device in the MEDTOX*Scan*® Reader cassette drawer.
- Close Reader drawer immediately (Reader automatically reads results after 10 min). Proceed to READ A TEST, #1 next page.

Operation

(Continued from previous page)

To Read A Test — in the MEDTOX*Scan*® Reader :

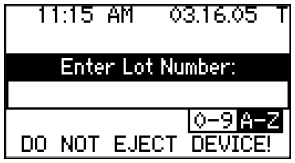
1. Insert Device

After inserting the PROFILE®-V MEDTOX*Scan*® Test Device and closing the drawer, a progress bar will show that the test device is being detected.

WARNING: Do not eject device while MEDTOX*Scan® *Reader is scanning! It may damage the instrument!

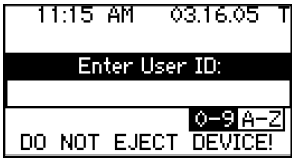
2. Enter Lot Number

Once the test device is detected, the Enter Device Lot screen appears. Enter the Device Lot Number using the MEDTOX*Scan*® Reader keypad or use the hand held barcode scanner.



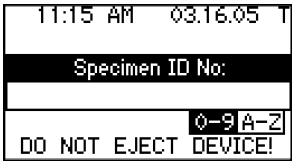
3. Enter User ID

Next, the Enter User ID screen appears. Enter the User ID with the keypad or barcode scanner.



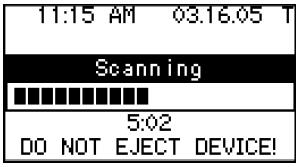
4. Enter Specimen ID

Next, the Enter Specimen ID screen appears. Enter the Specimen ID with the keypad or barcode scanner.



5. Scanning

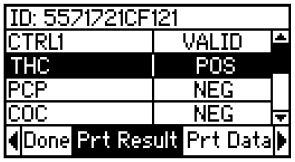
The scanning screen will appear after the Specimen ID has been entered. The timer at the bottom of the screen will show how much time remains until the test is complete.



6. View Results

The Results Screen appears when the test is complete. Scroll down to see all the results.

If Auto Print mode is turned on, the results will be printed automatically on the thermal printer. Choose “Prt Result” to print manually.



7. Press “CANCEL” to return to the WELCOME screen.

READING AND INTERPRETATION OF THE TEST RESULTS

The PROFILE®-V MEDTOX*Scan*® Test Devices are labeled with a barcode that identifies which tests are present on the device being run. Refer to specific product labeling for the combination of drug tests included on that test device.

PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read. The MEDTOX*Scan*® Reader will automatically read the control and test lines at the correct test position 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.

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 preliminary 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. Positive samples should be sent to a reference laboratory for more definitive 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.

Urine Collection and Handling

- Use fresh urine specimens. Urine specimens do not require any special handling or pretreatment. It is best to test urine specimens immediately after collection.
- If necessary, urine specimens may be refrigerated at 2° to 8°C for two days or frozen at -20°C or colder for longer periods. Stored Urine must be brought to ambient temperature (18-25°C or 64-77°F) and mixed well to assure a homogeneous sample prior to testing.
- Use a new urine cup and test for each urine specimen.

QUALITY CONTROL of the PROFILE®-V MEDTOX*Scan*® Reader System

The purpose of quality control is to ensure accuracy and reliability of results and to detect errors. MEDTOX recommends a Quality Control Program for monitoring the performance of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader that uses a combination of internal controls and external controls. Users should follow government regulations for the running of QC material.

Internal controls ensure that the test is working and that you are performing the test correctly. A control line (internal control) is included on each PROFILE®-V MEDTOX*Scan*® 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. 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.

External controls are urine-based control materials that contain the drugs to be tested at concentrations above the cutoff (positive control) or contain no drug (negative control). Run external controls as if they were patient samples. Refer to the instructions that accompany the external controls. You should run external controls routinely or as needed for any of the following reasons: (1) to practice the test with a known control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the reader or test device is not working properly, (5) if you have had a repeated unexpected test result, or (6) if you suspect that the test devices have been stored improperly. Should control results indicate a problem with the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System, please follow the instructions in the Troubleshooting Section below.

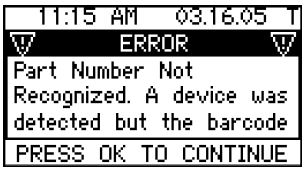
External quality control materials are available from MEDTOX and other commercial sources.

Contact MEDTOX at 1-877-643-5703 for further information.

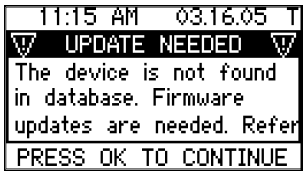
ERROR MESSAGES

The MEDTOX*Scan*® Reader will display an error message when a problem is detected.

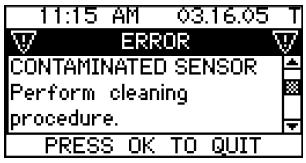
Part Number Not Recognized - This error appears if the device code is unknown or cannot be read by the instrument. The device code may be a new test type or the bar code may be damaged. If the bar code is damaged, the device code can be entered with the keypad. Press the **OK Key** to continue once the code has been entered. If the code is valid, the test procedure will resume and the User ID screen will appear.



Update Needed - This error will appear if the device code is not found. Pressing **OK Key** will return the interface to the welcome screen and cancel the test. If error persists, follow the Cleaning Cassette Procedure.



Contaminated Sensor - This error will appear when the MEDTOX*Scan*® Reader determines that the contact imaging sensor (CIS) is contaminated. Pressing **OK Key** will return the interface to the welcome screen and cancel the test. Follow the Cleaning Cassette Procedure to clean the contaminated sensor.



Please refer to the complete MEDTOX*Scan*® User Manual for error messages relating to the hardware, software and printer. If you do not recognize the error message, call Technical Support at 1-877-643-5703.

ROUTINE MAINTENANCE & CLEANING

MEDTOX recommends isopropyl alcohol wipes for routine cleaning of the exterior of the MEDTOX*Scan*® Reader and the device drawer. Refer to the MEDTOX*Scan*® Reader User Manual.
A specialized Cleaning Cassette is included for cleaning the internal sensor. The Cleaning Cassette is solely intended to clean the contact imaging sensor (CIS) in the MEDTOX*Scan*® Reader. The Cleaning Cassette should be used in conjunction with the MEDTOX*Scan*® QC Test Devices to confirm that the cleaning procedure has worked. Please refer to the MEDTOX*Scan*® Cleaning Cassette Quick Reference Guide for more detailed instructions.

WARNINGS

1. Avoid liquid spills on the components (MEDTOX*Scan*® Reader, Printer, Scanner, etc.).
2. Do not drop, or damage the components.
3. Do not open or tamper with the components. Only MEDTOX authorized personnel may service/ repair the components.
4. Keep the components clean and serviceable to assure continued reliability and performance.

TROUBLESHOOTING

Use the QC Test devices provided with the MEDTOX*Scan*® Reader 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 (dirt, dust or sample.)

The QC Test Devices function as an optical performance system check for the MEDTOX*Scan*® Reader only, not for the PROFILE®-V MEDTOX*Scan*® system, and they are not intended to replace the need for the external controls. 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. 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 MEDTOX*Scan*® Reader is functioning correctly. You should run the QC Test devices (1) if you suspect the MEDTOX*Scan*® Reader is not functioning properly, or (2) if you suspect the CIS is dirty, or (3) if the MEDTOX*Scan*® Reader has been dropped or damaged.

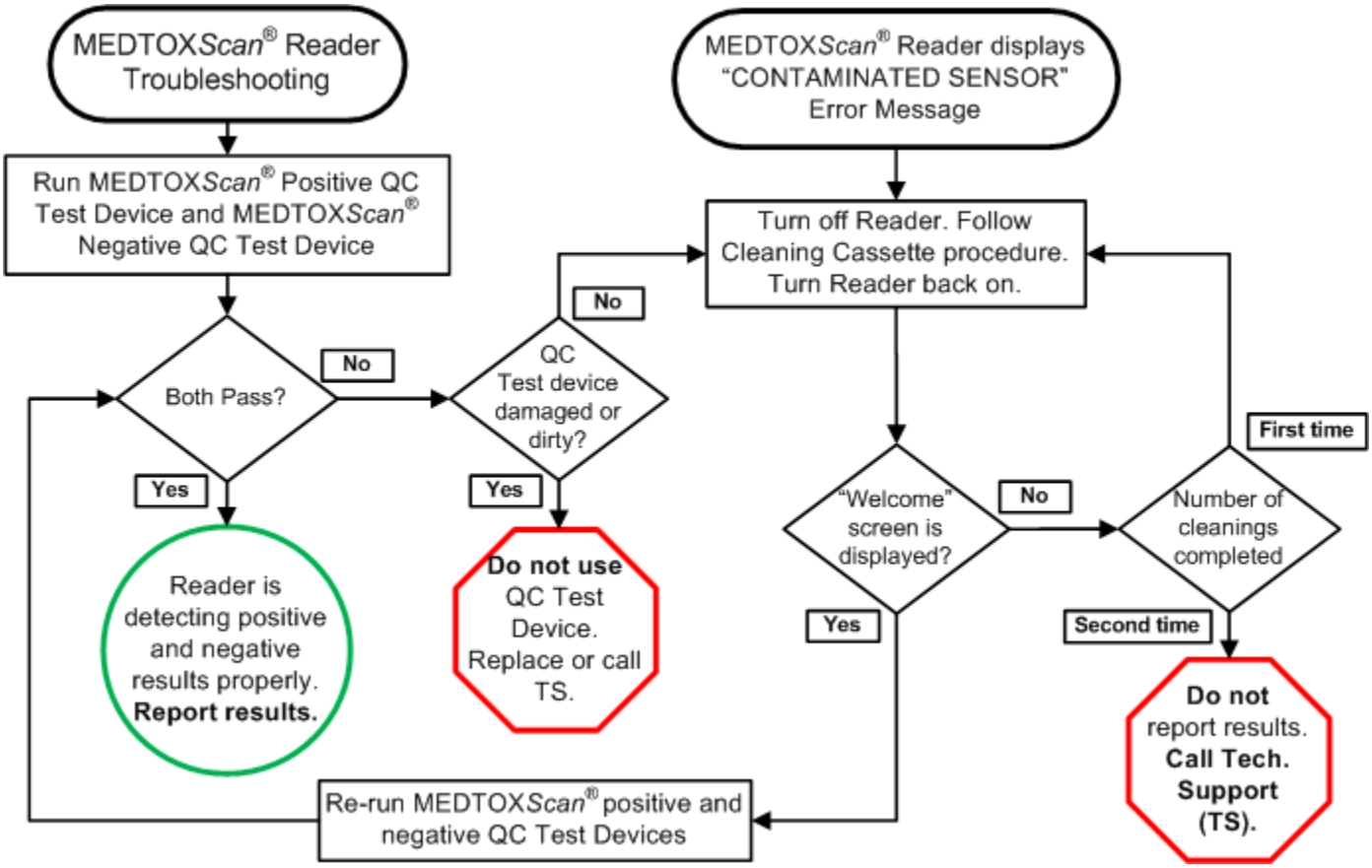
See Troubleshooting procedures, continued on next page.

TROUBLESHOOTING PROCEDURES:

For Test System — If you suspect that the PROFILE®-V MEDTOX*Scan*® Test Device or MEDTOX*Scan*® Reader is not working properly, or if you have had an unexpected test result, then:

(1) Be sure that the PROFILE®-V MEDTOX*Scan*® Test Devices have not expired.
(2) Run the positive and negative external controls.
(3) If both controls pass, run the QC Test Device for the MEDTOX*Scan*® Reader (see flowchart below).
    ⇒ If both pass, the MEDTOX*Scan*® Reader is operating properly.
    ⇒ If one or both QC Test Devices fail, check to see if the failed device is scratched or damaged. If scratches or damage are observed, contact Technical Support at 1-877-643-5703.
    ⇒ If the QC Test Devices are not scratched or damaged, proceed with the Cleaning procedure using the Cleaning Cassette or contact Technical Support.
(4) If either positive or negative external controls fail, be sure that the controls have not expired.
(5) If controls have not expired, repeat the controls. If both controls pass, report the results. If either control fails, contact Technical Support.

NOTE: Invalid or incorrect results may also be due to adulterated or improperly stored urine samples, or error in performing the test.



The MEDTOX*Scan*® Reader has been designed to provide you with reliable and worry-free service.
If for any reason, you have a problem with your equipment, please call
MEDTOX Technical Support at 1-877-643-5703
For complete product information refer to the PROFILE®-V MEDTOX*Scan*® Package Insert Rev 03/24 available at
www.medtoxdiagnostics.com/resources or contact Technical Support at 1-877-643-5703.

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