Adventist HealthCare

TRAINING UPDATE

Lab Location:	FWMC	**Date Distributed:**	9/22/25
Department:	Core lab, Chemistry/Urinalysis	**Due Date:**	10/1/25
		Implementation:	**10/1/25**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.C 1002 Profile®-V MEDTOXScan® Drugs of Abuse Test System (FWMC only) with QC log, AG.FW16
Description of change(s):

- The MedTox SOP has been converted to an AHC format.
- The FWMC MedTox SOP, FWMC-LAB-CHEM-0060 will be retired on October 1, 2025.
- The new SOP will become effective on that date.
- The procedure has also been **revised to require pH testing of each sample before performing the MedTox drug screen analysis.** The pH result will be entered on the QC form.

Read the new SOP with pH testing to ensure you understand.

Take the quiz.

Document your compliance with this training update by taking the quiz in the MTS system.

AHC.C 1002 Profile®-V MEDTOXScan® Drugs of Abuse Test System (FWMC only)

Copy of version 1.0 (approved, not yet effective)

Last Approval or Periodic Review Completed	9/20/2025
Next Periodic Review Needed On or Before	9/20/2027
Effective Date	10/1/2025

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/20/2025	1.0	Senda Beltaifa Senda Beltaifa MD	
Approval	Core lab approvals	9/17/2025	1.0	Robert SanLuis Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved, Not Yet Effective	Initial version	9/15/2025	10/1/2025	Indefinite

Technical SOP

Title	Profile®-V MEDTOXScan® Drugs of Abuse Test System	
Prepared by	Demetra Collier	Date: 9/11//25
Owner	Rob SanLuis	Date: 9/11/25

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Qualitative Drug Screen	Profile®-V MEDTOXScan®	UDRGT or UDRGW /w TCA

Synonyms/Abbreviations
Urine Drug Screen; Tox screen

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The PROFILE-V MEDTOXScan® Drugs of Abuse Test System includes the one-step, competitive, membrane-based immunochromatographic PROFILE®-V MEDTOXScan® Test Device and the MEDTOXScan® 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 MEDTOXScan® 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 MEDTOXScan® 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 MEDTOXScan® 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 MEDTOXScan® Reader screen or, optionally, can be printed.

The PROFILE®-V MEDTOXScan® Test Devices can only be used with the MEDTOXScan® Reader. The MEDTOXScan® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOXScan® Test Device. The PROFILE®-V MEDTOXScan® Test Devices cannot be visually read.

The PROFILE®-V MEDTOXScan® 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.

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

AMP	Amphetamine (d-Amphetamine)	500 ng/mL	MTD	Methadone	200 ng/mL
BAR	Barbituates (Butalbital)	200 ng/mL	OPI	Opiates (Morphine)	100 ng/mL
BZO	Benzodiazepine (Nordiazapam)	150 ng/mL	OXY	Oxycodone	100 ng/mL
BUP	Buprenorphine	10 ng/mL	PCP	Phencyclidine	25 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL	THC	Cannabinoids	50 ng/mL
mAMP	Methamphetamine	500 ng/mL	TCA	Tricyclic Antidepressants	300ng/mL

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Specimen Collection and/or Timing	Freshly voided urine specimens should be used for testing.

Component	Special Notations
Special Collection Procedures	No additives or preservatives. Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain a fresh specimen. Urine specimens should be handled and treated as if they are potentially infected. Preferred method is the Urine Collection Kit with specimen transferred to Urine Chemistry Collection Tube (yellow top).
Other	If Urine Collection Kit is not used, submit to Laboratory within 2 hours of collection.

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Urine
-Other Acceptable	None
Collection Container	Urine Collection Kit or sterile container
Volume - Optimum	15 mL
- Minimum	2 mL
Transport Container and Temperature	Urine Chemistry Collection Tube (yellow top- preservative free) or container at room temperature
Stability & Storage Requirements	Room Temperature: Test samples immediately
	Refrigerated: Up to 2 days 2-8°C
	Frozen: -20°C up to 1 month
Timing Considerations	Stored urine must be brought to ambient temperature 18-25°C and mixed well to assure homogeneous sample prior to testing.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Samples in Urine Analysis Preservative Tube are NOT acceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollections in the LIS.
Compromising Physical Characteristics	The Medtox Drugs of Abuse system is only for use with unadulterated preservative free, human urine samples Urines that are either extremely acidic (below pH 4.0) or basic (pH above 9.0) may produce erroneous results. If adulteration is suspected, obtain a new sample and re-test.
Other Considerations	Clear polystyrene containers may absorb some drugs; use of polypropylene container is advised.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
PROFILE®-V MEDTOXScan® Drugs of Abuse Test System kit	MEDTOX Catalog # 604032
Multistix 10 SG Reagent Strips for Urinalysis (for pH testing)	Siemens Reagent Strips Cat. # 2161

4.2 Reagent Preparation and Storage

Assay Kit: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System kit	
Contents:	Twenty-five (25) test devices in individual foil packages Twenty-five (25) disposable pipette tips
Storage	The kit, in its original packaging, should be stored at 2-25°C
Stability	Stable until the expiration date on the label
Preparation	Not applicable

5. CALIBRATORS/STANDARDS

Not Applicable

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Positive and Negative QC Device	Catalog # 833075
MEDTOX Negative	Catalog # 101183
MEDTOX Positive	Catalog # 102367

6.2 Control Preparation and Storage

Control	MEDTOX Toxicology Urine Controls (Negative and Positive)
Preparation	Allow controls to come to room temperature. Mix by gentle inversion. **DO NOT SHAKE.**
Storage/Stability	**Unopened:** • The controls are stable until the expiration on the box when stored at -10 to -20°C and protected from light or • The controls are stable until the expiration on the box when stored at 2-8°C **After Opening:** • The controls are stable for six months or until the expiration date, whichever comes first, when stored at -10 to -20°C (Controls can be aliquoted and frozen) • The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2-8°C Thaw controls as needed. Allow to come to room temperature followed by gentle swirling before use.

MEDTOXScan® QC Testing Device

6.3 Frequency

- MEDTOX Toxicology Urine Controls (liquid) are performed **once per week and with each new lot # or shipment** of kit/devices.
- MEDTOX QC devices (neg and pos) are performed and documented daily.
- Internal controls must be documented with each test performed.
- QC devices and external QC should also be run in the following circumstances:
  - Whenever you suspect that the reader or test device is not working properly
  - After any maintenance; after using cleaning device.
  - If you have an unexpected result

6.4 Tolerance Limits and Criteria for Acceptable QC

- **Internal QC:** The **MEDTOXScan® Reader** must report the result as Valid
- **QC Devices:** Negative and Positive QC devices: run daily and must report as expected

- **Do not** place any adhesive label on the devices
- **Do not** apply any type of liquid on to the devices
- **Do not touch** strips in viewing window of devices
- **Replace** QC test devices if strips are damaged
- **Keep** QC test device in sealed pouch while not in use

- **External Positive and Negative QC:**

IF	THEN
Control results are not as expected	7. Make sure the kit and QC have been stored properly • Use the cleaning device • Repeat the test using a new test device or a new kit, or lot # in that order as appropriate • If the above steps do not resolve the problem, suspend testing and notify your supervisor or tech in charge. Consult with the vendor.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

Record patient results and QC on the MEDTOXScan Drugs of Abuse Quality Control Log (AG. FW16).

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

MEDTOXScan® Reader

7.2 Equipment

- Refrigerator
- Printer
- Barcode Scanner

7.3 Supplies

- PROFILE®-V MEDTOXScan®) Drugs of Abuse Test System kit
- Pipette tips
- Positive and Negative QC Test Devices
- Cleaning Cassette (for use as needed)
- MiniPet™ pipettor (MEDTOX Part# 833077)
- Printer paper
- MEDTOX Toxicology Urine Controls (External QC)
- Multistix 10 SG Reagent Strips

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Test Set-up Protocol

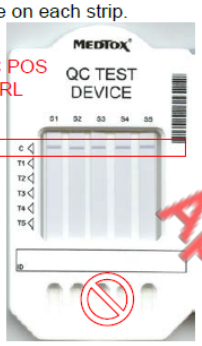
Perform Daily QC using the MEDTOXScan QC devices

Procedure:

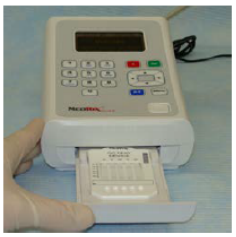
1) Set up and power on the MEDTOX*Scan*® Reader.

2) Remove QC Test devices from storage pouch.

The Positive device has one line on each strip.

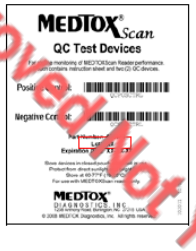


Visually examine the devices. Make sure the strips are free of dust, fingerprints, smudges or discoloration. Make sure the strips are not scratched, torn or bent. Do not add anything to the sample wells of the QC Test Devices.



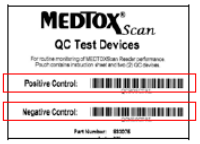
3) Place device in drawer of MEDTOX*Scan*® Reader and close.

4) At the prompt, Enter Device **Lot Number** and press "OK".



5) Enter **User ID** and press "OK"

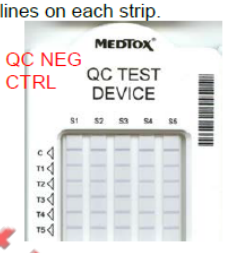
6) Scan POS or NEG barcode from pouch for **Specimen ID** and press "OK" (or manually enter).



7) Test results print out when reader scan is complete.

8) Repeat steps 3-7 with second device.

The Negative device has six lines on each strip.



9) Verify that test results are reported correctly:

All results are POS for the QCPOSCTRL device.

Sample ID: QCPOSCTRL

TCTRL1	VALID
S1T1	***POS***
S1T2	***POS***
S1T3	***POS***
S1T4	***POS***
S1T5	***POS***

~~~~~~~~ etc.

All results are NEG for the QCNEGCTRL device.

Sample ID: QCNEGCTRL

TCTRL1	VALID
S1T1	NEG
S1T2	NEG
S1T3	NEG
S1T4	NEG
S1T5	NEG

~~~~~~~~ etc.

8.2	Test Run
1.	Using a Multistix 10 SG test strip, test the pH of patient's urine sample by dipping test strip into urine completely covering the pH pad. Blot the side of the strip on a clean piece of gauze to remove excess sample. Read the pH value at the appropriate time. Record the pH on the QC log (AG.FW16). If sample pH is within the 4.0 to 9.0 pH range, proceed with testing. If the pH is < 4.0 or > 9.0 notify the patient's caregiver and request a new sample. Notify your supervisor.
2.	Open one pouch for each sample to be tested and mark the PROFILE®-V MEDTOXScan® Test Device. Label the device with patient identification. Make sure you only mark along the left edge of the test device (labeled "ID ▷") (You may notice a reddish-purple color in the sample well. This is normal, do not discard the test). Note: Ifdevice was stored refrigerated, allow it to come to room temperature (64-77°F before opening and using.)

8.2	Test Run
3.	Dispense 75µL of urine into sample well (indicated by ▽ on the test device). • Place a disposable yellow sample tip securely onto the end of the green (75µL) MiniPet™ • Grasp the MiniPe™t under its collar using the index and middle fingers. With the thumb, depress the plunger completely. • Holding the MiniPet™ vertically (straight up and down) lower the yellow tip no more than ¼ inch into the urine specimen. • With tip in the urine specimen **slowly** and **smoothly** release the plunger allowing it to rise completely. • 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. • 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.
4.	Repeat Step 2 for all sample wells with a ▽ above them. Wipe off any spills on the device.
5.	Place the test device in the MEDTOXScan® Reader cassette drawer and close the drawer immediately. The reader will read the barcode on the test device and determine its part number andtest configuration. It will prompt the user to enter Lot#, User ID#, and Specimen ID#, which can all be entered using the MEDTOXScan® Reader keypad or handheld barcode scanner. The MEDTOXScan® Reader will begin timing the assay once it detects the barcode and results will be displayed after the scan and analysis are complete.
6.	Discard disposable yellow MiniPet sample tip into a biohazard Sharps container. Store the MiniPet in a dry, secure location at room temperature (18-25 °C). If the MiniPet becomes damaged or does not function properly, it must be replaced. Notify your supervisor for replacement.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The MEDTOXScan® Reader will automatically read the control and test lines at the correct positions and display the test results for each drug. Results will print. The 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. PROFILE® – V MEDTOX Scan ® Test devices cannot be visually read.**

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
Positive	Report as "preliminary result is Detected, confirm by another method.

Negative	Report as Not Detected
Invalid	Do not report. Repeat the test with a new test device.

Message Code	Message
Verified by repeat analysis	Append –REP to the result

11. EXPECTED VALUES

11.1 Reference Ranges

None detected

11.2 Critical Values

None established

11.3 Standard Required Messages

None

12. CLINICAL SIGNIFICANCE

This test system is used to screen urine samples for one or more of the following drug classes prior to confirmatory testing:

Amphetamine (d-amphetamine) is detected on the Test Device only at the (AMP) position, methamphetamine (MAMP) is detected at the (MAMP) position. The amphetamines are a group of drugs that are central nervous system stimulants. This group includesamphetamine and methamphetamine.

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 usedto reduce anxiety and induce sleep.

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

Oxycodone (OXY) (Oxycontin®, Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribedfor 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.

Tricyclic Antidepressants (TCA) are a group of structurally related prescription drugs that are used to managedepression

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

13. PROCEDURE NOTES

- **FDA Status:** Cleared 510(k)
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

- The PROFILE®MEDTOXScan® Drugs of Abuse Test System is only for use with unadulterated preservative free, human urine samples. Urine samples that are either extremely acidic (below pH 4.0) orbasic (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.
- A presumptive positive result for any drug does not indicate the level of intoxication, administration route or concentration of that drug in the urine specimen.
- 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.
- Place PROFILE®-V MEDTOXScan® Test Devices in MEDTOXScan® Reader immediately after adding the sample. Once the test device has been read in the MEDTOXScan® 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.
- The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System is not intended for use in point-of-caresettings.
- There is a possibility that other substances and/or factors, e.g. technical or procedural errors, mayinterfere with the test and cause false results
- 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 MEDTOXScan5 Drugs of AbuseTest System may give a preliminary positive result if ingested at prescribed therapeutic doses

- The PROFILE®-V MEDTOXScan® 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.
- The PROFILE®-V MEDTOXScan® Test Devices must be used only with the MEDTOXScan® Reader. They cannot be visually read.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

See manufacturers package insert for details.

14.3 Interfering Substances

Refer to Limitations of Method (above)

14.4 Clinical Sensitivity/Specificity/Predictive Values

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System detects one or more of the following drugs at the cutoff levels listed below.

AMP	Amphetamine	500 ng/mL
BAR	Barbiturates (Butaibital)	200 ng/mL
BZO	Benzodiazepines (Nordiazepine)	150 ng/mL
BUP	Buprenorphine	10 ng/mL
COC	Benzoylecgonine	150 nglmL
MAMP	Metharnphetamine	500 ng/mL
MTD	Methadone	200 ng/mL
OPI	Morphine	100 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
THC	11-nor-9-carboxy-Δ^9-THC	50 ng/mL
TCA	Tricyclic Antidepressants (Desipramine)	300 ng/mL

15. SAFETY

Refer to the safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Safety Manual
2. Safety Data Sheets (SDS)
3. Laboratory Quality Control Program
4. Repeat Testing Requirements (Lab policy)
5. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
6. MEDTOXScan Drugs of Abuse Test QC Log (AG.FW 16)
7. Lot to Lot Cross Check Log (AG.F104)

17. REFERENCES

1. Profile®-V MEDTOXScan® Drugs of Abuse Test System, pkg insert (rev. 3/24)
2. MEDTOXScan QC Test Devices, Insert (rev. 3/18)
3. MESTOX /toxicology Urine Controls, Pkg Insert (4/14)

18. REVISION HISTORY

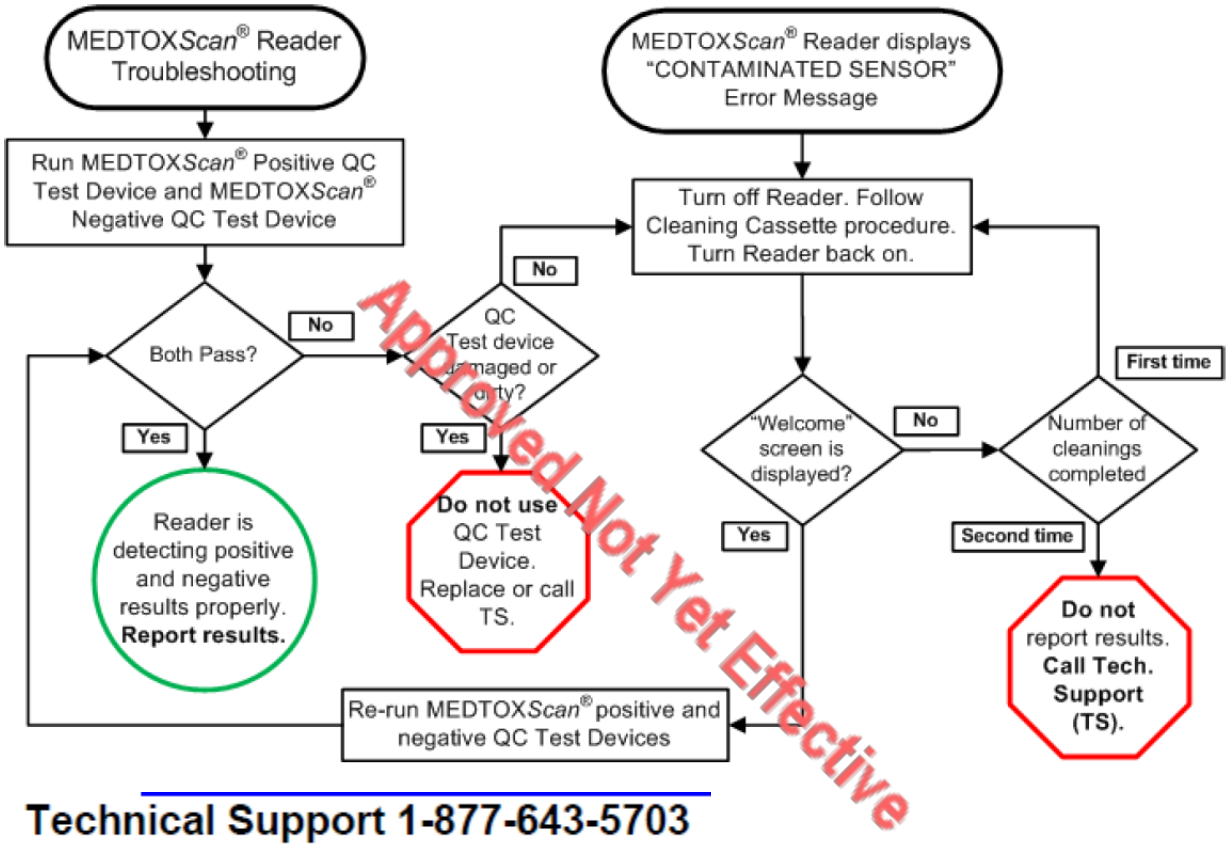
Version	Date	Section	Reason	Reviser	Approval
	9/15/25		This SOP preceded by FWMC-LAB_CHEM 0600 Profile®-V MEDTOXScan Drugs of Abuse Test System (retired)	D Collier	R SanLuis

19. ADDENDA

MEDTOXScan® Troubleshooting Procedure Using QC test Device

Addendum:

MEDTOXScan® Troubleshooting Procedure Using QC test Device



Technical Support 1-877-643-5703

Adventist HealthCare

MEDTOX SCAN DRUGS OF ABUSE TEST
QUALITY CONTROL LOG

Fort Washington Medical Center

1. **External Controls** are performed once per week and with each new lot of devices.
2. **QC Test devices are run daily.**
3. **Internal controls** must be documented each time the test is performed.
4. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Positive Control	Negative Control	Patient MRN	Patient MRN
Attach print out	Attach print out	Attach print out	Attach print out
Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No
		Sample pH_____	Sample pH_____
Tech code:	Tech code:	Tech code:	Tech code:

Weekly review:	Weekly review:	Monthly review:

Adventist HealthCare

MEDTOX SCAN DRUGS OF ABUSE TEST
QUALITY CONTROL LOG

Fort Washington Medical Center

1. **External Controls** are performed once per week and with each new lot of devices.
2. **Internal controls** must be documented each time the test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Patient **MRN**	**Patient** **MRN**	**Patient** **MRN**	**Patient** **MRN**
Attach print out	Attach print out	Attach print out	Attach print out
Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No	Internal QC Valid? ☐ Yes ☐ No
Sample pH_____	Sample pH_____	Sample pH_____	Sample pH_____
Tech code:	Tech code:	Tech code:	Tech code:

Weekly review:	Weekly review:	Monthly review: