MEDTOX®Scan QC Test Devices

INTENDED USE:

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. For *in vitro* diagnostic use only.

The QC Test Devices function as an optical performance system check for the MEDTOX*Scan*® Reader only, not the PROFILE®-V MEDTOX*Scan*® system, and 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*® 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 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.

The QC Test Devices should provide the expected positive or negative response for all test line and strip positions. **If expected results are not obtained, do not use MEDTOX*Scan*® Reader. Consult the MEDTOX*Scan*® Reader User Manual for detailed troubleshooting and cleaning instructions.**

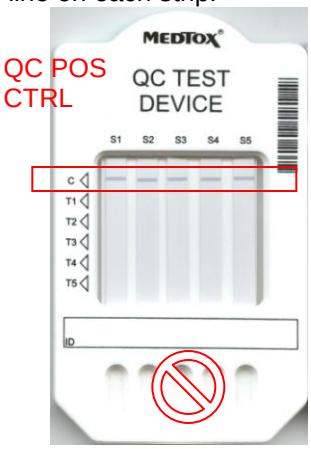
CONTENTS: One MEDTOX*Scan*® Positive QC Test Device and one MEDTOX*Scan*® Negative QC Test Device in light blocking storage bag – Part Number 833075.
The QC Devices are stable for at least five years at room temperature (18 - 25 ºC or 64 - 77 ºF) when kept in an unopened or resealed storage bag. Do not use past the expiration date. The QC Devices are also stable up to 13,000 hours in normal laboratory fluorescent lighting. Do not use devices if they have been exposed to light for a longer period of time.

PROCEDURE:

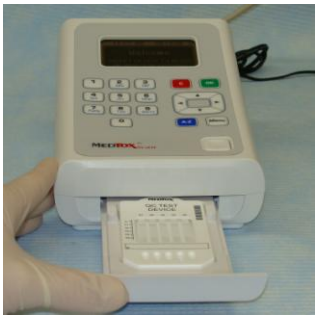
1) Set up and power on the MEDTOX*Scan*® Reader.

2) Remove QC Test devices from storage pouch.

The Positive device has one line on each strip.

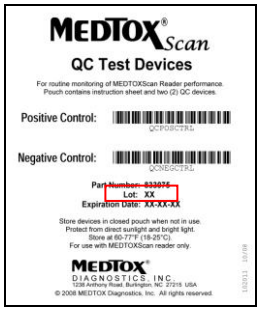


Visually examine the devices. Make sure the strips are free of dust, fingerprints, smudges or discoloration. Make sure the strips are not scratched, torn or bent. Do not add anything to the sample wells of the QC Test Devices.



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

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



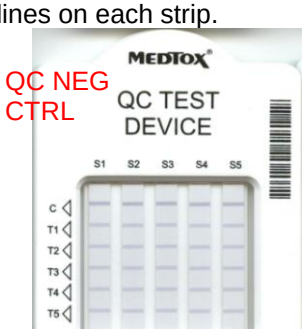
5) Enter **User ID** and press "OK"

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.
```

The test devices are labeled with the symbols S1 - S5 above the viewing window to identify Strip 1 (S1) to Strip 5 (S5) from left to right across. Line positions on each strip are identified by "C" and the symbols T1 - T5. The letter "C" represents the control line position and T1 – T5 refers to Test Position 1 (T1) to Test Position 5 (T5) from top to bottom of the viewing window.

For complete product information refer to the MEDTOXScan® User Manual or call Technical Support at 1-877-643-5703

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WARNINGS:

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 (open area in middle of device).
Replace QC Test Devices if strips are damaged.
Keep QC Test Devices in sealed pouch while not in use.

QUALITY CONTROL:

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.

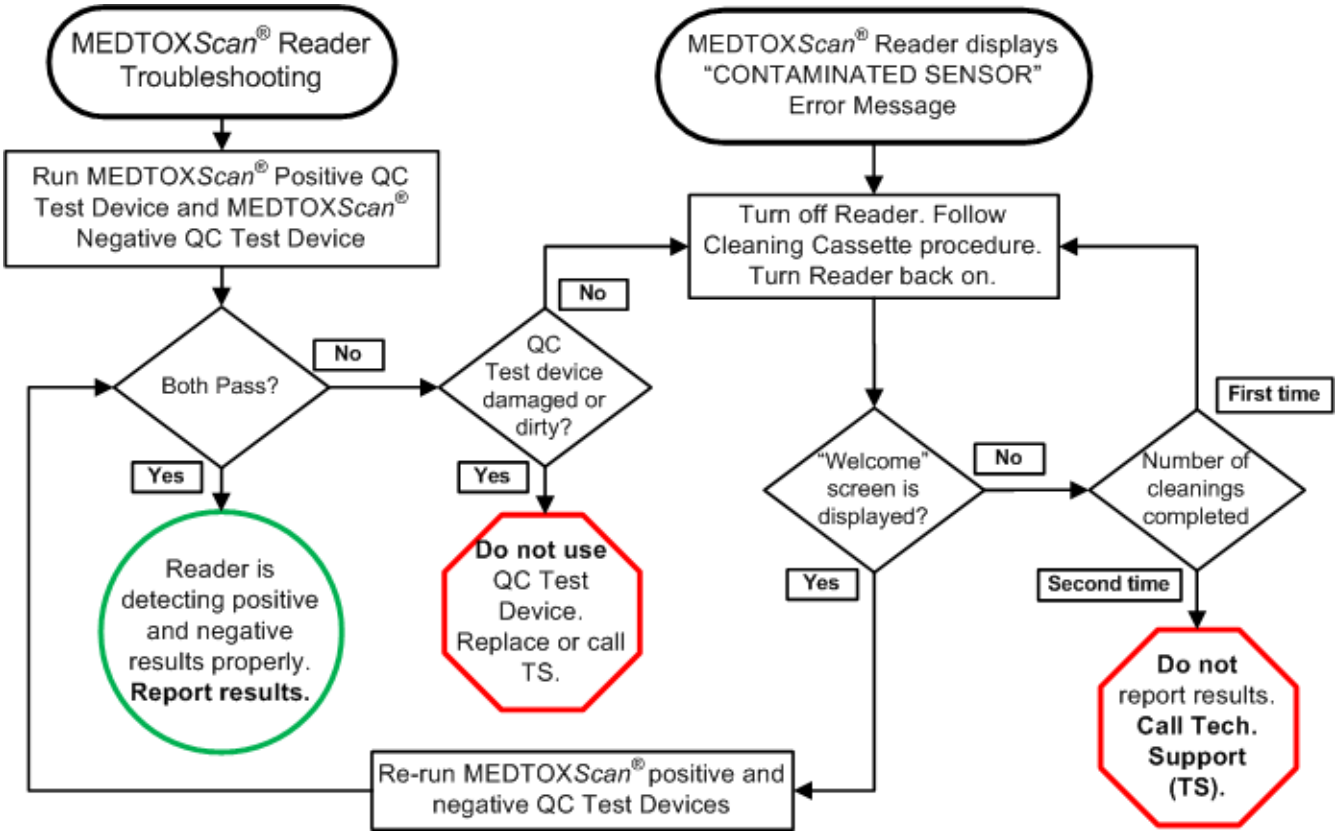
Internal controls ensure that the test is working and that you are performing the test correctly. A control line (internal control) is included on each PROFILE®-V MEDTOX*Scan*® test strip. Whether or not drug is present in the sample, a line must form at the Control (C) position on the test strip to 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). 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 test 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. External quality control materials are available from MEDTOX. Contact MEDTOX at 1-877-643-5703 for further information.

TROUBLESHOOTING:

Use the QC Test devices provided with the MEDTOX*Scan*® Reader to detect errors associated with the MEDTOX*Scan*® Reader and a contaminated color contact imaging sensor (CIS), and to verify that the CIS cleaning procedure using the MEDTOX*Scan*® Cleaning Cassette effectively removed any contamination. You should run the QC Test devices (1) if you suspect the MEDTOX*Scan*® Reader is not functioning properly, (2) if you suspect the CIS is dirty, or (3) if the MEDTOX*Scan*® Reader has been dropped or damaged. Refer to the MEDTOX*Scan*® Reader User Manual for details on the Cleaning Cassette Procedure and troubleshooting instructions. Contact MEDTOX Technical Support if you need any additional help at 1-877-643-5703.

MEDTOX*Scan*® TROUBLESHOOTING PROCEDURE USING QC TEST DEVICES:



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