#### PROFILE®-V MEDTOX SCAN® MAINTENANCE AND TROUBLESHOOTING FOR DRUGS OF ABUSE TEST SYSTEM

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| **Purpose**  | This section contains the necessary information to perform the maintenance and troubleshooting of the Profile®-V MedTox Scan® for Drugs of Abuse Test System.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Scope****Policy** | This section will provide the operator a detailed instruction of routine maintenance and cleaning and also troubleshooting the device.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_The operators must follow the maintenance and troubleshooting procedures to ensure reliable performance, minimal downtime, and to prevent costly factory and field service repairs. |
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| **Materials and Supplies** | * Isopropyl Alcohol wipes
* MedTox Scan QC Test Devices
* MedTox Scan Cleaning Cassette
* Mild liquid hand soap /detergent
* Paper towels

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| Safety or Special Safety Precautions  | All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety and the safety of others and adhering to all departmental and medical center safety policies and procedures.* For standard precautions and safety practices in the laboratory; see LGM 8000, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
* For Universal Body Substance precautions, see LGM 8005, specifically, but not limited to, exposure to body fluids.
* For proper hand washing, see LGM 8010, specifically, not limited to, proper hand washing.
* For proper infection control, see LGM 8004, specifically, but not limited to, proper use of gloves.
* For proper handling of regular and infectious waste, see LGM 8006, specifically, but not limited to, proper disposal of regular and biohazardous waste.
* For proper cleaning of work area, see LGM 8007 – Cleaning Work Areas.
* For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.
* For proper storage and disposal of chemical hazardous waste, see LGM 8012.

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| Procedure  | **Routine Maintenance and Cleaning**No maintenance other than periodic external cleaning is required of the operator. MedTox recommends using isopropyl alcohol wipes to clean the outside of the MedTox Scan® Reader and the device drawer. Do not immerse the reader in water or other liquids. **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 (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® Drugs of Abuse Test 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 the 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 MedTox Scan® Reader is functioning correctly. Run the QC Test Devices when:1. If you suspect the MedTox Scan® Reader is not functioning properly
2. If you suspect the CIS is dirty
3. If the MedTox Scan® Reader has been dropped or damaged.
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| Procedure | **QC Test Devices Procedure;**

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| 1. | Set up and power on the MedTox Scan® Reader. |
| 2. | Remove devices from storage pouch. The Positive device has one line on each strip. Visually examine the devices to be sure the strips in the device window are clean (free of dust, fingerprints, smudges or discoloration/yellowing) and undamaged (scratched, torn, or bent). Do not add sample to the sample wells of the QC Test Devices.  |
| 3. | Place device in MedTox Scan® Reader tray and close. |
| 4. | At the prompt, enter test device Lot number and press “OK”. |
| 5. | Enter “USER ID” and press “OK”. |
| 6. | Scan POS and NEG barcode from pouch for SPECIMEN ID and press “OK” (or manually enter). |
| 7. | Test results print out when QC test device 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. |
| 10. | If the results are all POS for the positive QC Test device and all NEG for the negative QC Test device, the MEDTOX Scan® Reader is reporting results correctly. Resume normal operation.*Document all QC Test Device results in the log sheet.* |
| 11. | If the test result does not match expected, then follow the flowchart to determine appropriate next steps which may include replacing the QC Test devices, cleaning the sensor, or calling Technical Support. |

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| Procedure | **Cleaning Cassette Procedures;**A MedTox Scan® Cleaning Cassette is required for this procedure. This procedure is appropriate if you get incorrect results running the QC Test Devices or if the MedTox Scan® Reader displays “CONTAMINATED SENSOR” error message. It is effective for cleaning contamination such as dirt, dust or sample accumulated on the contact imaging sensor (CIS).

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| 1. | **Disconnect** the MedTox Scan® Reader from the power supply. |
| 2. | Prepare the MedTox Scan® Cleaning Cassette by rinsing under running tap water. Apply one drop of mild liquid hand soap/detergent to the pad. Rinse thoroughly to remove any soap remnants. |
| 3. | Remove excess water by blotting Cleaning Cassette pad on paper towels. |
| 4. | Place moist cleaning cassette in MedTox Scan® Reader drawer. While holding down the “EJECT BUTTON”, slowly move the drawer in and out 10 times. Use the “TAPE TAIL” attached to the Cleaning Cassette to pull the drawer out while holding down the “EJECT BUTTON”. |
| 5. | If visible dirt is observed on the Cleaning Cassette pad, wash, rinse and blot the Cleaning Cassette again. Place the Cleaning Cassette in the drawer of the MedTox Scan® Reader and repeat step 4. |
| 6. | When finished cleaning the CIS, remove the Cleaning Cassette from the MedTox Scan® Reader drawer. |
| 7. | Re-connect power supply and power on the MedTox Scan® Reader. |
| 8. | If the Welcome Screen appears, then run the QC Test Devices to confirm that any contamination has been removed from the sensor and the MedTox Scan® Reader is functioning properly. |
| 9. | If the “CONTAMINATED SENSOR” ERROR MESSAGE DISPLAYS AGAIN AFTER THE FIRST CLEANING PROCEDURE, REPEAT Steps 1-7. |
| 10. | If the MedTox Scan® Reader still displays the error message after the Cleaning Cassette procedure has been done twice, call Technical Support. |
| 11. | Do not use to test patients until problem is resolved. |
| 12. | Document completion of procedure in the maintenance log sheet. |

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| Non-Controlled Documents | The following non-controlled documents support this procedure.* Operators Manual
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| Controlled Documents | The following controlled documents support this procedure. |
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|  | **Procedure** | **Number** |
|  | Profile®-V MedTox Scan® Sample Processing For Drugs of Abuse Test System | LCM 288 |
|  | Profile®-V MedTox Scan® Quality Control For Drugs of Abuse Test System | LCM 289 |
|  | Safety Practices | LGM 8000 |
|  | Infection Control | LGM 8004 |
|  | Universal Body Substance Precaution | LGM 8005 |
|  | Handling of Regular and Infectious Waste | LGM 8006 |
|  | Cleaning Work Areas | LGM 8007 |
|  | Hand washing Policy  | LGM 8010 |
|  | Storage and Disposal of Chemical Hazardous Waste | LGM 8012 |

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| Author Aida R. Legaspi, CLS |
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Reviewed and approved by:

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Document History Page

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