PROFILE®-V MEDTOX SCAN® QUALITY CONTROL FOR DRUGS OF ABUSE TEST SYSTEM

Purpose

The purpose of quality control is to ensure accuracy and reliability of results and to detect errors.

Scope

To monitor the performance of the Profile®-V MedTox Scan® Test Devices and the MedTox Scan Reader a combination of internal controls and external controls must be done.
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 position on the strip.to show that enough sample volume was used and that the reagents are migrating properly.
External controls are urine-based control materials that contain the drugs to be tested at concentrations above the cutoff (positive control) or contain no drugs (negative control).

Policy

Run external controls each day of patient testing. Running controls should be done on a monthly rotation basis between 3 shifts. Run the controls also when you open a new lot of devices, if you suspect that the reader or test device is not working properly, if you have had a repeated unexpected test result, or if you suspect that the test device have been stored improperly.

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Storage Stability

Unopened:

- The controls are stable until the expiration date when stored at -10 to -20°C and protected from light.
- The controls are stable until the expiration date when stored at 2-8°C.

After Opening:

- The controls are stable for 6 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 controls to come to room temperature followed by gentle swirling before use.

Materials and supplies

- Profile®-V MEDTOX Scan ® Drugs of Abuse Test System kit
- MEDTOX Scan Positive and Negative Toxicology Urine Controls
- Disposable pipette tips
- MiniPet pipettor
- Thermal printer and printer paper

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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.

Procedure

Allow controls to come to room temperature followed by gentle swirling or inversion before use. *Do not shake.* Pipette an appropriate aliquot of MEDTOX control urine as required by the drugs of abuse test device or screening method. Controls should be treated as any "unknown" specimen while following the specific protocol of the assay being used.

Continued on next page

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Interpretation/ Result

The positive MEDTOX control must test positive on the Profile®-V MedTox Scan® Drugs of Abuse Test System. The negative control must test negative. *Document and keep all QC print outs in the QC log sheet.*

Limitations

This control is meant to be used to validate the performance of immunoassay drug screening methods. This product is not meant to be used as a standard or calibrator.
The MEDTOX Scan Reader is calibrated and verified before shipment. No calibration is required of the operator.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- Operators Manual

Controlled Documents

The following controlled documents support this procedure.

Procedure	Number
Profile®-V MedTox Scan® Sample Processing For Drugs of Abuse Test System	LCM 288
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

Author

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Document History Page
Effective Date:

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 implemented