



MEDTOX Hospital Lab Quarterly Review

We are pleased to present the first quarterly newsletter focusing on the latest services and technologies for hospital laboratory testing. Our goal at MEDTOX has always been to provide our clients with the highest level of service in the industry and the Quarterly Review is another way to keep you informed and up-to-date on what is new at MEDTOX and in the industry.

We are excited to provide this new service and welcome any feedback.

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FDA Release



MEDTOX Scientific Receives FDA 510(k) Clearance for Additional Three Drugs On the PROFILE(r)-V MEDTOXScan(r) Drugs-of-Abuse Test System

ST. PAUL, Minn.(GLOBE NEWSWIRE) -- MEDTOX Scientific, Inc. (Nasdaq:MTOX - News), announced that it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its PROFILE(r)-V MEDTOXScan(r) Drugs-of-Abuse Test System with three additional drugs -- Oxycodone, Propoxyphene and Tricyclic Antidepressants.

The total number of drugs detectable on the system is now twelve. The MEDTOXScan(r) READER and expanded panel is the broadest panel with the lowest detection levels available with any FDA cleared reader in the market place.

The PROFILE(r)-V MEDTOXScan(r) Drugs-of-Abuse Test System consists of the PROFILE(r)-V MEDTOXScan(r) Test Devices and the MEDTOXScan(r) Reader. The Test Devices are one-step immunochromatographic tests for the rapid qualitative detection of one or more of the following drug classes and cutoff concentrations in human urine:

AMP	Amphetamine	500 ng/mL
BAR	Barbiturates	200 ng/mL
BZO	Benzodiazepines	150 ng/mL
COC	Cocaine	150 ng/mL
MAMP	Methamphetamine	500 ng/mL
MTD	Methadone	200 ng/mL
OPI	Opiates	100 ng/mL
PCP	Phencyclidine	25 ng/mL
THC	Cannabinoids	50 ng/mL
OXY	Oxycodone	100 ng/mL
PPX	Propoxyphene	300 ng/mL
TCA	Tricyclic Antidepressants	300 ng/mL

The Reader provides accurate, easy-to-use and cost effective testing for drugs-of-abuse. Results are available in 10 minutes for improved turn around time. There is an optional attached bar-code scanner for accurate entry of user ID, patient ID and lot number of the device. Test results will remain on the digital display until cleared by the operator. A printer provides a paper copy of the results for a permanent record. The Reader also has network integration capabilities and enhanced record storage of 1,000 results with improved record management.

The MEDTOXScan(r) Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The Positive and Negative QC Test Devices are intended to detect potential errors associated with the Reader such as a contaminated contact imaging sensor (CIS) and to verify the CIS cleaning procedure using the approved Cleaning Cassette which effectively removes any contamination.

The Test System is intended for professional use in a hospital laboratory setting. Currently MEDTOX has between 300 and 400 hospital clients utilizing MEDTOX's PROFILE(r) visually read cassettes for drugs-of-abuse detection. The new Test System will be marketed not only to those clients, but to the broader hospital market which is estimated in excess of 2,500 hospitals.

MEDTOX Scientific, Inc., headquartered in St. Paul, Minn., is a provider of high quality specialized laboratory testing services and on-site/point-of-collection testing (POCT) devices. The company also supports customers with complete logistics, data and program management services. MEDTOX is a leader in providing esoteric laboratory testing services to hospitals and laboratories nationwide. This includes both central laboratory and bio-analytical testing for pharmaceutical clinical trials. MEDTOX develops and manufactures diagnostic devices for quick and economical on-site/point-of-collection analysis for drugs-of-abuse, therapeutic drugs and biological and agricultural toxins and provides employment drug screening and occupational health testing. For more information see www.medtox.com.

Q & A about Methamphetamine

Q & A Involving: Amphetamine (AMP), Methamphetamine (mAMP) and MDMA (Ecstasy) on MEDTOX Onsite Screens (Sure-Screen®) Devices

- Question:** Can cough/cold/allergy medications containing pseudoephedrine cause the MEDTOX amphetamine and/or methamphetamine drug screen to be positive?

Answer: No. MEDTOX has conducted cross reactivity studies by "spiking" urine samples separately with 100 ng/ml of pseudoephedrine. The 'spiked' urine tested NEGATIVE for amphetamine and methamphetamine/MDMA (Ecstasy). (Note: 100 ug/ml is equivalent to 100,000 ng/ml). The screening cut-offs for amphetamine, methamphetamine and MDMA are respectively set at 500, 500, and 1,150 ng/ml for Profile V (Profile II at 1,000, 1,000, and 1500 ng/ml). Pseudoephedrine containing products are frequently located 'behind the counter' in many states; in addition, the quantity that can be purchased is limited and a buyer is usually required to sign for it. The product that is openly displayed and sold over the counter on store shelves usually contains phenylephrine (PE), instead of pseudoephedrine. The switch to phenylephrine was brought about by the widespread conversion of pseudoephedrine into methamphetamine. Conversion of phenylephrine (PE) into methamphetamine is much more difficult than it is with pseudoephedrine.
- Question:** Can cough/cold/allergy medications containing the pseudoephedrine 'replacement' phenylephrine (abbreviated 'PE' on many labels) cause the MEDTOX amphetamine and/or methamphetamine drug screen to be positive?

Answer: Yes, phenylephrine, the active ingredient of Sudafed PE, is structurally similar to methamphetamine and may cause a false positive methamphetamine screening result. It will not cause a positive amphetamine screen. To determine if methamphetamine is truly present, a suspected sample should be sent to the lab for GC/MS confirmation testing, since this methodology can differentiate the two.
- Question:** Can over the counter diet aids, asthma, or stimulant products containing ephedrine (ephedra/ ma huang) cause a positive MEDTOX methamphetamine screen?

Answer: Yes. Ephedrine is structurally similar to methamphetamine and may cause the MEDTOX mAMP screen to render a positive result. It will not cause a positive amphetamine screen. It is therefore important to send these positive screening samples to the lab for GC/MS confirmation testing. If the methamphetamine screen was 'false positive' due to ephedrine or some other cross reactant, the GC/MS confirmation (expanded amphetamine confirmation) will definitively rule out the following drugs: amphetamine, methamphetamine, MDMA, and MDA. Sympathomimetic (drugs acting as stimulants of the sympathetic nervous system) confirmation panels can be used to detect the presence of ephedrine in a suspicious sample.
- Question:** Will the MEDTOX AMP or mAMP Screen be positive if the person is taking methylphenidate (Ritalin™, Concerta™)?

Answer: No. Methylphenidate does not cross react with the AMP or mAMP/MDMA assays. Urines "spiked" with up to 100,000 ng/ml of methylphenidate screened 'negative' for amphetamine and methamphetamine. Abusers of methamphetamine frequently offer up an alibi for "crank" use claiming that they take Ritalin for an alleged attention deficit disorder. This sort of excuse is a poor one since Ritalin is structurally different and will not cause a positive screen for methamphetamine.
- Question:** Does Adderall™ (contains a mixture of amphetamine salts) cause a positive Amphetamine screen?

Answer: Yes. Adderall™, a drug widely used to treat attention deficit disorder (AAD) contains only AMPHETAMINE, there is no METHAMPHETAMINE in the product. Therefore, if this prescribed medication's concentration in the urine is near or exceeds the AMP cut-off threshold, the AMP screen will render a 'positive' result. The methamphetamine/ecstasy (mAMP/MDMA) screen will be negative however. A person who is prescribed Adderall must acquire a special type of prescription from his/her physician; the drug is strictly regulated under Federal Schedule II. This drug is found in populations of adolescent and adult patients being treated for ADD and ADHD.



Client questions and pertinent information

1. What Positive Control should I use with my Verdict and Profile II ER devices that have an OPIATE 300 (OPI3) Cut off?

Use the MEDTOX 300 Positive control part number 101830¹.

Example part numbers for these devices are: Verdict II 7 panel, 601622¹. For the Profile II ER 9, 10, 11 and 12 panel devices: part numbers are respectively: 601591¹, 601636¹, 601672¹, and 601674¹.

If you are using the Profile III ER 12 panel with part number 602118¹ or the Profile IV 12 panel, with part number 604001¹ you will use the 101830¹ control also. Note: The MEDTOX Negative control 101183¹ can be used with ALL MEDTOX screening devices.

¹ If you are ordering this from Cardinal, add 'SP' as a prefix to the number.

2. What Positive Control should be used with the MEDTOXScan Reader devices which have lower cutoffs for a number of constituents, including opiates?

Use the MEDTOXScan Positive Control part number 102081¹ for the following MEDTOXScan device part numbers: 604018¹, 604019¹, and 604020¹ (12, 9 and 7 panels respectively).

¹ If you are ordering this from Cardinal, add 'SP' as a prefix to the number.

3. COLD SPECIMEN (or Cold Devices) Causing erratic results:

Most, if not all, drug screens use an antibody/antigen reaction that is temperature sensitive (i.e. the cooler the temperature, the slower the reaction). Therefore, each product has an acceptable specimen temperature range for use when performing the test. Likewise, there is an acceptable temperature range for the 'screening device'. If you perform the drug screen with a refrigerated device that has not been allowed to reach 'room temperature' or a refrigerated sample that has not been brought to 'room temperature', you could be compromising the reaction (colored line development) which might cause one or more 'false positive' screen results. If you were to repeat the screen at a later time after the device and/or urine were at room temperature, the results might be different--i.e. some positive results on visually read devices might now appear as light lines (negative). With the Reader, the lighter lines that were present due to a cold urine/cold device may now develop into darker lines which will be read as negative if they exceeded the line intensity threshold. The Moral of the True Story-- If the devices and/or the urine are stored in the refrigerator, they must be brought back to ambient temperature 67-77°F before use!

4. CAP Results—Method Code '1363' (Lateral Flow Immunoassay) & Drug Screen "Cut Offs":

The proper Method Code for reporting ALL MEDTOX results on the CAP survey is '1363 Lateral Flow Immunoassay'. If you are using some other code for reporting MEDTOX results, please switch to method code '1363'. If you have switched from a Verdict or Profile II ER product to the MEDTOXScan product line, you need to make sure you are using the proper drug screen cut off values. The MEDTOXScan devices have a number of cutoffs that are lower than the Verdict and Profile II ER products--check the product insert or Instructions for Use (Quick Start Guide). The package insert is available on line at <http://www.medtox.com/ProductTraining.aspx>

5. Design Change for MEDTOXScan Cartridges:

This device is FDA cleared to be read only by the MEDTOXScan reader, and cannot be read visually like the Profile II ER and other visually read products. New lot numbers of the Profile V MEDTOXScan cartridges will have a different look to them. The major change, the test grid that appeared at the top of the device and the markings for the Control (C) and Test (T1-T4) lines along the left hand side of the device have been removed from the device top in recently produced product. The 'test position' and 'Control/Test' keys are not needed since the instrument uses the bar code to determine what device was inserted into the reader. The change is only to the graphics...you still have the same test capability and performance, and there is no change in test method or results.

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Please Contact Your Regional Hospital Laboratory Representative for Any of Your MEDTOX Needs.

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Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Nebraska, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington, and Wyoming

Did You Know

Did you know the Buprenorphine assay for the MEDTOXScan Reader has been submitted to the FDA for approval? Please look for notice of approval in a future issue of MEDTOX Hospital Lab Quarterly Review and www.medtox.com .

Did you know that MEDTOX is a full service reference laboratory? For over 25 years, we have continually added to our test menu list. You can find our test catalog at:
<http://www.medtox.com/TestCatalog.aspx>

Feedback

We'd love to hear from you. Please send any comments to: hmarketing@medtox.com We welcome any remarks, feedback or suggestions that you may have. Please forward this letter to a friend or business associate who may be interested as well.

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