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| **Urine Drugs of Abuse Screen by MEDTOXScan** | | | | | | | | |
| **Purpose** | This procedure provides instructions for performing URINE DRUGS OF ABUSE SCREEN on the MEDTOXScan® Reader using an *in vitro* diagnostic test for the qualitative determination of amphetamine, benzodiazepines, barbiturates, benzoylecgonine (cocaine metabolite), opiates, phencyclidine, cannabinoids, buprenorphine, tricyclic antidepressants, methadone, oxycodone, and methamphetamine in human urine. | | | | | | | |
| **Policy Statements** | This procedure applies to all personnel who perform testing on the MEDTOX*Scan*® Reader. | | | | | | | |
| **Principle** | The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System includes the one-step, competitive, membrane-based immunochromatographic PROFILE®-V MEDTOX*Scan*® Test Device and the MEDTOX*Scan*® 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 MEDTOX*Scan*® Test Device. The PROFILE®-V MEDTOX*Scan*® 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 (C) 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 MEDTOX*Scan*® 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 MEDTOX*Scan*® 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 MEDTOX*Scan*® Reader screen or, optionally, can be printed. | | | | | | | |
| **Clinical Significance** | **Amphetamine** (AMP), or d-amphetamine, is a central nervous system stimulant and is detected only at the AMP portion of test cartridge.  **Methamphetamine** (mAMP) is a central nervous system stimulant and is detected only at the mAMP portion of the test cartridge.  **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 used to reduce anxiety and induce sleep.  **Cocaine** (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.  **Opiates** (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.  **Phencyclidine** (PCP) is a hallucinogenic drug.  **Marijuana** (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.  **Buprenorphine** (BUP) is a potent analgesic often used in the treatment of opiate abusers.  **Tricyclic Antidepressants** (TCA) are a group of structurally related prescription drugs that are used to manage depression.  **Methadone** (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.  **Oxycodone** (OXY) is a semi-synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.  Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors influence the time period during which drug metabolites are detected in urine. These include the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume will lower the drug concentration in the urine and may decrease the detection period. Lower detection levels may increase the detection time window. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.   |  |  | | --- | --- | | Drug | Detection Period | | Amphetamine:  Acidic Conditions  Alkaline Conditions | 1-3 days  3-10 days | | Barbiturates:  Short-Acting  Long-Acting | Up to 6 days  Up to 16 days | | Benzodiazepines | 1-12 days | | Cocaine metabolite: | Up to 5 days  1 to 3 days typical | | Opiates:  Heroin  Morphine  Codeine | 1 day  1-3 days  1-3 days | | PCP:  Single Use  Chronic Use | 1-8 days  Up to 4 weeks | | THC:  Single Use  Chronic Use | 1-7 days  Less than 30 days typical | | Buprenorphine: | up to 3 days | | Methadone: | 1-3 days | | Methamphetamine:  Acid conditions  Alkaline conditions | 1-3 days  3-10 days | | Oxycodone: | 1-3 days | | Tricyclic Antidepressants | 1-7 days | | | | | | | | |
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| **Equipment and Materials** |  | | | | | | | |
|  | **Instrumentation** | | | | | | | |
|  | MedTox Scan device reader | | | | | https://www.medtoxdiagnostics.com/wp-content/uploads/MEDTOXScan-Reader-clip2.png | | |
|  | MedTox Printer | | | | |  | | |
|  | Handheld barcode scanner | | | | |  | | |
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|  | **Reagents** | | | | | | | |
|  | **Reagent** | **Product Number** | | **CHC Number** | | | **Storage/Stability** | **Description** |
| Profile-V Test cartridge (V12) | 604032 | | 33449 | | | Store refrigerated or RT (2-25C) until expiration or day of use. | 12 drug screening test cartridges, 25 per box. |
| Negative QC | 101183 | | 33451 | | | Store at frozen -20 to -10C until use. Once thawed store at 2-8C for up to 30 days. | 10mL Urine based control. |
| Positive QC | 102367 | | 33450 | | | Store at frozen -20 to -10C until use. Once thawed store at 2-8C for up to 30 days. | 30mL Gelatin Sol. with indicator, pH 5-7 |
| Control Cartridge | 553075 | | 33457 | | | Store at RT until lot expiration when kept in foil pouch. | 2 daily QC cartridges. Includes 1 positive and 1 negative simulation. |
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|  | **Supplies and Accessories** | | | | | | | |
|  | **Supply** | | **Product Number** | | **CHC Number** | | **Description** | |
| Cassette, Cleaning | | 88307 | | 33456 | | Cleaning cassette | |
| MedTox Paper | | 101885 | | 33453 | | MedTox printer paper | |
| 75 ul MLA style pipette | | N/A | | Spec. Order | |  | |
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|  | **Documents** | | | | | | | |
|  | * [CH 6.93.f1 MEDTOXScan Reader Maintenance Log](https://starnet.childrenshc.org/References/labsop/chem/assays/ch-6.93.f1-medtoxscan-reader-maintenance-log.pdf) | | | | | | | |
| **Sunquest Test Codes** | |  |  | | --- | --- | | **ABUS** includes | AMPS Amphetamine in urine | | BAR Barbiturate in urine | | BZO Benzodiazepine in urine | | COKE Cocaine in urine | | OPI Opiates in urine | | PCP Phencyclidine in urine | | THCS THC (cannabinoids) in urine | | BUPS Buprenorphine in urine | | TCAS Tricyclic Antidepressants in urine | | MTDS Methadone in urine | | OXYS Oxycodone in urine | | MAMP Methamphetamine in urine | | FENTS Fentanyl urine screen *(performed on Abbott Alinity c)* | | | | | | | | |
| **Sample** | Freshly voided urine specimens: collected in clean, polypropylene, unbreakable, leak-proof containers. If testing is not performed immediately on fresh urine, store refrigerated for up to 24 hours. Freeze if delayed more than 24 hours. Do not use polystyrene containers due to propensity for absorbing drugs.  Specimens should be collected without preservatives or additives.  **Minimum Volume:** 375 uL minimum volume will not allow repeat testing  **Stability:** Store at 2-8 °C for up to 48 hours. Frozen, up to 7 days.  **Rejection Criteria:**  Unlabeled or mislabeled specimens, specimens with preservative or additives, specimens collected in polystyrene containers | | | | | | | |
| **Risk & Safety** | Safety data sheets (MSDS/SDS) available from MedTox, Inc. The MedTox liquid quality controls contain an insignificant amount of sodium azide (0.05%) and unused amount may be disposed of in red biohazard trash. Used and unused expired cartridges may be disposed of in regular trash. | | | | | | | |
| **Calibration** | The MEDTOX Scan reader is calibrated and certified before shipping to the customer. No calibration is required of the operator. | | | | | | | |
| **Analytical Measuring Range (AMR)** | |  |  | | --- | --- | | **Drug** | **Cutoff Concentration** | | Amphetamine | 500 ng/mL | | Barbiturates | 200 ng/mL | | Benzodiazepines | 150 ng/mL | | Cocaine | 150 ng/mL | | Opiates | 100 ng/mL | | PCP | 25 ng/mL | | THC | 50 ng/mL | | Buprenorphine | 10 ng/mL | | Tricyclic Antidepressants | 300 ng/mL | | Methadone | 200 ng/mL | | Oxycodone | 100 ng/mL | | Methamphetamine | 500 ng/mL |   External liquid control has been certified by the manufacturer to test the cutoff values of each drug. | | | | | | | |
| **Quality Control** | **Internal Electronic Quality Control: MEDTOXScan QC Test Devices**  **Frequency:** Daily  **Stability**: The controls are good until expiration date at room temperature when kept in the light blocking storage bag  **Procedure:**   1. Place the test device in the MEDTOX*Scan*® Reader cassette drawer and close the drawer. 2. Enter the lot number from the QC device package 3. Enter your tech code or CE number 4. Scan the control barcode from the QC device package   **External Control:** **MEDTOX Toxicology Urine Controls**  **Frequency:** Two levels, Positive and Negative, weekly on Tuesdays  **Storage and Stability**   * **Unopened**: the controls are stable until expiration date when stored at -10° to -20° C and protected from light * **Opened:** Store the controls at 2-8°C for up to 30 days. Store in original bottle.   **NOTE:** The controls are also stable for 3 freeze/thaw cycles when stored and refrozen at -10° to -20° C and exposure to room temperature is minimized. To extend the number of determinations per bottle, use refrigerated storage conditions.  Procedure:   1. Allow bottle to come to room temperature. Mix well by swirling gently prior to opening and sampling. 2. Follow the Test Procedure section, below; instead of the sample ID, enter in the liquid QC lot number printed on the QC bottle.   Note: When Pipetting, immerse the pipette tip as little as possible into the sample solution.  Note: Do not rinse the pipette back and forth into the sample.  **Acceptable ranges:**   * Positive QC should yield positive and Negative QC should yield negative results. Any deviation for any analyte must be investigated, up to and including notification of the manufacturer. * In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section. * Do not load or release patients until QC is acceptable in Unity Real Time. * Drugs of Abuse QC should be entered under the Multi-Test data entry in Unity Real Time. Results will be entered as either Presumptive Positive for “POS” and Not Detected for “NEG” results. | | | | | | | |
| **Test Procedure** | **Sample and test cartridges must be at room temperature prior to testing.**  **Loading the cartridge and instrument**   1. Open one pouch for each sample to be tested and mark the PROFILE®-V MEDTOX*Scan*® Test Device with the patient name or sample ID. Make sure you only mark within the ID box on the test device and not near the barcode.   **Do not apply labels or tape to the PROFILE®-V MEDTOXScan® Test Device.**   1. With the MiniPet 75μL pipette or any 75uL pipette, dispense 75μL of urine into all sample wells (indicated by arrows on the test device). 2. Wick away any urine droplets on the top surface of the cartridge using a kim wipe to avoid contaminating the MEDTOX*Scan*® Reader sensor. 3. Immediately place the test device in the MEDTOX*Scan*® Reader cassette drawer and close the drawer. 4. Scan the cartridge Lot number 5. Enter your Sunquest tech code or CE number 6. Scan the Specimen ID number 7. After 10 minutes, the instrument will sound 3 beeps, results will print and automatically transfer to Sunquest. In case of instrument downtime, enter the results manually in MEM. Refer to Results Reporting section for details.   Note: The MEDTOX*Scan*® Reader will begin timing the assay once it detects the barcode and results will be displayed after the scan and analysis are complete. Tests cannot be incubated outside the MEDTOX*Scan*® Reader, and should not sit on the counter for any length of time after adding the sample. | | | | | | | |
| **Error Messages** | Contaminated Sensor: This error occurs when urine dries on the internal sensor of the machine. To clean the sensor follow the instructions included in the Cleaning Cassette Kit. If repeated errors occur after cleaning the sensor x2, contact the manufacturer.  Firmware Update: This error is typically triggered by cartridge barcode misprints by the manufacturer. To complete patient testing, attempt to run cartridge on alternate analyzer or check for alternate cartridge lot. Check remaining shipment for additional barcode errors, contact manufacturer for replacement if applicable. | | | | | | | |
| **Interferences** | There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false Results see operating manual for full list of interfering substances. Patients taking Phenobarbital could cause a positive barbiturate result. | | | | | | | |
| **Reference Ranges** | Negative | | | | | | | |
| Critical Value | Any positive result is considered a critical value and must be called according to the Critical Value Policy. | | | | | | | |
| **Limitations** | * 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. * There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false results. * The PROFILE®-V MEDTOX*Scan*® 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. * Gas Chromatography/Mass Spectroscopy is the recommended confirmatory method for most drugs. | | | | | | | |
| **Interpretation** | **Interpreting Results**  The MEDTOX*Scan*® Reader will automatically read the control and test lines at the correct test position and display the test results for each drug. The MEDTOX*Scan*® Reader displays the results as either “NEG” for a negative result, “POS” for a presumptive positive result, or “INVALID” for an invalid result. “VALID” will be displayed if valid results are obtained.  Repeat any result that returns an INVALID error. If the repeat value still yields INVALID, request a new sample. If INVALID is returned for the recollected sample, send the sample to MedTox for screening. | | | | | | | |
| **Result Reporting** | **Positive**: Report as POS   * A positive screen is a presumptive result only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectroscopy *(GC/MS)* is the preferred confirmatory method. * Confirmatory testing, when needed, requires the provider order the specific drug confirmatory test from Medtox. Medtox requires a minimum sample volume of 3 mL.   **Negative**: Report as NEG   * A negative result does not indicate drug-free sample. Rather, the drug in question may be at concentration less than the detectable cutoff for a positive result. For cutoff values, see AMR section. If a positive drug is suspected despite negative finding, the urine should be sent to MedTox for analysis by mass spectrometry.   Sunquest Function **OEM**:   1. Results are sent automatically to Sunquest as POS or NEG.   Every positive result will have the following comment automatically appended by Sunquest: “Unconfirmed result.  Confirmatory testing is recommended.  Unconfirmed screening results must not be used for non-medical purposes such as employment or legal testing.”   1. Accept (A), Modify (M), or Reject (R) according to Resulting Reporting in Chemistry procedure (CH 7.03).   Sunquest Function **MEM**: Result using Sunquest Worksheet ABUS. Type “POS” or “NEG” at each prompt. NOTE: Do not type “POSITIVE” or “P” as the correct comment will not append. | | | | | | | |
| **Sample Storage** | Promptly stopper tested specimen and store upright in numbered specimen rack by accession number. Immediately remove specimens to refrigerator/freezer storage. Save a 5 mL or more aliquot for 7 days in specimen storage freezer on positive screens in case of add-on confirmation testing. | | | | | | | |
| **References** | 1. MEDTOX*Scan*® Drugs of Abuse Test System Package Insert, MEDTOX Diagnostics, Inc., 1238 Anthony Road, Burlington, NC. Part Number 102038, Revised 07/2017. | | | | | | | |

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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Stephen Gripentrog/Erin Bartos | 12/1/19 | Initial Version |
|  | Matt Johnson | 7/1/2022 | Reviewed, added statement regarding verification of cutoff values. |
|  | Matt Johnson | 3/15/2023 | Reviewed, no changes. MCJ 3/15/2023 |
|  |  | Matt Johnson | 12/12/2023 | Update for 12 drug cartridge, new: BUP, TCA, MTD, OXY, MAMP |
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