

Rural Access to MAT in Pennsylvania

RAMP

Medication-Assisted Treatment: Urine Drug Screening Guide

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Introduction

Urine drug screening (UDS) can provide insight into Medication-Assisted Treatment (MAT) compliance and patient substance use to better inform clinical decision making and improve treatment outcomes.¹⁻³ This guide is intended to assist outpatient MAT providers in optimally utilizing UDS to monitor and manage treatment, and to help minimize the risk of medication misuse or diversion.

Considerations and Limitations of UDS

It is important to remember that UDS is one of many methods for monitoring MAT compliance. There are a few considerations that providers should keep in mind when conducting UDS for MAT patients:

1. The **goals of UDS** are to³:
 - a. Ensure the patient is taking the prescribed medication; and
 - b. Ensure the patient is not using any other substances which may negatively interact with MAT Medications and/or affect recovery.
2. **Point-of-care UDS (presumptive testing) has a few limitations**, including^{1,2}:
 - a. Inability to determine the length of time since last use;
 - b. Assays vary in sensitivity and specificity (some only confirm the presence of a class of drugs);
 - i. There is potential for false-positive results to occur due to certain foods and supplements;
 - ii. There is potential for false-negative results to occur due to testing thresholds;
 - c. Testing can be invasive when observed; and
 - d. Potential for samples to be substituted or adulterated even when observed.

Thus, it is recommended that providers implement additional compliance monitoring strategies beyond UDS like pill/film counts and Prescription Drug Monitoring Program (PDMP) checks. Additionally it is recommended that providers seek laboratory confirmation when UDS results are inconsistent with treatment goals or are in question.³

UDS Frequency

General guidelines are to conduct UDS more frequently early on in treatment, and to gradually lessen the frequency with evidence of treatment compliance and signs of recovery (improved physical health, abstinence from use, stable employment, stable interpersonal relationships, etc.)⁴. Providers should conduct UDS^{1,3}:

1. **When Assessing Patient Candidacy for MAT:**
 - a. As part of a comprehensive medical and psychosocial assessment; and
 - b. To assist with treatment planning and determining the appropriate pharmacotherapy and level of care.
2. **At Induction Appointments for Naltrexone, Buprenorphine, and Methadone:**
 - a. To confirm patient abstinence from opioids and minimize the potential for precipitated withdrawal to occur; and
 - b. To confirm the presence/absence of substances that may negatively interact with MAT medications (e.g. benzodiazepines).
3. **Regularly Throughout Treatment:**
 - a. At least weekly while in early recovery (first 90 days to 1 year⁵);
 - b. At least monthly as the patient progresses in recovery;
 - c. More or less frequently depending on patient substance use history;
 - d. When recent substance use is disclosed by the patient or is in question; or
 - e. If a patient is enrolled through judicial system program, as frequently as is required.

Additionally, less frequent testing (i.e. at intervals greater than monthly) should be considered on an individual basis for patients progressing in recovery. Testing frequency should be increased again for a patient who returns to use, and appropriate revisions to the treatment plan should be made.^{1,3}

Random Testing

Clinical guidelines recommend **random** testing be implemented whenever possible over fixed-schedule testing (e.g., every Friday).^{1,3} Conducting random testing can eliminate known “test free” time intervals where a patient may use without UDS detection. There are a number of methods for testing randomization.

One simple method for random testing is to¹:

1. Determine the maximum allowable time interval between testing (e.g. weekly, bi-weekly, or monthly); and
2. Utilize a random number generator to select the testing date(s) within this time interval.
 - Searching “random number generator” on Google will return links to a few different tools for doing this.

For Example:

A patient’s treatment plan indicates that they will be administered a UDS weekly. The provider assigns a number from 1-7 to each day of the week (in this example, the provider starts the week on Sunday). The provider then uses a random number generator to determine the day of the week that UDS will be administered for the next four weeks. The random number generator outputs 4, 7, 3, and 5. Thus, the patient’s UDS schedule for the next four weeks would be:

Week 1	Week 2	Week 3	Week 4
Wednesday	Saturday	Tuesday	Thursday

Random testing may be completed by contacting the patient to complete a test at the office within a reasonable timeframe (e.g. 24-48 hours) without providing prior notice. In instances where truly random testing cannot occur (for example, if a patient has transportation barriers that could prevent them from completing call-in testing) UDS testing may be conducted by randomly selecting an existing appointment date to complete the test without providing advanced notice to the patient.

Observed vs. Unobserved Urine Sample Collection

Direct observation of urine sample collection is generally utilized as a means to mitigate sample tampering, however, observation can be uncomfortable for both patients and staff involved.^{1,3} Time and resource barriers may inhibit a primary care office’s ability to conduct observed collection. Additionally, methods exist for substituting or adulterating samples even when testing is observed. Observation does not mitigate risk of sample adulteration via ingestion of certain foods or supplements such as high-nitrite cured meats or diuretics.¹

It is recommended that observed testing is reserved for extenuating circumstances for example, following an instance of sample tampering. There are a few strategies that can be implemented by primary care practices to minimize the risk of tampering during unobserved sample collection, including¹⁻³:

1. Not allowing patients to carry personal items with them into the bathroom collection area;
2. Removing potential adulterants (soap, bleach, etc.) from the collection area;
3. Placing blue dye or colored cleaner in the toilet bowl and tank;
4. Turning off the hot water supply to the collection area; and
5. Providing alternative hand-cleansing options.

Specimen Validity Testing

While point-of-care UDS testing equipment capabilities will vary from clinic to clinic, specimens should be evaluated for validity immediately following sample collection^{1,2}:

Documentation of Appearance (No Equipment Necessary)	Sample Validity Tests (If Available)
Sample Color	pH Level (>3 and <11 is consistent with human urine)
Unusual Temperature (e.g. "Too Hot to Hold" or "Ice Cold")	Creatinine Level (≥ 20 mg/dL is consistent with human urine)
Unusual Smell	Specific Gravity (1.003 to 1.030 is consistent with human urine)
Excessive Bubble Formation (upon shaking of sample)	Nitrite Level (>500 mcg/mL indicates adulteration)
Cloudiness or Floating Particles	Exact Temperature between 90-100° F or 32-38° C (Must be measured within 4 minutes of collection)

If a specimen fails validity testing or if sample validity is in question, consider asking the patient to provide another sample with or without direct observation.

Confirmatory (Definitive) Testing

Confirmatory testing, otherwise known as definitive testing, is generally completed in a laboratory via gas chromatography - mass spectrometry (GC-MS) or liquid chromatography – mass spectrometry (LC-MS) testing. These tests are "definitive" in that they are highly sensitive and specific, using equipment and methods to separate, identify, and quantify all substances in a sample.^{1,2}

Due to the limitations of point-of-care testing, there are a few situations in which providers should seek confirmatory testing¹:

1. Following a positive test result that is disputed by a patient;
2. Following evidence or suspicion of sample tampering or substitution;
3. Following evidence or suspicion of medication diversion;
4. Following patient self-reported use when more information regarding a specific substance and/or quantity is desired.

Reviewing UDS Results with Patients

When talking with patients, it is important to frame UDS testing as a therapeutic tool meant to support treatment and recovery. UDS results can have serious medical, social, and legal consequences for patients.¹⁻³ Providers are encouraged to provide positive feedback to patients following satisfactory results. Invalid or inconsistent UDS results should be reviewed with patients to explore barriers to treatment adherence and compliance rather than utilizing testing results for punitive measures, or as grounds for dismissal from an MAT program.^{1,3}

Beyond reviewing test results with patients, there are a few strategies providers may implement following invalid/inconsistent UDS results to further ensure treatment compliance and support patient recovery^{1,3}:

1. Discussing potential changes to the treatment plan with patients, encouraging more frequent engagement with case management, substance use disorder (SUD) counseling, and/or recovery support services;
2. Temporarily increase the frequency of compliance testing like UDS and pill/film counts;
3. Temporarily decrease the supply of take-home prescriptions;
4. For patients on Transmucosal buprenorphine formulations, consider conducting an observed dosing to ensure the patient is able to administer the medication properly.

If implementation of these strategies fails to remedy the situation, providers should consider the need to refer the patient to a higher level of care.

References

1. Jarvis M, Williams J, Hurford M, et al. Appropriate Use of Drug Testing in Clinical Addiction Medicine. *J Addict Med* 2017;11:163-73.
2. Moeller KE, Lee KC, Kissack JC. Urine Drug Screening: Practical Guide for Clinicians. *Mayo Clinic Proceedings* 2008;83:66-76.
3. Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families (TIP 63). Rockville, MD 20857: Substance Abuse and Mental Health Services Administration; 2018.
4. Recovery and Recovery Support. U.S Department of Health & Human Services, 2019. at <https://www.samhsa.gov/find-help/recovery>.
5. Substance Abuse and Mental Health Services Administration. Managing Depressive Symptoms in Substance Abuse Clients During Early Recovery Rockville, MD 20857: Substance Abuse and Mental Health Services Administration; 2008.

Appendix 1: Sample Primary Care MAT Program UDS Protocol

Primary Care MAT Program UDS Protocol – EXAMPLE

A. Urine Drug Screening (UDS) to Support Medication Assisted Treatment (MAT)

The following are directions for how to conduct random UDS for patients receiving MAT.

A.1 Determine the Random Urine Screening Schedule

1. The provider will review the patient's substance use history and treatment plan and determine the **maximum allowable time interval** between UDS testing:
 - a. The provider will consider any legal requirements placed upon the patient's treatment when determining the testing schedule (e.g. some judicial system programs may require testing weekly or at every appointment).
2. The provider will note the maximum allowable time interval (e.g. weekly, bi-weekly, or monthly) in the patient's electronic health record.
3. The provider will use a randomization method such as a random number generator select the testing date(s) for the next four testing cycles:
 - a. The provider will take into account patient transportation barriers and may adjust the testing dates to align with scheduled MAT appointments if call-in testing is not always feasible.
4. The provider will record the next four testing dates and test types (call-in or MAT appointment) in the patient's electronic health record.
5. The provider will notify scheduling staff of the upcoming testing schedule, noting that additional time should be allocated for MAT appointments where a UDS will be administered.
6. Proceed to:
 - a. **A.2.** for instructions on contacting patients for call-in screening; or
 - b. **A.3** for instructions on administering a UDS upon patient arrival at the office.

A.2 Conducting Call-in Screening

1. The office staff will review the UDS testing schedule daily.
2. The office staff will contact patients 24 hours in advance of testing to request completion of a UDS and confirm that they will come to the office for testing.
3. If a patient is unable to confirm attendance for the UDS, office staff will discuss plans with the provider for rescheduling testing and follow-up appropriately.
4. Proceed to **A.3**

A.3 Administering a Urine Drug Screen

1. Upon patient check-in, the office staff will notify the designated sample collector.

2. The collector will prepare the collection area bathroom, ensuring:
 - a. Potential adulterants such as soap and cleaning products are not accessible on sink tops or in cabinets;
 - b. Blue dye or colored cleaner is added to the toilet bowl and tank water;
 - c. The hot water supply to the collection area is turned off; and
 - d. Alternative hand cleansing methods are available.
3. The collector will escort the patient to the collection area and confirm with the patient that:
 - a. No personal items can be taken into the bathroom during sample collection;
 - b. The patient must provide the sample to the collector before flushing the toilet or washing their hands, or it will be requested that they provide another sample; and
 - c. Soap and/or alternative hand cleansing methods will be provided upon collection of the sample.
4. The collector will wait outside of the bathroom during sample collection.
5. The collector will provide the patient will soap and/or alternative hand cleansing methods following receipt of the sample and request that the patient wait in the waiting room.
6. Proceed to **A.4**

A.4 Assessing Sample Validity

1. The collector will immediately evaluate sample validity by:
 - a. Documenting Sample Characteristics and Abnormalities (**no equipment necessary**):
 - i. Sample color;
 - ii. Unusual temperature (e.g. “too hot” or “too cold”);
 - iii. Unusual smell;
 - iv. Excessive bubble formation (upon shaking of sample); and
 - v. Cloudiness or floating particles.
 - b. Completing Sample Validity Tests (**if testing equipment is available**):
 - i. pH Level
 - ii. Creatinine Level
 - iii. Specific Gravity

- iv. Nitrite Level
- v. Exact Temperature (Must be measured in within 4 minutes of collection)

2. The collector will review the sample characteristics and validity test results and document them in the patient’s EHR:

Sample Validity Test	Acceptable Range
pH Level	>3 and <11 is consistent with human urine
Creatinine Level	≥20 mg/dL is consistent with human urine
Specific Gravity	1.003 to 1.030 is consistent with human urine
Nitrite Level	>500 mcg/mL indicates adulteration
Exact Temperature	Between 90-100° F or 32-38° C

a. **If a sample has failed any of the validity tests or has abnormalities leading to reasonable suspicion of sample tampering, the collector will request the patient provide another sample, repeating steps A.3.1 through A.4.2.**

3. Once a sample has passed validity testing, proceed to **A.5** for instructions on assessing UDS testing results.

A.5 Assessing UDS Testing Results

A NOTE ON UDS TESTING EQUIPMENT:

It is highly recommended that providers utilize urine sample collection cups with built-in validity testing and drug testing. This is to ensure consistent and accurate sample testing by minimizing the potential for testing errors to occur when manual testing is completed with dip strips or dip cards.

Additionally, it is suggested that providers consider obtaining a Clinical Laboratory Improvement Amendments (CLIA) waiver and utilize CLIA waived testing cups. CLIA sets rigorous standards for acceptable ranges of testing accuracy and risk of error. Additionally, being CLIA waived and utilizing CLIA waived tests allows providers to bill for testing.

1. Using the valid sample, the collector will review the results of the UDS test, following the instructions included in the testing packaging.
2. The collector will note in the patient’s EHR:
 - a. The presence/absence of buprenorphine (for patients being prescribed buprenorphine);
 - b. The presence/absence of other legitimately-prescribed controlled substances (if applicable); and
 - c. The presence/absence of controlled substances not allowed under the patient’s treatment plan.
3. Proceed to:
 - a. **A.6** for instructions on reviewing call-in UDS results; or
 - b. **A.7** for instructions on reviewing UDS tests completed during an appointment.

A.6 Reviewing Call-in UDS Results

1. The provider will review the sample validity and UDS results and determine the need for definitive testing depending upon:

- a. Evidence or suspicion of sample tampering or substitution;
 - b. Evidence or suspicion of medication diversion;
 - c. An unexpected positive drug test for a substance not included or allowed by the patient’s treatment plan; or
 - d. Results consistent with the patient’s treatment plan.
2. If deemed necessary, the provider will send the sample to the lab for definitive testing, noting:
 - a. The specific category(s) or substance(s) of interest they are seeking more information on (e.g. “Requesting confirmation of presence/absence of heroin” or “requesting identification of specific amphetamine present in sample”).
 3. The Provider will note in the EHR plans to review the definitive testing results with the patient at the next appointment.
 4. Proceed to:
 - a. **A.8** for instructions for discussing consistent UDS results with patients; or
 - b. **A.9** for instructions for discussing inconsistent UDS results with patients.

A.7 Reviewing UDS results during an appointment

1. Prior to entering the examination room the provider will review the sample validity and UDS test results for:
 - a. Evidence or suspicion of sample tampering or substitution;
 - b. Evidence or suspicion of medication diversion;
 - c. An unexpected positive drug test for a substance not included or allowed by the patient’s treatment plan; or
 - d. Results consistent with the patient’s treatment plan.
2. Proceed to:
 - a. **A.8** for instructions for discussing consistent UDS results with patients; or
 - b. **A.9** for instructions for discussing invalid or inconsistent UDS results with patients.

A.8 Discussing Consistent UDS Results with Patients

1. The provider will review the results of the UDS with the patient during the appointment while reviewing any other recently completed laboratory testing, providing positive feedback regarding the treatment-consistent result.

A.9 Discussing Invalid or Inconsistent UDS Results with Patients

1. The provider will review the results of the validity testing and UDS test with the patient during the appointment, noting any:
 - a. Failed validity tests;

- b. Substance-positive UDS results;
 - c. Buprenorphine-negative UDS results.
2. The provider will ask permission to discuss the results with the patient in greater detail.
3. The provider will use motivational interviewing to review the results with the patient and:
 - a. Identify barriers to treatment compliance;
 - b. Identify feasible changes to the treatment plan;
 - c. Identify any additional supports/services needed; and
 - d. Identify the need for definitive testing (Note: this is only for UDS completed as part of an existing MAT appointment).
4. The provider will make any necessary referrals for treatment or services and document this in the patient's EHR.
5. The provider will update the treatment plan in the patient's EHR, noting any:
 - a. Changes in UDS testing and compliance testing frequency;
 - b. Changes in prescription dose, length, and supply;
 - c. Changes in required frequency of engagement with care management and SUD counseling.
6. The provider will make a note in the patient's EHR to follow up with the patient about progress related to these changes at the next appointment.

Appendix 2. Additional Resources Related to Compliance Testing

Additional Resources Related to Compliance Testing

Resource →	American Society of Addiction Medicine	Mayo Clinic Proceedings	Substance Abuse and Mental Health Services Administration
Topic ↓	<i>Appropriate Use of Drug Testing in Clinical Addiction Medicine</i>	<i>Urine Drug Screening: Practical Guide for Clinicians</i>	<i>Medications for Opioid Use Disorder (TIP 63)</i>
Clinical Use of Drug Testing	X	X	X
Types of Available Drug Testing	X	X	X
Compliance Test Selection	X	X	X
Presumptive vs. Definitive Testing	X	X	
UDS Limitations	X	X	
Compliance Testing Frequency	X		X
Window of Detection Times by Substance	X	X	
Signs of Urine Sample Tampering	X	X	
Urine Specimen Validity Testing	X	X	
Interpreting UDS Results	X	X	
Seeking Laboratory Confirmation	X	X	
Understanding False Positives	X	X	
Discussing UDS Results with Patients	X		X