

EDDP Panel-Dip Screening Device / frequently asked questions

EDDP TEST DEVICE OVERVIEW

What is EDDP?

Methadone, a Schedule II controlled substance, is often used in the treatment of opiate addiction and pain management; it also has a high potential for abuse. Methadone is metabolized primarily into two pharmacologically inactive metabolites, EDDP and EMDP.

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound (methadone)^[1].

EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) represents a better urine marker for monitoring methadone maintenance than testing for un-metabolized methadone alone.

Why is it important to test EDDP?

With an EDDP Panel-Dip device you'll know quickly and easily if your patient ingested then metabolized their methadone.

Monitoring the presence of EDDP is an accurate means to determine methadone therapy compliance or to reveal methadone diversion activity. Testing EDDP provides reliable metabolite results, solves the "extensive metabolizer" dilemma and alleviates tampering concerns.

Will this test replace methadone screening devices?

EDDP Panel-Dip tests provide a dependable supplement to standard methadone test devices—not a replacement. Reliable methadone drug screening should target both the urine metabolite (EDDP), and parent-drug (methadone).

What is an "extensive metabolizer"?

Some people in treatment may be categorized as "extensive metabolizers" of methadone. Thus, while a patient may be compliant, their urine may not contain enough methadone to indicate a positive result. These individuals are often denied further doses of methadone because they are believed to be diverting their medication.

How does this test alleviate tampering concerns?

Determining if a patient ingested their methadone is not possible with a parent-drug (methadone) screening device.

Many addicts who choose to divert or sell their methadone on the street are aware that adding ("spiking") a small amount of methadone into their urine specimen will produce a positive result; thus, making them appear compliant. This is a common tactic to circumvent standard methadone drug screens.

What type of device is it?

The safe and convenient Panel-Dip screening device is FDA 510(k) cleared to market, and is a lateral flow chromatographic immunoassay that provides qualitative detection of methadone metabolites in urine. Tests are for professional in vitro diagnostic use only.

How accurate is the EDDP Panel-Dip device?

Refer to the package insert for complete information on sensitivity, precision and specificity. Targeting EDDP provides fast and reliable preliminary screening results; validating patient ingestion. To confirm the presence and concentration of methadone in presumptive positive or negative specimens, an alternate method such as GC/MS should be considered (*see Requesting GC/MS Confirmation*).

Does the device help monitor methadone levels?

On-site test devices combined with quantitative analysis have the potential to improve the effectiveness of methadone maintenance and narcotic addiction. A screening device alone does not provide methadone levels; rather it screens for the presence of EDDP in urine. For therapeutic drug level monitoring consider alternate methods including: urine laboratory screening and confirmation, or peak and trough blood/serum testing.

Who should use the device?

Tests are well-suited for licit methadone maintenance monitoring, initial patient admissions, or when revealing diversion activity is critical. It will also prove reliable for determining illicit use within criminal situations including drug courts, probation, parole, child welfare, etc.

Who should not use the device?

The use of an on-site screening device for decision making may subject some Opioid Treatment Programs (OTP's) to the requirements of CLIA Federal guidelines. If an OTP falls under CLIA requirements, they must register and use CLIA waived devices^[2]. Federal and State regulations vary regarding urine testing requirements, frequency, and type of test allowed. Check regulations to ensure on-site testing kits are permitted for your agency.

What is the cut-off level for this device?

The test identifies EDDP with cut-off level at 300 ng/mL.

What is the detection window for this test?

The window of detection for EDDP is within 24 hours of ingestion. The elimination half-life of methadone is approximately 15-55 hours with about 5-50% of a dose eliminated as methadone and 3-25% as EDDP. Large individual variations in elimination do occur due to urine pH, urine volume, dose, rate of metabolism, drug interaction, etc.

TEST DEVICE PROCEDURES

How does the test work?

The test procedure for the EDDP screening device is identical to our other popular Reditest® Panel-Dip devices; simply collect, dip and read results. As with all of our test devices, a detailed package insert is included with every order.

For complete Panel-Dip training and procedures, including an interactive certification quiz, please view our online instructions here: www.redwoodtoxicology.com/products/doa_panel-dip.html

Telephonic training is also provided to all clients via our toll-free hotline at (877) 444-0049.

INTERPRETING RESULTS

How do I know if the test is positive?

If the test is presumptive positive, red lines appear in the control region (C), and no line will appear in the test region (T) next to the target drug. The test area must be snow white to be considered positive. A positive result indicates that the drug concentration is above the detectable level.

What should I do if I have a positive result?

Clinical consideration and professional judgment should be applied to any drug of abuse test result, including a preliminary positive result. Factors affecting illicit and licit drug use should also be considered.

A positive result indicates that the drug concentration is above the indicated cut-off level. Any positive result obtained with this urine screening test is presumptive and should be confirmed by an alternate method such as GC/MS (*see Requesting GC/MS Confirmation*).

How do I know if the test is negative?

If the test is presumptive negative, red lines appear in the control region (C) and next to the drug name in the test region (T). The negative result indicates that the drug concentration is below the detectable level. The shade of red in the test region will vary, but it should be considered presumptive negative, even if there is a faint pink line.

What should I do if I have a negative result?

Clinical consideration and professional judgment should be applied to any drug of abuse test result, including a preliminary negative result. Factors affecting illicit and licit drug use should also be considered.

A negative result indicates that the drug concentration is below the indicated cut-off level. Any negative result obtained with this urine screening test is presumptive and should be confirmed by an alternate method such as GC/MS (*see Requesting GC/MS Confirmation*).

Does a negative result indicate drug-free urine?

A negative result does not necessarily indicate drug-free urine. Negative results may be obtained when a drug is present in the urine, but below the cut-off level. Diluting a sample or adding interfering substances is another common method used to alter positive findings. Patients who are positive for methadone but negative for the EDDP metabolite need careful evaluation; this result is consistent with a tampered specimen.

How do I request GC/MS laboratory confirmation?

You may request a GC/MS confirmation test by writing "EDDP", or the Panel Code Number "597" on the chain of custody label. You may also request to have your labels updated to include this as a test option.

What factors could cause the test to be invalid?

A control line will be present if the test device is working properly. If a control line does not appear, repeat the test. Insufficient specimen volume or incorrect procedural techniques are most likely the reasons for control line failure. Review the procedure and repeat the test using a new device.

Improper testing procedure, unsealed packaging, damaged membrane and unsuitable specimens could also cause the test to be invalid. If further assistance is required, please contact us at (877) 444-0049.

What are common ways to tamper with urine samples?

Diluting a sample or adding interfering substances are common methods for attempting to alter positive findings.

STORAGE

What temperature should the urine specimens be stored at?

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

What is the shelf life of the EDDP Panel-Dip device?

The test has a shelf life of 24 months from the date of manufacture.

What is the storage temperature for the device?

Room temperature. Store as packaged in the sealed foil pouch at 2-30°C (36-86°F).

REFERENCES:

- [1] Baselt, R.C., *Disposition of Toxic Drugs and Chemicals in Man*, 6th Ed., Foster City, CA., 2002. 643
- [2] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration—Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs (TIP 43). 2005

Please refer to the package insert for more detail on this product.



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