



EDDP – 100 / 300 ng/ml

TABLE OF CONTENTS

1. What Is EDDP?	1
What are the Benefits of One Step EDDP Tests?	1
Target Markets & Product Positioning	1
Market Opportunity	1
Main Competition	2
2. Principle of the Test	3
4. Technical Information for One Step EDDP Tests	4
5. Features & Benefits	4
6. FAQs	5

EDDP One Step Tests

Sales Support & Technical Information



1. What Is EDDP?

2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), is an inactive metabolite of methadone, a narcotic pain reliever that is occasionally found on the illicit drug market.

What are the Benefits of One Step EDDP Tests?

1. Easy to read results
2. Accurate
3. Rapid results - allows for immediate decision
4. 2 year shelf life
5. No instrumentation required

Target Markets & Product Positioning

Sales Strategy

There is a market demand for an EDDP-specific test as a supplement or replacement for methadone testing. Methadone is not only a drug of abuse, but is also used as a treatment for opiate addiction. Patients taking methadone for opiate addiction are considered to be in "methadone maintenance." In the United States alone, there are nearly 1,000,000 heroin addicts; 20% of them, or nearly 200,000 people, are on methadone maintenance. Every individual prescribed methadone for opiate addiction is subject to drug testing. Drug testing is conducted to make sure the patient is actually taking the methadone and to ensure no other drugs are present (such as heroin).

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure which makes them very difficult to detect using an immunoassay targeted to the native compound. Compounding this problem, there is a subsection of the population who are classified as "extensive metabolizers" of methadone. In these individuals, although they are compliant with their methadone maintenance, their urine specimen does not contain enough parent methadone to yield a positive drug screen. As a result, these individuals are often denied further doses of methadone because they are incorrectly believed to be diverting their medication. In addition, many addicts who choose to divert or sell their methadone on the street are aware that adding a small amount of the drug to the urine specimen will produce a positive result on a parent methadone-based drug screen. This is a common tactic to circumventing accurate drug screening.

FDA-cleared, CE-marked EDDP reagent-based assays are currently for sale throughout the US and Europe. Since EDDP represents a better urine marker for methadone maintenance than unchanged methadone, it is believed the drug testing industry will soon standardize methadone testing to require detection of the EDDP metabolite.

Market Opportunity

Market Segments

- Workplace
- Criminal Justice System
- Corrections
- Probation / Parole
- Rehabilitation
- Drug Courts
- Prisons

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Main Competition

Microgenics Corporation

Microgenics is a Fremont, CA-based company, founded in 1986, offering a range of diagnostics, calibrators and controls for drugs of abuse, specimen validity, therapeutic drug monitoring and patient care. Product lines include rapid tests and enzyme immunoassay (EIA), as well as instrument calibration verification and document services.

In 1999 Microgenics merged with Diagnostic Reagents, Inc. (DRI) as part of an acquisition by Sybron Intl Corp. (later Apogent Technologies, the parent company of ABI until 2003), and in 2004 Apogent merged with Fisher Scientific.

Microgenics EDDP Rapid Drugs of Abuse Panel Test

Microgenics offers a urine panel test in Canada through Diagnostix, Ltd., in a BZO/COC/OPI/EDDP configuration. This test detects EDDP at a cut-off of 100 ng/mL at 5 minutes, and has been approved by Health Canada. There is no information regarding the availability of this product in other regions. Diagnostix claims to be the exclusive distributor of this product.

CEDIA® DAU EDDP Assay



Microgenics introduced its patented CEDIA (cloned enzyme donor immunoassay) immunoassay system in 1986, and although this trademark was held for a time by Boehringer Mannheim, this company and the trademark are now owned by Roche Diagnostics. Microgenics still sells CEDIA reagent kits for drugs of abuse and therapeutic drug monitoring.

This reagent system requires the use of a clinical chemistry analyzer. Such machines typically cost \$10,000 - \$300,000 in the US, depending on the desired feature set. This kit has a cut-off concentration of 100 ng/mL in urine and a detectable limit of 6.3 ng/mL, at a sensitivity of 95.4% and a specificity of 98.2% vs. High Performance Liquid Chromatography (HPLC).

This product is cleared for sale in the US, submitted to the US FDA by Boehringer Mannheim in 1998.

DRI® Methadone Metabolite (EDDP)

Microgenics also distributes the DRI® Methadone Metabolite (EDDP) reagent kit. This product was developed by Diagnostic Reagents, Inc., and became part of Microgenics' product line after the company's 1999 merger/acquisition. This reagent kit was submitted to the US FDA in 1993, one of the first EDDP diagnostic kits on the market.

This reagent system requires the use of a clinical chemistry analyzer. When originally submitted to the FDA, it had a cut-off concentration of 300 ng/mL and a detectable limit of 75 ng/mL. In 2003 Microgenics submitted a similar kit under the same name, with a cut-off concentration of 300 and 1,000 ng/mL in urine and a semi-quantitative range of 31-2,000 ng/mL. % Agreement with GC/MS was reported to be 95%.



EDDP One Step Tests

Sales Support & Technical Information



Lin-Zhi International, Inc.

Lin-Zhi is a Sunnyvale, CA-based company that sells EIA kits for drugs of abuse.

Methadone Metabolite Enzyme Immunoassay

This reagent system requires the use of a clinical chemistry analyzer. The cut-off concentrations for these tests in urine and oral fluid are 300 and 20 ng/mL, respectively, with detectable limits of 15 ng/mL (urine) and 1 ng/mL (oral fluid).

At the time of this writing (Oct. 2006), only the urinary EIA test has been submitted to FDA (approved 2003).

2. Principle of the Test

One Step EDDP Tests are immunoassays based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

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4. Technical Information for One Step EDDP Tests

Parameter	Product Description
Intended Use	A lateral-flow immunoassay for the specific, qualitative detection of EDDP (methadone metabolite) in human urine
Intended Customer	Professional
Technology	Competitive, lateral-flow immunoassay with colloidal gold as visual indicator
Test format	Single device, single strip, panel
Specimen to be tested	Urine
Sample storage	3 days at 2-8°C Long-term storage at -20°C
Workflow	<ol style="list-style-type: none"> 1. Device: Add 3 drops of urine into sample well; wait 5 minutes and read results 2. Strip or Panel: Immerse panel/strip into urine for 10-15 seconds. Wait 5 minutes and read results.
Time to result	5 minutes
Result stability	Up to 8 hours after test initiation
Endpoint	Positive: Colored control line (C) and absence of colored line in test line (T) region Negative: Colored lines in control (C) and test (T) regions
Cutoff level	100 ng/mL for EDDP 300 ng/mL for EDDP coming soon
Sensitivity	>90% correlation with solutions spiked to +/-50% of cutoff
Precision	Within-run, between-run and between-operator precision at three independent sites with correlation of >99% across all lots, operators and sites for specimens spiked to +/-50% (with a 95% confidence interval).
Specificity	Analysis of cross-reactivity with current interfering compounds list
Predicate device	Microgenics EDDP reagent and GC/MS for positive specimens
External controls	Commercial source if possible; In-house controls if commercial source unavailable
Storage conditions	2-30°C
Shelf life	24 months from date of manufacture
Brand options	Innovacon, SureStep, INSTALERT

5. Features & Benefits

One Step EDDP Tests

<u>FEATURE</u>	<u>BENEFIT</u>
All testing components included in kit	<ul style="list-style-type: none"> • No additional equipment needed • Easy to use - can be used anywhere at anytime
Results in 5 minutes	<ul style="list-style-type: none"> • Quick test results • Rapid turnaround time
Competitive price	<ul style="list-style-type: none"> • Best overall value regarding quality and price. The savings are passed on to our customers!

EDDP One Step Tests

Sales Support & Technical Information



6. FAQs

1. PROCEDURE

Q: **How does the test work?**

A: One Step EDDP Tests are lateral flow chromatographic immunoassays for the qualitative detection of multiple drugs and drug metabolites in urine.

Q: **What factors could cause the test to be invalid?**

A: Improper testing procedure, unsealed packaging, damaged membrane and unsuitable specimens could cause the test to be invalid.

Q: **If a pouch is punctured or the seal is broken, can the test still be used?**

A: Desiccants are included in each pouch. If the pouch seal has been broken, the desiccants would no longer be efficient at absorbing moisture and the contents would have been exposed to moisture. Therefore, the test should not be used.

Q: **If the expiration date on the pouch has been passed, can the test still be used?**

A: No. Do not use beyond the expiration date.

2. INTERPRETATION

Q: **Do I have to wait the full 5 minutes before reading the drug test results?**

A: Yes. It is important that you wait to see if a line in the test region appears before reading your result. This might take up to 5 minutes for the test region line to appear.

Q: **If the test is left for longer than 10 minutes before reading the result, are the results reliable?**

A: Yes. The drug test results remain stable for up to one hour after test initiation.

Q: **The test line is very faint and the control line is very strong at the 5 minute read time. What does this mean?**

A: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.

Q: **Does a negative result indicate drug-free urine?**

A: 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 of the test.

Q: **What should I do if the result is positive?**

A: A positive result indicates that the drug concentration is above the indicated cutoff level. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Q: **What are common ways to tamper with urine samples?**

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

3. STORAGE

Q: What temperature should the urine specimens be stored at?

A: 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.

Q: What is the shelf life of One Step EDDP Tests?

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

Q: What is the storage temperature?

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