INSTANT-VIEW® Methadone Urine Test *(Cassette)* CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
This device is a qualitative immunoassay intended to provide qualitative screening results for methadone in human urine at a cutoff concentration of 300ng/ml. It is for health care professional use only.

This assay provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST
Methadone, also called Dolophine, Methadose and Amidone, possesses many of the pharmacologic properties of morphine and is approximately equipotent as an analgesic when administered parenterally. Unlike morphine, however, methadone produces marked sedative effects with repeated administration as a result of drug accumulation. Methadone has been used as a major substitute for opiates, such as heroin, morphine, and codeine in drug maintenance treatment clinics. It is administered either orally or by intravenous or intra-muscular injection. The duration of effect of methadone is 12-24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3, 3-diphenylpyrrolidine). The percentage of methadone excreted unchanged in urine is 5-50%, much higher than EDDP and EMDP, of the dose in 24 hours. Large individual variations in the percentage of unchanged methadone excreted in urine have been observed due to urine pH, urine volume, dose and rate of metabolism, etc. Methadone has been found remaining in urine at levels higher than 1,000 ng/ml 24 hours after overdose. Therefore the concentration of methadone in human urine has been used as a marker of methadone abuse.

PRINCIPLE OF THE PROCEDURE
This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-methadone antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with methadone-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The methadone in the urine specimen competes with the methadone–BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-methadone antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of methadone in the urine specimen is below the cutoff (300 ng/ml), the Test line appears as a visible burgundy line. If the level of methadone in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line, regardless of the presence of methadone.

REAGENTS AND MATERIALS SUPPLIED
- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection containers
- Timer

STORAGE AND STABILITY
Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F). 15°C 30°C

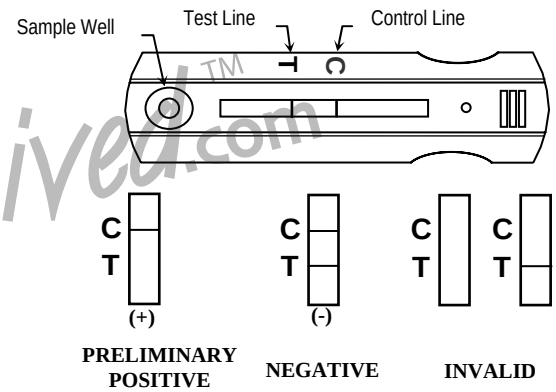
SPECIMEN COLLECTION
1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for up to 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

PRECAUTION
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing**.
2. Remove the test device from its pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.**



Positive:
If only the C line appears, the test indicates that the methadone level in the sample is at a cutoff of 300 ng/ml or higher.
Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:
If both C line and T line appear, the test indicates that the methadone level is below 300 ng/ml.
Note: A faint T line should be considered negative.

Invalid:
If no C line develops in 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL
- **Built-in Control Features**
  This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the testing with a new device.
- **External Quality Control**
  Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

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LIMITATIONS

1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if present in the sample. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES

This test is designed to detect methadone in human urine at a cutoff concentration of 300 ng/ml.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, and compared with GC/MS results.

The results agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Ten (10) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 97.5%.

		MTD Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	<75% (0~225)	0	192	192	100%
	75%~Cutoff (225~300)	10	18	28	64.3%
	Cutoff~125% (300~375)	36	0	36	100%
	Positive (>375)	144	0	144	100%
Total		190	210	400	97.5%

2. Precision

The precision was determined by replicate assays of four different levels of samples with three different production lots. The device was tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable interlot variation occured across the three (3) different lots of devices.

3. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)
(-)-α-Methadol	*800*
(-)-α-Acetylmethadol (LAAM)	*1000*

4. Interference

To determine the interference of structurally unrelated analytes, the following analytes were spiked into known drug-free urine pools, as well as the methadone positive (spiked with methadone to the level of 300 ng/ml) urine pools and were tested. No significant interference with either negative or positive results was observed at the concentrations listed in the following table:

Compounds listed in this table found not to interfere with the test results at the concentration of 1mg/ml:	
Acetaminophen	*Cortisone*
Acetylsalicylic Acid	*Dextromethorphan*
Amikacin	*Ethanol*
Amitriptyline	*Lidocaine*
Ampicillin	*Methanol*
Arterenal	*Oxalic Acid*
Aspirin	*Penicillin-G (Benzylpenicillin)*
Atropine	*Phenylpropanalamine*
Benzoic Acid	*Ranitidine*
Caffeine	*Salicyclic Acid*
(+)-Chlorpheniramine	*Thioridazine*
Codeine	*Trifluoperazine*

Biological Analytes	Concentration
Albumin	*2 mg/ml*
Bilirubin	*1 mg/ml*
Creatine	*1 mg/ml*
Hemoglobin	*1 mg/ml*
Glucose	*2 mg/ml*
PH	*5.0 – 9.0*
Vitamin C (L-Ascorbic Acid)	*1 mg/ml*
Uric Acid	*1 mg/ml*

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results.

REFERENCES

- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p472-474, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. p.53 (69): 11970 (1988).
- Wilson, John, Abused Drugs II, a Laboratory Pocket Guide., AACC Press. Washington, DC; 1994.

30°C 15°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contains sufficient for < n > tests		Consult instructions for use
	For IVD performance evaluation only	2	Do not reuse
	Caution, consult accompanying documents	CE	CE Mark

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