

INSTANT-VIEW[®] Morphine/Opiates (300) Urine Dip-Strip Test

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 morphine in human urine at a cutoff level of 300 ng/ml. It is for health care professional use only.

The US Substance Abuse and Mental Health Services Administration (SAMHSA) commonly recommends the screening levels for morphine to be at a concentration of 2000 ng/ml.

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

The detection of morphine in human urine has been widely used to assess the abuse of opiates. Morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine) belong to the class of drugs called opiates. Opiates are central nervous systems stimulating drugs. Overdose and extended usage of opiates may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Morphine is rapidly absorbed from an oral dose and from intra-muscular and subcutaneous injection. It is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine. The quantitatively most important metabolite is excreted in the urine to an extent of 67-70% of the given dose in 48 hours. Heroin is rapidly metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine. Codeine is extensively metabolized, 10-15% of the dose is demethylated to form morphine and norcodeine.

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-morphine 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 morphine-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The morphine in the urine specimen competes with the morphine-BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-morphine 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 morphine in the urine specimen is below the cutoff (300 ng/ml), the Test line appears as a visible burgundy line. If the level of morphine 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 morphine.

REAGENTS AND MATERIALS SUPPLIED

- 50 test strips each sealed in a pouch with a desiccant.
- 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 containing desiccant.

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



SPECIMEN COLLECTION

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

PRECAUTION

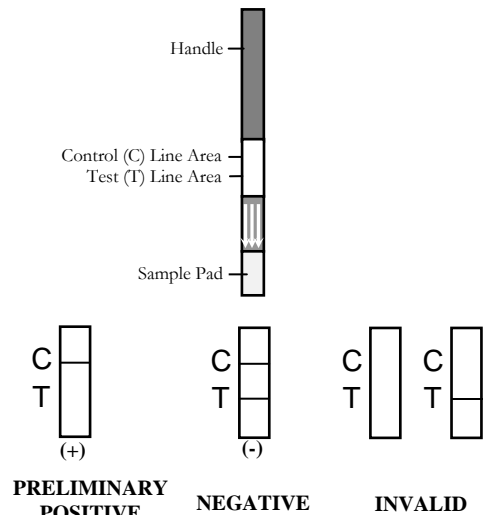
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Open the foil pouch at the notch and remove the test device.
3. Dip the device in the specimen for at least 10 seconds. Keep the specimen surface at the level indicated by the arrow sign on the device.
4. Remove the device from the specimen, and place it on a flat, dry surface.
5. 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 morphine 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 the C line and T line appear, the test indicates that the morphine level is below 300 ng/ml.

Note: A very faint T line should be considered negative.

Invalid:

If no C line develops within 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 appearance of the burgundy C line indicates that an adequate volume of specimen has been absorbed and the capillary flow has occurred. The C line should always appear. If the Control line does not develop within 5 minutes, the result is invalid. In this case, review the whole procedure and repeat test 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.

INSTANT-VIEW[®] Morphine/Opiates (300) Urine Dip-Strip Test

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 analytical 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. When suspected, collect a fresh specimen and redo the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These samples may interfere with the test and cause false results.

EXPECTED VALUES

This test is capable of detecting morphine at a cutoff level of 300 ng/ml or higher.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. Ninety four (94) 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). Thirteen (13) discrepancies were observed on the specimens at the level between 75% of the cutoff and the cutoff.

The overall agreement was 96.5%.

		MOR 300 Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	180	180	100%
	<75% (0-225)	0	12	12	100%
	75%~Cutoff (225-300)	13	11	24	45.8%
	Cutoff~125% (300-375)	24	0	24	100%
	Positive (>375)	136	0	136	100%
Total		173	203	376	96.5%

2. Precision

Precision was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty-pooled drug-free human urine specimens were spiked with morphine at different levels. All specimens were blind labeled and tested. The results are as follows:

Morphine Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	-	+	-	+	-
0	8	0	8	0	8	0	8
225	8	3	5	1	7	2	6
300	8	7	1	7	1	7	1
375	8	8	0	8	0	8	0
600	8	8	0	8	0	8	0

The results indicate a 92.5% concordance with the expected results.

3. Cross-Reactivity

A study was conducted using morphine-related compounds to determine the cross-reactivity of the test.

Morphine structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level:

Description	Concentration (ng/ml)
Morphine	300
Codeine	300
Ethyl Morphine	300
Hydromorphone	400
Morphine-glucuronide	500
Meperidine	30000
Oxycodone	1000

4. Interfering Substances

The following compounds, often found in urine, were spiked in urine pools containing 0, or 300 ng/ml morphine were tested, with this Morphine Urine Test. No effects were observed from those Analytes at 1.0 mg/ml.

Compounds tested and found not to interfere with the results of the test at 0, or 300 ng/ml morphine in urine (Concentration at 1.0 mg/ml):

Acetaminophen	Cortisone
Acetylsalicylic Acid	Dextromethorphan
Amikacin	Ethanol
Amitriptyline	Lidocaine
Ampicillin	Methadone
Arterenal	Methanol
Aspirin	Oxalic Acid
Benzoic Acid	Penicillin-G (Benzylpenicillin)
Benzoylcegonine	β-phenylthylamine
Caffeine	Phenylpropanalamine
(+)-Chlorpheniramine	Ranitidine
(+/-)-Chlorpheniramine	Salicylic Acid
Cocaine	Thioridazine

Biological Analytes	Concentration
Albumin(serum)	2,000 µg/ml
Bilirubin	1,000 µg/ml
Creatine	1,000 µg/ml
Hemoglobin	1,000 µg/ml
Glucose	2,000 µg/ml
pH	5.0 – 9.0
Vitamin C (L-Ascorbic Acid)	1,000 µg/ml
Uric Acid	1,000 µg/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; p528-530, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. p. 53 (69): 11970 (1988).



Temperature limitation



Use by
YYYY-MM



Batch/Lot code



In vitro diagnostic
medical device



Manufacturer



Catalog number



Contains sufficient for < n >
tests



Consult instructions for
use



Do not reuse



CE Mark



Caution, consult accompanying
documents

ALFA SCIENTIFIC DESIGNS INC.



POWAY, CA 92064 – USA
MADE IN USA



REF 3098

Obelis s.a
Avenue de Tervueren,
34, Bte 44
B-1040 Brussels
Tel.: +32.2.732.59.54
Fax: +32.2.732.60.03
Email: mail@obelis.net