

One Step Morphine Urine Test

One Step Morphine Urine Test is a rapid one step test for the qualitative detection of morphine and its principal metabolites in human urine at specified cut-off level. For in vitro diagnostic use only. For professional use only.

INTENDED USE

The One Step Morphine Urine Test is a lateral flow chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 300 ng/ml. This assay provides only a qualitative, preliminary analytical test 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 used.

SUMMARY

The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principal metabolites of opiates are morphine, morphine-3-glucuronide, normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the urine of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.

PRINCIPLE

One Step Morphine Urine Test is a competitive immunoassay that is used to screen for the presence of morphine in urine. It is chromatographic absorbent device in which morphine and its metabolites in a sample competitively combined to a limited number of anti-morphine monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the morphine monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-morphine monoclonal antibody (mouse) conjugate binds to the morphine-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, morphine in the sample binds to the morphine monoclonal antibody conjugate preventing the morphine monoclonal antibody conjugate from binding to the morphine-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. 25 tests per kit, one test in one pouch.
2. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use. .
4. Dropper.

STORAGE AND STABILITY

Store at 4 ~ 30 °C in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

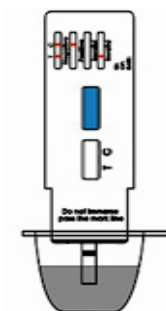
Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).

Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18°C to30°C)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

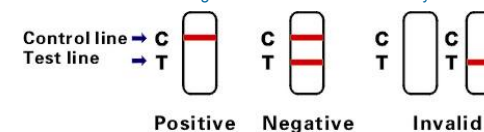
Negative (-)

A rose-pink band is visible in the control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the One Step Morphine Test. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

| Result | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|----------|---|--|--|---|
| Positive | 0 | 3 | 19 | 20 |
| Negative | 29 | 8 | 1 | 0 |

% agreement among positives is 97.5% (95% Confidence Interval 82%- 100%)

% agreement among negatives is 92.5% (95% Confidence Interval 77%- 100%)

Viewer B:

| Result | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|----------|---|--|--|---|
| Positive | 0 | 3 | 19 | 20 |
| Negative | 29 | 8 | 1 | 0 |

% agreement among positives is 97.5% (95% Confidence Interval 82%- 100%)

% agreement among negatives is 92.5% (95% Confidence Interval 77%- 100%)

Viewer C:

| Result | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|----------|---|--|--|---|
| Positive | 0 | 4 | 19 | 20 |
| Negative | 29 | 7 | 1 | 0 |

% agreement among positives is 97.5% (95% Confidence Interval 82%- 100%)

% agreement among negatives is 90% (95% Confidence Interval 74.5%- 100%)

From the results of the above tables, the total results are showed as below:

The average positive agreement is 97.5%

The average negative agreement is 91.7%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, and the cutoff + 50%. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot.

Lot 1

| Approximate concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|--------------------------|----------------------------|
| 150 | 90 | 90/0 |
| 220 | 90 | 77/13 |
| 300 | 90 | 28/62 |
| 375 | 90 | 8/82 |
| 450 | 90 | 0/90 |

Lot 2

| Approximate Concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|--------------------------|----------------------------|
| 150 | 90 | 90/0 |
| 220 | 90 | 77/13 |
| 300 | 90 | 28/62 |
| 375 | 90 | 8/82 |
| 450 | 90 | 0/90 |

Lot 3

| Approximate Concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|--------------------------|----------------------------|
| 150 | 90 | 90/0 |
| 220 | 90 | 77/13 |
| 300 | 90 | 28/62 |
| 375 | 90 | 6/84 |
| 450 | 90 | 0/90 |

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test morphine, its metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

| Component | Concentration (ng/ml) |
|----------------------------|-----------------------|
| Morphine | 300 |
| Heroin | 300 |
| Codeine | 300 |
| Ethyl Morphine | 300 |
| Hydrocodone | 5,000 |
| Hydromorphone | 5,000 |
| Morphine-3-β-d-glucuronide | 1,000 |

| | |
|----------------------|--------|
| o-Monoacetylmorphine | 400 |
| Oxycodone | 30,000 |
| Thebaine | 30,000 |

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with morphine at 50% below and 50% above cutoff level. One step morphine urine test was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with morphine at 50% below and 50% above cutoff levels. One step morphine urine test was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a morphine concentration 50% below the cutoff, and urine with a morphine concentration 50% above the cutoff. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

| | |
|----------------------|-----------------------------------|
| 4-Acetamidophenol | Labetalol |
| Acetophenetidin | Loperamide |
| N-Acetyprocainamide | Maprotiline |
| Acetysalicylic acid | Meprobamate |
| Aminoprvine | Metadone |
| Amityptiline | Methoxyphenamine |
| Amorbarbital | (+) 3,4-Methylenedioxyamphetamine |
| Amoxicillin | (+)3,4-Methylenedioxyamphetamine |
| Ampicillin | Nalidixic acid |
| l-Ascorbic Acid | Nalorphine |
| D.L-Amphetamine | Naloxone |
| Apormorphine | Naltrexone |
| Aspartame | Naproxen |
| Atropine | Niacinamide |
| Benzilic acid | Nifedipine |
| Benzoic acid | Norethindrone |
| Benzoylcaonine | D-Norpropoxyphene |
| Benzphetamine | Noscapine |
| Bilirubin | D.L-Octopamine |
| (±) Chlorpheniramine | Oxalic acid |
| Caffeine | Oxazepam |
| Cannabidiol | Oxolinic acid |
| Chloralhydrate | Pentobarbital |
| Chloramphenicol | Perphenazine |
| Chlordiazepoxide | Phencyclidine |
| Chlorothiazide | Phenelzine |







(±)Chlorpheniramine
 Chlorpromazine
 Chlorquine
 Cholesterol
 Clomipramine
 Clonidine
 Cocaine hydrochloride
 Cortisone
 (-)cotinine
 Creatinine
 Dextromethorphan
 Diazepam
 Diclofenac
 Diflunisal
 Diaoxin
 Diphenhydramine
 Doxylamine
 Ecaonine dydrochloride
 Ecqonine methylester
 (-)-ψ-Ephedrine
 Fenoprofen
 Furosemide
 Gentisic acid
 Hemoglobin
 Hydrocortisone
 O-Hydroxyhippuric acid
 p-Hydroxy-methamphetamine
 3-Hydroxytyramine
 Ibuprofen
 Imipramine
 Iproniazid
 (±)soproterenol
 Isoxsuprine
 Ketamine
 Ketoprofen

Phenobarbital
 Phentermine
 L-Phenylephrine
 β-Phenylethylamine
 Phenylpropanotamine
 Prednisone
 D.L-Propranolol
 D-Propoxyphene
 D-Pseudoephedrine
 Quinine
 Ranitidine
 Salicylic acid
 Secobarbital
 Serotonin (5-Hydroxytyramine)
 Sulfamethazine
 Sulindac
 Temazepam
 Tetrahydrocortisone,3 Acetate
 Tetrahydrocortisone,(β-D glucuronide)
 Tetrahydrozoline
 Thiamine
 Thioridazine
 D.L-Tyrosine
 Tolbutamide
 Triamterene
 Trifluoperazine
 Trimethoprim
 Triptamine
 D.L-Tryptophan
 Yramine
 Uric acid
 Verapamil
 Zomepirac

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Index of Symbols

| | | | |
|---|---|---|-------------------------|
|  | For <i>in vitro</i> diagnostic use only |  | Store between 4 ~ 30 °C |
|  | Do not reuse |  | Manufacturer |
|  | Keep away from sunlight |  | Keep dry |

Version 13/09/2010