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INTENDED USE

The Morphine Rapid Test is a qualitative, competitive binding immunoassay for the rapid determination of morphine in human urine specimens. The presence of morphine in urine as low as 300 ng/ml can be detected in less than 5 minutes.

SUMMARY

The morphine Rapid Test is an easy, fast, and visually read screening chromatographic immunoassay method. The test system employs specific monoclonal antibody to selectively identify morphine and its metabolites in urine with a high degree of sensitivity. It has been developed for the determination of heroin, morphine, and codeine in urine at the concentration of 300-ng/ml set by the National Institute on Drug Abuse.

PRINCIPLE

The Morphine Rapid Test is a chromatographic immunoassay (CIA) for the detection of morphine and its metabolites in a specimen. The morphine and its metabolites in a specimen will compete with the morphine conjugate, which is immobilized on a porous membrane for binding of a specific monoclonal antibody-gold conjugate. Labeled specific antibody-gold conjugate mixes with urine specimen and binds to the free drug present forming an antibody-antigen complex. This complex will prevent the formation of a pink band when the drug is above the detection level of 300 ng/ml. Therefore a positive specimen will not show a pink band on test region, while the presence of the pink band on the test region indicates a negative result.

PRECAUTION

1. For *in vitro* diagnostic use only.
2. Do not use after the expiration date.
3. Test device should remain sealed until ready for use.

STORAGE

Store the test kit refrigerated or at room temperature (2-25°C) in sealed pouch under dry condition.

SPECIMEN COLLECTION AND STORAGE

Collect a urine specimen in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2-8°C) and stored up to 3 days. Bring refrigerated samples to room temperature before testing. Urine specimen exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE

1. Test should be performed at room temperature.
2. Do not open the pouch until ready to perform the test.
3. Label the device with specimen identification.
4. Dispense 3 drops (150 µl) specimen to the sample well (S) with a transfer pipette.
5. Read the result within 5 minutes; do not interpret result after 10 minutes.

INTERPRETATION OF RESULT

Positive: Only one color band appears in the control region (C).

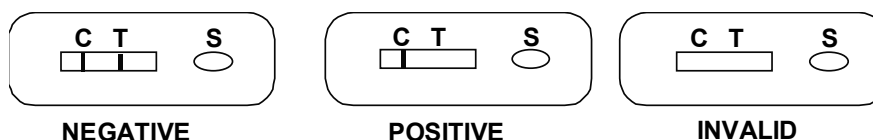


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Negative: Two bands appear, one in the control region (C) and another one in the test region (T).

Invalid: If no bands appear, or a test band appears without a control band, the test is invalid.

Note: Do not interpret result after 10 minutes.



LIMITATION

1. The test is designed for use with human urine only.
2. There is possibility that factors such as technical or procedural errors, as well as additional substance in the urine specimen that are not listed blow, may interfere with the test and cause erroneous results.
3. The test detects only the presence of morphine in urine. It does not provide any indication of intoxication.
4. The test result read after 10 minutes may not be consistent with the original reading obtained within the 5 minutes test period.

PERFORMANCE CHARACTERISTIC

SENSITIVITY

The Test detects morphine, opiates and opiates in urine at an average of 300 ng/ml.

SPECIFICITY

Compounds not detected:

Acetaminophen	Methylphenidate
Acetophenetidin	Niacinamine
Acetylsalicylic Acid	Noscapine
Amoxicillin	Oxalic Acid
Ampicillin	Oxazepam
Apomorphine	Oxycodone
Benzoic Acid	Penicillin G
Benzoyllecgonine	Pentazocaine
Caffeine	Penopropfen
Cannabidiol	Phendimetrazine
Cholesterol	Phenelzine

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Diazepam	d-propoxyphene
Digoxin	Propaanolol
Diphenhydramine	Quinine
Doxylamine	Salicylic Acid
Ecgonine Methyl Ester	Secofamethazine
Furosemide	Sulfamethazine
Glutethmine	Sulindac
5-Hydroxytryptamine	Temazepam
Hydrochlorothiazide	Tetracycline
Indomethacin	Thiamterene
Ketoprofen	d,1-Thyroxine
Labetalol	Triamterene
Lidocaine	Trimethoprim
Maprotiline	Trimipramine
Meprobamate	Tryptamine
Methadone	d,1-Tryptophan
Methaqualone	Uric Acid
Methamphetamine	Zomepirac

REFERENCE

1. Cone, E.J.: J. Anal. Toxicol., 1993, 17:156-164
2. Department of Health and Human Services, Fed. Regist., 1988, 53:11970-11989
3. Walsh, T.D.: Pharm. J., 1983, 10:525-527