RapidDrugs(Opiate(Morphine))Screening Test Kit(Urine)

The Rapid Drugs Opiate (Morphine)) Screening Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Opiate (Morphine) (OPI) in human Urine specimens.

For*In-VitroDiagnostic*Useonly

ORDERINFORMATION

Pack Size	REF
01Test	POPI01
05 Tests	POPI05
10 Tests	POPI 10
25 Tests	POPI 25
50 Tests	POPI 50

CLINICALSIGNIFICANCE

Opiate (OPI) refers to any drug that is derived from the opium poppy,including the natural products, Morphine and Codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to anydrug that acts on the opioid receptor. Opioid analgesics comprise alarge group of substances, which control pain by depressing the centralnervous system. Large doses of Morphine can produce higher tolerancelevels and physiological dependency in users, and may lead tosubstance abuse. Morphine is excreted unmetabolized, and is also themajor metabolic product of codeine and heroin. Morphine is detectablein the urine for several days after an opiate dose.
The test is most often used to screen for drug use. It's often required bythe court system and some workplaces.

PRINCIPLE

The RapidDrugs (Opiate (Morphine)) Screening Test Kit(Urine) detectsOpiate (Morphine) through visual interpretation of color development onthe strip. The assay relies on the competition for binding antibody**.**Drugconjugates are immobilized on the test region of the membrane. Duringtesting, the specimen reacts with antibodies conjugated to colored goldnano particles. The mixture then migrates through the membrane bycapillary action, and interacts with reagents on the membrane. If thereare insufficient drug molecules in the specimen, the antibody-coloredparticle conjugate will bind to the drug conjugates, forming a coloredband at the test region of the membrane. Therefore, a colored bandappears in thetest regionwhen the urine is negativefor thedrug.If drugmolecules are present in the urine above thecut-off concentration of thetest, they compete with the immobilized drug conjugate on the testregion for limited antibody binding sites. This will prevent attachment ofthe antibody-colored particle conjugate to the test region. Therefore, theabsence of a colored band at the test region indicates a positive result.The appearance of a colored band at the control region serves as aprocedural control, indicating that the proper volume of specimen hasbeen added and membrane wicking has occurred**.**

KITCOMPONENTS

• TestCassettes•Droppers•Package Insert

MATERIALSREQUIREDBUTNOTPROVIDED

• SpecimenCollectionContainers•Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after theexpiration date.
2. Wear protective gloves while handling specimens wash thoroughlyafterwards.
3. The device is sensitive to humidity as well as heat. Therefore, takeout the device from seal pouch before test.
4. Donotmixreagentsfrom different lot.
5. Disposeallthesamplesandkitsproperlyaspertheinstructionafter test in accordance in GLP.
6. Followthe testingprocedureexactlyasmentioninthe insert.

STORAGEANDSTABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C).The test device must remain in the sealed pouch until use. DONOT FREEZE.
2. Donotusebeyond theexpirationdate.
3. Do not usethetest kit, ifthepouch isdamagedorsealisbroken.

SPECIMENCOLLECTION&PREPARATION

- The RapidDrugs(Opiate (Morphine))Screening Testisintendedfor use with human urine specimens only.
- Urine collected atanytime of theday may beused.
- Urinespecimensmustbecollectedinclean,drycontainers.
- Turbidspecimensshouldbecentrifuged,filtered,orallowedtosettle and only the clear supernatant should be used for testing.
- Performtestingimmediatelyafterspecimencollection.
- Do not leave specimens at room temperature for prolongedperiods. Urine specimens may be stored at 2-8°C for up to 2 days.For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozenspecimens must be completely thawed and mixed well prior totesting. Avoid repeated freezing and thawing of specimens.
- Ifspecimens are to be shipped, pack them in compliance with allapplicable regulations for transportation of etiological agents**.**Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONSFORUSE

Allowthetestdevice,specimenand/or buffertoequilibrateatroom temperature (15-30°C) before testing.

1. Bringthepouchtoroomtemperaturebeforeopeningit.Removethe test cassette from the sealed pouch and use it within 1 hour.
2. Placethe cassetteona clean andlevelsurface.
3. Holdthedroppervertically and transfer 2dropsofUrine(approximately 50 µL)
4. Waitfor thecoloredline(s)toappear.Readresults at5 minutes.
   Note:Donot interprettheresultafter10minutes.

INTERPRETATIONOFRESULTS

PositiveResult	
NegativeResult	

1) Positive
The control line is the only visible line on the test device. This isindicative of presence of OPI above 300 ng/ml
2) Negative
The control line and Test line is visible line on the test device. This noOPI detected or OPI below 300 ng/ml
3) Invalid
The controlline failsto appear. Insufficient specimen volume orincorrect procedural techniques are the likeliest reasons for control linefailure. Repeat the test using a new test device.

QualityControl

Internal procedural controls are included in the test individually. Acoloredlineappearing incontrollineregion(C)istheinternalprocedural

control. It confirms sufficient specimen volume and correct proceduraltechnique. Control standards are not supplied with this kit; however, it isrecommended that positive and negative controls be tested as a goodlaboratory practicetoconfirmthetest procedure and to verify proper testperformance.

LimitationsoftheTest

1. The Rapid Drugs (Opiate (Morphine)) Screening Test is forprofessional in vitro diagnostic use, and should be only used for thequalitative detection of Opiate (Morphine).
2. This assay provides a preliminary analytical test result only. A morespecific alternative chemical method must be used in order to obtain aconfirmed analytical result. Gas chromatography/mass spectrometry(GC/MS) has been established as the preferred confirmatory method bythe National Institute on Drug Abuse (NIDA). Clinical consideration andprofessional judgment should be applied to any test result, particularlywhen preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well asother substances and factors may interfere with the test and cause falseresults

Performancecharacteristics

Cut off Value

The RapidDrugs (Opiate(Morphine)) ScreeningTest Kit can detect OPIas low as 300ng/ml.

DiagnosticPerformance

A total of 140 normal human urine specimens were collected fromhuman subjects and 3 positive control samples tested by Rapid Drugs(Opiate (Morphine)) Screening Test Kit. These specimens wereconfirmed by commercially available kit. Comparison for all subjects isshowed in the following table.

Commercial OPIRapidTest Results	Opiate(Morphine) RapidTest		Total
	Positive	Negative	
Positive	3	0	3
Negative	2	138	140
Total	5	138	143

Relative Sensitivity: 100%, Relative Specificity: 98.57%, OverallAgreement: 98.60%

Precision

Between-run precision has been determined by 3 independent assayson the same 2 specimens: Three different lots of the Rapid Drugs(Opiate (Morphine)) Screening Test Kit have been tested over a 3-daysperiod using negative and positive specimens. The specimens werecorrectly identified >99% of the time

Specificityandcross-reactivity

The following substances were tested and confirmed did not interferewith Rapid Drugs (Opiate (Morphine)) Screening Test Kit at the listedconcentrations.

Substances	Concentration
Glucose	2000 mg/dl
HumanAlbumin	2000 mg/dl
Humanhemoglobin	10mg/dl
Urea	4000 mg/dl
Uricacid	10mg/d

To evaluate the analog cross-reactivity of the devices, the target drug,drug metabolites and the same class compounds that may cross-reactwith the target drugs are tested by Opiate (Morphine) screening rapidtest.

All the compounds are added to drug-free urine at three differentconcentration levels. The final results are as following table. It displaysthe limits of detection forthe specified drugs or their analog. Belowtheselevels, the analog drugs show no cross-reactivity to target drugs.

Drugsderivative	Concentration(ng/ml)
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500

BIBLIOGRAPHY

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2. 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse.Rockville: Department of Health and Human Services, NationalInstitute on Drug Abuse; 1986.
3. 3. Substance Abuse and Mental Health Services Administration.Mandatory Guidelines for Federal Workplace Drug TestingPrograms. 53

GLOSSARYOFSYMBOL

	ConsultInstructionforUse
	CatalogNumber
	Storebetween
	Manufacturer
	Keepawayfrom sunlight

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