FD Morphine Test

Introduction

The opiates such as heroin, morphine, and codein are derived from the resin of the opium poppy. Morphine and morphine glucuronide are not metabolized and can be found in the urine sample of a person who has taken morphine. Heroin and codein are quickly metabolized to morphine in the body Therefore, the presence of morphine or morphine glucuronide in urine is an indication of use of either heroin , morphine or codein.

FD Morphine Test is a lateral flow one-step, competitive immunoassay, This test is fast and easy to perform , dose not need any instrumentation and results are read visually . The test system employs unique monoclonal antibodies to selectively identify morphine in urine samples with a high degree of sensitivity. The cut off concentration for morphine has been developed at 300ng/ml, the concentration , as set by National Institute on Drug Abuse, (NIDA), USA.

FD Morphine Test is designed for qualitative detection of morphine in human urine and hence, the screening purpose. The result of the test shall be re-confirmed by more specific and accurate methods , such as gas chromatography/mass spectrometry (GC/MS) as suggested by NIDA. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Note: Since the sensitivity of the Thin Layer Chromatography(TLC) is less than the FD Morphine Test, the former is not recommended as confirmatory test . However , since TLC can distinguish between different morphine derivatives , it can be used as complementary test .

PRINCIPLE OF THE TEST

One Step test for morphine is based on the principle of competitive inhibition immunoassay, in which a chemically labeled drug (morphine-BSA) competes with the drug, which may be present in urine, for limited antibody binding sites. The test device consists of a membrane strip, which is pre-coated with morphine-BSA conjugate on the test line and anti mouse antibody on the control line. The antibody used in the test is murine monoclonal anti morphine antibody coated on colloidal gold particles and are placed on the special pads at one end of the test. This part will come in to contact with urine sample first.

In the absence of drug in the urine the Anti morphine colloid gold conjugate moves with the sample by capillary action along the membrane until it reaches the immobilized morphine BSA conjugate in the test band region.

At this point morphine BSA binds with anti morphine colloidal gold conjugate and forms a visible red color line. Therefore the formation of a visible color line on the test band region shows the urine sample tested for morphine is negative.

On the other hand when the drug is present in the urine, the drug/metabolite antigen will bind to anti morphine colloidal gold conjugate and occupys the binding sites. If the concentration of the morphine in urine sample is 300 ng/ml or more , all binding sites of anti morphine colloidal gold conjugate will be saturated and no site will be left for morphine BSA . Therefore, absence of the color bond on the test region indicates a positive result.A control band with a different antigen/antibody reaction is also added to membrane strip to indicate that the test is performed properly. This control line should always be seen.

A negative urine sample produces two distinct color bands, and a positive sample produces only one color band in the control zone.

Test procedure:

1)Tear the package using the tear notches on the top of each package.
2)Remove the test carefully. The membrane (white sheet located in the middle of the test ,) shall not be touched on any circumstances.
3)Obtain a sample of urine in a container or test tube. The height of the urine in container should be about 1-1.5 cm .
3) Insert the test into the sample . The end of the test marked by the arrows should be in the sample. Note that the sample level shall not exceed the line beneth the arrows.
4) Read the results after 2 minutes . The lines will appear sooner, but for the reaction to stabilize it is advised to wait for 2 minutes.

Notes:

- Keep the tests sealed in packaging pouches .
- Store between 8 c to 30 c
- Do not refrigerate or freeze.

Performance Characteristics:

1 Accuracy: A side by side comparison was performed using another popular commercial Morphine rapid test . Samples were collected from 3 different laboratories which routinely perform drug screening tests. Total of samples were 265 . The positive results had been confirmed by TLC in laboratories. The results are as follow:

Comparison with Commercially available rapid morphine test:

Method		Other Rapid Morphine Test		Total Result
FD Morphine Test	Results	Positive	Negative	
	Positive	125	0	125
	Negative	0	140	140
Total Result		125	140	265
% agreement		>99%	>99%	>99%

Sensitivity compared with the Other Test: >99%
Specificity compared with the Other Test: >99%
PPV Compared with Other Test: > 99%
NPV Compared with Other Test:> 99%

Comparison with TLC:

Method		TLC		Total Result
FD Morphine Test	Results	Positive	Negative	
	Positive	119	6	125
	Negative	0	140	140
Total Result		119	146	265
% agreement		>99%	>95%	>97%

Sensitivity compared with the TLC: >99%
Specificity compared with the TLC: >95%
PPV Compared with TLC: > 95%
NPV Compared with TLC:> 99%

2- Sensitivity:

The negative urine was collected and was spiked with Morphine at the levels specified in left column of following table . The results shows that the sensitivity of FD morphine test is >99% for 50% below and 50% above the cut off concentration.

Morphine Conc.	% of Cut off	# of samples	Positive	Negative
0	0	40	0	40
150	-50%	40	0	40
300	Cut off	40	40	0
450	+50%	40	40	0

3-Specificity:

Following compounds are detected by the FD Morphine tests:

Morphine:	Codein
Morphine 3β D glucoronide	Norocodein
Normorphine	Hydrocodon
Hydromorphine	Oxycodone
Heroin	Thebaine
Naloxane	

4- Pecision;

A study was conducted using 3 different Addiction rehabilitation Clinics . A pooled negative urine sample were spiked my morphine to obtain 150 ng/ml (low 50% cut off) , 300 ng/ml (cut off) and 450 ng/ml (high 50% cut off) concentrations. 3 different batches of tests was distributed in these 3 labs. The overall purpose was to demonstrate within run , between run and between operator precision.

Morphine Conc.	#of samples per site	Clinic 1		Clinic 2		Clinic 3	
		Neg	Pos	Neg	Pos	Neg	Pos
0	20	20	0	20	0	20	0
150	20	17	3	17	3	15	5
300	20	0	20	0	20	0	20
450	20	0	20	0	20	0	20

Drug Interefernce:

The antibody used in this test is highly specific monoclonal anti morphine antibody which has been tested by the manufacturing company with 700 drugs. Neither of these 700 drugs showed cross reactivity.

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