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IVD



See external label



$\Sigma=25$ tests



2°C-30°C

REF

Cat # 121058-1

OneStep

Opiates/Heroin/Morphine Urine

RapiCard™ InstaTest

Cat. # 121058-1

FOR THE QUALITATIVE ASSESSMENT OF OPIATES AND ITS METABOLITE IN HUMAN URINE

For in vitro Diagnostic and Forensic Use

INTENDED USE

The Cortez Diagnostics Inc. OneStep OPI RapiCard™ InstaTest is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Opiates and its metabolite in human urine specimens. The presence of morphine in human urine above a cut-off level of 300 ng/ml can be detected. This assay has not been evaluated in the point of care location and is for use by Healthcare Professionals only.

SAMHSA recommends a cut-off concentration of 2000 ng/ml for Opiates Test

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION

Opioid analgesics comprised of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted non-metabolized and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after opiates dose. However, the length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

TEST PRINCIPLE

The Cortez OneStep OPI RapiCard™ InstaTest is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between morphine-dye conjugate and free morphine which may be present in the urine specimen being tested. When morphine is present in the urine specimen, it competes with morphine-dye conjugate for the limited amount of anti-morphine antibody which is immobilized on the nitrocellulose membrane. When the amount of morphine is equal or more than the cut-off, 300 ng/ml, it will prevent the binding of morphine-dye conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIALS PROVIDED

1. Instructions for use.
2. OneStep OPI RapiCard™ InstaTest device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
Test zone: contains Morphine bovine protein antigen conjugates.
Control zone: contains Goat anti-mouse IgG antibody.
Conjugate pad: contains mice monoclonal anti-morphine antibody.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

The test device should be stored at 2 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

It is required that approximately 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8°C or frozen up to 7 days. Specimens should be thawed and brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which is not provided with this test kit are commercially available.

The Cortez Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

The control line does not appear, the test should be discarded and the obtained result is invalid.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 μ l) of sample in to the sample well.
5. Read the results at 5 minutes after adding the sample.

Do not interpret the result after 5 minutes.

INTERPRETATION OF RESULTS

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the Opiates concentration in the specimen is either zero or less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the Opiates level in the specimen is above the cut-off level.

Invalid:

If there is no colored band in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A borderline (+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.

There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The OneStep OPI RapiCard™ InstaTest is a qualitative assay. It identifies opiate in human urine at a concentration of 300 ng/ml or higher. The concentration of the opiate cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez OPI test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of morphine. One hundred and twenty three urine specimens with confirmed morphine and codeine concentrations were evaluated in this study. The results are summarized and presented below:

Cortez OPI Test	(-)		(+)		Percent agreement with GC/MS
	GC/MS Negative (less than -25% cut off)	Near cutoff negative (between -25% and c/o)	Near cutoff positive (between c/o and +25%)	GC/MS Positive (greater than +25% cut off)	
Positive	0	2	5	70	97.4
Negative	35	7	1	3	91.3
Total	35	9	6	73	

Positive % agreement: 97.4, Negative % agreement: 91.3.

Six specimens were found discrepant between the Cortez OPI and GC/MS method. When compared those data, 50% (3 out of 6) of the discrepancy specimens were found between -25% and +25% cut-off concentration (225 – 375 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of Cortez OPI test is determined to be 300ng/ml.

C. Precision

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test results were found to have no significant differences between the three observers.

Device	Control Con. ng/ml	No. of Tested	No. of positive			No. of borderline #			No. of negative		
			1*	2*	3*	1*	2*	3*	1*	2*	3*
OPI	150	40							40	40	40
	225	40				8	5	6	32	35	34
	300	40	38	37	38	2	3	2			
	375	40	40	40	40						
	450	40	40	40	40						

D. Specificity

The specificity for Cortez OPI test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The OneStep OPI RapiCard™ InstaTest performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with Cortez OPI test at the listed concentrations.

Glucose	2000 mg/dl,
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl,
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity

The following table lists compounds that are detected by Cortez OPI test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Con. (ng/ml)	Compounds	Con. (ng/ml)
Morphine	300	Morphine-3-β-glucuronide	300
Codeine	300	Ethylmorphine	300
Hydromorphone	300	Nalorphine	750
Heroin	1250	Hydrocodone	1250
Normorphine	2000	Norcodeine	2500
Naloxone	25000	Natrexone	100000
Oxycodone	> 100 µg/ml		

Each listed substance that commonly found in the urine was evaluated and indicated negative result at concentration of 100 µg/ml unless specified.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital	Amphetamine	Arterenol
Aspartame	Ascorbic acid	Atrophine	Caffeine
Camphor	Chloroquine	Chlopheniramine	Cortisone
Deoxyephedrine	Dextromethorphan	Digitoxin	Digitoxin
Diphenhydramine	Ecgonine	Ecgonine methyl ester	Ephedrine
Epinephrine	Gentisic	Guaiacol glycer ester	Histamine
Hydrochlorothiazide	Homatrophine	Imipramine	Ibuprofen
Isoproterenol	Ketamine	Lidocaine	Meperidine
Methadone	Methamphetamine	3,4±MDMA	Methaqualone
Methylphenidate	Neomycin	Niacinamide	Oxazepam
Perphenazine	Penicillin G	Phenylethylamine-α	Phenylpropanolamine
Promethazine	Pseudoephedrine	Quinine antidine	Salicylic acid
Tetrahydrozoline	Theophylline	11-nor-Δ ⁸ -THC-9-COOH (10 µg/ml)	Tetracycline
11-nor-Δ ⁸ -THC-9-COOH (10 µg/ml)	Thioridazine	Trifluoperazine	Tryptophan
Tyramine			

REFERENCES

1. Urine testing for drugs of abuse, NIDA Research Monograph 73 (1986)
2. Steven B. Karch, Drugs of abuse hand book, CRC Press, 1st. Ed. (1998)
3. Ray H. Liu and Bruce A. Goldberger, Handbook of workplace drug testing, AACC Press, Washington DC (1995)

Date Adopted	Reference No.
2004-10-18	DA-Opiates/Heroin/Morphine Urine-2009



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