



CORTEZ DIAGNOSTICS, INC.

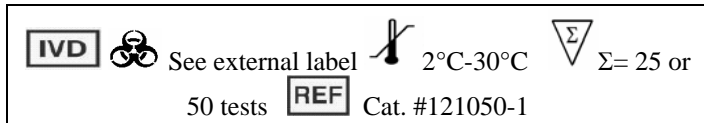
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OneStep 6 Drug RapiCard InstaTest

INTENDED USE

The OneStep 6-Drug Screen InstaTest is an immunochromatographic assay for rapid, qualitative detection of the following drugs and their principal metabolites in urine at the specified cut-off concentrations:

TEST ZONE	DRUG CLASS	SENSITIVITY
1	METHAMPHETAMINE	500 ng/ml
2	OPIATES/MORPHINE	300 ng/ml
3	MARIJUANA/TETRAHYDROCANNABINOL	50 ng/ml
4	AMPHETAMINE	1000 ng/ml
5	COCAINE/BENZOYLECGONINE	300 ng/ml
6	BENZODIAZEPINE	300 ng/ml

Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

The OneStep 6-Drug Screen InstaTest is an easy, fast, qualitative, visually read, competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of monoclonal and polyclonal antibodies to selectively identify Methamphetamine, Morphine, Marijuana, Amphetamine, Cocaine, Benzodiazepines and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. Cocaine, marijuana, amphetamines, and morphine are the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration. Benzodiazepines and opiates are also among a class of heavily abused prescription drugs. The opiates detectable by this test include illicit opiates as well as components of common antidepressants, cough and anti-diarrheal medications. The sensitivity of the OneStep 6-Drug Screen InstaTest is set at 500 ng/ml for Methamphetamine, 300 ng/ml for Morphine, 50 ng/ml for Marijuana, 1000 ng/ml for Amphetamine, 300 ng/ml for Cocaine, and 300 ng/ml for Benzodiazepines.

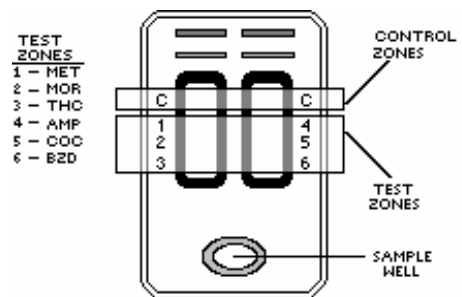
PRINCIPLE OF THE TEST

The OneStep 6-Drug Screen InstaTest is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with chemically labeled drug compounds for limited antibody binding sites. By utilizing antibodies that are

specific to different drug classes, the test permits independent, simultaneous detection of six drugs from a single sample. The approximate run time is 10 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone (marked "1 - 6") for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen-antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose-pink color band is produced in each Control Zone (marked "C") by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition and verifying that the reagents are chemically



active.

REAGENTS AND MATERIALS PROVIDED

- | | |
|--------------------------------------|---|
| 1. Test Devices. | Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide. |
| 2. Transfer Pipettes. | Individually sealed in foil pouch with test device. |
| 3. Test Instructions. | |
| <i>Optional</i> | |
| 4. Urine Cups | |
| 5. Negative Control | Contains 1 ml of buffered protein solution with sodium azide. |
| 6. Methamphetamine Positive Control. | Contains 1 ml of MET 1500 ng/ml in a buffered protein solution with sodium azide. |
| 7. Morphine Positive Control | Contains 1 ml of MOR 1000 ng/ml in a buffered protein solution with sodium azide. |
| 8. Marijuana (THC) Positive Control | Contains 1 ml of THC 150 ng/ml in a buffered protein solution with sodium azide. |
| 9. AMP Positive Control | Contains 1 ml of AMP 3000 ng/ml in a buffered protein solution with sodium azide. |
| 10. COC Positive Control | Contains 1 ml of COC 1000 ng/ml in a buffered protein solution with sodium azide. |
| 11. BZD Positive Control | Contains 1 ml of BZD 1000 ng/ml in a buffered protein solution with sodium azide. |

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

WARNINGS AND PRECAUTIONS

1. For *in vitro diagnostic* and *professional* use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.

TEST PROCEDURE

1. Bring patient samples and kit components to room temperature (15 - 28 °C).
2. Remove a Test Cassette from the foil pouch and place it on a level surface. Discard the pouch and dessicant.
3. Holding the transfer pipette vertically, add 6 drops of urine to the sample well.

Note: For optimal performance, allow each drop to be completely absorbed before adding the next.

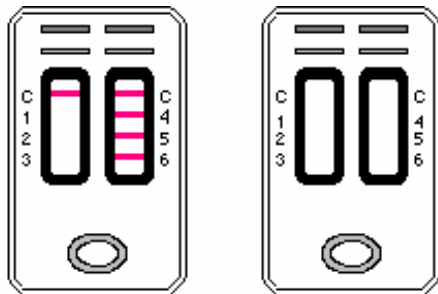
4. Wait 10 minutes and read the result.

INTERPRETATION OF RESULTS

Important: Two control lines are necessary in order to validate test results. If a rose-pink color band fails to appear in one or both Control Zones ("C"), discard the cassette and retest the sample using a new device.

EXAMPLE

(Actual test results may vary)



POSITIVE
MET, MOR, THC

INVALID

NEGATIVE
AMP, COC, BZD

Positive: A rose-pink band is visible in each control zone. No color band appearing in the appropriate test zone indicates a positive result for the corresponding drug of that specific test zone.

Negative: A rose-pink band is visible in each control zone and the appropriate test zone, indicates that the concentration of the corresponding drug in that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in either or both control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

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

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Methamphetamine, opiates, marijuana, amphetamine, cocaine and benzodiazepines in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for the quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The OneStep 6-Drug Screen InstaTest detects Methamphetamine, morphine, marijuana, amphetamine, cocaine, benzodiazepine and their major metabolites in urine at concentrations equal to or greater than 300 ng/ml for Methamphetamine, opiate, cocaine, and benzodiazepine, 1000 ng/ml for amphetamine, and 50 ng/ml for marijuana.
2. **Specificity.** A study was conducted with the OneStep 6-Drug Screen InstaTest to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Methamphetamine-related substances yield positive results for Methamphetamine:

(±) 3,4-Methylenedioxymethamphetamine (MDMA)	500 ng/ml
p-Hydroxymethamphetamine	5,000 ng/ml
Methoxyphenamine	50,000 ng/ml
d-Amphetamine	50,000 ng/ml
(±) 3,4-Methylenedioxyamphetamine (MDA)	50,000 ng/ml

The following Morphine-related substances yield a positive result for Morphine:

Morphine-3-b-D-Glucuronide	300 ng/ml	Naloxone	5,000 ng/ml
Codéine	300 ng/ml	Thebaine	1,500 ng/ml
Norcodéine	2,000 ng/ml	Naltrexone	5,000 ng/ml
Nalorphine	300 ng/ml	Imipramine	50,000 ng/ml
Hydrocodone	500 ng/ml	Atropine	100,000 ng/ml
Hydromorphone	300 ng/ml	Meperidine	100,000 ng/ml
Oxycodone	1,000 ng/ml	Ranitidine	100,000 ng/ml
Levorphanol	600 ng/ml		

The following Marijuana-related substances yield positive results for Marijuana:

11-Nor-Δ-8-Tetrahydrocannabinol	50 ng/ml
11-Nor-Δ-9-Tetrahydrocannabinol	500 ng/ml
Δ-9-Tetrahydrocannabinol	20,000 ng/ml
Cannabinol	50,000 ng/ml
Diflunisal	100,000 ng/ml

The following Amphetamine-related substances yield positive results for Amphetamine:

d-Amphetamine	1000 ng/ml	Thyramine	100,000 ng/ml
l-Amphetamine	25,000 ng/ml	(±)3,4-Methylenedio	
d,l-Amphetamine	1000 ng/ml	xyamphetamine(MDA)	1,000 ng/ml
(±)Phenylpropanolamine	50,000 ng/ml	Pseudoephedrine	100,000 ng/ml
B-Phenethylamine	90,000 ng/ml	Ephedrine	250,000 ng/ml

The following Cocaine-related substances yield positive results for Cocaine:

Benzoylcegonine	300 ng/ml
Cocaine	300 ng/ml
Isoxsuprine	1,500 ng/ml

The following Benzodiazepine-related substances yield positive results for Benzodiazepine:

Alprazolam	62.5 ng/ml	Flurazepam	100 ng/ml
Bromazepam	250 ng/ml	Lorazepam	250 ng/ml
Clobazam	2,500 ng/ml	Lormetazepam	250 ng/ml
Chlordiazepoxide	2,500 ng/ml	Medazepam	1,000 ng/ml
Clorazepate	50 ng/ml	Nitrazepam	250 ng/ml
Clonazepam	500 ng/ml	Oxazepam	250 ng/ml
Diazepam	50 ng/ml	Prazepam	100 ng/ml
Desmethyldiazepam	50 ng/ml	Temazepam	100 ng/ml
Flunitrazepam	250 ng/ml	Triazolam	100 ng/ml

Table II: Compounds tested and found not to cross-react with the test

Acetophenetidin	100 µg/ml	Ibuprofen	100 µg/ml
N-Acetylprocainamide	200 µg/ml	(-) Isoproterenol	120 µg/ml
Acetylsalicylic acid	300 µg/ml	Iproniacid	120 µg/ml
Amitriptyline	100 µg/ml	Isoxsuprine	130 µg/ml
Amobarbital	100 µg/ml	Ketamine	130 µg/ml
Amoxicillin	130 µg/ml	Ketoprofen	140 µg/ml
l-Amphetamine	100 µg/ml	Labelalol	100 µg/ml
Apomorphine	100 µg/ml	Lidocaine	100 µg/ml
ASP-PHE Methyl Ester	100 µg/ml	Loperamide	150 µg/ml
Benzilic Acid	300 µg/ml	Niacinamide	170 µg/ml
Benzoic Acid	280 µg/ml	Nifedipine	140 µg/ml
Benzphetamine	100 µg/ml	Maprotiline	140 µg/ml
Chlorothiazide	320 µg/ml	Meprobamate	100 µg/ml
Chlorpromazine	100 µg/ml	Methadone	100 µg/ml
Cholesterol	160 µg/ml	Methaqualone	100 µg/ml
Clomipramine	230 µg/ml	(S)-6-methoxy-a-methyl- 2-naphthaleneacetic acid	250 µg/ml
Clonidine	100 µg/ml	Methylphenidate	100 µg/ml
Cortisone	120 µg/ml	Methylprylon	100 µg/ml
(-) Cotinine	100 µg/ml	Nalidixic acid	130 µg/ml
Creatinine	190 µg/ml	Norethindrone	100 µg/ml
Deoxycorticosterone	170 µg/ml	d-Norpropoxyphene	100 µg/ml
Dextromethorphan	100 µg/ml	Noscapine	100 µg/ml
Diflofenac	100 µg/ml	Nylidrin	190 µg/ml
Diffusal	100 µg/ml	d,l-Octopamine	190 µg/ml
Digoxin	150 µg/ml	Oxalic acid	400 µg/ml
Diphenhydramine	200 µg/ml	Oxolinic Acid	110 µg/ml
4-Dimethylamantopyrine	100 µg/ml	Oxycodone	100 µg/ml
Doxylamine	100 µg/ml	Oxymetazoline	100 µg/ml
(+) Ephedrine	130 µg/ml	Papaverine	120 µg/ml
(±) Ephedrine	160 µg/ml	Penicillin-G	120 µg/ml
d-y-Ephedrine	290 µg/ml	Pentazocaine	100 µg/ml
b-Estradiol	110 µg/ml	Prednisolone	120 µg/ml
Estrone-3-sulfate	100 µg/ml	Promazine	120 µg/ml
Ethyl-p-aminobenzoate	180 µg/ml	Promethazine	220 µg/ml
Genitic acid	200 µg/ml	d-Propoxyphene	100 µg/ml
Guaiacol Glyceryl		Quinidine	100 µg/ml
Ether Carbonate	226 µg/ml	Salicylic acid	100 µg/ml
Glucuronic acid	200 µg/ml	Secobarbital	100 µg/ml
5-Hydroxytryptamine	100 µg/ml	Sulfamethazine	150 µg/ml
Hippuric acid	200 µg/ml	Sullindac	120 µg/ml
Hydralazine	100 µg/ml	Tetracycline	200 µg/ml
Hydrochlorothiazide	100 µg/ml	Tetrahydrocortisone	100 µg/ml
3-Hydroxytryamine	160 µg/ml		

3. **Accuracy:** Approximately 55 positive specimens above the cut-off concentration for each of the 6 specific drugs were evaluated using the , gas chromatography/mass spectrophotometry (GC/MS), and a commercially available enzyme immunoassay (EIA) for drug abuse. More than 100 drug-free specimens were also evaluated. The results are presented in **Table III** below.

Table III:

DRUG/METABOLITE	SYVA EMIT EIA II (+/-)	GC/MS (+/-)	INSTASTRIP (+/-)
MET (METHAMPHETAMINE)			
> 500 NG/M	53/0	53/0	53/0
< 500 NG/ML	1/102	1/103	2/101
MOR (MORPHINE)			
> 300 NG/ML	56/0	54/2	56/0
< 300 NG/ML	2/103	1/105	1/104
THC (MARIJUANA/TETRAHYDROCANNABINOL)			
> 50 NG/ML	63/0	63/0	63/0
< 50 NG/ML	1/142	0/142	0/142
AMP (AMPHETAMINE)			
> 1000 NG/ML	49/0	48/1	49/0
< 1000 NG/ML	1/110	2/109	0/111
COC (COCAINE/BENZOYLECGONINE)			
> 300 NG/ML	53/0	52/1	53/0
< 300 NG/ML	1/108	1/109	1/108
BZD (BENZODIAZEPINE)			
> 300 NG/ML	58/4	60/2	62/0
< 300 NG/ML	5/116	2/119	3/118

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Benzodiazepine Test

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