COC Surface Test Panel
Package Insert

REF DCO-X14	English

【INTENDED USE】

The COC Surface Test Panel is a rapid immunochromatographic assay for the qualitative detection of Cocaine at cut-off 300 ng/mL.

With this surface test, you can test:

1. Minimal traces of drugs adhering to surfaces such as furniture, utilitarian objects etc. as residues.
2. Solid substances such as tablets and powder.
3. Urine samples, which can be used to detect drug use.
4. Liquids from ampoules or other containers that may contain suspicious substances.

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

【SUMMARY】

Cocaine (COC) is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking.

The Cocaine (COC) assay contained within the COC Surface Test Panel yields a positive result when the COC concentration exceeds 300 ng/mL.

【PRINCIPLE】

During testing, the specimen migrates upward by capillary action. A drug, if present in the specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains membrane strip coated with Cocaine-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Cocaine.

【PRECAUTIONS】

- Use only once.
- Do not touch the free endings of the strip to avoid contamination.
- Do not dip the panel above the maximum deepness level mark.
- Do not spill the samples into the reaction zone.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the test after expiration date.
- Do not use the test after damage of the packaging foil.
- Use test right after unwrapping.
- Please take the specificity and the cross reactivity into account for evaluation.
- Store and transport the test always at 2-30 °C.
- **Strong acid, alkali, oxidation and corrosion liquid is not suitable for this test, thick, oily liquid is not suitable for this test.**

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30 °C. The test is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Test panels
- Package insert

Materials Required but Not Provided

- Specimen collection containers
- Timer

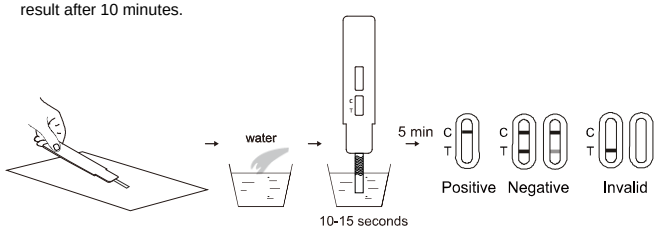
【DIRECTIONS FOR USE】

Allow the test and/or controls to reach room temperature (15-30°C) prior to testing.

Remove the test panel from the sealed pouch and use it as soon as possible.

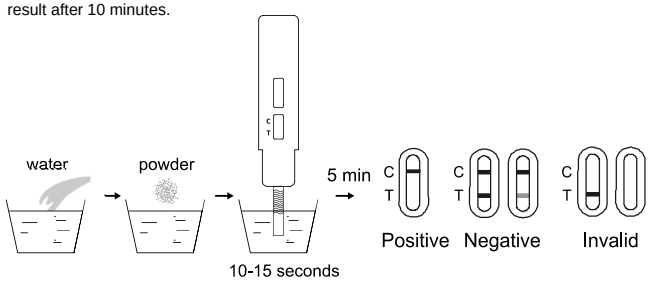
For surfaces:

1. Remove the panel cap and wipe with the panel over the surface in which the drugs are suspected.
2. With the arrow pointing toward the water, **immerse the test panel vertically in the water for at least 10 to 15 seconds**. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, **read the results at 5 minutes**. Do not interpret the result after 10 minutes.



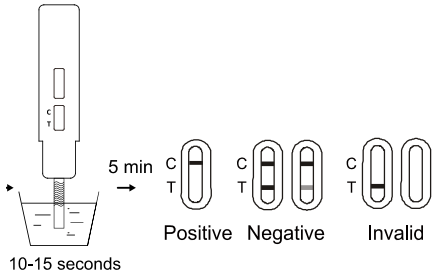
For solids:

1. Prepare specimen collection containers and solid sample.
2. Pour solid sample into the specimen collection containers.
3. At least **1mg solid diluted with 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
4. Remove the panel cap, with the arrow pointing toward the water **immerse the test panel vertically in the diluted specimen for at least 10 to 15 seconds.** Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
5. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



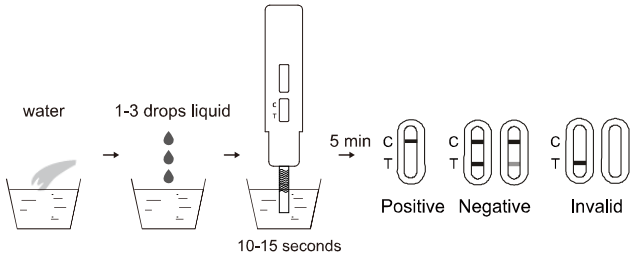
For urine:

1. Collect urine in a clean and dry container.
2. Remove the panel cap, with the arrow pointing toward the specimen, **immerse the test panel vertically in the specimen for at least 10 to 15 seconds.** Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



For liquids:

1. Prepare specimen collection containers and liquid sample.
2. Pour **one to three drops of suspicious liquid into 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
3. Remove the panel cap, with the arrow pointing toward the specimen, i**mmerse the test panel vertically in the specimen for at least 10 to 15 seconds**. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



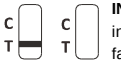
【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the control region (C) and no colored line appears in the Test region (T). The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.



INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The COC Surface Test Panel provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications.[1,2]

【PERFORMANCE CHARACTERISTICS】

Accuracy

A comparison was conducted using the COC Surface Test Panel and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
COC Surface Test Panel	Results	Positive	Negative	
	Positive	111	3	114
	Negative	2	134	136
Total Results		113	137	250
% Agreement		98.2%	97.8%	98%

Analytical Sensitivity

The following table lists different concentration drugs that are detected by the COC Surface Test Panel at 5 minutes.

COC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
150	-50%	30	30	0
225	-25%	30	26	4
300	Cut-off	30	13	17

375	+25%	30	3	27
450	+50%	30	0	30
900	300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the COC Surface Test Panel at 5 minutes.

Compound	Concentration (ng/mL)
Benzoylecgonine	300
Cocaine HCl	200
Cocaethylene	12,500
Ecgonine	30,000

Precision

A study was conducted at three sites using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

COC Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free or Cocaine positive specimen. The following compounds show no cross-reactivity when tested with the COC Surface Test Panel at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetominophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diflunisal	Dextromethorphan	Promazine
Acetylsalicylic acid	Digoxin	Zomepirac	Promethazine
Aminopyrine	Diphenhydramine	Prednisolone	D,L-Propranolol
Amitryptyline	Doxylamine	Meprobamate	D-Propoxyphene
Amobarbital	Ecgonine methylester	Morphine-3-D	D-Pseudoephedrine
Amoxicillin	(-)-ψ-Ephedrine	glucuronide	Quinidine
Ampicillin	Erythromycin	Morphine Sulfate	Quinine
L-Ascorbic acid	β-Estradiol	Nalidixic acid	Ranitidine
Apomorphine	Estrone-3-sulfate	Naloxone	Salicylic acid
Aspartame	Ethyl-p-aminobenzoate	Naltrexone	Secobarbital
Atropine	Fenoprofen	Naproxen	Serotonin
Benzilic acid	Furosemide	Niacinamide	Sulfamethazine
Benzoic acid	Gentisic acid	Nifedipine	Sulindac
Benzphetamine	Hemoglobin	Norcodein	Temazepam
Bilirubin	Hydralazine	Norethindrone	Tetracycline
(±-Brompheniramine	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone
Caffeine	Hydrocodone	Noscapine	3-Acetate
Cannabidiol	Hydrocortisone	D,L-Octopamine	Tetrahydrocortisone
Cannabinol	O-Hydroxyhippuric acid	Oxalic acid	3-(β-D glucuronide)
Chloralhydrate	Verapamil	Oxazepam	Tetrahydrozoline
Chloramphenicol	Meperidine	Oxolinic acid	Thebaine
Chlordiazepoxide	3-Hydroxytyramine	Oxycodone	Thiamine
Chlorothiazide	Ibuprofen	Oxymetazoline	Thioridazine
(±)-Chlorpheniramine	Imipramine	Papaverine	D,L-Tyrosine
Chlorpromazine	Iproniazid	Penicillin-G	Tolbutamide
Chlorquine	(±)-Isoproterenol	Pentobarbital	Triamterene
Cholesterol	Isoxsuprine	Perphenazine	Trifluoperazine
Clomipramine	Ketamine	Phencyclidine	Trimethoprim
Clonidine	Ketoprofen	Phenelzine	Trimipramine
Codeine	Labetalol	Phenobarbital	Tryptamine
Cortisone	Levorphanol	Phentermine	D,L-Tryptophan
(-) Cotinine	Loperamide	L-Phenylephrine	Tyramine
Creatinine	Maprotiline	β-Phenylethylamine	Uric acid
Deoxycorticosterone	Phenylpropanolamine	D,L-Amphetamine	(±)-3,4-Methylenediox
p-Hydroxy-	(±)-3,4-Methylenedioxy-		

【BIBLIOGRAPHY】

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747.
2. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Caution		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use
	Manufacturer				

Hangzhou AllTest Biotech Co.,Ltd.
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Number: 145331002
Revision date: 2023-09-14