
INTENDED USE

The One Step Cocaine Test is a qualitative, competitive binding immunoassay for the rapid determination of cocaine in human urine specimens. The presence of cocaine in urine as low as 300 ng/ml can be detected in less than 5 minutes.

PRINCIPLE

The Cocaine Rapid Test is a chromatographic immunoassay(CIA) for the analysis of specific compounds in a urine specimen. These specific compounds compete with the cocaine conjugate that is immobilized on a porous membrane support with limited monoclonal antibody sites. Labeled cocaine monoclonal antibody gold conjugate mixes with the urine specimen and binds to the free cocaine forming an antibody-antigen complex. This complex competes with immobilized cocaine conjugate in the test region preventing the formation of a pink band when the cocaine is above the detection level of 300 ng/ml. A negative specimen produces two distinct pink colored bands one in the test region and one in the control region. A positive specimen produces only one pink colored band in the control region.

PRECAUTION

1. The test is for *in vitro* diagnostic use only.
2. Do not use after expiration date.
3. Test device should remain sealed until ready for use.

STORAGE

The kits should be stored refrigerated or at room temperature (2-25°C) in the sealed pouch under dry condition. Under this condition the test is stable for 12 months.

SPECIMEN COLLECTION AND STORAGE

Collect a urine specimen in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2-8 °C) and stored up to 3 days. Urine specimen exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE

1. Bring all specimens to room temperature (18-25°C).
2. Do not open the pouch until ready to use.
3. Remove dipstick strip by tearing the pouch.
4. Carefully place the white end of the reaction strip into the urine sample. A 10 to 30 second dip into the urine is sufficient.
5. Remove end of test strip from the urine sample and start watch or timer.
6. Read the result within 5 minutes, no longer than 10 minutes.

INTERPRETATION OF RESULT

POSITIVE

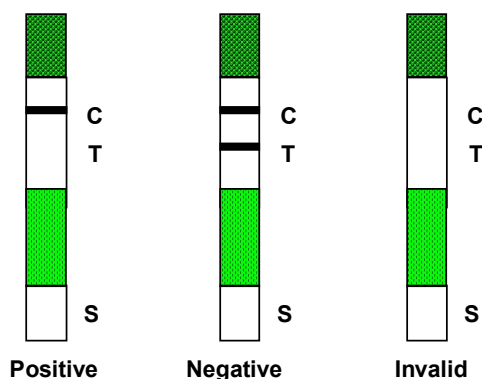
Only one pink colored band appears in the control region.

NEGATIVE

Two pink colored bands appear, one in the control region and one in the test region.

INVALID

If no bands appear after 10 minutes, the result is invalid. The protocol may not have been followed correctly or the test may be deteriorated. The test should be performed using a new test. **Note:** Do not interpret result after 10 minutes.



LIMITATION

1. The test is designed for use with human urine specimens only.
2. There is possibility that factors such as technical or procedural errors, as well as additional substances in the urine specimen that are not listed below, may interfere with the test and cause erroneous results.
3. The test detects only the presence of cocaine in urine, it does not provide any indication of intoxication. A test result read after 10 minutes may not be consistent with the original reading obtained within the 5 minute test period.

PERFORMANCE CHARACTERISTIC

SENSITIVITY

The Cocaine Rapid Test detects an average of 300 ng/ml benzoylecgonine and 500 ng/ml cocaine HCl in urine specimen.

SPECIFICITY

Compounds not detected at following concentration in ug/ml with the test

Acetaminophen	5-Hydroxytryptamine	Phenolbutazone
Acetophenetidin	Hydrochlorothiazide	Phenylpropanolamine
Acetylsalicylic acid	Imipramine	Procaine HCl
Aminopyrine	Ketoprofen	Propiomazine
Amobarbital	Lidocaine	d-propoxyphene
Ampicillin	Meperidine	Propaanolol
Apomorphine	Methamphetamine	Quinine
Benzoic acid	Methypylon	Salicylic acid
Benzocaine	Morphine sulfate	Secobarbital
Caffeine	Methaqualone	Sulfamethazine
Cannabidiol	Methamphetamine	Sulindac
Chlorpheniramine	Naproxen	Temazepam
Chlorpromazine	Niacinamide	Tetracycline
Codeine	Norethindrone	Thiamine
Dextromethorphan	Noscapine	d,l-Thyroxine
Diazepam	Oxalic acid	Triamterene
Digoxin	Oxazepam	Trimethoprim
Diphenhydramine	Oxycodone	Trifluoperazine
Erythromycin	Penicillin G	Tryptamine
Estriol	Pentazocaine	d,l-Tryptophan
Gentisic acid	Penopropfen	Zomepirac
Glutethimine	Phendimetrazine	

REFERENCE

1. Stewart D.J., Clin. Pharmacol. Ther. 1979, 25: 264-268
2. Ambre J., J. Anal. Toxicol. 1985, 9: 241-245