



National Collection Network

CRLstat™ Monitec® 5 Multi-Drug Screen Panel OPI2000/MET1000/THC50/COC300/PCP25

Catalog # X04-PC12

Intended Use

The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel is an *in vitro* screen test for the rapid detection of opiates, methamphetamine, THC, cocaine and phencyclidine in human urine at or above the following cut-off concentrations:

OPI	Morphine	2000 ng/ml †
MET	Methamphetamine	1000 ng/ml †
THC	11-nor- Δ 9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml †
COC	Benzoyllecgonine	300 ng/ml †
PCP	Phencyclidine	25 ng/ml †

† SAMSHA mandated cut-off concentration

The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel provides visual qualitative results and is intended for professional *in vitro* diagnostic use only. It is not intended for over-the-counter sale to non-professionals.

The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel provides only a preliminary screening test result. For a quantitative result or to confirm positive results obtained by CRLstat™, a more specific alternative method must be used. The Substance Abuse and Mental Health Services Administration (SAMHSA), formerly the National Institute on Drug Abuse (NIDA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

Summary and Explanation

OPI: Heroin, morphine and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. Thus, the presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, morphine and other opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days.^{2,3} 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 usage, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

MET: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Methamphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized as deaminated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine can be detected in the urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.^{2,3}

THC: THC use may impair short-term memory and inhibit learning capacity. It may also alter mood and sensory perceptions, cause loss of coordination, induce anxiety, paranoia, hallucinations, depression, confusion, and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur. Long-term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea.

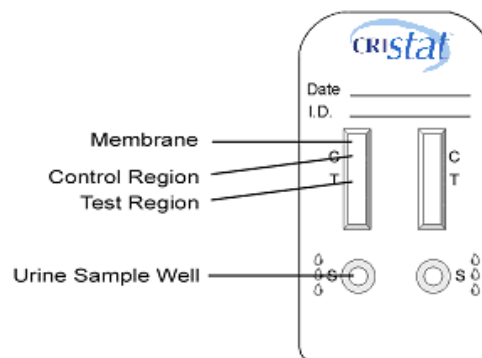
COC: Cocaine derived from the leaves of the coca plant, is a potent central nervous system stimulant, and has been used as a local anesthetic. Cocaine use induces euphoria, confidence, and a sense of increased energy; these psychological effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is generally smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as "crack", which is likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoyllecgonine and can generally be detected for 24-60 hours after cocaine use or exposure.²

PCP: Phencyclidine is an arylchlorhexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, Angel Dust, Crystal Cyclone, Love Boat, Hog, or Killer Weed. PCP can produce lethargy, disorientation, and loss of coordination, visual distortion, euphoria, ataxia, and even coma. PCP can be taken orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about three days.

Test Principle

Urine based screening tests for drugs of abuse are available from simple immunoassay tests to complex analytical procedures. Due to speed and sensitivity, immunoassays have become the most widely accepted method for urine-based drugs of abuse screening tests. The CRLstat™ family of urine drug screen tests is based on the principle of the highly specific immunochemical reactions between antigens and antibodies.¹ The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Test is based on a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The test device contains two membrane strips, onto which the drug conjugates are pre-coated at specific regions known as the test regions. Colored antibody-colloidal gold conjugates are coated onto a pad and placed at one end of each membrane. In the test procedure, a sample of urine is added to each of the sample wells and allowed to migrate across the membranes by capillary action. If any drug is present in the urine sample, it competes with the drug conjugate, which is immobilized on the membrane, for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at the test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the test region of the membrane. The presence of a color band at the test region indicates a negative result for the test.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.



Reagents

Protein conjugates for morphine, methamphetamine, THC, benzoyllecgonine and phencyclidine are coated onto the test regions of the membranes.

The colored conjugate pad for each strip contains monoclonal antibodies for morphine, methamphetamine, THC, benzoyllecgonine and phencyclidine.

Materials Provided

Each NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel Kit contains:

- 1 Package Insert (directions for use).
- 25 Test Cassettes (Test Cards). Each cassette test is packaged individually in a foil pouch with a disposable pipette and a desiccant.

Warnings and Precautions

- FOR *IN VITRO* DIAGNOSTIC USE ONLY
- For professional use only.
- The test device should remain in its original sealed pouch until ready for use. Discard the test device if package is ripped or torn.
- Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and dropper pipette for each urine sample.

Product Storage

The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel pouch should be stored at room temperature (15°–30°C) until the expiration date on the pouch. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

The NCN CRLstat™ Monitec® 5 Multi-Drug Screen Panel is formulated for use with urine specimens. Use only freshly voided, untreated urine.⁴ Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

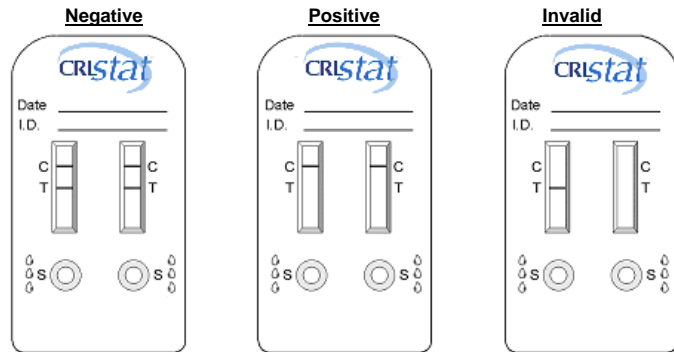
Note: All materials coming into contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid direct contact and follow good laboratory practice.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature prior to testing. Do not open pouch until ready to perform the assay.

1. Remove the test device from the sealed pouch.
2. Draw the urine sample up the pipette and dispense 3 drops (approximately 0.15 ml) into each of the sample wells. Avoid adding drops that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.
3. Once the control bands (C) appear in 5 minutes or less, results are ready to interpret. Results are stable and may be interpreted up to 15 minutes after control bands form.

Interpretation of Results



*Note: The above results are for illustration purposes only, see the explanations below for interpretation of results.

Negative: The presence of a colored band at the control region (C) and a colored band at a specific test region regardless of the intensity indicate that the result is negative for that particular test.

Positive: The presence of a colored band at the control region (C) and the absence of a colored band at the test region indicate a positive result for that particular test.

Invalid: No band appears at the control region (C). The test is inconclusive even if there is a band in the test region. If the test device does not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be considered negative. The NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Panel provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with questionable test bands and positive results be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Quality Control

Internal control: The NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Panel device has a built-in internal procedural control. The appearance of the control band (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Limitations of Procedure

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural error as well as other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list 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 drugs of abuse and certain food and/or medication.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.

- If it is suspected that the sample may have been tampered, a new specimen should be collected.

Performance Characteristics

Precision

For each specific drug test, drug-free normal urine was spiked with a drug standard to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a total of 25 tests were performed to validate the test performance around the cut-off concentration. The results for each of the NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Tests are summarized below:

Drug Test	Total # of Test / Conc.	Concentration							
		-50%		-25%		+25%		+50%	
		-	+	-	+	-	+	-	+
OPI in OPI/MET strip	25	25	0	25	0	3	22	0	25
MET in OPI/MET strip	25	25	0	25	0	3	22	0	25
THC in THC/COC/PCP strip	25	25	0	25	0	4	21	0	25
COC in THC/COC/PCP strip	25	25	0	25	0	4	21	2	23
PCP in THC/COC/PCP strip	25	25	0	25	0	4	21	1	24

Accuracy

The accuracy of the NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Panel was evaluated in comparison to the results from GC/MS analysis or predicate method using commercially available immunoassay. Forty (40) presumed negative urine samples were collected from volunteer donors and tested with both the NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Panel and the predicate method. Of the 40 presumed negative urine samples tested, all were found negative by both methods (100% agreement).

Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) were blind labeled and evaluated. The results are summarized below:

Drug Test	GC/MS Neg. (below C/O)	GC/MS Near Pos. (+25% to C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS	
				Neg (-)	Pos (+)
OPI in OPI/MET strip	Pos. (+)	0	5	35	100%
	Neg. (-)	5	0	0	
MET in OPI/MET strip	Pos. (+)	0	4	36	100%
	Neg. (-)	3	0	0	
THC in THC/COC/PCP strip	Pos. (+)	0	5	34	100%
	Neg. (-)	5	1	0	
COC in THC/COC/PCP strip	Pos. (+)	0	4	35	100%
	Neg. (-)	5	1	0	
PCP in THC/COC/PCP strip	Pos. (+)	0	9	30	100%
	Neg. (-)	7	1	0	

Specificity

The NCN CRLstatTM Monitec[®] 5 Multi-Drug Screen Panel performance at cut-off level is not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for each drug test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

OPI 2000 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	2,000	Hydrocodone	5,000
Codeine	2,000	Hydromorphone	2,500
Dihydrocodeine	2,000	Morphine	2,000
Ethyl morphine	2,000	Morphine-3-β-D-Glucuronide	5,000
Heroin	2,000	Nalorphine	20,000

MET 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	50,000	d-Methamphetamine	1,000
p-Hydroxymethamphetamine	10,000	l-Methamphetamine	50,000
d,l-3,4-MDMA	1000	Procaine	100,000

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-Hydroxy-Δ9-THC	2,500
Cannabinol	50,000	Δ-8-Tetrahydrocannabinol	7,000
11-nor-Δ-8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ-9-THC-9-COOH	50		

COC 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoylecgonine	300	Ecgonine	100,000

PCP 25 ng/ml

Compound	ng/ml
Phencyclidine	25

Interference

The following compounds were found not to cross-react with the NCN CRLstat™ Monitect® 5 Multi-Drug Screen Panel when tested at concentration of 100 µg/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)
Acetone
6-Acetylmorphine (*except OPI assay*)
Acetylsalicylic acid (Aspirin)
Albumin
Allobarbitol
Alphenal
Alprazolam
Aminopyrine
Amitriptyline
Amobarbital
Amoxapine
Amoxicillin
Aprobarbital
d-Amphetamine (*except MET assay*)
l-Amphetamine (*except MET assay*)
Ampicillin
Apomorphine
l-Ascorbic Acid (Vitamin C)
Aspartame
Aspartamine
Atropine
Barbital
Benzilic acid
Benzocaine (Ethyl p-Aminobenzoate)
Benzoic acid
Benzoylcegonine (*except COC assay*)
Benzphetamine
Bilirubin
Bromazepam
d-Brompheniramine
Butabarbital
Butalbital
Butethal
Caffeine
Cannabidiol (*except THC assay*)
Cannabinol (*except THC assay*)
Chloralhydrate
Chlordiazepam-HCl-Di(H₂O)
Chlordiazepoxide
Chloroquine
d-Chlorpheniramine
d,l-Chlorpheniramine
l-Chlorpheniramine
Chlorpromazine
Cholesterol
Clobazam
Clomipramine
Clonazepam
Codeine (*except OPI assay*)
Cortisone
l-Cotinine
Creatine
Creatinine
Cyclobenzaprine
Delorazepam
Deoxycorticosterone
Desipramine
Desmethyldiazepam
Dexbrompheniramine
Dextromethorphan
Diazepam
Dihydrocodeine (*except OPI assay*)
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine (3-Hydroxytyramine)
Doxepin
Doxylamine
Ecgonine (*except COC assay*)
Ecgonine Methyl Ester
l-Ephedrine
l-Epinephrine
d-Epinephrine
d,l-Ephedrine (*except MET assay*)
Erythromycin
Estazolam
β-Estradiol
Estrone-3-Sulfate
Ethanol
Ethyl Morphine (*except OPI assay*)
Ethyl-p-aminobenzoate
2-Ethylidene-1.5-Dimethyl-1.3.3-Diphenylpyrrolidone
Flunitrazepam
Flurazepam
Furosemide
Gentisic acid
Glucose
Glutethimide
Guaiacol Glyceryl Ether
Hemoglobin
Heroin (*except OPI assay*)
Hippuric acid
Hydrochlorothizide
Hydrocodone (*except OPI assay*)
Hydrocortisone
Hydromorphone (*except OPI assay*)
p-Hydroxymethamphetamine (*except MET assay*)
11-Hydroxy-Δ-9-THC (*except THC assay*)
Ibuprofen
Imipramine
l-Isoproterenol
d,l-Isoproterenol
Lidocaine
Lorazepam
Lormetazepam
Medazepam
Meperidine
Methadone
d,l-Methadone
Methamphetamine (*except MET assay*)
Methaqualone
Methoxyphenamine
N-Methyl-Ephedrine
(1R,2S) N-Methyl-Ephedrine
2-Methylamine-Propiophenone
d,l-3,4-Methylenedioxymethamphetamine (*except MET assay*)
d,l-3,4-Methylenedioxyamphetamine
Methylphenidate
Morphine (*except OPI assay*)
Morphine-3-β-D-Glucuronide (*except OPI assay*)
Nalidixic acid
Nalorphine (*except for OPI assay*)
Naloxone
d-Naproxen
Niacinamide
Nitrazepam
Nordiazepam
Nordoxepin
d,l-Norephedrine
Norethindrone
d-Norpropoxyphene
Nortriptyline
Oxalic Acid
Oxazepam
Oxolinic acid
Oxycodone
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocaine
Pentobarbital
Perphenazine
Phencyclidine (*except PCP assay*)
Pheniramine
Phenobarbital
Phenothiazine (Thiodiphenylamine)
Phentermine
Phenylephrine
β-Phenylethylamine
Prednisolone
Prazepam
Procaine
Promazine

Promethazine
d-Propoxyphene
Protryptiline
d-Pseudoephedrine
Pyrolidine
Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital
Serotonin
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Δ8-THC (*except THC assay*)
Δ9-THC (*except THC assay*)
11-nor-Δ8-THC-9-Carboxylic Acid (*except THC assay*)
11-nor-Δ-9-THC-9-Carboxylic Acid (*except THC assay*)
Tetrahydrocortisone
Thiamine
Thioridazine
Triazolam
Trifluoperazine
Trimethobenzamide
Trimipramine Maleate
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

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