GENACHECK

RAPID SELF-TEST KIT FOR TWELVE (12) **DRUGS**

5 MINS

- Easy-to-Use
- FDA Cleared for At-Home Use
- Multiplex Test of Twelve (12) Substances
- Rapid One Step Test (5 Minutes)

Website: www.genabio.com | Email: info@genabio.com | Phone: 1-800-614-3365

ACCURACY

Eighty (80) clinical urine specimens underwent analysis using GC/MS and the GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs. Each test was conducted by three operators. The samples were categorized by concentration into five groups: drug-free, less than half the cut-off, near cut-off negative, near cut-off positive, and high positive. The obtained relative sensitivity and specificity results are outlined in below table.

Performance	AMP	BAR	BZO	COC	MTD	MET	OPI	OXY	PCP	PPX	THC	TCA
Relative sensitivity	95.8%	93.3%	91.7%	95.0%	95.0%	95.8%	88.0%	93.3%	91.7%	95.0%	95.8%	95.0%
Relative specificity	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

ANALYTICAL SENSITIVITY/PRECISION

Sensitivity and precision studies were conducted using spiked samples, targeted at concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off, +75% cut-off, and +100% cut-off. These samples were aliquoted into containers and blind-labeled before testing. Testing was performed by three operators twice a day for 25 days. Data obtained from all operators indicated >99% correlation at +/-50% of each assay cut-off.

EFFECT OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples representing normal, high, and low specific gravity ranging from 1.000 to 1.035 were spiked with drugs at concentrations 25% below and 25% above cut-off levels. GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not impact the test results.

EFFECT OF URINARY pH

The pH of a negative urine pool aliquot was adjusted within the range of 4.00 to 9.00 in 1 pH unit increments and spiked with the target drug at concentrations 25% below and 25% above the cut-off levels. The spiked, pH-adjusted urine was then tested using GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs. The results confirm that varying pH ranges do not interfere with the test's performance.

CROSS-REACTIVITY

A comprehensive study was conducted to assess the cross-reactivity of the test with compounds found in drug-free urine or positive urine for Amphetamine, Buprenorphine, Cocaine, Ecstasy, EDDP (Methadone Metabolite), Marijuana, Methadone, Methamphetamine, Morphine, Oxazepam, Oxycodone, Phencyclidine, Propoxyphene, Secobarbital, and Tricyclic Antidepressants. The following compounds exhibited no interference when tested with GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs at a concentration of 100 µg/ml.

NON-CROSS-REACTING COMPOUNDS

Acetophenetidin	Cotinine (-)	Cortisone	Pseudoephedrine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinidine
Acetylsalicylic acid	Dexamethasone	Labetalol	Quinine
Amiloride	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Desipramine	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Droperidol	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrozoline
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine HCL
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D, L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol- (+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

LAY USER STUDY

A lay user study was conducted at three designated user sites, involving 140 participants with diverse backgrounds. In the dip card device study, participants were subjected to drug sample testing. These individuals had varied educational and professional backgrounds, spanning ages from 21 to over 50.

Urine samples were meticulously prepared at different concentrations, including negative, +/-75%, +/-50%, and +/-25% of the cut-off, achieved by spiking drug(s) into drug-free pooled urine specimens. The concentrations of these samples were validated using Gas Chromatography/Mass Spectrometry (GC/MS).

Each prepared sample was aliquoted into individual containers and blind-labeled for unbiased testing. Participants were provided with a package insert, one blind-labeled sample, and a dip card. The summarized results are outlined below.

Drugs	% of Cut-Off	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		The percentage agreement (%)
				No. of Positive	No. of Negative	
AMP 500	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	125	0	20	100%
	-50% Cut-Off	20	250	0	20	100%
	-25% Cut-Off	20	375	1	19	95%
	+25% Cut-Off	20	625	19	1	95%
	+50% Cut-Off	20	750	20	0	100%
	+75% Cut-Off	20	875	20	0	100%
BAR 300	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	75	0	20	100%
	-50% Cut-Off	20	150	0	20	100%
	-25% Cut-Off	20	225	1	19	95%
	+25% Cut-Off	20	375	19	1	95%
	+50% Cut-Off	20	450	20	0	100%
	+75% Cut-Off	20	525	20	0	100%
BZO 300	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	75	0	20	100%
	-50% Cut-Off	20	150	0	20	100%
	-25% Cut-Off	20	225	1	19	95%
	+25% Cut-Off	20	375	19	1	95%
	+50% Cut-Off	20	450	20	0	100%
	+75% Cut-Off	20	525	20	0	100%
COC 150	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	37.5	0	20	100%
	-50% Cut-Off	20	75	0	20	100%
	-25% Cut-Off	20	112.5	2	18	90%
	+25% Cut-Off	20	187.5	18	2	90%
	+50% Cut-Off	20	225	20	0	100%
	+75% Cut-Off	20	262.5	20	0	100%
MTD 300	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	75	0	20	100%
	-50% Cut-Off	20	150	0	20	100%
	-25% Cut-Off	20	225	1	19	95%
	+25% Cut-Off	20	375	19	1	95%
	+50% Cut-Off	20	450	20	0	100%
	+75% Cut-Off	20	525	20	0	100%

Drugs	% of Cut-Off	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		The percentage agreement (%)
				No. of Positive	No. of Negative	
MET 500	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	125	0	20	100%
	-50% Cut-Off	20	250	0	20	100%
	-25% Cut-Off	20	375	2	18	90%
	+25% Cut-Off	20	625	18	2	90%
	+50% Cut-Off	20	750	20	0	100%
	+75% Cut-Off	20	875	20	0	100%
OPI 2000	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	500	0	20	100%
	-50% Cut-Off	20	1,000	0	20	100%
	-25% Cut-Off	20	1,500	2	18	90%
	+25% Cut-Off	20	2,500	18	2	90%
	+50% Cut-Off	20	3,000	20	0	100%
	+75% Cut-Off	20	3,500	20	0	100%
OXY 100	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	25	0	20	100%
	-50% Cut-Off	20	50	0	20	100%
	-25% Cut-Off	20	75	2	18	90%
	+25% Cut-Off	20	125	18	2	90%
	+50% Cut-Off	20	150	20	0	100%
	+75% Cut-Off	20	175	20	0	100%
PCP 25	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	6	0	20	100%
	-50% Cut-Off	20	12.5	0	20	100%
	-25% Cut-Off	20	19	2	18	90%
	+25% Cut-Off	20	31	18	2	90%
	+50% Cut-Off	20	37.5	20	0	100%
	+75% Cut-Off	20	44	20	0	100%
PPX 300	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	75	0	20	100%
	-50% Cut-Off	20	150	0	20	100%
	-25% Cut-Off	20	225	1	19	95%
	+25% Cut-Off	20	375	18	2	90%
	+50% Cut-Off	20	450	20	0	100%
	+75% Cut-Off	20	525	20	0	100%
THC 50	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	12.5	0	20	100%
	-50% Cut-Off	20	25	0	20	100%
	-25% Cut-Off	20	38	2	18	90%
	+25% Cut-Off	20	63	19	1	95%
	+50% Cut-Off	20	75	20	0	100%
	+75% Cut-Off	20	88	20	0	100%
TCA 1000	-100% Cut-Off	20	0	0	20	100%
	-75% Cut-Off	20	250	0	20	100%
	-50% Cut-Off	20	500	0	20	100%
	-25% Cut-Off	20	750	2	18	90%
	+25% Cut-Off	20	1250	18	2	90%
	+50% Cut-Off	20	1500	20	0	100%
	+75% Cut-Off	20	1750	20	0	100%

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	GenaCheck Rapid Self-Test Kit for Five (5) Drugs; GenaCheck Rapid Self-Test Kit for Twelve (12) Drugs
Classification Name:	ENZYME IMMUNOASSAY, BENZODIAZEPINE
Product Code:	JXM
Device Class:	2
Regulation Number:	862.3170
Medical Specialty:	Toxicology
Registered Establishment Name:	GENABIO DIAGNOSTICS INC
Registered Establishment Number:	3016609999
Premarket Submission Number:	K163704
Owner/Operator:	Genabio Diagnostics Inc.
Owner/Operator Number:	10063095
Establishment Operations:	Repackager/Relabeler; Complaint File Establishment

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GENABIO

GenaCheck™ Rapid Self-Test Kit For Twelve (12) Drugs Test

Instructions For Use

For in vitro diagnostic Use Only
For Over-The-Counter Use Only

For testing of any combination of the following drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Methadone (MTD), Methamphetamine (MET), Opioids (OPI), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Cannabis (THC) and Tricyclic antidepressants (TCA).

A rapid, one step screening test for the simultaneous, qualitative detection of any of the above twelve drugs metabolites in human urine.

Preparation

HOW TO COLLECT URINE?

• Urinate directly into a self prepared urine collection cup.

• Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.

• The residual urine sample in the urine collection cup is for your self-testing.

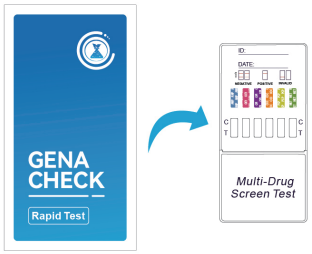
Specimen Storage

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). Frozen specimens should be thawed and mixed well before testing.

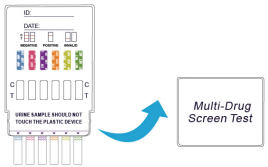
Test Procedure

Allow the test card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

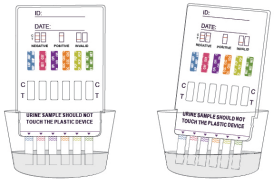
Remove the test card from the foil pouch.



Remove the cap from the test card.



Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic cassette.



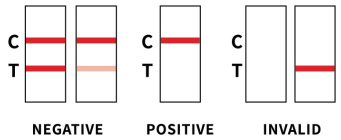
Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.

Read results at 5 minutes.

Note:

Do not interpret result after 5-minute timepoint has passed.

Result Interpretation



(Please refer to the illustration above)

NEGATIVE: Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

NOTE: The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

Review the procedure and repeat the test using a new test cassette. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

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

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT:

The result obtained is considered preliminary for a reason.

To confirm the presence of a drug of abuse, the sample must be tested by a laboratory. If any sample does not yield a negative result, it should be sent to a laboratory for further testing.

What is a False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What is a False Negative Test?

The definition of a false negative test is that the initial testing of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Methadone (MTD), Methamphetamine (MET), Opioids (OPI), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Cannabinoids (THC) are present but aren't detected by GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test. If the sample is diluted, or the sample is adulterated that may cause false negative result.

Intended Use

Urine based tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine.

Drug (Identifier)	Calibrator	Cut-off Levels (ng/mL)
Amphetamine (AMP)	D-Amphetamine	500
Cocaine (Coc)	Benzoylecgonine	150
Cannabinoids (THC)	11-nor-Δ⁹-THC-9 COOH	50
Opioids (OPI)	Morphine	2000
Benzodiazepines (BZO)	Oxazepam	300
Barbiturates (BAR)	Secobarbital	300
Methadone (MTD)	Methadone	300
Phencyclidine (PCP)	Phencyclidine	25
Trihydric Antidepressants (TCA)	Nortriptyline	1000
Propoxyphene (PPX)	Propoxyphene	300
Methamphetamine (MET)	Methylenedioxy-methamphetamine	500
Oxycodone (OXY)	Oxycodone	100

This assay provides only a preliminary analytical 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. Clinical consideration and professional judgment should be applied when interpreting any drug of abuse test result, particularly in cases where preliminary positive results are obtained.

Summary

The GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test is a rapid urine screening test that can be performed without the use of an instrument. The test is intended for Over-The-Counter (OTC) use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing - the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmatory testing of a preliminary positive result are provided.

Reagents

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

Warnings And Precautions

• For Over-The-Counter use only. For in vitro diagnostic use only.

• Do not use after the expiration date.

• The Test Card should remain in the sealed pouch until use.

• All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

• The used Test Card should be discarded according to local regulations.

Storage And Stability

Store as packaged in the foil pouch either at room temperature or refrigerated 2-30°C (36-86°F). The Test Card is stable through the expiration date printed on the box and the foil pouch.

The Test Card must remain in the foil pouch until use.

Keep away from direct sunlight, moisture and heat.

DO NOT FREEZE.

Do not use the Test Card beyond the expiration date.

Materials

Materials Provided:

2 x Test Card(s)
1 x Instructions for Use

Materials Required But Not Provided:

Urine Collection Cup, Timer, Disposable Gloves, Mailing Box*, Plastic Sealed Bag*, Identification Label*, Labeled Vials*,
* For Laboratory Confirmatory Test (See Confirmation Testing Section)

Limitations

• The GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test provides only a qualitative, preliminary analytical result. A secondary analytical substance in the urine specimen may cause erroneous results.

• There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

• Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.

• A positive result does not indicate level of intoxication, administration route or concentration in urine.

• A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

• The test does not distinguish between drugs of abuse and certain medications.

• A positive result might be obtained from certain foods or food supplements.

Frequently Asked Questions

Q. What does the GenaCheck™ Rapid Self-Test Kit for Twelve (12) Drugs Test do?

A: This test indicates if Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Methadone (MTD), Methamphetamine (MET), Opioids (OPI), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Cannabis (THC) and Tricyclic antidepressants (TCA) are present in urine above a certain cut-off level. The testing is done in two steps. First, a quick at-home test is performed. Second, if the test suggests that drugs may be present, send the sample to a laboratory for confirmatory testing.

Q. What is "cut-off level"?

A: The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

Q. What are drugs of abuse?

A: Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

Q. How accurate is the test?

A: The tests are sensitive to the presence of drugs in urine sample. These tests are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.

Q. Does a preliminary positive test mean the drug of abuse is present in the sample?

A: This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

Additional Information And Resources

A healthcare provider, or any of the following organizations listed below can be contacted for additional information and/or counseling regarding substance abuse prevention and treatment.

Center for Substance Abuse Treatment (CSAT): 1-877-SAMHSA-7, www.samhsa.gov

The National Council on Alcoholism and Drug Dependence (NCADD): www.ncadd.org

CONFIRMATORY TESTING: MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

• Ensure that the Labeled Vial is about two third (2/3) full and that the cap is tightly closed.

• Check the label identifying the drug that was a preliminary positive result.

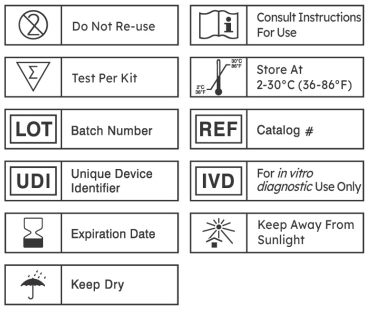
• Be sure to write your Cell Phone Number on the mailing box that the laboratory can send you the message with the confirmed results along with the Personal Identification Number.

• Place the Labeled Vial in the plastic bag and seal the plastic bag.

• Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.

• Place the mailing box in any US Postal Service Office.

Index Of Symbols



Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00-17:00 EST).

Manufactured For Genabio Diagnostics Inc.

Address: 19 Crosby Dr., Ste 220, Bedford, MA 01730, USA
Phone: 1-800-614-3365
Hours of Operation: 9:00-17:00 EST
Email: info@genabio.com
Website: www.genabio.com
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Rev. 00
Effective Date: March 1, 2024

COMPANY INTRODUCTION

Genabio is a global leader in the production of over-the-counter self-testing products, with an impressive sales record of over $100 million in the past three years. Our extensive customer base spans across the USA, Canada, the UK, Japan and India.

A significant aspect of our product range is the FDA approval, including the COVID-19 Rapid Self-Test Kit. These sought-after products can be found in thousands of locations, including renowned pharmacy chains like Walgreens, leading hospitals such a NYU Langone Health, accredited laboratories like SV Diagnostics Labs and Molecular Testing Labs, and various government departments.

In 2023, Genabio marked a pivotal moment in initiating our listing and financing efforts in Hong Kong. Simultaneously, we are focused on enhancing our brand identity and emphasizing clinical research within the United States. This commitment to research and development aligns with our expansion plans, which encompass increasing our production capacity in both the United States and China.

Our overarching vision is to be the world's foremost provider of self-testing solutions, offering precise, user-friendly, and cost-effective health diagnostics for individuals worldwide.

Our mission is to enhance global health awareness and accessibility, by delivering quality, FDA-approved self-test kits, by driving innovation, and by expanding our reach to ensure individual scan monitor their health with precision and convenience.

CONTACT US

Website: www.genabio.com

Email: info@genabio.com

Phone: 1-800-614-3365