T-Dip® Kratom (KRA) Urine Test Panel

Catalogue No. See Box label

The T-Dip® Kratom (KRA) Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of Kratom (KRA) in human urine with below cutoff concentration and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level	Minimum Detection Time	Maximum Detection Time
Kratom (KRA)	Mitragynine	300 ng/mL	7 hours	3 days

It is intended for forensic use only.

The test provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the test kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (39ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time of Kratom (KRA) is 7 hours, urine specimens may be collected 7 hours after the suspected drug use.

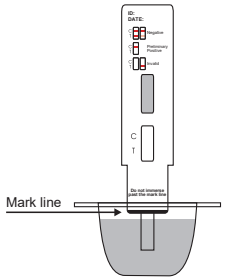
HOW TO COLLECT URINE?

Instruct the donor to void directly into the urine collection cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the urine collection cup with urine specimen.

TEST PROCEDURE

Test should be performed at room temperature 18ºC-30ºC (65ºF-86ºF).

1. Remove the test device from the foil pouch by tearing at the notch. Use it as soon as possible.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine specimen for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



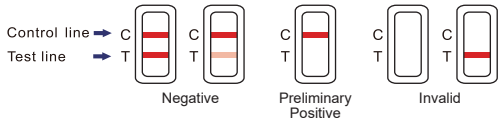
Note: Results after more than 5 minutes may be not accurate and should not be read.

READING THE RESULTS

Negative (-)
A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)
A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid
If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in each of the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.



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

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests.

What Is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by the T-Dip® Kratom (KRA) Urine Test Panel. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by the T-Dip® Kratom (KRA) Urine Test Panel. If the specimen is diluted, or the specimen is adulterated that may cause false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time.

TEST LIMITATIONS

1. This test kit has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use it to test anything other than urine.
2. Adulterated urine samples may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drug or the level of intoxication.

SUMMARY

Kratom (Mitragyna speciosa) is a plant indigenous to Thailand and Southeast Asia. Kratom leaves produce complex stimulant and opioid-like analgesic effects. In Asia, it is often used to stave off fatigue and to manage pain, diarrhea, cough, and opioid withdrawal. Recently, kratom has become widely available in the United States and Europe by means of smoke shops and the Internet. The clinical manifestations of kratom are not well defined and studies are limited, but its safety profile has become a national and international concern, primarily due to excessive consumption being linked to increase in hospital visits for hepatic injury, seizures, coma, and death. The main active ingredients include Mitragynine and 7-Hydroxymitrgynine, which can be detected in urine up to 72 hrs [1-3].

PRINCIPLE

The T-Dip® Kratom (KRA) Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs in urine. It is chromatographic absorbent device in which drugs in a specimen competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test device should be discarded.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty urine specimens were analyzed by GC/MS or LC-MS/MS and by the T-Dip® Kratom (KRA) Urine Test Panel. Each test was read by three viewers. Samples were divided by concentration into five categories: Drug Free, Less than Half the Cutoff, Near Cutoff Negative, Near Cutoff Positive, and High Positive. Results were as follows:

Result		Drug Free	Less than Half the Cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (Greater than 50% above the cutoff)	% Agreement with GC/MS or LC/MS
Viewer A	+	0	0	2	20	20	100%
	-	10	10	18	0	0	95%
Viewer B	+	0	0	1	20	20	100%
	-	10	10	19	0	0	97.5%
Viewer C	+	0	0	2	20	20	100%
	-	10	10	18	0	0	95%

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff -100%, cutoff -75%, cutoff -50%, cutoff -25%, cutoff, cutoff +25%, cutoff +50%, cutoff +75% and the cutoff +100%. All concentrations were confirmed with GC/MS or LC-MS/MS. The study was used three different lots of the T-Dip® Kratom (KRA) Urine Test Panel. The data are summarized below:

Approximate Concentration of Sample (ng/mL)	Number of Determinations per Lot	Results (Negative/Positive)		
		Lot 1	Lot 2	Lot 3
0	50	50/0	50/0	50/0
75	50	50/0	50/0	50/0
150	50	50/0	50/0	50/0
225	50	50/0	50/0	50/0
300	50	3/47	5/45	4/46
375	50	0/50	0/50	0/50
450	50	0/50	0/50	0/50
525	50	0/50	0/50	0/50
600	50	0/50	0/50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than theconcentrations listed below.

Substance	Concentration (ng/mL)
Kratom (KRA)	
Mitragynine	300
7-Hydroxymitragynine	600

Effect of Urinary Specific Gravity

The results demonstrate that the urinary specific gravity range of 1.000~1.035 does not affect the test results.

Effect of Urinary pH

The results demonstrate that the range of urinary pH from 4 to 9 does not interfere with the performance of test.

Interfering Substances

The following compounds were added to drug-free urine, urine with drug concentration 25% below the cutoff, and urine with drug concentration 25% above the cutoff for the corresponding T-Dip® Kratom (KRA) Urine Test Panel. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetaminophen	Effexor	Nimodipine
Acetophenetidin	Enalapril Maleate	Nitroglycerin
Acetylsalicylic Acid	Erythromycin	Norethindrone
Acyclovir	Esomeprazole Magnesium	N-Acetylprocainamide
Afrin	β-Estradiol	O-Hydroxyhippuric Acid
Albumin (100mg/dL)	1% Ethanol	Olanzapine
Aminophylline	Fenofibrate	Omeprazole
Aminopyrine	Fenoprofen	Oxalic Acid
Amiodarone Hydrochloride	Fentanyl Citrate	Oxolinic Acid
Amlodipine Mesylate	Fluoxetine Hydrochloride	Oxymetazoline
Amoxicillin	Fluvoxamine	Ondansetran
Ampicillin	Furosemide	Paliperidone
Apomorphine	Gabapentin	Pantoprazole
Aripiprazole	Gentisic Acid	Papaverine
Aspartame	Glibenclamide	Paroxetine Hydrochloride
Atomoxetine	Gliclazide	Penfluridol
Atorvastatin Calcium	Glipizide	PenicillinV Potassium
Atropine	Glucose	Penicillin-G
Benzilic Acid	Haloperidol	Phenelzine
Benzoic Acid	Hemoglobin	Pioglitazone Hydrochloride
Bilirubin	Hydrochlorothiazide	Piracetam
Bupropion	Hydrocortisone	Pravastatin Sodium
Captopril	3-Hydroxytyramine	Prednisone
Carbamazepine	Isosorbide Dinitrate	Propylthiouracil
Cefradine	Isoxsuprine	Quetiapine Fumarate
Cephalexin	Ibuprofen	Quinine
Chloral Hydrate	Ketoconazole	Ranitidine
Chloramphenicol	Ketoprofen	Rifampicin
Chlorothiazide	Ketamine	Risperidone
Cholesterol	Labetalol	Salicylic Acid
Ciprofloxacin Hydrochloride	Lamotrigine	Serotonin
Citalopram	Levofloxacin Hydrochloride	Sertraline Hydrochloride
Clarithromycin	Levonorgestrel	Sildenafil Citrate
Clonidine	Levothyroxine Sodium	Simvastatin
Clopidogrel Hydrogen Sulphate	Lidocaine Hydrochloride	Sodium Valproate
Clozapine	Lisinopril	Spironolactone
Conjugated Estrogens	Lithium Carbonate	Sulfamethazine
Cortisone	Liverite	Sulindac
Creatinine	Loperamide	Tetracycline
(-) Cotinine	Loratadine	Tetrahydrocortisone 3 -acetate
chlorpheniramine	Magnesium	Tetrahydrocortisone 3-(β-D glucuronide)
D,L-Octopamine	Meperidine	Tetrahydrozoline
D,L-Propranolol	Meprobamate	Thiamine
D,L-Tyrosine	Metoprolol Tartrate	Thioridazine
Deoxycorticosterone	Mifepristone	Topiramate
Dextromethorphan	Mirtazapine	Tramadol Hydrochloride
Diclofenac	Montelukast Sodium	Trazodone Hydrochloride
Diflunisal	Mosapride Citrate	Triamterene
Digoxin	Minocycline	Trifluoperazine
Diphenhydramine	Nalidixic Acid	Trimethoprim
Dirithromycin	Naproxen	Uric Acid
Domperidone	Niacinamide	Valproate
D-Pseudoephedrine	Nifedipine	Verapamil
Duloxetine	Nikethamide	Vitamin B2
Dicyclomine		Vitamin C

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

1. Tayaboli K: Kratom, a dangerous player in the opioid crisis. J Comm Hos Inter Med Perspective, 2018, 8 (3):107-110
2. Warner ML: Opioids. The pharmacology and toxicology of Kratom: from traditional herb to drug of abuse. Int J Legal Med. 2016 Jan 130 (1): 127-
3. Hawks RL: Urine Testing for Drug of Abuse, National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986
4. Baselt RC: Disposition of Toxic Drugs and Chemicals in Man. Eighth edition. Foster City, CA. Biomedical Publications, 2008, pp 616-619

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
National Clearinghouse for Alcohol and Drug Information www.health.org 1-800-729-6686
Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4°C - 30°C (39°F - 86°F)


Keep dry


Do not re-use

Manufactured by Guangzhou Wondfo Biotech Co., LTD Guangzhou, Guangdong, China 510663

Made in China