KRA

One Step
Kratom Test Strip
Package Insert

A rapid, one step test for the qualitative detection of Mitragynines in human urine.

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The KAT One Step Kratom Test Strip is a lateral flow chromatographic immunoassay for the detection of Mitragynine in urine at a cut-off concentration of 300 ng/mL. Please refer to analytical specificity table in this package insert.

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 to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Kratom is from a leaf of the Kratom plant, it's a natural narcotic produced mainly in southern Thailand, containing mitragynine and 7-Hydroxymitragynine. It is often used to relieve chronic diseases, alcohol, etc., and relieve the pain caused by withdrawal of opium. A pain - eating cocktail made from the pain bearing leaves is the most common and readily available drug drink in southern Thailand. It can cause drowsiness and paralysis.. [1]

The KAT One Step Kratom Test Strip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Mitragynines in urine. The KAT One Step Kratom Test Strip yields a positive result when the concentration of Mitragynine exceeds the 300 cutoff level.

PRINCIPLE

The KAT One Step Kratom Test Strip is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Mitragynines, if present in the urine specimen below the cutoff concentration, will not saturate the binding sites of the antibody in the test strip. The Mitragynine conjugate will be captured by antibody and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Mitragynines level exceeds the cutoff concentration because it will saturate all the binding sites of anti-Mitragynine antibodies.

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

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

REAGENTS

The test strip contains monoclonal anti-Mitragynine antibody-coupled particles and Mitragynine-protein conjugates. A goat antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For professional *in vitro* diagnostic use only. Do not use after the expiration date
- The test strip 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 strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

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

MATERIALS

Materials Provided

- Test strips
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

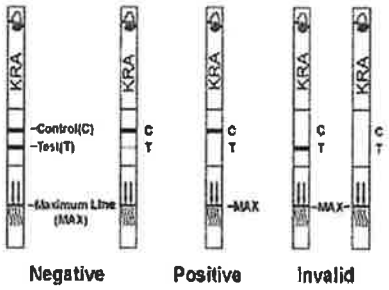
Allow the test strip, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration below)

Test Results



NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another colored line should be in the test region (T). This negative result indicates that the Mitragynine concentration is below the detectable level (300 ng/mL).

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Mitragynine concentration exceeds the detectable level (300 ng/mL).

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 with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored 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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The KAT One Step Kratom Test Strip provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [2,3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.

4. Certain medications containing Mitragynine derivatives may produce a positive result. Additionally, foods and tea containing poppy products (the origin of the Kratom) may also produce a positive result.
5. A Positive Result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
6. A Negative Result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
7. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the KAT One Step Kratom Test Strip and a leading commercially available KAT rapid test. The following results were tabulated:

Method		Other KAT Rapid Test		Total Results
KAT One Step Test Strip	Results	Positive	Negative	
	Positive	150	0	150
	Negative	0	150	150
Total Results		150	150	300
% Agreement with this commercial kit		>99%	>99%	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with Mitragynine at the following concentrations:
0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL and 450 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Mitragynine Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	25	5
300	Cutoff	30	16	14
375	+25%	30	3	27
450	+50%	30	0	30

Specificity

The following table lists compounds that are positively detected in urine by the KAT One Step Kratom Test Strip at 5 minutes.

Compound	Concentration (ng/mL)
(-)-mitragynine	300
7-Hydroxymitragynine	500

Precision

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens were blind labeled and tested at each site. The results are given below:

Mitragynine conc. (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	45	15	0	15	0	15	0
150	45	13	2	13	2	15	0
225	45	5	10	7	8	10	5
375	45	0	15	1	14	0	15
450	45	0	15	0	15	0	15

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 150 ng/ml and 450 ng/ml of Mitragynine respectively. The KAT One Step Kratom Test Strip was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Mitragynine to 150 ng/ml and 450 ng/ml. The spiked, pH-adjusted urine was tested with the KAT One Step Kratom Test Strip in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Mitragynine positive urine. The following compounds show no cross-reactivity when tested with the KAT One Step Kratom Test Strip at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Erythromycin	Oxymetazoline
Acetophenetidin	β-Estradiol	Papaverine
N-Acetylprocainamide	Estrone-3-sulfate	Penicillin-G
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Pentazocine
Aminopyrine	Fenoprofen	Pentobarbital
Amitryptyline	Furosemide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
	Hydralazine	Phenobarbital
L-Ascorbic acid	Hydrochlorothiazide	Phentermine
D,L-Amphetamine	Hydrocortisone	L-Phenylephrine
Apomorphine	O-Hydroxyhippuric acid	β-Phenylethylamine
Aspartame	p-Hydroxy-methamphetamine	Phenylpropanolamine
Atropine	3-Hydroxytyramine	Prednisone
Benzilic acid	Ibuprofen	D,L-Propanolol
Benzoic acid	Imipramine	D-Propoxyphene
Benzoylecgonine	Iproniazid	D-Pseudoephedrine
Benzphetamine	(±) Isoproterenol	Quinidine
Bilirubin	Isoxsuprine	Quinine
(±)-Brompheniramine	Ketamine	Ranitidine
Caffeine	Ketoprofen	Salicylic acid
Cannabidiol	Labetalol	Secobarbital
Chloralhydrate	Loperamide	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide	Meperidine	Sulindac
Chlorothiazide	Meprobamate	Temazepam
(±) Chlorpheniramine	Methadone	Tetracycline
Chlorpromazine	Methoxyphenamine	Tetrahydrocortisone, 3 Acetate
Chloquine	(+) 3,4-Methylenedioxy-amphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cholesterol	(+) 3,4-Methylenedioxy-methamphetamine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine		Thioridazine
Cocaine hydrochloride	Naloxone	D, L-Tyrosine
Cortisone	Naltrexone	Tolbutamide
(-) Cotinine	Naproxen	Triamterene
Creatinine	Niacinamide	Trifluoperazine
Deoxycorticosterone	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	D-Norpropoxyphene	Tryptamine
Diclofenac	Noscapine	D, L-Tryptophan
Diflunisal	D,L-Octopamine	Tyramine
Digoxin	Oxalic acid	Uric acid
Diphenhydramine	Oxazepam	Verapamil
Doxylamine	Oxolinic acid	Zomepirac
Ecgonine hydrochloride		
Ecgonine methylester		
(-) Ψ Ephedrine		

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