Kratom Dip Test

One Step Kratom Test Dip Card (Urine)

Package Insert

For Forensic Use Only

Package insert for testing of Kratom.
Read all instructions first and familiarize yourself with the materials before testing.

INTENDED USE

The One Step Kratom Test Dip Card (Urine) is a lateral flow chromatographic immunoassay for the detection of *Kratom and its metabolites* in human urine.

Test	Calibrator	Cutoff (ng/mL)
Kratom (KRA)	Mitragynine	250

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) and Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. This test does not distinguish between drugs of abuse and certain medications.

SUMMARY

Kratom leaves produce narcotic-like effects when smoked, chewed, or drank as a suspension, which have recently attracted significant attention due to increased use in Western cultures as an alternative medicine. It is used in therapy for opiate addiction and chronic pain management. The addiction potential and adverse health consequences are becoming an important issue for health authorities. Extensive use of kratom results in prolonged sleep. The withdrawal symptoms include hostility, aggression, muscle pain and inability to work

The One Step Kratom Test Dip Card (Urine) yields a positive result when the Mitragynine in urine exceeds 250 ng/mL.

PRINCIPLE

The One Step Kratom Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drug which may be present in the urine specimen competes against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below it's cutoff concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the specific drug strip. The presence of drug above the cutoff concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip 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.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse the test.
- The test dip card should remain in the sealed pouch until use.
- Avoid cross-contamination of specimen by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Humidity and temperature can adversely affect results.
- The used test dip card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C) until the expiry date printed on the pouch.
- The test dip card must remain in the sealed pouch until use.
- The kit should be kept out of direct sunlight.
- **DO NOT FREEZE.**
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

MATERIALS

Materials Provided

- Individually packaged single dip card
- Package insert

Materials Required But Not Provided

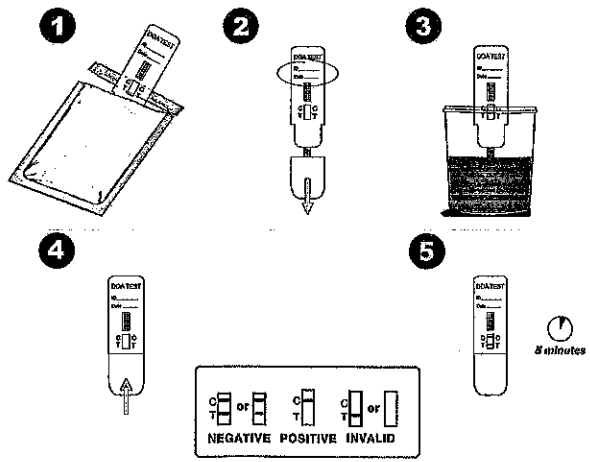
- Collection container/cup
- Timer

DIRECTIONS FOR USE

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

1) Remove the test dip card from the foil pouch and use as soon as possible.
2) If needed, label the device with patient or control identifications. Remove the cap from the test device.
3) With the arrows pointing toward the urine specimen immerse the sample tip vertically in the urine specimen for at least 10 – 15 seconds.
4) Replace the cap back on the device and place the device on a flat surface.
5) Read results at 5 minutes.

DO NOT INTERPRET RESULTS AFTER 10 MINUTES



INTERPRETATION OF RESULTS

NEGATIVE: Two lines appear. One color line should be in the control region ©, and another color line in the test region (T).
This negative result indicates that the drug concentration is below the detectable level.
NOTE: The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. This is a qualitative test only and cannot determine the concentration of analytes in the specimen.

POSITIVE: One color line appears in the control region ©. 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 dip card. If the problem persists, discontinue using the lot immediately and contact your distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region © 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 KRA Test should only be used for the qualitative detection of drugs of abuse in urine.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC-MS/MS) have been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step Kratom Test Dip Card (Urine) at a read time of 5 minutes.

Compound	Concentration (ng/mL)
Mitragynine	250
Mitragynine Metabolite	250
7-Hydroxymitragynine	600

Effect of the Urine pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 8 in 1 pH unit increments and spiked with Mitragynine at 50% below and 50% above cutoff levels. The spiked, pH-adjusted urine was tested with the One Step Kratom Test Dip Card (Urine). The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Effect of the Urine Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with Mitragynine at 50% below and 50% above cutoff levels. The One Step Kratom Test Dip Card (Urine) was tested using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Interference

The following compounds were evaluated for potential positive or negative interference with the KRA dip card. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the KRA Dip Card. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL

Non-Interfering Compounds

(-)-Epinephrine	Diflunisal	MDEA	S(-)-Methcathinone
(R)-(-)-Phenylephrine	Diphenhydramine	MDMA	Salicylamide
(S)-(-)-Propranolol	Dopamine	MDPV	Secobarbital
6β-Naltrexol	Doxepin	Mephedrone	Seroquel
Acetaminophen	Erythromycin	Methadone	Serotonin
Acetone	Estrone 3-sulfate	Methamphetamine	Sertraline HCL
Alpha-Hydroxyhippuric acid	Fenoprofen	Methaqualone	Sodium Oxalate
Amoxicillin	Fentanyl	Mirtazapine	Sulfamethazine
Amphetamine, AMP	Fludiazepam	N-Acetylprocainamide	Sulindac
Ampicillin	Fluvoxamine	Naloxone	Tetracycline
α-PVP	Gabapentin	Naltrexone	Tetrahydrocannabinol
Aspartame	Guaifenesin	Nortriptyline	Thiamine
Aspirin	Hemoglobin human	Octopamine	Tolbutamide
Barbital	Human Albumin	Oxolinic acid	Tramadol
Bilirubin	Hydralazine	Oxycodone	Trans-2-phenylcyclopropylamine
Brompheniramine	Hydrocodone	Oxymetazoline	Trazodone
Buspirone	Ibuprofen	Papaverine	Triamterene
Caffeine	Isoxsuprine	Pentylone	Tryptamine
Chloramphenicol	JWH-018	Perphenazine	Tyrosine
Chloroquine	JWH-018 metabolites	Phenelzine	
Chlorothiazide	Kanamycin	Phenytoin	
Chlorpheniramine	Ketoprofen	Prednisolone	
Cholesterol	Loperamide	Pseudoephedrine	
Codeine	Paynantheine	Quinacrine	
Dextromethorphan	Lorazepam	Quinine	

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

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