One Step Kratom (KRA)Test

Package Insert

Package insert for testing of Kratom in Human Urine

A rapid, one step screening test for the simultaneous, qualitative detection of the specified drug and its metabolites in human urine.

For forensic use only.

INTENDED USE & SUMMARY

Urine based tests for 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 drugs of abuse.

The **One Step Kratom（KRA）Test** is a lateral flow chromatographic immunoassay for the qualitative detection for the specified compound and its drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Kratom	Mitragynine	250

This test will detect other related compounds, please refer to the 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 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 (KRA) Test** yields a positive result when the Mitragynine in urine exceeds 250 ng/mL.

REAGENTS

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

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- The device 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 device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30℃). The Test Strip is stable through the expiration date printed on the sealed pouch. The Test Strip 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 precipitates 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℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Device
- Package Insert

Materials Required But Not Provided

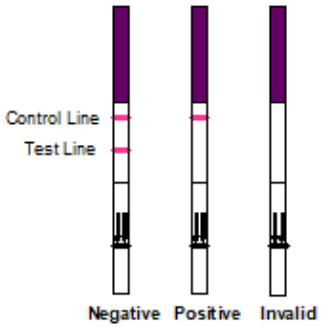
- Specimen Collection Container
- Timer

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30℃ (59-86℉)] prior to testing.

1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flat on a non-absorptive clean surface.
5) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(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 (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/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 (Drug/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 panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

QUALITY CONTROL

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

LIMITATIONS

1. The **One Step Kratom（KRA）Test** 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. There is a possibility 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. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

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 (KRA) Test at a read time of 5 minutes.

Drug	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 Mitrgynine at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Kratom (KRA)Test. 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 Mitrgynine at 50% below and 50% above cut-off levels. The One Step Kratom (KRA)Test 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.

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 One Step Kratom (KRA) Test at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

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