Jiangsu Well Biotech Co., Ltd

Kratom Dip Test

The Kratom Dip test is a rapid, one-step immunoassay for the qualitative detection of its main active ingredient Mitragynine and 7-Hydroxyitragynine in human urine at the following cut-off concentration:

KRA	Mitragynine	300 ng/ml

This device provides only preliminary drug test results. To obtain a quantitative result or a confirmation of a presumptive positive result, a more specific alternative method must be used. GC/MS or LC/MS is the preferred confirmatory method. Professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated.

Technology and Explanation

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).

Test principle

The Kratom Dip test is a rapid lateral fluid immunoassay utilizing specific antibodies to qualitatively detect mitragynine and its derivatives at the cutoff concentration of 300 ng/ml in human urine. The assay is based on competitive immunoassay procedure in which the drug conjugates immobilized on nitrocellulose membrane compete with the drugs if present in specimen for the limited amount of antibody on colloidal gold conjugates. If there is no drug present or the drug concentration in the specimen is below cutoff level, the red colloidal gold conjugate will bind to the drug conjugate at the specific test region, to form a visible band which indicated a negative result. If there is drug present in the specimen at above cutoff level, the drug will bind to the limited antibodies on colloidal gold, leaving no antibody available for binding to the drug conjugates on membrane. Thus, the absences of a test line band indicates a presumptive positive result for the drug.

Reagents

The Kratom Dip test contains one membrane strip which consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad. Mitragynine protein conjugate is coated onto specific region on the membrane known as the “Test Region”, and the colloidal gold conjugate pad contains specific anti-Mitragynine antibody colloidal gold conjugates coated onto a fibrous pad.

Precautions

- For *Forensic , Insurance and workplace* Use only
- The test device is for single use and should remain in its original sealed pouch until ready for use.
- Do not use after the expiration date indicated on the kit.
- Handle all urine specimens as if potentially infectious. The used device should be discarded according federal, state and local regulation.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

Materials Provided

1. 1 Package Insert
2. Test devices packaged individually in a foil pouch with desiccant.

Storage and Stability

1. Store at 4°C-30°C. Do not open pouch until ready to perform the assay.
2. Keep away from direct sunlight moisture and heat.

Specimen Collection and Handling

The Kratom Dip test is formulated for use with urine specimens. Use only freshly voided, untreated urine. Urine sample should be collected so that testing may be performed as soon as possible, preferably during the same day. Previous refrigerated and frozen specimens must be brought to room temperature before testing.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature (15–30°C) prior to testing. Do not open pouch until ready to perform the assay.

1. Remove the test device from the sealed pouch and use the device as soon as possible.
2. Dip the sample pad of the test device into the sample for at least 15 seconds until sample shows up in window area.
3. Place the cap onto the device, lay it on a flat surface.
4. Read results at 5-20 minutes.

Interpreting Test Results

Negative Result

A red colored band should be observed in control region (C), and test region.

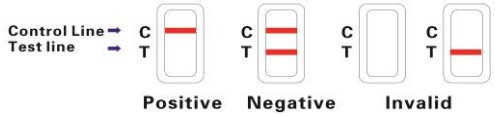
The color and density of the test band may vary for control and drug test region.

Presumptive Positive Result

When the control band is visible in the control region (C) and **no** band appears at the test region, the result is a presumptive positive.

Invalid

When no band appears in the control (C) region, the test is invalid regardless of the result in the test region. If the test is invalid, check testing procedures. Repeat the test using a new device.



Important: Do not compare color intensity of one band to another.

Any dark or light red band is observed in the test region along with the presence of the control line (C), the sample should be considered negative. For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.

Quality Control

The device has built-in control band in each window at the control regions (C) to indicate that the test has performed properly. If the control bands do not appear, the test device should be discarded. The use of external controls is strongly recommended as good laboratory testing practice to verify test performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens.

Laboratories should comply with all federal, state, and local laws, guidelines and regulations.

Limitations of Procedure

- The assay is designed for human urine use only.
- The test only provides a qualitative, preliminary results. Positive results only indicate the presumptive presence of drug and do not indicate or measure intoxication. A more specific analytical method like GC/MS or LC/MS is preferred to confirm the results.
- Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

Performance Characteristics

Analytical sensitivity Pooled negative urine was spiked with Mitragynine standard at various concentrations (0%, 50%, 150% and 300%). For each control, 30 tests were performed to validate the performance of the assay. The results of the Kratom Dip Test are summarized below:

Drug Device	Control Concentration (Cutoff level)							
	0%		50%		150%		300%	
	-	+	-	+	-	+	-	+
Mitragynine	30	0	30	0	0	30	0	30

Specificity

The specificity of each drug test was evaluated by adding its structurally related compounds to negative urine sample. The results are expressed as the lowest concentration of the compound, in ng/ml, that produced a positive result.

Compound	Concentration ng/ml	% of cross reactivity
Mitragynine	300	100
7-Hydroxymitragynine	500	60

Interference

The Kratom Dip Test performance at ±50% cut-off levels is not affected by spiked urine controls with pH range of 2.0 to 8.5.The following compounds were tested no interfering with assay performance when tested at concentration of 10 µg/ml (10,000ng/ml).

Acetone	Hemoglobin
Acetaminophen	Human IgA
Albumin from human serum	Human IgG
l-Ascorbic Acid	Human IgM
Aspartame	Ibuprofen
Benzocaine	Isopropanol
Benzoic acid	Ketamine
Bilirubin	Lidocaine
Caffeine	Naloxone
d-Chlorpheniramine	Naltrexone hydrochloride
Cholesterol	d-Naproxen
Dextromethorphan	Pentazocine
Diphenhydramine	Promazine
Doxylamine	Promethazine
1R, 2S l- Ephedrine *(except MET assay)*	Ranitidine
1S, 2R d-Ephedrine	Riboflavin
l-Epinephrine	Salicylic acid
Erythromycin	Serotonin
Ethanol	Thiamine
Glutethimide	Tryptamine

Bibliography of Suggested Reading

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