CEDIA™ Mitragynine (Kratom) Assay

thermo scientific

For Criminal Justice and Forensic Use Only

REF 10026604 (3 x 17 mL Kit)
10026612 (65 mL Kit)

Intended Use

The CEDIA™ Mitragynine Assay is a homogenous enzyme immunoassay for the qualitative and/or semi-quantitative estimation of mitragynine in human urine at a cutoff concentration of 50 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect mitragynine in human urine. This product is intended to be used by trained professionals only. **The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) or Liquid chromatography/ tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.**

Clinical and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary results are used. For Criminal Justice and Forensic Use Only.

Summary and Explanation of the Test

Kratom, the common name for the plant Mitragyna speciosa, is commonly used in Southeast Asia for its opioid agonistic properties[1]. The main alkaloids in Kratom include mitragynine, speciogynine, speciociliante, paynantheine, and 7-hydroxymitragynine[2]. The common route of ingestion consists of chewing and smoking Kratom leaves as well as drinking tea brewed using Kratom leaves[2]. In the United States, Kratom can be purchased in various forms, including capsules, powders, e-liquid, and chocolate bars. Kratom is not a controlled substance, but is listed as a "drug of concern" by the U.S. Drug Enforcement Administration[3]. However, Kratom is illegal in some states and cities: this currently includes Alabama, Arkansas, Indiana, Tennessee, Vermont, Wisconsin and the District of Columbia, along with at least three cities — Denver, San Diego and Sarasota, Florida. Legislation was considered in six other states — Florida, Kentucky, New Hampshire, New Jersey, New York and North Carolina.[4]

The CEDIA Mitragynine Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system[5]. The assay is based on the bacterial ß-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzymes that, in the assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically at 570 nm.

In this assay, the analyte in the sample competes with the analyte conjugated to the inactive fragment (enzyme donor) of the ß-galactosidase for the antibody binding site. If the analyte is present in the sample, it binds to the antibody, leaving the inactive enzyme fragment free to form an active enzyme. If the analyte is not present in the sample, antibody binds to the analyte conjugated on the inactive fragment, inhibiting the re-association of inactive ß-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.

Reagents

1 EA Reconstitution Buffer
Contains buffer salts, mouse monoclonal anti-mitragynine derivative antibody 0.8 – 1.0 mg/L, stabilizer, and preservative.

1a EA Reagent
Contains 0.171 g/L Enzyme Acceptor *(Escherichia coli)*, buffer salts and preservative.

2 ED Reconstitution Buffer
Contains buffer salts, stabilizers, and preservatives

2a ED Reagent
Contains 0.175 mg/L Enzyme Donor *(Escherichia coli)* conjugated to mitragynine derivative, 1.67 g/L chlorophenol red-ß-D-galactopyranoside, stabilizers, detergent and preservative.

Additional Materials Required (sold separately):

Ref	Kit Description
10022753	CEDIA Negative Calibrator II (1 x 7.5 mL)
10026590	CEDIA Mitragynine Calibrator 20 ng/mL (1 x 5 mL)
10026591	CEDIA Mitragynine Calibrator 50 ng/mL (1 x 5 mL)
10026592	CEDIA Mitragynine Calibrator 100 ng/mL (1 x 5 mL)
10026593	CEDIA Mitragynine Calibrator 200 ng/mL (1 x 5 mL)
10026594	CEDIA Mitragynine Low and High Controls (2 x 5 mL each)

⚠ Warnings and Precautions

The reagents are harmful if swallowed.
Danger:
Powder reagents contain ≤ 53% w/w Bovine Serum Albumin (BSA) fragments and ≤ 2% w/w Sodium Azide.
Liquid reagents contain ≤ 0.03% Bovine Serum, ≤ 0.09% Sodium Azide, and ≤ 0.09% Drug-Specific Antibody (Mouse).

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 - Harmful to aquatic life with long-lasting effect
EUH032 - Contact with acids liberates very toxic gas.

Avoid breathing dust/mist/vapors/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/ attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

In the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, and state regulations.

In the case of damaged packaging on arrival, contact your technical support representative (refer to back page of this Package Insert).

Reagent Preparation and Storage

For preparation of the solutions, refer to the section below. Remove the kit from refrigerated storage (2-8°C) immediately prior to preparation of the solutions.

Prepare the solutions in the following order to minimize possible contamination.

R2 Enzyme Donor Solution

Connect Bottle 2a (ED reagent) to Bottle 2 (ED Reconstitution Buffer) using one of the enclosed adapters. Mix by gentle inversion, ensuring that all the lyophilized material from Bottle 2a is transferred into Bottle 2. Avoid the formation of foam. Detach Bottle 2a and adapter from Bottle 2 and discard. Cap Bottle 2 and let stand approximately 5 minutes at room temperature (21-25°C). Mix again. Record the reconstitution date on the bottle label. Place the bottle directly into the reagent compartment of the analyzer or into refrigerated storage (2-8°C) and let stand 30 minutes before use.

R1 Enzyme Acceptor Solution

Connect Bottle 1a (EA reagent) to Bottle 1 (EA Reconstitution Buffer) using one of the enclosed adapters. Mix by gentle inversion, ensuring that all the lyophilized material from Bottle 1a is transferred into Bottle 1. Avoid the formation of foam. Detach Bottle 1a and adapter from Bottle 1 and discard. Cap Bottle 1 and let stand approximately 5 minutes at room temperature (21-25°C). Mix again. Record the reconstitution date on the bottle label. Place the bottle directly into the reagent compartment of the analyzer or into refrigerated storage (2-8°C) and let stand 30 minutes before use.

⚠ ***NOTE 1:*** The components supplied in this kit are intended for use as an integral unit. Do not mix components from different lots.

⚠ ***NOTE 2:*** Avoid cross-contamination of reagents by matching reagent caps to the proper reagent bottles. The R2 solution (Enzyme Donor) should be yellow-orange in color. A red or red-purple color indicates that the reagent has been contaminated and must be discarded.

⚠ ***NOTE 3:*** The R1 and R2 solutions must be at the reagent compartment storage temperature of the analyzer before performing the assay. Refer to the analyzer specific application sheet for additional information.

Store reagents at 2-8°C. **DO NOT FREEZE.**

For shelf life of the unopened components, refer to the box or bottle labels for the expiration date.

R1 Solution: 60 days refrigerated on analyzer or at 2-8°C.

R2 Solution: 60 days refrigerated on analyzer or at 2-8°C.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed.

Specimens kept at room temperature that do not receive initial test within 5 days of arrival at the laboratory should be placed into a secure refrigeration unit at 2 to 8°C for up to 14 days.[5, 7] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C. Studies have shown mitragynine analytes in urine are stable at -20°C up to 5 days.[6]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[8]

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

The CEDIA Mitragynine Assay is intended for use on automated clinical analyzers. Instruments capable of maintaining a constant temperature, pipetting, mixing reagents, measuring enzymatic rates at 570 nm and timing the reaction accurately can be used to perform this immunoassay.

Refer to specific application instructions for each analyzer for chemistry parameters before performing the assay.

Quality Control and Calibration

Quality Control

Each laboratory should establish its own calibration frequency.

Qualitative analysis

For qualitative analysis, use the CEDIA Mitragynine 50 ng/mL calibrator as a cutoff level.

Semi-quantitative analysis

For semi-quantitative analysis, use all five calibrators.

Good laboratory practice requires the use of control specimens to ensure proper assay performance. Ensure that control results are within the established ranges, as determined by laboratory procedures and guidelines. If results fall outside of the established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own quality control testing frequency.

Results and Expected values

Qualitative

The 50 ng/mL calibrator is used as a cutoff reference for distinguishing 'positive' from 'negative' samples. A sample that exhibits a change in absorbance values (Δ A) equal to or greater than that obtained with the cutoff calibrator is considered as positive. A sample that exhibits a change in absorbance value (Δ A) lower than that obtained with the cutoff calibrator is considered as negative.

Semi-quantitative

An estimate of drug concentrations in the samples can be obtained by running a standard curve with all calibrators and estimating sample concentrations off the standard curve. Sample results above the high calibrator should be diluted with negative urine and retested.

Limitations

1. A positive result from this assay indicates only the presence of mitragynine or kratom alkaloids and does not necessarily correlate with the extent of physiological and psychological effects. This is a screening test. All positive results must be confirmed via GC/MS or LC-MS/MS.

2. It is possible that substances other than those investigated in the specificity study may interfere with the test and cause false results.

3. Care should be taken when reporting concentration results since there are many factors (e.g. fluid intake and other biologic factors) that may influence a urine test result.

4. Performance characteristics for the CEDIA Mitragynine Assay performance have not been established with body fluids other than human urine.

Specific Performance Characteristics

Typical performance results obtained on a Beckman Coulter AU680 analyzer are shown below. The results obtained in your laboratory may differ from these data.

Precision

Twenty day precision was performed using samples spiked with mitragynine, at 25% increments or decrements from the 50 ng/mL cutoff. Samples were tested in replicates of 2 (n=2), twice a day for 20 days (total n=80 for each level) in both qualitative and semi-quantitative modes. The results of the Precision study are shown below.

Qualitative Study Analysis

Mitragynine Spike Concentration (ng/mL)	% of Cutoff 50 ng/mL	LC-MS/MS (ng/mL)	Total Precision (n=80)			
			Number of Determinations	Immunoassay Results (Negative/ Positive)	Within-run CV (%)	Total-run CV (%)
0	-100%	N/A	80	80/0	0.48	1.39
12.5	-75%	12.8	80	80/0	0.47	1.32
25	-50%	24.7	80	80/0	0.51	1.34
37.5	-25%	37.7	80	80/0	0.60	1.30
50	100%	50.7	80	79/1	0.49	1.23
62.5	+25%	61.6	80	0/80	0.58	1.25
75	+50%	72.4	80	0/80	0.47	1.23
87.5	+75%	88.7	80	0/80	0.50	1.23
100	+100%	101	80	0/80	0.42	1.09

Semi-Quantitative Study Analysis

Mitragynine Spike Concentration (ng/mL)	% of Cutoff 50 ng/mL	LC-MS/MS (ng/mL)	Total Precision (n=80)			
			Number of Determinations	Immunoassay Results (Negative/ Positive)	Within-run CV (%)	Total-run CV (%)
0	-100%	N/A	80	80/0	N/A	N/A
12.5	-75%	12.8	80	80/0	6.70	8.03
25	-50%	24.7	80	80/0	3.66	5.08
37.5	-25%	37.7	80	80/0	2.08	2.63
50	100%	50.7	80	77/3	2.03	2.47
62.5	+25%	61.6	80	0/80	3.04	3.25
75	+50%	72.4	80	0/80	1.94	2.65
87.5	+75%	88.7	80	0/80	1.88	2.36
100	+100%	101	80	0/80	1.79	2.38

Accuracy

One hundred patient samples were analyzed by the CEDIA Mitragynine Assay in both qualitative and semi-quantitative modes and the results were compared to LC-MS/MS. The assay has 100% concordance with LC-MS/MS.

Qualitative Accuracy study with LC-MS/MS as reference method

Candidate Device Results	Negative	< 50% of Cutoff concentration by LC-MS/MS (< 25 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (25 – 49 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (50 – 75 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 75 ng/mL)
Positive	0	0	0	5	45
Negative	42	4	4	0	0

Semi-Quantitative Accuracy study with LC-MS/MS as reference method

Candidate Device Results	Negative	< 50% of Cutoff concentration by LC-MS/MS (< 25 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (25 – 49 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (50 – 75 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 75 ng/mL)
Positive	0	0	0	5	45
Negative	42	4	4	0	0

Note: Samples containing 4,000 ng/mL to 12,000 ng/mL mitragynine can result in a potential sample carry-over below the 20 ng/mL calibrator. A wash step is recommended after testing samples with high mitragynine concentrations. Refer to the application sheet of each clinical analyzer for the wash instructions.

Analytical Recovery and Linearity

To demonstrate the linearity for purposes of sample dilution and quality control of the entire assay range, drug-free urine was spiked to the high calibrator level of mitragynine (200 ng/mL) and diluted with drug-free urine to generate 10 intermediate levels. Each sample was run in replicates of 5 in semi-quantitative mode, and the average was used to determine percent recovery compared to the expected target value. When comparing the result observed (y) and target (x) value, using the least squares regression technique, the regression equation and correlation were as follows: y=0.9951x – 1.0959, and r^2 value was 0.9983.

Target Mitragynine Value (ng/mL)	Observed Value (ng/mL)	Recovery (%)
0	-0.1	N/A
10	9.7	97.0
20	19.2	96.2
40	37.0	92.6
60	58.2	97.0
80	78.7	98.3
100	94.3	94.3
120	116.7	97.3
140	141.0	100.7
160	163.2	102.0
180	180.5	100.3
200	193.0	96.5

Specificity

The cross-reactivity of mitragynine, mitragynine metabolites, and other kratom alkaloids in the CEDIA Mitragynine Assay were evaluated by adding known amounts of each analyte to drug-free urine. As indicated by the results in the table below, mitragynine exhibited 100% cross-reactivity, while mitragynine metabolites and other kratom alkaloids demonstrated lower cross-reactivity.

Kratom alkaloids and mitragynine metabolites	Tested Concentration (ng/mL)	Pos/Neg	Cross-reactivity (%)
Mitragynine	50	Pos	100
7-OH-Mitragynine	35,000	Pos	0.14
Paynantheine	25,000	Pos	0.2
Speciociliatine	25,000	Pos	0.2
Mitragynine acid (16-Carboxy-Mitragynine)	300	Pos	16.7
9-Hydroxycorynantheidine (9-O-Desmethyl-Mitragynine)	3125	Pos	1.6

The potential cross-reactivity of opiate and opioid compounds in the CEDIA Mitragynine Assay was evaluated at the concentrations indicated. Most compounds demonstrated minimal cross-reactivity.

Cross reactivity of opiate and opioid compounds

Opiate and Opioid Compounds	Tested Concentration (ng/mL)	Pos/Neg	Cross-reactivity (%)
6-Acetyl morphine	100,000	Neg	< 0.05
6-Acetyl codeine	100,000	Neg	< 0.05
Buprenorphine	100,000	Neg	< 0.05
Codeine	100,000	Neg	< 0.05
Dextromethorphan	100,000	Neg	< 0.05
Dihydrocodeine	100,000	Neg	< 0.05
Dihydromorphine	100,000	Neg	< 0.05
EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	60,000	Pos	0.08
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	100,000	Neg	< 0.05
Ethylmorphine	100,000	Neg	< 0.05
Fentanyl	100,000	Neg	< 0.05
Gabapentin	100,000	Neg	< 0.05
Diacetylmorphine (Heroin)	100,000	Neg	< 0.05
Hydrocodone	100,000	Neg	< 0.05
Hydromorphone	100,000	Neg	< 0.05
*LAAM (Levo-alpha-acetyl-methadol)	100,000	Neg	< 0.05

Table cont.

Opiate and Opioid Compounds	Tested Concentration (ng/mL)	Pos/Neg	Cross-reactivity (%)
Levorphanol	100,000	Neg	< 0.05
Meperidine	100,000	Neg	< 0.05
*Methadone	100,000	Neg	< 0.05
Morphine	100,000	Neg	< 0.05
Morphine-3ß-D-glucuronide	100,000	Neg	< 0.05
Morphine-6ß-D-glucuronide	100,000	Neg	< 0.05
Nalbuphine	100,000	Neg	< 0.05
Nalorphine	100,000	Neg	< 0.05
Naloxone	100,000	Neg	< 0.05
Naltrexone	100,000	Neg	< 0.05
Norbuprenorphine	100,000	Neg	< 0.05
Norcodeine	100,000	Neg	< 0.05
Norhydrocodone	100,000	Neg	< 0.05
Normeperidine	100,000	Neg	< 0.05
Norpropoxyphene	100,000	Neg	< 0.05
Noroxycodone	100,000	Neg	< 0.05
Noroxymorphone	100,000	Neg	< 0.05
Oxycodone	100,000	Neg	< 0.05
Oxymorphone	100,000	Neg	< 0.05
*Phencyclidine	100,000	Neg	< 0.05
Propoxyphene	100,000	Neg	< 0.05
Tapentadol	100,000	Neg	< 0.05
N-desmethyl-tapentadol	100,000	Neg	< 0.05
Tramadol	100,000	Neg	< 0.05
N-desmethyl-tramadol	100,000	Neg	< 0.05
O-desmethyl-tramadol	100,000	Neg	< 0.05

* LAAM, Methadone, and Phencyclidine at 100,000 ng/mL will give negative results below 50 ng/mL cutoff, and may have semi-quantitative values around 20-30 ng/mL.

The potential cross-reactivity posed by structurally unrelated drugs in the CEDIA Mitragynine Assay was evaluated at the concentrations indicated. A drug was considered to cross-react if the observed mitragynine concentrations result exceeded 50 ng/mL. As shown in the tables below, all the compounds evaluated, exhibited minimal cross-reactivity at the concentrations tested.

Structurally unrelated compounds spiked at the concentration listed below into negative urine

Structurally unrelated compounds	Tested Concentration (ng/mL)	Pos/Neg	Cross-reactivity (%)
5-Fluoro-AB PINACA	100,000	Neg	< 0.05
10,11 Dihydrocarbamazepine	100,000	Neg	< 0.05
11-nor-Δ^9-THC-COOH	100,000	Neg	< 0.05
Acetaminophen	1,000,000	Neg	< 0.005
Acetylsalicylic acid	1,000,000	Neg	< 0.005
*Alprazolam	100,000	Neg	< 0.05
*AM-2233	100,000	Neg	< 0.05
AMB-FUBINACA	100,000	Neg	< 0.05
Amitriptyline	100,000	Neg	< 0.05
Amoxicillin	100,000	Neg	< 0.05
Amphetamine	100,000	Neg	< 0.05
Benzoylecgonine	100,000	Neg	< 0.05
Bromazepam	100,000	Neg	< 0.05
Brompheniramine	100,000	Neg	< 0.05
Captopril	100,000	Neg	< 0.05
Chlorpromazine	100,000	Neg	< 0.05
*Chloroquine	100,000	Neg	< 0.05

Table cont.

Structurally unrelated compounds	Tested Concentration (ng/mL)	Pos/Neg	Cross-reactivity (%)
Cimetidine	100,000	Neg	< 0.05
Clonidine	100,000	Neg	< 0.05
Clomipramine	100,000	Neg	< 0.05
Clorazepate	100,000	Neg	< 0.05
Desipramine	100,000	Neg	< 0.05
Digoxin	100,000	Neg	< 0.05
Diphenhydramine	100,000	Neg	< 0.05
Doxepine HCl	100,000	Neg	< 0.05
Enalapril	100,000	Neg	< 0.05
Estazolam	100,000	Neg	< 0.05
Fluphenazine	100,000	Neg	< 0.05
Fluoxetine	100,000	Neg	< 0.05
Hydroxyzine	100,000	Neg	< 0.05
Ibuprofen	100,000	Neg	< 0.05
Imipramine	100,000	Neg	< 0.05
Maprotiline	100,000	Neg	< 0.05
m-CPP	100,000	Neg	< 0.05
Medazepam	100,000	Neg	< 0.05
MDPV	100,000	Neg	< 0.05
Methamphetamine	100,000	Neg	< 0.05
Methaqualone	100,000	Neg	< 0.05
Naproxen	100,000	Neg	< 0.05
Nitrazepam	100,000	Neg	< 0.05
N-Ethyl Pentylone	100,000	Neg	< 0.05
Nortryptiline	100,000	Neg	< 0.05
Nordiazepam	100,000	Neg	< 0.05
Oxazepam	100,000	Neg	< 0.05
Perphenazine	100,000	Neg	< 0.05
Phenelzine	100,000	Neg	< 0.05
Phenobarbital	100,000	Neg	< 0.05
Promethazine	100,000	Neg	< 0.05
Protriptytine	100,000	Neg	< 0.05
Ranitidine	100,000	Neg	< 0.05
Risperidone	100,000	Neg	< 0.05
Secobarbital	100,000	Neg	< 0.05
Sulpiride	100,000	Neg	< 0.05
Trazodone	100,000	Neg	< 0.05
Triazolam	100,000	Neg	< 0.05
Triprolidine	100,000	Neg	< 0.05
Verapamil	100,000	Neg	< 0.05
Zolpidem	100,000	Neg	< 0.05

*Alprazolam, AM-2233 and Chloroquine at 100,000 ng/mL will give negative results below 50 ng/mL cutoff, and may have semi-quantitative values around 20-30 ng/mL.

Interference

The potential interference of endogenous physiologic substances on the performance of the CEDIA Mitragynine Assay was assessed by spiking known compounds of potentially interfering substances into drug-free urine. In the presence of the compounds listed below, no interference was observed.

Compound	Tested Concentration (mg/dL)	Pos/Neg
Acetone	500	Neg
Ascorbic Acid	150	Neg
Caffeine	10	Neg
Creatinine	400	Neg
Ethanol	1000	Neg
Galactose	5	Neg
Glucose	1000	Neg
Hemoglobin	150	Neg
Human Serum Albumin	200	Neg
Oxalic acid	50	Neg
Riboflavin	3	Neg
Sodium Chloride	1000	Neg
Urea	1000	Neg

Urine pH

Drug-free urine adjusted to different pH ranging from pH 3.0 and pH 11.0 were demonstrated not to interfere with the CEDIA Mitragynine Assay, in both qualitative and semi-quantitative modes.

Urine pH	Pos/Neg
pH 3.0	Neg
pH 4.0	Neg
pH 5.0	Neg
pH 6.0	Neg
pH 7.0	Neg
pH 8.0	Neg
pH 9.0	Neg
pH 10.0	Neg
pH 11.0	Neg

Specific Gravity

Drug-free urine samples with specific gravity ranging in value from 1.004 to 1.031 were demonstrated not to interfere with the CEDIA Mitragynine Assay, in both qualitative and semi-quantitative modes.

Specific Gravity	Pos/Neg
1.004	Neg
1.005	Neg
1.006	Neg
1.006	Neg
1.011	Neg
1.015	Neg
1.019	Neg
1.021	Neg
1.024	Neg
1.025	Neg
1.031	Neg

References

1. Gong F, Gu H, Xu Q, Kang W. Genus *Mitragyna*: Ethnomedicinal uses and pharmacological studies. Phytopharmacology. 2012; 3(2): 263 – 272.
2. Hassan Z, Muzaimi M, Navaratnam V et al. From Kratom to mitragynine and its derivatives: Physiological and behavioral effects related to use, abuse, and addiction. *Neuroscience and Biobehavioral Reviews.* 2013; 37: 138 – 151.
3. Statement from FDA commissioner Scott Gottlieb, MD, on new warning letters FDA is issuing to companies marketing kratom with unproven medical claims; and the agency's ongoing concerns about kratom. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620106.htm (accessed January 21, 2019)
4. https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/12/04/as-kratom-use-surges-some-states-enact-bans (accessed January 17, 2019).
5. Henderson D, Friedman SB, Harrid JD et al. CEDIA, A new homogenous immunoassay system. *Clin Chem.* 1986; 32(9): 1637 – 1641.
6. Le D, Goggin MM, and Janis GC. Analysis of Mitragynine and Metabolites in Human Urine for Detecting the use of the Psychoactive Plant Kratom. J*ournal of Analytical Toxicology.* 2012; 36: 616 – 625.
7. Fu H, Cid FX, Dworkin N, Cocores J, Shore, G. Screening and Identification of Mitragynine and 7-Hydroxymitragynine in Human Urine by LC-MS/MS. *Chromatography.* 2015; 2: 253 – 264.
8. Health and Human Services Mandatory Guidelines. *Federal Register, Mandatory Guidelines For Federal Workplace Drug Testing Programs: Final Rule, Federal Register,* 82 FR 7920 – 2017 (October 1, 2017).

Glossary:

http://www.thermofisher.com/symbols-glossary

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