PRODUCT SPECIFICATION

A Novel Test for Mitragynine (Kratom)

Increasingly abused as an alternative to opioids

Mitragynine is the major alkaloid found in leaf extracts from the Kratom plant (Mitragyna speciosa) grown in Southeast Asia. The leaves are smoked, brewed as tea, ground into powder and mixed in chocolate bars, energy drinks or gel capsules. These can be purchased in smoke shops or over the internet. Scientific studies indicate that the active alkaloid, mitragynine, acts on the opioid receptors causing both psychological and physiological dependence.¹

Kratom is used worldwide as a recreational drug and is growing in popularity as an alternative to opioids. At low doses, users report increased physical energy, alertness and sociability. At moderate to high doses, users begin to experience the opioid-like effects with a reduction in pain or reduced effects from opioid witihdrawal.² Although Kratom metabolism studies are limited, one case study reported that mitragynine can be found in the urine 3-14 days after cessation in a chronic user.³

Kratom is not a controlled substance but is listed by the Drug Enforcement Agency (DEA) as a "drug of concern", since it can result in severe health effects or even death. ^{4,5} Kratom is illegal in seven states (Alabama, Arkansas, Indiana, Tennessee, Vermont, Wisconsin, and the District of Columbia) and three cities (Denver, San Diego and Sarasota, Florida). Legislation to ban Kratom was previously considered in six other states – Florida, Kentucky, New Hampshire, New Jersey, New York, and North Carolina. ⁶

The National Poison Control Data System (NPDS) noted a 52.5 fold increase in exposures to Kratom usage between 2011 and 2017, and the FDA has officially reported at least 44 deaths associated with its use.^{4,7} In a 2018 press release, the FDA



announced that Kratom is not safe and there is scientific data indicating that Kratom has high potential for addiction and abuse. As such, the FDA has not approved Kratom for medical use.

Benefits of using the Thermo Scientific[™] CEDIA[™] Mitragynine Assay

- Specifically detects mitragynine, the major active alkaloid of Kratom
- Excellent Correlation to LC-MS/MS: >99%
- Highly precise around the cutoff: CV <3.5%
- Applications available on a range of clinical analyzers
- Qualitative and Semi-quantitative detection

For Criminal Justice and Forensic Use Only



Accuracy

The CEDIA Mitragynine Assay uses a 50 ng/mL cutoff calibrator. 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.

		LC-MS/MS	
		+	-
CEDIA Mitragynine Assay	+	50	0
(50 ng/mL cutoff)	-	0	50

Specificity

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

Kratom Alkaloids	Tested Concentration (ng/mL)	Pos/Neg	Cross- reactivity (%)
Mitragynine	50	Pos	100
7-0H-Mitragynine	35,000	Pos	0.14
Paynantheine	25,000	Pos	0.20
Speciociliatine	25,000	Pos	0.20

Precision

Twenty day precision was performed on a Beckman Coulter AU680 analyzer 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 precision in qualitative mode is <2% CV and in semi-quantitative modes < 10% CV.

Ordering Information: 800-232-3342

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Part #	Description	Size		
Reagent				
10026604	CEDIA Mitragynine Reagent Kit, Indiko	3 x 17 mL		
10026612	CEDIA Mitragynine Reagent Kit	65 mL		
Calibrators				
10022753	CEDIA Negative Calibrator II CJ&F	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		
Controls				
10026594	CEDIA Mitragynine Control Set; 37.5 and 62.5 ng/mL	2 x 5 mL		

References

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- 2. Drugs of Abuse, A DEA Resource Guide: 2017 Edition, pg 84
- FG Kapp, HH Maurer, V Auwärter, M Winkelmann, M Hermanns-Clausen. Intrahepatic Cholestatis Following Abuse of Powdered Kratom (Mitragyna speciosa) J. Med Toxicol. (2011) 7:227-231
- S Post, HA Spiller, T Chounthirath, GA Smith. Kratom exposures reported to United States poison control centeres: 2011-2017, Clinical Toxicology, DOI: 10.1080/15563650.2019.1569236, 20 Feb 2019
- 5. Gerald Gianutsos, The DEA Changes its Mind on Kratom. US Pharm. 2017;41(3):7-9
- 6. https://www.pewtrusts.org/en/researchand-analysis/blogs/stateline/2017/12/04/ as-kratom-use-surges-some-states-enact-bans (accessed January 17, 2019)
- 7. https://www.drugabuse.gov/publications/drugfacts/kratom (accessed March 1, 2019)
- FDA In Brief: FDA objects to kratom compound intended for use as an alternative to prescription opioids and promoted with unproven clams to treat addiction. Press Release, FDA, Feb. 26, 2018

In the United States:

For customer service, call 1-800-232-3342 To fax an order, use 1-800-829-8115

To order online: mgc-masorders@thermofisher.com

Find out more at thermofisher.com/diagnostics

Patent pending



