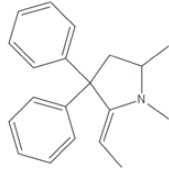


EDDP Specific Urine

Homogeneous Enzyme Immunoassay (HEIA™)

IMMUNALYSIS



Formula: C₂₀H₂₃N

Systematic Name: 2-ethylidene-1, 5-dimethyl-3,3-diphenylpyrrolidine

About EDDP: EDDP is the primary metabolite of methadone. It is excreted in the bile and urine together with the other metabolite EMPD. EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value, dose, and the patient's metabolism. Therefore, detection of the metabolite EDDP instead of methadone itself is useful because interferences of the patient's metabolism are avoided. EDDP can be detected within 4 to 6 hours after use. It can be cleared by the body within 2 to 3 days after use.

Administration: Pill, sublingual tablet, and oral formulations.

Elimination: Methadone has a typical half life of 15 to 55 hours and metabolizes by N-demethylation to its main metabolite, 2-ethylidene-1, 5-dimethyl-3,3-diphenylpyrrolidine (EDDP) and then N-demethylates to its secondary metabolite, 2-ethyl-5-methyl-3,3-diphenylpyrrolidine (EMDP). The considerable variation in Methadone metabolism and excretion is apparently due to genetic variability in the production of the associated enzymes CYP3A4, CYP2B6 and CYP2D6.¹⁻⁴

Abuse Potential: Methadone is a Schedule II controlled analgesic; it has the potential for being abused and is subject to criminal diversion.

FDA Cleared

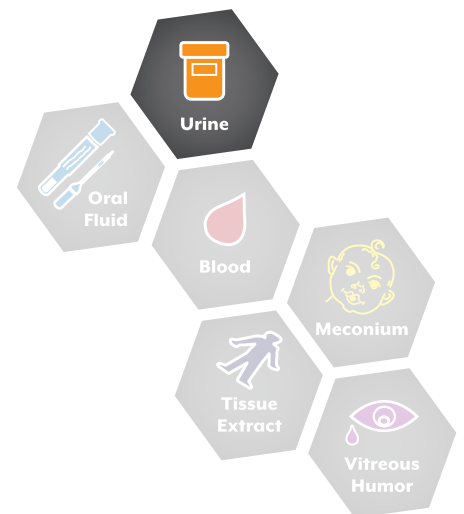
Indication of Methadone Ingestion

Cutoffs at 100, 300, or 1000 ng/mL

Semi-Quantitative or Qualitative Testing

Accurate and Reliable

Liquid, Ready to Use



1. Totah, R.A. et al. Enantioselective Metabolic Interactions and Stereoselective Human Methadone Metabolism. *Journal of Pharmacology and Experimental Therapeutics*. 321: 389-399 (2007).
2. Orsulak, P.J. et al. Clinical Application of the CEDIA EDDP (Methadone Metabolite) Assay. Poster section 2, SOFT-TIAFT (1998).
3. Preston, K.L. et al. Methadone and Metabolite Urine Concentration in Patients Maintained on Methadone. *Journal of Pharmacology and Experimental Therapeutics*. 27: 332-341 (2003).
4. Eap, C.B. et al. "Pharmacokinetics and Pharmacogenetics of Methadone: Clinical Relevance." *Heroin Addiction and Related Clinical Problems: The Official Journal of EUROPAD, European Opiate Addiction Treatment Association* 1 (1): 19-34 (1999).



EDDP Specific Urine (HEIA™)

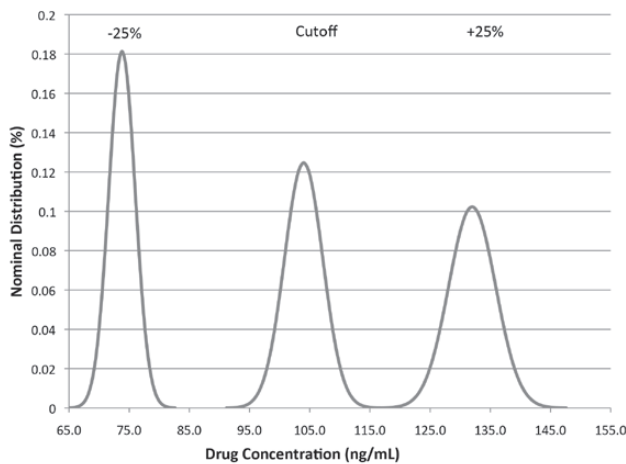


Assay Specifications

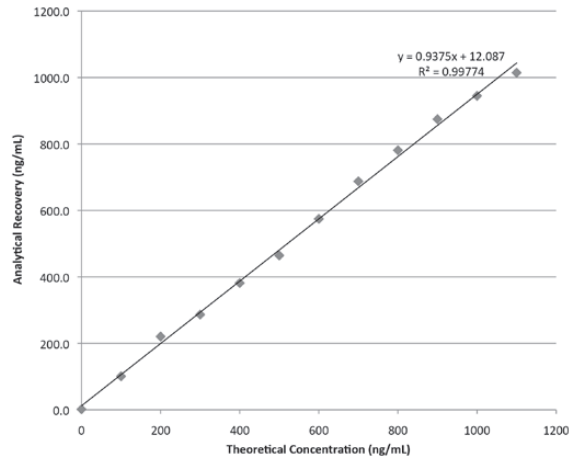
Methodology: Homogeneous Enzyme Immunoassay

Cutoff: 100 ng/mL **Calibration Range:** 0-1000 ng/mL

Overlap: EDDP (100 ng/mL Cutoff)



Analytical Recovery: EDDP



ORDER - EDDP Specific Urine (HEIA)

Catalog #	Description
349UR-0025	25 mL kit
349UR-0060W	60 mL wedge kit
349UR-0100	100 mL kit
349UR-0500	500 mL kit
Please refer to the product insert for calibrator and control set information	
Neg-10-1	10 mL Negative Standard

Cross-Reactivity

Analyte	Analyte Concentration (ng/mL)	Cross-Reactivity (%)
EDDP	100	100.00
Methadone	700,000	0.01
EMDP	1,000,000	<0.01
Chlorpromazine	90,000	0.11
Diphenhydramine	1,000,000	0.01
Methylphenidate	100,000	0.10
Doxylamine	1,000,000	<0.01
LAAM	1,000,000	<0.01
(±)-alpha methadol	1,000,000	0.01
(-)-iso-methadone	100,000	<0.10

LC-MS/MS Confirmation (100 ng/mL)

		Positive	Negative
HEIA (100 ng/mL)	Positive	40	1
	Negative	0	39

Semi-Quantitative Precision at 100 ng/mL

Interday Precision (n = 80)

Concentration (ng/mL)	Result	Total Result
25	NEG	80 Negative
50	NEG	80 Negative
75 Control LOW	NEG	80 Negative
100 Calibrator	n/a	10 Negative / 70 Positive
125 Control HIGH	POS	80 Positive
150	POS	80 Positive
175	POS	80 Positive
200	POS	80 Positive