



Buprenorphine Assay

Highly specific to free Buprenorphine and Norbuprenorphine, this innovative immunoassay for the qualitative and semi-quantitative detection of buprenorphine shows virtually no cross-reactivity to commonly prescribed opiates and opioids. The antibody employed binds specifically and almost equally to free buprenorphine and its main metabolite norbuprenorphine, thus eliminating potential false-positive results caused by other opiate glucuronides possibly present in the urine sample.

Assay Characteristics

- Antibody specific to Buprenorphine and Norbuprenorphine
- Extremely low cross-reactivity to morphine and other opioids, i.e. codeine, dihydrocodeine, tramadol, etc.
- Liquid, ready-to-use reagents, calibrators, and controls – no reconstitution
- Application protocols for all major clinical chemistry analysers
- Packaging tailored to your laboratory's needs
- Use of synthetic material to enhance stability of calibrators and controls and decrease risk of contamination



Background

Buprenorphine is a semi-synthetic opioid derived from thebaine, a natural alkaloid of the opium poppy. As a powerful analgesic with an approx. 25 to 40 times higher potency than morphine, buprenorphine has been used for several years now as medication for moderate to severe pain, in peri-operative analgesia, and for the treatment of heroin addiction in replacement therapy.

Buprenorphine is widely used to prevent withdrawal symptoms. It may itself cause dependency and there is considerable

potential for diversion and abuse. Typical signs for a buprenorphine overdose include confusion, dizziness, pinpoint pupils, hallucinations, hypotension, respiratory difficulty, seizures and coma.

Buprenorphine is metabolized by N-dealkylation to norbuprenorphine, followed by glucuronide conjugation of both buprenorphine and norbuprenorphine. The amount of norbuprenorphine excreted in urine generally exceeds that of conjugated buprenorphine.



Cross-Reactivities

Analyte	Analyte Concentration	Cross Reactivity
Buprenorphine	5 ng/mL	100 %
Norbuprenorphine	5.5 ng/mL	90.91 %
Buprenorphine Glucuronide	3 000 ng/mL	0.17 %
Norbuprenorphine Glucuronide	4 000 ng/mL	0.13 %
6-Acetylmorphine	100 000 ng/mL	N/D
Codeine	100 000 ng/mL	N/D
Dihydrocodeine	100 000 ng/mL	N/D
Morphine	100 000 ng/mL	N/D
Morphine-3-Glucuronide	100 000 ng/mL	N/D
Morphine-6-Glucuronide	100 000 ng/mL	N/D

Within-Run Precision

The samples were tested after calibration in a single run, performing 20 replicates each level on a Beckman Coulter AU400 Analyser System.

5 ng/mL Cutoff	Blank	Low Control	Cutoff Calibrator	High Control	Calc. Limits
Target (ng/mL)	0.00	3.75	5.00	6.25	LDD
Mean (ng/mL)	0.07	3.98	4.55	6.34	0.32
Within-run SD (ng/mL)	0.16	0.23	0.15	0.22	LoD
Within-run CV (%)		5.90	3.31	3.52	0.55
N	20	20	20	20	LoQ
Recovery (%)		106.1	91.0	101.4	1.51

Accuracy

A total of 100 human urine samples were assayed with the Immunalysis Buprenorphine Assay at 5 ng/mL on the Roche Hitachi 717 analyser against LC-MS/MS:

5 ng/mL semi-quantitative	LC-MS/MS	
	+	-
Hitachi 717	+	37
	-	0
		63

Ordering Information

Reagents	Size	Order No.
Buprenorphine HEIA Kit	25 mL	36UR-0025
	60 mL	336UR-0060W
	100 mL	336UR-0100
Calibrators		
Buprenorphine Calibrator, 5 ng/mL	1 x 10 mL	C336UR-10-1
Buprenorphine Calibrator Set, 0, 5, 10, 20, 40 ng/mL	5 x 10 mL	C336UR-10-5
Controls		
Buprenorphine Control Set, 3.75 and 6.25 ng/mL	2 x 10 mL	C336UR-10-2

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