

6-ACETYLMORPHINE ENZYME IMMUNOASSAY 510(k) Cleared

Liquid Homogeneous Enzyme Immunoassay

Lin-Zhi International's LZI 6-Acetylmorphine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of 6-acetylmorphine in human urine at a cutoff value of 10 ng/mL. The reagent kit, calibrators, and controls are ready-to-use and have 18 months of real-time stability data. The results shown below were performed on the Hitachi 717.

Precision

Oualitative

Results were measured in mA/min

	Within-Run (N=22)		Total (N=88)			
	Mean	SD	%CV	Mean	SD	%CV
0 ng/mL	358.6	2.2	0.6%	358.6	2.4	0.7%
2.5 ng/mL	380.0	2.5	0.7%	380.0	2.8	0.7%
5 ng/mL	399.4	2.2	0.6%	399.4	2.4	0.6%
7.5 ng/mL	419.5	2.4	0.6%	419.5	2.7	0.6%
10 ng/mL	437.4	2.2	0.5%	437.4	2.6	0.6%
12.5 ng/mL	454.8	2.0	0.4%	454.8	3.0	0.7%
15 ng/mL	470.4	3.8	0.8%	470.4	4.6	1.0%
17.5 ng/mL	489.2	2.3	0.5%	489.2	3.0	0.6%
20 ng/mL	500.1	2.2	0.4%	500.1	2.8	0.6%

Semi-Quantitative

Results were measured in ng/mL

	Within-Run (N=22)		Total (N=88)		
	Mean	Qualitative Response	Mean	Qualitative Response	
0 ng/mL	0.2	Neg	0.2	Neg	
2.5 ng/mL	2.8	Neg	2.8	Neg	
5 ng/mL	5.1	Neg	5.1	Neg	
7.5 ng/mL	7.4	Neg	7.4	Neg	
10 ng/mL	9.7	Neg	9.7	Neg	
12.5 ng/mL	12.2	Pos	12.2	Pos	
15 ng/mL	14.6	Pos	14.6	Pos	
17.5 ng/mL	17.7	Pos	17.7	Pos	
20 ng/mL	19.9	Pos	19.9	Pos	

Method Comparison

Qualitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	0	7	31	95.0%
Neg	10	14	16	2	0	100.0%

Semi-Quantitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	0	6	31	93.0%
Neg	10	14	16	3	0	100.0%

Cross Reactivity Structurally Related Compounds

Compounds	[] Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Codeine	500,000	0.0%
Dextromethorphan	100,000	0.0%
Dihydrocodeine	500,000	0.0%
Heroin	200	3.83%
Hydrocodone	300,000	0.0%
Hydromorphone	100,000	0.0%
Imipramine	200,000	0.0%
Levorphanol	100,000	0.0%
Meperidine	800,000	0.0%
Morphine	100,000	0.0%
Morphine-3-Glucuronide	600,000	0.0%
Morphine-6-Glucuronide	600,000	0.0%
Nalorphine	100,000	0.0%
Naloxone	500,000	0.0%
Naltrexone	300,000	0.0%
Norcodeine	600,000	0.0%
Normorphine	100,000	0.0%
Oxycodone	500,000	0.0%
Oxymorphone	100,000	0.0%

Structurally Unrelated Compounds

Table below shows the maximal concentration of the compound tested without interference.

Compounds	[] Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Benzoylecgonine	500,000	0.0%
Chlorpromazine	250,000	0.0%

For additional product performance details, see product insert.

Ordering Information

Ref#	Product		Size
0290	6-Acetylmorphine EIA, Small Kit	(R_1/R_2) 100)/37.5 mL
0291	6-Acetylmorphine EIA, Large Kit	(R_1/R_2) 100	0/375 mL
0299	6-Acetylmorphine Negative Calibrator		5 mL
0292	6-Acetylmorphine 5 ng/mL Low Calibr	ator	5 mL
0293	6-Acetylmorphine 10 ng/mL Cutoff Ca	librator	5 mL
0294	6-Acetylmorphine 20 ng/mL Inter. Cali	ibrator	5 mL
0295	6-Acetylmorphine 40 ng/mL High Calil	brator	5 mL
0297	6-Acetylmorphine 7.5 ng/mL Level 1 C	ontrol	5 mL
0298	6-Acetylmorphine 12.5 ng/mL Level 2 0	Control	5 mL

DA: 10/23/2024

