

Lin-Zhi International, Inc.

dedicated to the development of
innovative and quality products for
clinical diagnostics



FDA 510k CLEARED OXYCODONE LIQUID HOMOGENEOUS E.I.A.

Lin-Zhi International's Oxycodone assay is a homogeneous enzyme immunoassay, and intended for use in the qualitative and semi-quantitative determination, of Oxycodone and its metabolite, Oxymorphone in human urine at cutoffs of 100 and 300 ng/mL.

Liquid Homogeneous Enzyme Immunoassay

- 2 Cutoffs: 100 & 300 ng/mL
- Ready to use
- 12 month minimum shelf life
- Fully automated results in minutes
- LOD (100ng/mL Cutoff): 7.5 ng/mL
- LOD (300ng/mL Cutoff): 15 ng/mL
- Available in small & large test kits
- Small test kit is 100/37.5 mL R1/R2
- Large test kit is 1000/37.5 mL R1/R2

Cross Reactivity

Compound	Target Concentration (ng/mL)	Cross Reactivity	Target Concentration (ng/mL)	
			300 ng/mL Cutoff	100 ng/mL Cutoff
Oxycodone	300	Positive	100	Positive
Hydrocodone	550	Positive	175	Positive
Hydromorphone	1,200	Positive	250	Positive
Oxymorphone	325	Positive	125	Positive

Precision: Qualitative

100 ng/mL Cutoff

N=120 (mA/min)	Within-Run Precision			Total Precision		
	Mean	SD	%CV	Mean	SD	%CV
75 ng/mL	281	1.8	0.6%	281	3.0	1.1%
100 ng/mL	296	1.9	0.7%	296	3.6	1.2%
125 ng/mL	319	2.0	0.6%	319	4.3	1.4%

300 ng/mL Cutoff

N=120 (mA/min)	Within-Run Precision			Total Precision		
	Mean	SD	%CV	Mean	SD	%CV
225 ng/mL	296	1.8	0.6%	296	2.2	0.7%
300 ng/mL	331	2.2	0.7%	331	3.1	0.9%
375 ng/mL	356	2.1	0.6%	356	2.6	0.7%

Precision: Semi-Quantitative

100 ng/mL Cutoff

N=120 (ng/mL)	Within-Run Precision			Total Precision		
	Mean	SD	%CV	Mean	SD	%CV
75 ng/mL	281	1.8	0.6%	281	3.0	1.1%
100 ng/mL	296	1.9	0.7%	296	3.6	1.2%
125 ng/mL	319	2.0	0.6%	319	4.3	1.4%

300 ng/mL Cutoff

N=120 (ng/mL)	Within-Run Precision			Total Precision		
	Mean	SD	%CV	Mean	SD	%CV
225 ng/mL	225	4.8	2.1%	225	5.8	2.6%
300 ng/mL	280	5.1	1.9%	280	6.8	2.4%
375 ng/mL	368	6.4	1.8%	368	9.4	2.6%

ORDERING INFORMATION

Cat #	Product	Size
0240	OXY E.I.A.	Small
0241	OXY E.I.A.	Large
0242	75 ng/mL Calibrator/Control	5 mL
0243	100 ng/mL Calibrator	5 mL
0244	125 ng/mL Calibrator	5 mL
0245	225 ng/ml Calibrator/Control	5 mL
0246	300 ng/mL Calibrator	5 mL
0247	375 ng/mL Control	5 mL
0248	500 ng/mL Calibrator	5 mL
0249	800 ng/mL Calibrator	5 mL

Analytical Recovery

