

HYD 300

HYDROCODONE ENZYME IMMUNOASSAY 510(k) Cleared FOR 300 ng/mL CUTOFF

Liquid Homogeneous Enzyme Immunoassay

Lin-Zhi International's LZI Hydrocodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of hydrocodone and its metabolite, hydromorphone, in human urine at a cutoff value of 300 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 Beckman Coulter AU480.

Precision

Qualitative - Results were measured in ΔOD, mAU

	Within-Run (N=22)		Total (N=88)	
	# Samples	Result	# Samples	Result
0 ng/mL	22	22 Neg	88	88 Neg
75 ng/mL	22	22 Neg	88	88 Neg
150 ng/mL	22	22 Neg	88	88 Neg
225 ng/mL	22	22 Neg	88	88 Neg
300 ng/mL	22	11 Neg/11 Pos	88	37 Neg/51 Pos
375 ng/mL	22	22 Pos	88	88 Pos
450 ng/mL	22	22 Pos	88	88 Pos
525 ng/mL	22	22 Pos	88	88 Pos
600 ng/mL	22	22 Pos	88	88 Pos

Semi-Quantitative - Results were measured in ng/mL

	Within-Run (N=22)		Total (N=88)	
	# Samples	Result	# Samples	Result
0 ng/mL	22	22 Neg	88	88 Neg
75 ng/mL	22	22 Neg	88	88 Neg
150 ng/mL	22	22 Neg	88	88 Neg
225 ng/mL	22	22 Neg	88	88 Neg
300 ng/mL	22	8 Neg/14 Pos	88	41 Neg/47 Pos
375 ng/mL	22	22 Pos	88	88 Pos
450 ng/mL	22	22 Pos	88	88 Pos
525 ng/mL	22	22 Pos	88	88 Pos
600 ng/mL	22	22 Pos	88	88 Pos

Method Comparison

Qualitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	2	6	32	95.0%
Neg	20	12	6	2	0	95.0%

Semi-Quantitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	2	6	32	95.0%
Neg	20	12	6	2	0	95.0%

Cross Reactivity

Hydrocodone & Metabolites

Compounds	[] Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Hydrocodone	300	99.7%
Hydromorphone	375	78.1%
Hydromorphone Glucuronide	625	49.2%
Dihydrocodeine	8750	3.3%
Norhydrocodone	30,000	0.5%

Structurally Related Compounds

Compounds	[] Equivalent to Cutoff (ng/mL)	% Cross Reactivity
6-monoacetylmorphine	6500	1.6%
Codeine	3000	3.5%
Codeine-6-Glucuronide	15,000	0.6%
Dextromethorphan	100,000	0.0%
Morphine	5000	2.0%
Morphine-3-Glucuronide	13,000	0.8%
Morphine-6-Glucuronide	50,000	0.2%
Nalbuphine	100,000	0.0%
Naloxone	100,000	0.0%
Norbuprenorphine	100,000	0.0%
Norcodeine	100,000	0.0%
Noroxycodone	100,000	0.0%
Noroxymorphone	100,000	0.0%
Oxycodone	5000	2.1%
Oxymorphone	7500	1.3%

For additional product performance details, see product insert.

Ordering Information

Ref #	Product	Size
0390	Hydrocodone EIA, Small Kit (R ₁ /R ₂)	100/37.5 mL
0391	Hydrocodone EIA, Large Kit (R ₁ /R ₂)	1000/375 mL
0001	Universal Negative Calibrator	5 mL
0392	Hydrocodone 150 ng/mL Low Calibrator	5 mL
0393	Hydrocodone 300 ng/mL Cutoff Calibrator	5 mL
0394	Hydrocodone 500 ng/mL Inter. Calibrator	5 mL
0395	Hydrocodone 800 ng/mL High Calibrator	5 mL
0397	Hydrocodone 225 ng/mL Level 1 Control	5 mL
0398	Hydrocodone 375 ng/mL Level 2 Control	5 mL

DA: 10/23/2024

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ISO 13485:2016

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SAL/0104-1.HYD.300.Rev.5

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