MAMP

510(k) Cleared METHAMPHETAMINE ENZYME IMMUNOASSAY

Liquid Homogeneous Enzyme Immunoassay

Lin-Zhi International's LZI Methamphetamine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of d-methamphetamine in human urine at a cutoff value of 500 ng/mL when calibrated against d-methamphetamine. 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 clinical analyzers.

Precision

Oualitative Analysis

Results were measured in \(\Delta mA/min \)

	Within-Run (N=22)			Total (N=88)		
_	Mean	SD	%CV	Mean	SD	%CV
0 ng/mL	92.6	0.7	0.7%	92.6	1.0	1.1%
125 ng/mL	122.1	0.7	0.6%	122.1	1.0	0.8%
250 ng/mL	167.2	1.0	0.6%	167.2	1.4	0.8%
375 ng/mL	210.0	1.1	0.5%	210.0	1.6	0.8%
500 ng/mL	244.9	1.3	0.6%	244.9	1.9	0.8%
625 ng/mL	273.5	1.5	0.6%	273.5	2.2	0.8%
750 ng/mL	296.5	2.2	0.7%	296.5	2.5	0.9%
875 ng/mL	318.1	1.8	0.6%	318.1	2.4	0.7%
1000 ng/mL	336.5	2.1	0.6%	336.5	3.0	0.9%

Semi-Quantitative Analysis

Results were measured in \(\Delta mA/min \)

	Within-Run (N=22)		Total (N=88)			
	Mean	SD	%CV	Mean	SD	%CV
0 ng/mL	6.0	4.8	N/A	6.0	5.5	N/A
125 ng/mL	112.3	2.7	2.4%	112.3	4.0	3.6%
250 ng/mL	249.6	2.8	1.1%	249.6	4.6	1.9%
375 ng/mL	387.1	4.6	1.2%	387.1	5.4	1.4%
500 ng/mL	513.5	6.1	1.2%	513.5	8.3	1.6%
625 ng/mL	635.6	7.5	1.2%	635.6	9.6	1.5%
750 ng/mL	751.0	8.1	1.1%	751.0	12.1	1.6%
875 ng/mL	868.4	11.9	1.4%	868.4	14.9	1.7%
1000 ng/mL	987.7	11.3	1.1%	987.7	15.2	1.5%
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Method Comparison

Qualitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	0	9	37	97.9%
Neg	20	16	12	1	0	100.0%

Semi-Quantitative Accuracy Study

	Neg	< 50 % Cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % Cutoff	% Agree- ment
Pos	0	0	0	9	37	97.9%
Neg	20	16	12	1	0	100.0%

Cross Reactivity Structurally Related Compounds

Compounds	Cutoff Equivalent Conc (ng/mL)	% Cross Reactivity
d-Amphetamine	10,000	2.54%
l-Amphetamine	12,000	1.02%
Atomoxetine	500,000	0.03%
Benzphetamine	500,000	0.03%
d-Ephedrine	150,000	0.32%
d,l-Ephedrine	200,000	0.21%
<i>l</i> -Ephedrine	100,000	0.35%
Fenfluramine	4000	10.83%
Flephedrone; 4-FMC	200,000	0.16%
3-Hydroxy-Tyramine	500,000	0.04%
Mephentermine	25,000	0.43%
l-Methamphetamine	5000	9.73%
PMA	400	3.19%
PMMA	500	74.94%
MDA	1400	2.04%
MDEA	10,000	3.50%
MDMA	1000	38.91%
Mephedrone; 4-MMC; PMMC	100,000	0.39%
Phenethylamine	25,000	1.18%
Phenmetrazine	40,000	1.05%
Phentermine	20,000	0.20%
Phenylephrine	300,000	0.16%
d,l-Phenylpropanolamine	150,000	0.06%
d-Pseudoephedrine	112,500	0.39%
l-Pseudoephedrine	200,000	0.09%
Tyramine	400,000	0.09%

For additional product performance details, see product insert.

Ordering Information

Ref#	Product	Size
0350	Methamphetamine EIA, Small Kit (R ₁ /R ₂) 100	/37.5 mL
0351	Methamphetamine EIA, Large Kit (R_1/R_2) 1000)/375 mL
0001	Universal Negative Calibrator	5 mL
0352	Methamphetamine 250 ng/mL Low Calibrator	5 mL
0353	Methamphetamine 500 ng/mL Cutoff Calibrator	5 mL
0354	Methamphetamine 1000 ng/mL Intermediate Calibra	tor 5 mL
0355	Methamphetamine 2000 ng/mL High Calibrator	5 mL
0357	Methamphetamine 375 ng/mL Level 1 Control	5 mL
0358	Methamphetamine 625 ng/mL Level 2 Control	5 mL

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