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BENZODIAZEPINE ENZYME IMMUNOASSAY 510(k) Cleared

Liquid Homogeneous Enzyme Immunoassay

Lin-Zhi International's LZI Benzodiazepine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of benzodiazepine in human urine at a cutoff value of 200 ng/mL or 300 ng/mL when calibrated against oxazepam. 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

Qualitative analysis

Results were measured in Δ mA/min

	Within-Run (N=21)			Run-to-Run (N=12)		
	Mean	SD	%CV	Mean	SD	%CV
Negative	361.0	3.1	0.9 %	360.0	2.5	0.7 %
100 ng/mL	417.8	3.5	0.8 %	417.9	2.5	0.6 %
200 ng/mL	455.5	3.5	0.8 %	457.0	1.9	0.5 %
300 ng/mL	483.3	3.5	0.7 %	483.6	2.4	0.6 %
1000 ng/mL	559.7	4.9	0.7 %	561.8	3.3	0.6 %

Semi-quantitative analysis

Results were measured in ng/mL

	Within-Run (N=21)			Run-to-Run (N=12)		
	Mean	SD	%CV	Mean	SD	%CV
100 ng/mL	105.7	7.6	7.2 %	95.8	6.4	6.7 %
200 ng/mL	203.6	5.9	2.9 %	192.0	6.5	3.4 %
300 ng/mL	281.8	11.1	3.9 %	294.8	15.5	5.3 %
400 ng/mL	373.9	15.3	4.1 %	398.6	15.4	3.9 %

Method Comparison

200 ng/mL cutoff		GC/MS or HPLC	
		Pos	Neg
LZI Benzodiazepine EIA	Pos	64	2
	Neg	8	42

300 ng/mL cutoff		GC/MS or HPLC	
		Pos	Neg
LZI Benzodiazepine EIA	Pos	61	2
	Neg	11	42

Cross Reactivity

The following table summarizes the approximate quantity of each compound that is equivalent in assay reactivity to the 200 ng/mL and 300 ng/mL benzodiazepine cutoffs or the maximal concentration of the compound tested that gave a response with cross-reactivity below the response of the cutoff calibrators

Compounds	Concentration (ng/mL) at 200 ng/mL	Concentration (ng/mL) at 300 ng/mL
Oxazepam	200	300

Structurally Related Compounds

Compounds	Concentration (ng/mL) at 200 ng/mL cutoff	Concentration (ng/mL) at 300 ng/mL cutoff
7-aminoflunitrazepam	67,000	1,000
α -hydroxyalprazolam	275	425
Alprazolam	75	100
Bromazepam	2,100	5,000
Clorazepate	65	125
Chlordiazepoxide	750	1,300
Clobazam	169	247
Clonazepam	80	200
Diazepam	50	70
Efavirenz	500,000	500,000
Flunitrazepam	90	135
Flurazepam	50	75
Lorazepam	43	54
Lormetazepam	23	70
Medazepam	23	70
Midazolam	330	450
Nitrazepam	150	220
Nordiazepam	290	450
Norfludiazepam	15	25
Prazepam	75	105

Structurally Unrelated Compounds

Compounds	Concentration (ng/mL) at 200 ng/mL cutoff	Concentration (ng/mL) at 300 ng/mL cutoff
7-aminoflunitrazepam	67,000	1,000
α -hydroxyalprazolam	275	425
Alprazolam	75	100
Bromazepam	2,100	5,000
Clorazepate	65	125
Chlordiazepoxide	750	1,300

For additional product performance details, see product insert.

Ordering Information

Ref #	Product	Size
0130	Benzodiazepine EIA Kit, small test kit (R_1/R_2)	100/37.5 mL
0131	Benzodiazepine EIA Kit, large test kit (R_1/R_2)	1000/375 mL
0001	Universal Negative Calibrator	5 mL
0132	Benzodiazepine 100 ng/mL Low Calibrator	5 mL
0133	Benzodiazepine 200 ng/mL Cutoff Calibrator	5 mL
0134	Benzodiazepine 300 ng/mL Intermediate Calibrator	5 mL
0135	Benzodiazepine 1000 ng/mL High Calibrator	5 mL
0136	Benzodiazepine 400 ng/mL Control	5 mL

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