

# AMP500

## AMPHETAMINES 500 ENZYME IMMUNOASSAY 510(k) Cleared

### Liquid Homogeneous Enzyme Immunoassay

**Lin-Zhi International's** LZI Amphetamines 500 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of methamphetamine and amphetamine 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.

### Precision

#### Qualitative analysis

Results were measured in mA/min

|            | Within-Run (N=22) |     |       | Total (N=88) |     |       |
|------------|-------------------|-----|-------|--------------|-----|-------|
|            | Mean              | SD  | %CV   | Mean         | SD  | %CV   |
| 0 ng/mL    | 273.5             | 2.8 | 1.0 % | 273.5        | 3.4 | 1.2 % |
| 125 ng/mL  | 314.5             | 2.2 | 0.7 % | 314.5        | 3.0 | 0.9 % |
| 250 ng/mL  | 359.0             | 2.2 | 0.6 % | 359.0        | 3.4 | 0.9 % |
| 375 ng/mL  | 398.2             | 3.0 | 0.8 % | 398.2        | 4.1 | 1.0 % |
| 500 ng/mL  | 431.3             | 3.0 | 0.7 % | 431.3        | 4.3 | 1.0 % |
| 625 ng/mL  | 459.6             | 3.8 | 0.8 % | 459.6        | 5.2 | 1.1 % |
| 750 ng/mL  | 489.2             | 3.9 | 0.8 % | 489.2        | 5.4 | 1.1 % |
| 875 ng/mL  | 509.7             | 4.1 | 0.8 % | 509.7        | 5.1 | 1.0 % |
| 1000 ng/mL | 533.1             | 3.7 | 0.7 % | 533.1        | 4.8 | 0.9 % |

#### Semi-quantitative analysis

Results were measured in ng/mL

|            | Within-Run (N=22) |      |       | Total (N=88) |      |       |
|------------|-------------------|------|-------|--------------|------|-------|
|            | Mean              | SD   | %CV   | Mean         | SD   | %CV   |
| 0 ng/mL    | 5.6               | 5.3  | N/A   | 5.6          | 7.5  | N/A   |
| 125 ng/mL  | 128.3             | 6.4  | 5.0 % | 128.3        | 8.4  | 6.6 % |
| 250 ng/mL  | 252.9             | 6.1  | 2.4 % | 252.9        | 9.1  | 3.6 % |
| 375 ng/mL  | 369.6             | 11.4 | 3.1 % | 369.6        | 14.6 | 4.0 % |
| 500 ng/mL  | 489.9             | 11.7 | 2.4 % | 489.9        | 15.9 | 3.2 % |
| 625 ng/mL  | 605.3             | 17.6 | 2.9 % | 605.3        | 19.3 | 3.2 % |
| 750 ng/mL  | 746.5             | 16.3 | 2.2 % | 746.5        | 18.9 | 2.5 % |
| 875 ng/mL  | 867.7             | 22.9 | 2.6 % | 867.7        | 25.6 | 3.0 % |
| 1000 ng/mL | 1024.2            | 34.0 | 3.3 % | 1024.2       | 41.8 | 4.1 % |

### Method Comparison

#### Qualitative Accuracy Study

|     | Neg | < 50%<br>below<br>the cutoff | Near<br>Cutoff<br>Neg | Near<br>Cutoff<br>Pos | > 50%<br>above<br>the cutoff | % Agree-<br>ment |
|-----|-----|------------------------------|-----------------------|-----------------------|------------------------------|------------------|
| Pos | 0   | 4                            | 9                     | 9                     | 34                           | 100%             |
| Neg | 4   | 20                           | 6                     | 0                     | 0                            | 69.8%*           |

#### Semi-Quantitative Accuracy Study

|     | Neg | < 50%<br>below<br>the cutoff | Near<br>Cutoff<br>Neg | Near<br>Cutoff<br>Pos | > 50%<br>above<br>the cutoff | % Agree-<br>ment |
|-----|-----|------------------------------|-----------------------|-----------------------|------------------------------|------------------|
| Pos | 0   | 4                            | 10                    | 9                     | 34                           | 100%             |
| Neg | 4   | 20                           | 5                     | 0                     | 0                            | 67.4%*           |

### Cross Reactivity

#### Amphetamines Compounds

| Compounds                 | Target<br>(ng/mL) | Observed Value<br>(ng/mL) | % Cross-<br>reactivity |
|---------------------------|-------------------|---------------------------|------------------------|
| <i>d</i> -amphetamine     | 500               | 480.7                     | 96.1%                  |
| <i>d</i> -methamphetamine | 500               | 489.4                     | 97.9%                  |

#### Structurally Related Compounds

| Compounds                                  | Target<br>conc | Observed Value<br>(ng/mL) | % Cross-<br>Reactivity |
|--|----------------|---------------------------|------------------------|
| <i>l</i> -Amphetamine                      | 12,000         | 271.6                     | 2.3%                   |
| <i>d</i> -Ephedrine                        | 150,000        | 400.7                     | 0.3%                   |
| <i>l</i> -Ephedrine                        | 200,000        | 409.1                     | 0.2%                   |
| Fenfluramine                               | 4,000          | 433.3                     | 10.8%                  |
| Mephentermine                              | 25,000         | 57.4                      | 0.2%                   |
| <i>l</i> -Methamphetamine                  | 5,000          | 386.1                     | 7.7%                   |
| para-Methoxyamphetamine<br>(PMA)           | 400            | 433.8                     | 108.4%                 |
| Methylenedioxy-<br>amphetamine (MDA)       | 1,400          | 306.0                     | 21.9%                  |
| Methylenedioxyethyl-<br>amphetamine (MDEA) | 10,000         | 441.9                     | 4.4%                   |
| Methylenedioxymeth-<br>amphetamine (MDMA)  | 1,250          | 427.1                     | 34.2%                  |
| Phenethylamine                             | 25,000         | 411.4                     | 1.7%                   |
| Phentermine                                | 20,000         | 416.3                     | 2.1%                   |
| <i>d,l</i> -Phenylpropanolamine            | 150,000        | 403.9                     | 0.3%                   |
| <i>d</i> -Pseudoephedrine                  | 150,000        | 422.3                     | 0.3%                   |
| <i>l</i> -Pseudoephedrine                  | 200,000        | 106.9                     | 0.1%                   |
| Tranilcypromine                            | 50,000         | 399.1                     | 0.8%                   |

For additional product performance details, see product insert.

### Ordering Information

| Ref # | Product  | Size        |
|-------|--|-------------|
| 0100  | Amphetamines EIA Kit, small test kit ( $R_1/R_2$ ) | 100/37.5 mL |
| 0101  | Amphetamines EIA Kit, large test kit ( $R_1/R_2$ ) | 1000/375 mL |
| 0001  | Universal Negative Calibrator                      | 5 mL        |
| 0102  | Amphetamines 250 ng/mL Low Calibrator              | 5 mL        |
| 0103  | Amphetamines 500 ng/mL Cutoff Calibrator           | 5 mL        |
| 0104  | Amphetamines 1000 ng/mL Intermediate Calibrator    | 5 mL        |
| 0105  | Amphetamines 2000 ng/mL High Calibrator            | 5 mL        |
| 0107  | Amphetamines 375 ng/mL Level 1 Control             | 5 mL        |
| 0108  | Amphetamines 625 ng/mL Level 2 Control             | 5 mL        |

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