LZI Oral Fluid Amphetamine Enzyme Immunoassay

IVD For In Vitro Diagnostic Use Only

REF S0040b (75/37.5 mL R_1/R_2 Kit)
S0041b (750/375 mL R_1/R_2 Kit)

2ºC – 8ºC

Rx ONLY

Lin-Zhi International, Inc.

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Amphetamine Enzyme Immunoassay (EIA) is a homogeneous enzyme immunoassay intended for the qualitative and semi-quantitative determination of *d*-amphetamine in neat human oral fluid, collected into an LZI Oral Fluid Collector, at the cutoff value of 50 ng/mL. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

The assay provides a rapid screening procedure for determining the presence of *d*-amphetamine in human oral fluid. The assay provides only a preliminary analytical result. A more specific alternative analytical chemistry method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS) is the preferred confirmatory methods (1, 2). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Summary and Explanation of Test

Amphetamines are a class of phenethylamine drugs that have sympathomimetic activity, which imitate the stimulating actions of the endogenous neurotransmitter (3). The ability of amphetamines to alleviate fatigue, improve mental and physical performances, elevate mood, and produce euphoria have led to the abuse of these legitimate drugs. Amphetamines are psychologically and physiologically addicting. Chronic, high dose abuse can lead to a psychosis condition indistinguishable from acute schizophrenia (4).

The most common amphetamines include *d*-methamphetamine and *d*-amphetamine (5). Analogs of amphetamine such as 3, 4-methylenedioxymethamphetamine (MDMA; Ecstasy) and 3, 4-methylenedioxyamphetamine (MDA) have recently become popular at "rave parties" in both the United States and Europe (3, 6).

Amphetamines can be taken orally, intravenously, or by smoking or snorting. They are rapidly absorbed from the gastrointestinal tract and then either metabolized in the liver or excreted in urine unchanged (3, 4). The parent drugs of amphetamines enter oral fluid through passive diffusion from the blood stream into the oral fluid. The detection of amphetamine in oral fluid is an indication of recent use of amphetamine (7).

Assay Principle

The LZI Oral Fluid Amphetamine Enzyme Immunoassay is a homogeneous enzyme immunoassay (8) with ready-to-use liquid reagents. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent (4). Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, amphetamine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when drug is present in the sample, antibody will bind to free drug, and the unbound amphetamine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

Reagents Provided

Antibody/Substrate Reagent (R_1): Contains mouse monoclonal anti-amphetamine antibody, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09 %) as a preservative.
Enzyme-drug Conjugate Reagent (R_2): Contains amphetamine-labeled G6PDH in buffer with sodium azide (0.09 %) as a preservative.

Calibrators and Controls*

** Calibrators and Controls are sold separately and contain a negative synthetic oral fluid matrix with sodium azide as a preservative.*

ORAL FLUID AMPHETAMINE Calibrator/Control	REF #
Oral Fluid Negative Calibrator	S0001
Low Calibrator: Contains 20 ng/mL *d*-amphetamine	S0042b
Cutoff Calibrator: Contains 50 ng/mL *d*-amphetamine	S0043b
Intermediate Calibrator: Contains 100 ng/mL *d*-amphetamine	S0044b
High Calibrator: Contains 140 ng/mL *d*-amphetamine	S0045b
Level 1 Control: Contains 37.5 ng/mL *d*-amphetamine	S0046b
Level 2 Control: Contains 62.5 ng/mL *d*-amphetamine	S0047b

Collectors**

*** Collectors are sold separately.*

ORAL FLUID Collector	REF #
LZI Oral Fluid Collector: 50 mL Polypropylene Centrifuge Tube	S0000b

Precautions and Warning

- *This test is for in vitro diagnostic use only.*
- *Harmful if swallowed.*
- *Reagent contains sodium azide as a preservative, which may form explosive compounds in metal drain lines. When disposing such reagents or wastes, always flush with a large volume of water to prevent azide build-up. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).*
- *Do not use the reagents beyond their expiration dates.*

Reagent Preparation and Storage

The reagents are ready to use. No reagent preparation is required. All assay components should be refrigerated at 2 – 8ºC when not in use.

Specimen Storage and Shipping

Note: If oral fluid samples cannot be analyzed immediately, they may be stored in amber glass vials and refrigerated (2-8ºC) for up to seven days or frozen (-20ºC) for up to two months (9).

Samples should always be shipped cold (2-8ºC), packed in gel ice, and shipped for next day delivery (within 24 hours). Failure to store or ship samples under these conditions may result in a significant decrease in recovery of analyte.

Specimen Collection and Handling

Oral fluid samples should be collected into a device without an absorbing pad, such as the LZI Oral Fluid Collector (a 50 mL polypropylene centrifuge tube) (10).

Prior to testing, samples should be frozen overnight (at minimum) and then allowed to thaw at room temperature. Samples should then be spun for five minutes at 3000 rpm to remove particulates. Only the clear top layer should be assayed for EIA testing and/or confirmatory testing. Samples should be at room temperature (18-25ºC) for testing.

Samples do not require dilution or any additional correction factors.

Fresh and properly stored oral fluid samples should be within the normal pH range of 6-8; however, any sample with pH ranging from 3-10 can be tested without any pretreatment of the samples.

Handle all oral fluid specimens as if they are potentially infectious.

Instrument

Clinical chemistry analyzers capable of maintaining a constant temperature, pipetting sample, mixing reagents, measuring enzyme rates at 340 nm and timing the reaction accurately can be used to perform this homogeneous immunoassay. Performance characteristics presented in this package insert have been validated on the Hitachi 717. If other instruments are used, performance will need to be validated by the laboratory.

Assay Procedure

Analyzers with the specifications indicated above are suitable for performing this homogeneous enzyme immunoassay. Refer to the specific parameter used for each analyzer before performing the assay. Typical assay parameters used for the Hitachi 717 analyzer include a 20 µL sample, 150 µL of antibody reagent (R_1), and 75 µL of enzyme conjugate reagent (R_2) in 37ºC incubation temperature, 30-35 reading frames, and 340 nm primary wavelength.

For qualitative analysis, use the 50 ng/mL as the cutoff calibrator. For semi-quantitative analysis, use all five calibrators and the two controls. Recalibration should be performed after reagent bottle change or if there is a change in calibrators or reagent lot. Two levels of controls are also available for monitoring the cutoff level: 37.5 ng/mL and 62.5 ng/mL.

Calibration and Quality Control

Good laboratory practices recommend the use of at least two levels of control specimens (one positive and one negative control near the cutoff) to ensure proper assay performance. Controls should be run with each new calibration and after specific maintenance or troubleshooting procedures as detailed in the instrument system manual. Each laboratory should establish its own control frequency. If any trends or sudden change in control values are observed, review all operating parameters, or contact LZI technical support for further assistance. Laboratories should comply with all federal, state, and local laws, guidelines, and regulations.

Results

Note: A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests.

Qualitative: The cutoff calibrator, which contains 50 ng/mL of *d*-amphetamine, is used as a reference for distinguishing positive from negative samples. A sample with a change in absorbance (ΔmA/min) equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance (ΔmA/min) lower than that obtained with the cutoff calibrator is considered negative.

Semi-Quantitative: The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for verification by a confirmatory method such as GC/MS or LC/MS, or (2) permitting laboratories to establish quality control procedures. This mode requires a calibration curve that can be established with the five assay calibrators and two controls.

Limitations

1. *A positive result from the assay indicates only the presence of d-amphetamine. The test is not intended for quantifying this single analyte in samples.*
2. *A positive result does not necessarily indicate drug abuse.*
3. *A negative result does not necessarily mean a person did not take d-amphetamine.*
4. *There is a possibility that other substances and/or factors not listed above may interfere with the test and cause incorrect results (e.g., technical or procedural error, fluid intake, endogeneous or exogeneous interferents).*
5. *Positive results should be confirmed by other affirmative, analytical chemistry methods (e.g., chromatography), preferably GC/MS or LC/MS.*
6. *The test is designed for use with human oral fluid only.*

Typical Performance Characteristics

The results shown below were performed with a Hitachi 717 automated chemistry analyzer.

Precision:

Semi-quantitative analysis: The following concentrations were determined with reference curves from five calibrators. Results are as follows:

50 ng/mL Cutoff Result:		Within Run (n=22)		Total Precision (n=88)	
Sample [ ] (ng/mL)	% of Cutoff	# Samples	EIA Result	# Samples	EIA Result
0 ng/mL	0 %	22	22 Neg	88	88 Neg
12.5 ng/mL	25 %	22	22 Neg	88	88 Neg
25 ng/mL	50 %	22	22 Neg	88	88 Neg
37.5 ng/mL	75 %	22	22 Neg	88	88 Neg
50 ng/mL	100 %	22	11 Pos/ 11 Neg	88	36 Pos/ 52 Neg
62.5 ng/mL	125 %	22	22 Pos	88	88 Pos
75 ng/mL	150 %	22	22 Pos	88	88 Pos
87.5 ng/mL	175 %	22	22 Pos	88	88 Pos
100 ng/mL	200 %	22	22 Pos	88	88 Pos

Qualitative analysis: The following concentrations were evaluated. Results are as follows:

50 ng/mL Cutoff Result:		Within Run (n=22)		Total Precision (n=88)	
Sample [ ] (ng/mL)	% of Cutoff	# Samples	EIA Result	# Samples	EIA Result
0 ng/mL	0 %	22	22 Neg	88	88 Neg
12.5 ng/mL	25 %	22	22 Neg	88	88 Neg
25 ng/mL	50 %	22	22 Neg	88	88 Neg
37.5 ng/mL	75 %	22	22 Neg	88	88 Neg
50 ng/mL	100 %	22	8 Pos/ 14 Neg	88	46 Pos/ 42 Neg
62.5 ng/mL	125 %	22	22 Pos	88	88 Pos
75 ng/mL	150 %	22	22 Pos	88	88 Pos
87.5 ng/mL	175 %	22	22 Pos	88	88 Pos
100 ng/mL	200 %	22	22 Pos	88	88 Pos

Accuracy: A total of 85 unaltered clinical specimens were tested with the Oral Fluid Amphetamine Enzyme Immunoassay and confirmed by either GC/MS or LC/MS. Specimens having a *d*-amphetamine concentration greater than 50 ng/mL by GC/MS are defined as positive, and specimens with concentrations below 50 ng/mL by GC/MS are defined as negative in the table below. Near cutoff samples are defined as ± 50 % of the cutoff value. The correlation results are summarized as follows:

Semi-Quantitative Accuracy Study:

50 ng/mL Cutoff	Neg	<50 % of the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agree-ment
Positive	0	0	0	10	32	97.7 %
Negative	22	11	9	1*	0	100.0 %

The following table has the result for the discordant sample:

Cutoff Value 50 ng/mL	Assay Result		Sample Testing Method	
Sample	GC/MS or LC/MS (ng/mL)	Pos/Neg Result	LZI EIA (ng/mL)	Pos/Neg Result
51*	63	Pos	45.7	Neg

Qualitative Accuracy Study:

50 ng/mL Cutoff	Neg	<50 % of the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agree-ment
Positive	0	0	0	10	32	97.7 %
Negative	22	11	9	1*	0	100.0 %

The following table has the result for the discordant sample:

Cutoff Value 50 ng/mL	Assay Result		Sample Testing Method		
Sample	GC/MS or LC/MS (ng/mL)	Pos/Neg Result	LZI EIA (mA)	EIA Cutoff Rate (mA)	Pos/Neg Result
51*	63	Pos	433.8	441.8	Neg

Analytical Recovery: To demonstrate linearity for purposes of sample dilution and quality control (see semi-quantitative results section), synthetic drug free oral fluid matrix was spiked with *d*-amphetamine and was serially diluted. Each sample was run in 10 replicates and the average was used to determine the functional linearity range of the assay. When comparing the result (y) and target (x) value using the least squares regression technique, the regression equation and correlation are as follows:

$y = 1.0555x - 0.7832$, $r^2 = 0.9945$

Target Concentration (ng/mL)	Determined (ng/mL)	% Recovery
140	141.7	101.2 %
120	134.3	111.9 %
100	104.7	104.7 %
80	81.0	101.2 %
60	60.7	101.2 %
50	53.1	106.2 %
40	42.4	105.9 %
30	30.9	103.0 %
20	18.8	94.0 %
0	0.2	N/A

Specificity:

The cross reactivity of structurally related compounds were tested by spiking various concentrations of each substance into synthetic drug-free oral fluid matrix, and then evaluated with the assay's calibrated dose-response curve. The following table summarizes the approximate quantity of each compound that is equivalent in assay reactivity (within ±25 %) to the 50 ng/mL *d*-amphetamine cutoff.

Amphetamine Compounds:

Cross-reactant	Spiked Concentration (ng/mL)	% Cross-reactivity
d-Amphetamine	50	100.06 %
l-Amphetamine	3,000	1.42 %

Structurally Related Amphetamine Compounds:

Cross-reactant	Spiked Concentration (ng/mL)	% Cross-reactivity
Dimethylamylamine (DMAA)	100,000	0.05 %
d-Ephedrine	300,000	0.00 %
d,l-Ephedrine	300,000	0.00 %
l-Ephedrine	200,000	0.00 %

Structurally Related Amphetamine Compounds, continued:

Cross-reactant	Spiked Concentration (ng/mL)	% Cross-reactivity
Fenfluramine	200,000	0.02 %
3-Hydroxy-Tyramine	200,000	0.01 %
Isoxsuprine	250,000	0.00 %
MDA(3,4-methylenedioxy-amphetamine)	150	27.40 %
MDMA(3,4-methylenedioxy-methamphetamine)	10,000	0.05 %
Mephentermine	100,000	0.02 %
d-Methamphetamine	10,000	0.04 %
l-Methamphetamine	50,000	0.00 %
Phendimetrazine	100,000	0.00 %
Phenethylamine	10,000	0.46 %
Phenmetrazine	100,000	0.03 %
Phentermine	2,000	1.60 %
d,l-Phenylpropanolamine	20,000	0.19 %
PMA(*para*-Methoxyamphetamine)	500	7.62 %
d-Pseudoephedrine	250,000	0.00 %
l-Pseudoephedrine	250,000	0.00 %

There is a possibility that metabolites of the compounds listed above may interfere with the Amphetamine immunoassay and cause false results.

Structurally Unrelated Pharmacological Compounds:
The following structurally unrelated compounds were spiked into the synthetic drug-free oral fluid matrix to the desired concentrations and then spiked with *d*-amphetamine to a final concentration of 0 ng/mL, the negative control concentration of 37.5 ng/mL, or the positive control concentration of 62.5 ng/mL. The spiked solution was evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds. Results are summarized in the following table:

Cross-reactant	Spiked [ ] (ng/mL)	Spiked AMP Concentration			
		% Cross	0 ng/mL	37.5 ng/mL	62.5 ng/mL
Acetaminophen	60,000	0.01 %	Neg	Neg	Pos
Acetylsalicylic acid	60,000	0.00 %	Neg	Neg	Pos
Amobarbital	60,000	0.00 %	Neg	Neg	Pos
Benzoylecgonine	60,000	0.00 %	Neg	Neg	Pos
Bromopheniramine	50,000	0.01 %	Neg	Neg	Pos
Bupropion	15,000	0.02 %	Neg	Neg	Pos
Buspiron	20,000	0.01 %	Neg	Neg	Pos
Caffeine	60,000	0.00 %	Neg	Neg	Pos
Chlorpheniramine	20,000	0.01 %	Neg	Neg	Pos
Chlorpromazine	20,000	0.00 %	Neg	Neg	Pos
Codeine	50,000	0.00 %	Neg	Neg	Pos
Dextromethorphan	60,000	0.00 %	Neg	Neg	Pos
Doxepine	15,000	0.01 %	Neg	Neg	Pos
Meperidine	60,000	0.00 %	Neg	Neg	Pos
Methadone	50,000	0.01 %	Neg	Neg	Pos
Methapyrilene	15,000	0.00 %	Neg	Neg	Pos
Methaqualone	15,000	0.01 %	Neg	Neg	Pos
Morphine	50,000	0.00 %	Neg	Neg	Pos
Oxazepam	50,000	0.00 %	Neg	Neg	Pos
Phencyclidine	50,000	0.00 %	Neg	Neg	Pos
Phenobarbital	50,000	0.00 %	Neg	Neg	Pos
Phenothiazine	50,000	0.00 %	Neg	Neg	Pos
Procainamide	60,000	0.01 %	Neg	Neg	Pos
Promethazine	20,000	0.00 %	Neg	Neg	Pos
Propoxyphene	60,000	0.00 %	Neg	Neg	Pos
Propranolol	60,000	0.00 %	Neg	Neg	Pos
Ranitidine	60,000	0.00 %	Neg	Neg	Pos
Scopolamine	60,000	0.00 %	Neg	Neg	Pos
Secobarbital	60,000	0.00 %	Neg	Neg	Pos
Sertraline	15,000	0.00 %	Neg	Neg	Pos
Thioridazine	60,000	0.00 %	Neg	Neg	Pos
Trazodone	60,000	0.00 %	Neg	Neg	Pos
Trifluoperazine	20,000	0.00 %	Neg	Neg	Pos
Trifluopromazine	20,000	0.00 %	Neg	Neg	Pos
Valproic Acid	60,000	0.00 %	Neg	Neg	Pos
Methapyrilene	15,000	0.00 %	Neg	Neg	Pos
Methaqualone	15,000	0.01 %	Neg	Neg	Pos
Morphine	50,000	0.00 %	Neg	Neg	Pos

It is possible that other substances and/or factors not listed above may interfere with the test and cause false positive results.

Interference: Endogenous Substances
The following endogenous compounds were spiked into the synthetic drug-free oral fluid matrix to the desired concentrations and then spiked with *d*-amphetamine to a final concentration of 0 ng/mL, the negative control concentration of 37.5 ng/mL, or the positive control concentration of 62.5 ng/mL. The spiked solution was evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds at physiologically relevant concentrations as all spiked samples gave correct corresponding positive/negative results against the cutoff value of 50 ng/mL. Results are summarized in the following table:

Interfering Substances	Spiked [ ] (mg/mL)	Spiked AMP Concentration		
		0 ng/mL	37.5 ng/mL Control	62.5 ng/mL Control
None		Neg	Neg	Pos
AscorbicAcid	10.00	Neg	Neg	Pos
Bilirubin	0.05	Neg	Neg	Pos
Cholesterol	0.45	Neg	Neg	Pos
Cotinine	0.01	Neg	Neg	Pos
γ-globulin	0.80	Neg	Neg	Pos
hemoglobin	0.60	Neg	Neg	Pos
Human Serum Albumin	5.00	Neg	Neg	Pos
Nicotine	0.03	Neg	Neg	Pos
Sodium Chloride	18.00	Neg	Neg	Pos
pH 3	N/A	Neg	Neg	Pos
pH 4	N/A	Neg	Neg	Pos
pH 5	N/A	Neg	Neg	Pos
pH 6	N/A	Neg	Neg	Pos
pH 7	N/A	Neg	Neg	Pos
pH 8	N/A	Neg	Neg	Pos
pH 9	N/A	Neg	Neg	Pos
pH 10	N/A	Neg	Neg	Pos

Interference: Exogenous Substances
The following potentially interfering compounds were spiked into the synthetic drug-free oral fluid matrix to the desired concentrations and then spiked with *d*-amphetamine to a final concentration of 0 ng/mL, the negative control concentration of 37.5 ng/mL, or the positive control concentration of 62.5 ng/mL. The spiked solution was evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds at physiologically relevant concentrations, as all spiked samples gave correct responding positive/negative results against the cutoff value of 50 ng/mL. Results are summarized in the following table:

Interfering Substances	Spiked [ ] (%V/V)	Spiked AMP Concentration		
		0 ng/mL	37.5 ng/mL Control	62.5 ng/mL Control
None		Neg	Neg	Pos
Alcohol (Ethanol)	5	Neg	Neg	Pos
Coffee	5	Neg	Neg	Pos
Cough syrup	5	Neg	Neg	Pos
Cranberry Juice	5	Neg	Neg	Pos
Sugar	50 mg/mL	Neg	Neg	Pos
Milk	5	Neg	Neg	Pos
Mouthwash	5	Neg	Neg	Pos
Orange juice	5	Neg	Neg	Pos
Soft drink (Coke)	5	Neg	Neg	Pos
Tea	5	Neg	Neg	Pos
Toothpaste (Aquafresh Satur. Sol.)	5	Neg	Neg	Pos
Water	5	Neg	Neg	Pos

Open (re-capped) vial Stability for Calibrators and Controls
Real time (2 - 8ºC) and accelerated stability studies (at room temperature and 30ºC) were carried out for 17 months (568 Days) and results indicated degradation at all three conditions was minimal. Thermal stability data supports at least 18 months of shelf life storage at 2-8ºC.

Closed Stability for Reagent Shelf-life:
Real-time stability studies were carried out for 17 months (568 Days) and results indicated degradation was minimal. Real-time stability data also supports at least 18 months of shelf life storage at 2-8ºC.

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10. LZI Oral Fluid Sample Preparation Sheet.

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