LZI Opiate 2000 Enzyme Immunoassay

IVD For In Vitro Diagnostic Use Only

REF 0330 (100/37.5 mL R_1/R_2 Kit)
0331 (1000/375 mL R_1/R_2 Kit) 2°C 8°C

Lin-Zhi International, Inc.

Intended Use

The Lin-Zhi International, Inc. (LZI) Opiate 2000 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of morphine in human urine at a cutoff value of 2000 ng/mL. The assay is designed for prescription use with a number of automated clinical chemistry analyzers.

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) are 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

Opiates are naturally occurring alkaloids derived from the opium poppy, *Papaver somniferum* (3). Common opiates include morphine, codeine and heroin, which is a semi-synthetic derivative of morphine. Morphine and codeine are potent analgesics. They are among the most effective and common medications for treatment of mild to severe pain. However, these prescription drugs are frequently abused for their central nervous system (CNS) effects. Heroin is the most commonly abused opiate (4). It may be snorted, smoked, or dissolved and injected subcutaneously or intravenously. Opiates are absorbed rapidly and primarily metabolized in liver (4-6). Heroin is converted quickly to 6-acetylmorphine or morphine, which is excreted in urine both unchanged and as glucuronide conjugates. Excretion takes place over 2 to 3 days. Codeine is excreted in urine as glucuronides, norcodeine, or as morphine. The presence of opiates in urine indicates the use of heroin, morphine, codeine, and/or other synthetic opiates structurally related to morphine, such as hydromorphone and hydrocodone.

Assay Principle

The LZI Opiate 2000 assay is a homogeneous enzyme immunoassay ready-to-use liquid reagent. 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 (7). 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, opiate-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 binds to free drug; the unbound opiate-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 a 340 nm primary wavelength.

Reagents Provided

Antibody/Substrate Reagent (R_1): Contains mouse monoclonal anti-morphine 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 glucose-6-phosphate dehydrogenase (G6PDH) labeled with morphine in buffer with sodium azide (0.09 %) as a preservative.

Calibrators and Controls*

**Calibrators and controls are sold separately and contain negative human urine with sodium azide as a preservative.*

OPIATE 2000 Calibrators	REF
Negative Calibrator	0001
Low Calibrator: Contains 1000 ng/mL morphine	0332
Cutoff Calibrator: Contains 2000 ng/mL morphine	0333
Intermediate Calibrator: Contains 4000 ng/mL morphine	0334
High Calibrator: Contains 6000 ng/mL morphine	0335

OPIATE 2000 Controls	REF
Level 1 Control: Contains 1500 ng/mL morphine	0337
Level 2 Control: Contains 2500 ng/mL morphine	0338

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).*
- *Do not use the reagents beyond their expiration dates.*
- Rx ONLY *For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.*

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 Collection and Handling

Urine samples may be collected in plastic or glass containers. Some plastics may absorb drugs. Use of plastics such as polyethylene is recommended (9). Use fresh urine specimens for the test. If the sample cannot be analyzed immediately, it may be refrigerated at 2-8ºC for up to seven days (10). For longer storage, keep sample frozen at -20ºC and then thaw before use. Studies have shown opiate analytes in urine are stable at -20ºC up to 12 months (11, 12). Samples should be at room temperature (18-25ºC) for testing. Samples with high turbidity should be centrifuged before analysis. Adulteration may cause erroneous results. If sample adulteration is suspected, obtain a new sample and both samples should be forwarded to the laboratory for testing.
Handle all urine specimens as if they are potentially infectious.

Instrument

Clinical chemistry analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzyme rates at a 340 nm primary wavelength 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 (13, 14).

Assay Procedure

Analyzers with the specifications indicated above are suitable for performing this homogeneous enzyme immunoassay. Refer to the specific parameters used for each analyzer before performing the assay. Typical assay parameters used for the Hitachi 717 analyzer include a 8 µL sample, 200 µL of antibody reagent (R_1), and 75 µL of enzyme conjugate reagent (R_2) in 37ºC incubation temperature, 30-35 reading frames, and a 340 nm primary wavelength. For qualitative analysis use the 2000 ng/mL as the cutoff calibrator. For semi-quantitative analysis, use all five calibrators. Recalibration should be performed after reagent bottle change or there is a change in calibrators or reagent lot. Two levels of controls are also available for monitoring the cutoff level: 1500 ng/mL and 2500 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 value 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 preliminary positive test result does not necessarily mean a person took illegal drugs and a negative test result does not necessarily mean a person did not take illegal drugs. There are number of factors that influence the reliability of drug tests.

Qualitative: The cutoff calibrator which contains 2000 ng/mL of morphine is used as a reference for distinguishing a preliminary 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 a preliminary 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, LC/MS or (2) permitting laboratories to establish quality control procedures.
When an approximation of concentration is required a calibration curve can be established with five calibrators. The concentration of opiates in the sample may then be estimated from the calibration curve.

Limitations

1. *A preliminary positive result from the assay indicates only the presence of opiates. The test is not intended for quantifying this single analyte in samples.*
2. *A preliminary positive result does not necessarily indicate drug abuse.*
3. *A negative result does not necessarily mean a person did not take illegal drugs.*
4. *Care should be taken when reporting results as numerous factors (e.g., fluid intake, endogenous or exogenous interferents) may influence the urine test result.*
5. *Preliminary 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 urine only.*
7. *The test is not for therapeutic drug monitoring.*

Typical Performance Characteristics

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

Precision:

Qualitative analysis: The three calibrators and two levels of controls were evaluated. Typical results (mA/min) are as follows:

Concentration	Within Run (N=22)			Total Precision (N=88)		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	229.2	1.7	0.7 %	229.2	1.9	0.8 %
500 ng/mL	271.2	1.7	0.6 %	271.2	2.2	0.8 %
1000 ng/mL	335.9	1.5	0.4 %	335.9	2.7	0.8 %
1500 ng/mL	384.7	1.7	0.4 %	384.7	2.8	0.7 %
2000 ng/mL	414.5	2.7	0.7 %	414.5	3.5	0.9 %
2500 ng/mL	441.9	1.9	0.4 %	441.9	3.1	0.7 %
3000 ng/mL	461.9	3.4	0.7 %	461.9	4.2	0.9 %
3500 ng/mL	478.6	3.0	0.6 %	478.6	3.5	0.7 %
4000 ng/mL	489.4	2.2	0.5 %	489.4	2.9	0.6 %

2000 ng/mL Cutoff		Within Run (N=22)		Total Precision (N=88)	
Concentration	% of Cutoff	# Samples	EIA Result	# Samples	EIA Result
0 ng/mL	0 %	22	22 Neg	88	88 Neg
500 ng/mL	25 %	22	22 Neg	88	88 Neg
1000 ng/mL	50 %	22	22 Neg	88	88 Neg
1500 ng/mL	75 %	22	22 Neg	88	88 Neg
2000 ng/mL	100 %	22	13 Neg/ 9 Pos	88	55 Neg/ 33 Pos
2500 ng/mL	125 %	22	22 Pos	88	88 Pos
3000 ng/mL	150 %	22	22 Pos	88	88 Pos
3500 ng/mL	175 %	22	22 Pos	88	88 Pos
4000 ng/mL	200 %	22	22 Pos	88	88 Pos

Semi-quantitative analysis: The concentrations of the cutoff level and the two levels of controls were determined with reference curves from five calibrators. Typical results (ng/mL) are as follows:

Concentration	Within Run (N=22)			Total Precision (N=88)		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	64.9	21.4	36.6 %	64.9	25.7	39.6 %
500 ng/mL	448.9	18.1	4.1 %	448.9	22.1	4.9 %
1000 ng/mL	1014.4	24.2	2.4 %	1014.4	24.8	2.4 %
1500 ng/mL	1559.8	20.1	1.3 %	1559.8	22.6	1.4 %
2000 ng/mL	2018.4	32.2	1.6 %	2018.4	37.6	1.9 %
2500 ng/mL	2492.3	46.4	1.9 %	2492.3	47.0	1.9 %
3000 ng/mL	3065.5	87.9	2.9 %	3065.5	90.1	2.9 %
3500 ng/mL	3608.7	76.9	2.2 %	3608.7	110.4	3.1 %
4000 ng/mL	4013.2	84.0	2.1 %	4013.2	96.9	2.4 %

2,000 ng/mL Cutoff		Within Run (N=22)		Total Precision (N=88)	
Concentration	% of Cutoff	# Samples	EIA Result	# Samples	EIA Result
0 ng/mL	0 %	22	22 Neg	88	88 Neg
500 ng/mL	25 %	22	22 Neg	88	88 Neg
1000 ng/mL	50 %	22	22 Neg	88	88 Neg
1500 ng/mL	75 %	22	22 Neg	88	88 Neg
2000 ng/mL	100 %	22	4 Neg/ 18 Pos	88	29 Neg/ 59 Pos
2500 ng/mL	125 %	22	22 Pos	88	88 Pos
3000 ng/mL	150 %	22	22 Pos	88	88 Pos
3500 ng/mL	175 %	22	22 Pos	88	88 Pos
4000 ng/mL	200 %	22	22 Pos	88	88 Pos

Limit of Detection: Sensitivity, defined as the lowest concentration that can be differentiated from negative urine with 95 % confidence, was tested to be 200 ng/mL.

Accuracy: One-hundred-fifty (150) unaltered clinical urine specimens were tested with the LZI Opiate 2000 Enzyme Immunoassay and confirmed with GC/MS or LC/MS. Specimens having a morphine concentration greater than 2,000 ng/mL by GC/MS or LC/MS are defined as positive, and specimens with lower concentrations by GC/MS or LC/MS are defined as negative in the table below. Adjusted GC/MS or LC/MS values corrected for cross-reactivity, molecular weight, and excretion rates (15, 16). The correlation results are summarized as follows (near cutoff samples are defined as ± 50 % of the cutoff value):

Qualitative Accuracy Study:

2000 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agreement
Positive	0	0	4*	19	33	100.0 %
Negative	20	43	31	0	0	95.8 %

The following table summarizes the result for the discordant samples:

2000 ng/mL Cutoff	Assay Result		Sample Testing Method	
	GC/MS or LC/MS	LZI EIA	Adjusted GC/MS or LC/MS (ng/mL)	LZI EIA (mA/min)
Sample #88*	-	+	1708	411.0
Sample #90*	-	+	1726	412.9
Sample #94*	-	+	1853	411.5
Sample #96*	-	+	1869	415.7

Discrepant samples are based on a 2,000 ng/mL cutoff concentration with 408.8 mA/min absorbance values.

Semi-Quantitative Accuracy Study:

2000 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agreement
Positive	0	0	8*	19	33	100.0 %
Negative	20	43	27	0	0	91.7 %

The following table summarizes the result for the discordant samples:

2000 ng/mL Cutoff	Assay Result		Sample Testing Method	
	GC/MS or LC/MS	LZI EIA	Adjusted GC/MS or LC/MS (ng/mL)	LZI EIA (ng/mL)
Sample #66*	-	+	1160	2,020.4
Sample #82*	-	+	1708	2,115.8
Sample #89*	-	+	1715	2,073.5
Sample #90*	-	+	1726	2,067.1
Sample #91*	-	+	1745	2,062.0
Sample #93*	-	+	1854	2,062.1
Sample #94*	-	+	1853	2,180.1
Sample #96*	-	+	1869	2,116.3

Analytical Recovery: To demonstrate linearity for purposes of sample dilution and quality control (see semi-quantitative results section), a drug-free urine pool spiked with morphine 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 follow:

$y = 1.078x - 85.072$, $r^2 = 0.993$

Expected Value (ng/mL)	Observed Value (ng/mL)	%Recovery
6000	6811.5	113.5 %
5400	5837.7	108.1 %
4800	4881.5	101.7 %
4200	4239.4	100.9 %
3600	3622.1	100.6 %
3000	3008.0	100.3 %
2400	2380.2	99.2 %
1800	1842.9	102.4 %
1200	1252.9	104.4 %
600	596.8	99.5 %
200	214.4	107.2 %
0	80.7	N/A

Specificity: Various potentially interfering substances were tested for cross-reactivity with the assay. Test compounds were spiked into the drug-free urine calibrator matrix to various concentrations and evaluated against the cutoff calibrator.
The table listed the concentration of each test compound that gave a response approximately equivalent to that of the cutoff calibrator or the maximal concentration of the compound tested that gave a response below the response of the cutoff calibrator.

Structurally Related Opiate Compounds:

Compound	Target [ ] (ng/mL)	Observed Value (ng/mL)	% Cross-Reactivity
6-Monoacetyl Morphine	2000	2234.7	111.74 %
Codeine	1900	2164.4	113.92 %
Dextromethorphan	400,000	439.9	0.110 %
Dihydrocodeine	7000	2226.4	31.81 %
Heroin	2600	2079.1	79.97 %
Hydrocodone	15,000	2345.6	15.64 %
Hydromorphone	12,500	2354.0	18.83 %
Levorphanol	56,000	2175.0	3.88 %
Morphine	2000	2036.8	101.84 %
Morphine-3-Glucuronide	5000	2002.9	40.06 %
Morphine-6-Glucuronide	2500	2098.2	83.93 %
Nalbuphine	30,000	64.4	0.215 %
Naloxone	9000	66.5	0.739 %
Naltrexone	1,200,000	477.3	0.040 %
Norcodeine	305,000	2020.4	0.66 %
Normorphine	30,000	239.1	0.797 %
Oxycodone	600,000	2240.8	0.37 %
Oxymorphone	1,020,000	2033.5	0.20 %
Thebaine	15,000	2022.8	13.49 %
Codeine-6-β-Glucuronide	2000	2159.0	107.95 %
Norhydrocodone	1,000,000	1497.2	0.15 %
Hydromorphone-3B-D-Glucuronide	50,000	2068.7	4.14 %

Structurally Unrelated Pharmacological Compounds:

Compound	Target [ ] (ng/mL)	Observed Value (ng/mL)	% Cross-Reactivity
Acetaminophen	3,000,000	0.0	0.000 %
Acetylsalicylic Acid	2,000,000	0.0	0.000 %
Albuterol	70,000	0.0	0.000 %
Amitriptyline	25,000	0.0	0.000 %
Amobarbital	300,000	0.0	0.000 %
d-Amphetamine	3,000,000	121.8	0.004 %
Benzoylecgonine	3,000,000	0.0	0.000 %
Bupropion	3,000,000	75.8	0.003 %
Caffeine	1,500,000	0.0	0.000 %
Carbamazepine	3,000,000	77.0	0.003 %
Chlorpromazine	5000	0.0	0.000 %
Clomipramine	500,000	623.3	0.125 %
Desipramine	1000	61.9	6.190 %
Doxepine	50,000	108.7	0.217 %
Ecgonine	3,000,000	0.0	0.000 %
Ephedrine	3,000,000	211.8	0.007 %
Fentanyl	300	0.0	0.000 %
Fluoxetine	60,000	0.0	0.000 %
Fluphenazine	750,000	401.9	0.054 %
Ibuprofen	3,000,000	61.7	0.002 %
Imipramine	200,000	449.6	0.225 %
Lidocaine	60,000	99.6	0.166 %
Maprotiline	75,000	84.5	0.113 %
Meperidine	30,000	262.8	0.876 %
Methadone	400,000	529.2	0.132 %
Methapyrilene	600,000	590.1	0.098 %
Methaqualone	51,000	0.0	0.000 %
Metronidazole	700,000	0.0	0.000 %
Nicotine	10,000	25.7	0.257 %
Nortriptyline	360,000	84.8	0.024 %
Oxazepam	3,000,000	0.0	0.000 %
Phencyclidine	360,000	0.0	0.000 %
Phenobarbital	120,000	0.0	0.000 %
Propoxyphene	110,000	0.0	0.000 %
Ranitidine	318,000	208.1	0.065 %
Secobarbital	100,000	0.0	0.000 %
Talwin	100,000	0.0	0.000 %
Thioridazine	6000	0.0	0.000 %
Tramadol	330,000	550.8	0.167 %
Valproic Acid	2,000,000	64.2	0.003 %

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

Endogenous Compound Interference Study:

Interfering Substance	Spiked [ ] (mg/dL)	Spiked Morphine Concentration		
		0ng/mL (ng/mL)	1500 ng/mL (ng/mL)	2500 ng/mL (ng/mL)
Acetone	1000	0.0	1664.0	2714.9
Ascorbic Acid	1500	0.0	1697.1	2833.9
Creatinine	500	0.0	1750.7	2733.7
Ethanol	1000	21.7	1793.7	2507.5
Galactose	10	11.3	1898.0	2558.6
γ-Globulin	500	18.9	1652.6	2744.5
Glucose	3000	0.0	1826.9	2683.5
Hemoglobin	300	44.3	1719.4	2770.3
Human Serum Albumin	500	31.5	1643.9	2728.5
Oxalic Acid	100	12.3	1635.0	2567.6
Riboflavin	0.3	31.9	1468.8	2407.9
Sodium Chloride	6000	15.3	1666.8	2632.5
Urea	6000	30.3	1677.6	2564.3

pH Interference Study:

pH	Spiked Morphine Concentration		
	0 ng/mL	1500 ng/mL	2500 ng/mL
pH 3	2.7	1633.6	2691.8
pH 4	21.9	1690.0	2620.4
pH 5	0.0	1600.8	2647.0
pH 6	0.0	1688.7	2577.8
pH 7	20.4	1636.0	2546.2
pH 8	6.0	1612.2	2651.5
pH 9	0.0	1629.5	2606.9
pH 10	0.0	1644.6	2659.3
pH 11	3.7	1612.6	2592.6

Specific Gravity: Samples ranging in specific gravity from 1.000 to 1.025 were tested in qualitative mode against pooled processed urine samples at 0 ng/mL, 1500 ng/mL, or 2500 ng/mL (negative calibrator, negative control, and positive control for the 2000 ng/mL cutoff). No interference was observed.

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Additions, deletions, or changes are indicated by a change bar in the margin.
For technical assistance please call: (408) 970-8811.

Manufacturer:
Lin-Zhi International, Inc.
2945 Oakmead Village Court
Santa Clara, CA 95051
USA
Tel: (408) 970-8811
Fax: (408) 970-9030
www.lin-zhi.com

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