LZI Oxycodone Enzyme Immunoassay

IVD For In Vitro Diagnostic Use Only

REF 0240b (100/37.5 mL R_1/R_2 Kit)
0241b (1000/375 mL R_1/R_2 Kit)

2ºC – 8ºC

Lin-Zhi International, Inc.

Intended Use

The Lin-Zhi International, Inc. (LZI) Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of oxycodone in human urine, at cutoff values of 100 ng/mL and 300 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

Oxycodone is a semi-synthetic narcotic analgesic prescribed for pain management in patients with moderate to severe pain. The drug is approximately equipotent with morphine, but has a higher oral/parenteral dose (3). Similar to morphine, oxycodone can produce drug tolerance and therefore has the potential of being abused. Oxycodone is metabolized by N- and O-demethylation into oxymorphone and noroxycodone. The oxymorphone metabolite is a potent narcotic analgesic and the noroxycodone is relatively inactive. Between 33-61 % of a single dose of oxycodone is excreted in the 24-hour urine as free drug (13-19 %) and conjugated oxycodone (7-29 %), conjugated oxymorphone (13-14 %) and an unknown amount of noroxycodone (3).

Assay Principle

The Oxycodone 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 (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, oxycodone-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 the free drug; the unbound oxycodone-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-oxycodone 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 oxycodone 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.*

OXYCODONE Cutoff Calibrators	REF
Negative Calibrator	0001
Low Calibrator: Contains 50 ng/mL oxycodone	0252b
Cutoff Calibrator 1: Contains 100 ng/mL oxycodone	0243b
Cutoff Calibrator 2: Contains 300 ng/mL oxycodone	0246b
Intermediate Calibrator: Contains 500 ng/mL oxycodone	0248b
High Calibrator: Contains 800 ng/mL oxycodone	0249b

OXYCODONE 100 Cutoff Controls	REF
Level 1 Control: Contains 75 ng/mL oxycodone	0242b
Level 2 Control: Contains 125 ng/mL oxycodone	0244b

OXYCODONE 300 Cutoff Controls	REF
Level 1 Control: Contains 225 ng/mL oxycodone	0245b
Level 2 Control: Contains 375 ng/mL oxycodone	0247b

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 (5).*
- *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. Use of plastics such as polyethylene is recommended (6). If the sample cannot be analyzed immediately, it may be refrigerated at 2-8ºC for up to seven days. For longer storage, keep sample frozen at -20ºC and then thaw before use. Studies have shown oxycodone analytes in urine are stable at -20ºC for up to six months (7). 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 forward both samples 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, the Beckman Coulter® AU680, Beckman Coulter AU480, and the Synermed IR500 clinical analyzers.

Assay Procedure

Refer to the specific parameters used for each analyzer before performing the assay. For qualitative analysis, use either the 100 ng/mL or 300 ng/mL cutoff calibrator. For semi-quantitative analysis, use all six calibrators. Recalibration should be performed after reagent bottle change or if there is a change in calibrators or reagent lot. Two levels of controls are available for monitoring of each cutoff level. Use the 75 ng/mL and 125 ng/mL controls for the 100 ng/mL cutoff, and use the 225 ng/mL and 375 ng/mL controls for the 300 ng/mL cutoff level.

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, as well as all 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 a number of factors that influence the reliability of drug tests.

Qualitative: The cutoff calibrator, which contains 100 ng/mL or 300 ng/mL of oxycodone, 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 six calibrators. The concentration of oxycodone 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 oxycodone. The test is not intended for quantifying these single analytes 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 results.*
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 calibrator and two levels of controls were evaluated. Typical results (ΔmA/min) are as follows:

100 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
25 ng/mL	25 %	22	22 Neg	88	88 Neg
50 ng/mL	50 %	22	22 Neg	88	88 Neg
75 ng/mL	75 %	22	22 Neg	88	88 Neg
100 ng/mL	100 %	22	16 Neg/ 6 Pos	88	63 Neg/ 25 Pos
125 ng/mL	125 %	22	22 Pos	88	88 Pos
150 ng/mL	150 %	22	22 Pos	88	88 Pos
175 ng/mL	175 %	22	22 Pos	88	88 Pos
200 ng/mL	200 %	22	22 Pos	88	88 Pos

300 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
75 ng/mL	25 %	22	22 Neg	88	88 Neg
150 ng/mL	50 %	22	22 Neg	88	88 Neg
225 ng/mL	75 %	22	22 Neg	88	88 Neg
300 ng/mL	100 %	22	21 Neg/ 1 Pos	88	65 Neg/ 23 Pos
375 ng/mL	125 %	22	22 Pos	88	88 Pos
450 ng/mL	150 %	22	22 Pos	88	88 Pos
525 ng/mL	175 %	22	22 Pos	88	88 Pos
600 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 six calibrators and controls. Typical results (ng/mL) are as follows:

100 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
25 ng/mL	25 %	22	22 Neg	88	88 Neg
50 ng/mL	50 %	22	22 Neg	88	88 Neg
75 ng/mL	75 %	22	22 Neg	88	88 Neg
100 ng/mL	100 %	22	13 Neg/ 9 Pos	88	49 Neg/ 39 Pos
125 ng/mL	125 %	22	22 Pos	88	88 Pos
150 ng/mL	150 %	22	22 Pos	88	88 Pos
175 ng/mL	175 %	22	22 Pos	88	88 Pos
200 ng/mL	200 %	22	22 Pos	88	88 Pos

Semi-quantitative analysis, continued:

300 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
75 ng/mL	25 %	22	22 Neg	88	88 Neg
150 ng/mL	50 %	22	22 Neg	88	88 Neg
225 ng/mL	75 %	22	22 Neg	88	88 Neg
300 ng/mL	100 %	22	19 Neg/ 3 Pos	88	62 Neg/ 26 Pos
375 ng/mL	125 %	22	22 Pos	88	88 Pos
450 ng/mL	150 %	22	22 Pos	88	88 Pos
525 ng/mL	175 %	22	22 Pos	88	88 Pos
600 ng/mL	200 %	22	22 Pos	88	88 Pos

Accuracy 100 ng/mL Cutoff: Eighty-nine (89) unaltered clinical urine specimens were tested with the LZI Oxycodone Enzyme Immunoassay and confirmed with GC/MS or LC/MS. Specimens having an oxycodone concentration greater than 100 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. The correlation results are summarized as follows (near cutoff samples are defined as ± 50 % of the cutoff value):

Qualitative Accuracy Study:

100 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	%Agreement
Positive	0	0	0	7	38	93.75 %
Negative	20	9	12	3*	0	100.0 %

The following table summarizes the result for the three discordant samples:

Cutoff Value (100 ng/mL)	Sample Testing Method	
	LZI EIA	GC/MS or LC/MS (ng/mL)
Sample #42*	-	108
Sample #43*	-	110
Sample #48*	-	135

Discrepant samples are based on a 100 ng/mL cutoff concentration with 325.7 mAU/min, 314.7 mAU/min, and 325.7 mAU/min absorbance values.

Semi-Quantitative Accuracy Study:

100 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agreement
Positive	0	0	0	7	38	93.75 %
Negative	20	9	12	3*	0	100.0 %

The following table summarizes the result for the three discordant samples:

Cutoff Value (100 ng/mL)	Sample Testing Method	
	LZI EIA	GC/MS or LC/MS (ng/mL)
Sample #42*	-	108
Sample #43*	-	110
Sample #48*	-	135

Accuracy 300 ng/mL Cutoff: One hundred and one (101) unaltered clinical urine specimens were tested with the LZI Oxycodone Enzyme Immunoassay and confirmed with GC/MS or LC/MS. Specimens having an Oxycodone concentration greater than 300 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. The correlation results are summarized as follows (near cutoff samples are defined as ± 50 % of the cutoff value):

Qualitative Accuracy Study:

300 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agreement
Positive	0	0	1*	11	43	96.1 %
Negative	20	18	11	2**	0	98.0 %

The following table summarizes the result for the three discordant samples:

Cutoff Value (300 ng/mL)	Sample Testing Method	
	LZI EIA	GC/MS or LC/MS (ng/mL)
Sample #49*	+	288
Sample #52**	-	309
Sample #54**	-	336

Discrepant samples are based on a 300 ng/mL cutoff concentration with 466.1 mAU/min absorbance values.

Semi-Quantitative Accuracy Study:

300 ng/mL Cutoff	Neg	< 50 % below the cutoff	Near Cutoff Neg	Near Cutoff Pos	> 50 % above the cutoff	% Agree-ment
Positive	0	0	1*	11	43	96.1 %
Negative	20	18	11	2**	0	98.0 %

The following table summarizes the result for the three discordant samples:

Cutoff Value (300 ng/mL)	Sample Testing Method	
	LZI EIA	GC/MS or LC/MS (ng/mL)
Sample #49*	+	288
Sample #52**	-	309
Sample #54**	-	336

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

$y = 0.974x + 1.4518$, $r^2 = 0.998$

Expected Value (ng/mL)	Observed Value (ng/mL)	%Recovery
800	801.4	100.2 %
700	657.1	93.9 %
600	585.3	97.6 %
500	494.4	98.9 %
400	383.9	96.0 %
300	302.9	101.0 %
200	190.5	95.2 %
100	102.2	102.2 %
50	50.4	100.8 %
0	1.6	N/A

Specificity: Cross-reactivity of various potential interfering drugs were tested by spiking various concentrations of each substance into drug-free urine, 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 to either 100 ng/mL or 300 ng/mL oxycodone cutoff or the maximal concentration of the compound tested that gave a response below the response of the cutoff calibrators.

Structurally Related Compounds: 100 ng/mL Cutoff

Compound	Equivalent [ ] to 100 ng/mL (ng/mL)	% Cross-Reactivity
Oxycodone	100	110.40 %
Hydrocodone	22,300	0.58 %
Hydromorphone	14,100	0.68 %
Oxymorphone	115	87.91 %
Noroxycodone	1100	9.70 %
Noroxymorphone	1000	11.96 %
Codeine	60,000	0.16 %
Dextromethorphan	1,000,000	0.01 %
Dihydrocodeine	250,000	0.04 %
Levorphanol	60,000	0.17 %
Naloxone	9000	0.93 %
Norcodeine	1,000,000	0.02 %
Morphine	50,000	0.22 %
Oxymorphone-Glucuronide	85	135.88 %
Codeine-6-b-Glucuronide	5000	0.06 %
Morphine-3-Glucoronide	250,000	0.01 %
6-AM	62,100	0.01 %
NorBuprenorphine	100,000	0.00 %

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

Structurally Unrelated Pharmacological Compounds: 100 ng/mL Cutoff

Compound	Equivalent [ ] to 100 ng/mL (ng/mL)	% Cross	Oxycodone Concentration		
			0 ng/mL	75 ng/mL Control	125 ng/mL Control
Acetaminophen	500,000	0.001 %	Neg	Neg	Pos
Acetylsalicylic Acid	500,000	0.000 %	Neg	Neg	Pos
Amobarbital	500,000	0.001 %	Neg	Neg	Pos
Benzoylecgonine	500,000	0.003 %	Neg	Neg	Pos
Bromopheniramine	100,000	0.002 %	Neg	Neg	Pos
Bupropion	500,000	0.001 %	Neg	Neg	Pos
Caffeine	500,000	0.001 %	Neg	Neg	Pos
Chlorpheniramine	500,000	0.001 %	Neg	Neg	Pos
Chlorpromazine	500,000	0.001 %	Neg	Neg	Pos
d,l-Phenylpropanolamine (Phenethylamine)	250,000	0.003 %	Neg	Neg	Pos
d-Ephedrine	500,000	0.003 %	Neg	Neg	Pos
l-Ephedrine	300,000	0.001 %	Neg	Neg	Pos

Structurally Unrelated Pharmacological Compounds: 100 ng/mL Cutoff, continued:

Compound	Equivalent [ ] to 100 ng/mL (ng/mL)	% Cross	Oxycodone Concentration		
			0 ng/mL	75 ng/mL Control	125 ng/mL Control
d-Methamphetamine	250,000	0.004 %	Neg	Neg	Pos
Ecgonine (Ecgonine Methyl-ester)	500,000	0.001 %	Neg	Neg	Pos
Meperidine	500,000	0.004 %	Neg	Neg	Pos
Methadone	500,000	0.001 %	Neg	Neg	Pos
Nicotine	500,000	0.002 %	Neg	Neg	Pos
Norpropoxyphene	100,000	0.002 %	Neg	Neg	Pos
Phencyclidine	250,000	0.012 %	Neg	Neg	Pos
Promethiazine	500,000	0.002 %	Neg	Neg	Pos
Propranolol	100,000	0.003 %	Neg	Neg	Pos
Secobarbital	500,000	0.001 %	Neg	Neg	Pos
Trazodone	500,000	0.001 %	Neg	Neg	Pos
Tyramine	500,000	0.002 %	Neg	Neg	Pos
Valproic Acid	500,000	0.001 %	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.

Structurally Related Compounds: 300 ng/mL Cutoff

Compound	Equivalent [ ] to 300 ng/mL (ng/mL)	% Cross-Reactivity
Oxycodone	300	102.07 %
Hydrocodone	66,000	0.46 %
Hydromorphone	41,800	0.54 %
Oxymorphone	340	88.35 %
Noroxycodone	3100	7.27 %
Noroxymorphone	4700	6.59 %
Codeine	250,000	0.11 %
Dextromethorphan	4,500,000	0.01 %
Dihydrocodeine	1,100,000	0.03 %
Levorphanol	300,000	0.12 %
Naloxone	20,000	1.60 %
Norcodeine	2,500,000	0.01 %
Morphine	125,000	0.25 %
Oxymorphone-Glucuronide	200	153.15 %
Codeine-6-b-Glucuronide	10,000	0.02 %
6-AM	183,600	0.01 %
NorBuprenorphine	100,000	0.00 %
Morphine-3-Glucoronide	500,000	0.01 %

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

Structurally Unrelated Pharmacological Compounds: 300 ng/mL Cutoff

Compound	Equivalent [ ] to 100 ng/mL (ng/mL)	% Cross	Oxycodone Concentration		
			0 ng/mL	225 ng/mL Control	375 ng/mL Control
Acetaminophen	500,000	0.001 %	Neg	Neg	Pos
Acetylsalicylic Acid	500,000	0.000 %	Neg	Neg	Pos
Amobarbital	500,000	0.001 %	Neg	Neg	Pos
Benzoylecgonine	500,000	0.003 %	Neg	Neg	Pos
Bromopheniramine	100,000	0.002 %	Neg	Neg	Pos
Bupropion	500,000	0.001 %	Neg	Neg	Pos
Caffeine	500,000	0.001 %	Neg	Neg	Pos
Chlorpheniramine	500,000	0.001 %	Neg	Neg	Pos
Chlorpromazine	500,000	0.001 %	Neg	Neg	Pos
d,l-Phenylpropanolamine (Phenethylamine)	250,000	0.003 %	Neg	Neg	Pos
d-Ephedrine	500,000	0.003 %	Neg	Neg	Pos
l-Ephedrine	300,000	0.001 %	Neg	Neg	Pos
d-Methamphetamine	250,000	0.004 %	Neg	Neg	Pos
Ecgonine (Ecgonine Methyl-ester)	500,000	0.001 %	Neg	Neg	Pos
Meperidine	500,000	0.004 %	Neg	Neg	Pos
Methadone	500,000	0.001 %	Neg	Neg	Pos
Nicotine	500,000	0.002 %	Neg	Neg	Pos
Norpropoxyphene	100,000	0.002 %	Neg	Neg	Pos
Phencyclidine	250,000	0.012 %	Neg	Neg	Pos
Promethiazine	500,000	0.002 %	Neg	Neg	Pos
Propranolol	100,000	0.003 %	Neg	Neg	Pos
Secobarbital	500,000	0.001 %	Neg	Neg	Pos
Trazodone	500,000	0.001 %	Neg	Neg	Pos
Tyramine	500,000	0.002 %	Neg	Neg	Pos
Valproic Acid	500,000	0.001 %	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: 100 ng/mL Cutoff
The following endogenous compounds were spiked into negative urine and the two levels of controls (75 ng/mL and 125 ng/mL) for the assay. The spiked solution is evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds at physiological relevant concentrations as all spiked samples gave correct responding positive/negative results against the cutoff value of 100 ng/mL. Results are summarized in the following table:

Interfering Substances	Spiked [ ] (mg/dL)	Oxycodone Concentration		
		0 ng/mL	75 ng/mL Control	125 ng/mL Control
Acetone	1000	Neg	Neg	Pos
Ascorbic Acid	400	Neg	Neg	Pos
Creatinine	500	Neg	Neg	Pos
Ethanol	1000	Neg	Neg	Pos
Galactose	10	Neg	Neg	Pos
γ-Globulin	500	Neg	Neg	Pos
Glucose	1500	Neg	Neg	Pos
Hemoglobin	300	Neg	Neg	Pos
Human Serum Albumin	500	Neg	Neg	Pos
Sodium Chloride	3000	Neg	Neg	Pos
Oxalic Acid	100	Neg	Neg	Pos
Urea	2000	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
pH 11	N/A	Neg	Neg	Pos

Interference: Endogenous Substances: 300 ng/mL Cutoff
The following endogenous compounds were spiked into negative urine and the two levels of controls (225 ng/mL and 375 ng/mL) for the assay. The spiked solution is evaluated against the assay's calibration curve. Results indicate there is no major interference with these compounds at physiological relevant concentrations as all spiked samples gave correct responding positive/negative results against the cutoff value of 300 ng/mL. Results are summarized in the following table:

Interfering Substances	Spiked [ ] (mg/dL)	Oxycodone Concentration		
		0 ng/mL	225 ng/mL Control	375 ng/mL Control
Acetone	1000	Neg	Neg	Pos
Ascorbic Acid	400	Neg	Neg	Pos
Creatinine	500	Neg	Neg	Pos
Ethanol	1000	Neg	Neg	Pos
Galactose	10	Neg	Neg	Pos
γ-Globulin	500	Neg	Neg	Pos
Glucose	1500	Neg	Neg	Pos
Hemoglobin	300	Neg	Neg	Pos
Human Serum Albumin	500	Neg	Neg	Pos
Sodium Chloride	6000	Neg	Neg	Pos
Oxalic Acid	100	Neg	Neg	Pos
Urea	2000	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
pH 11	N/A	Neg	Neg	Pos

Specific Gravity: Specific gravity samples ranging in value from 1.000 to 1.0275 were tested with the assay in the presence of 0 ng/mL, 75 ng/mL, 225 ng/mL, and 375 ng/mL of oxycodone and no interference was observed.

Note: All endogenous substances listed above and specific gravity samples, were also tested in qualitative mode. No interference is observed. The results are identical to the semi-quantitative mode as all samples gave correct positive/negative result corresponding to the cutoff values of either 100 ng/mL or 300 ng/mL.

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Additions, deletions, or changes are indicated by a change bar in the margin.
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