Lin-Zhi International, Inc.
Santa Clara, CA 95051
Tel: (408) 970-8811
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Reagent Name Hydrocodone 300 C/O REF C68823 DxC 500 AU Urine Settings

Calibrator Name LZI Hydrocodone 300 Qualitative Calibrator Ref C68830

The information provided in this application sheet is intended as a supplement to the package insert.
Refer to the package insert for information on intended use, reagent storage, and additional performance data.

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev		Discipline	Chemistry
Test ID	HYD300			Calculated Result	☐
LIS Code	HYD300			Result Type	Qualitative

UNITS AND RANGE SETTINGS

Urine

Use Settings from	None	Units	None	Decimal Places	x.x
Test Kind	General	Revision	01		☒ Multi Reagent Switch
Reagent Name	HYD	Reagent ID	249		☐ FSE Test
	ABB Name HYD1G	Parameter Long Name	Hydrocodone 300 C/O C68823 HYD1G Urine		

Region ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME

Sample Volume	12 µL	Dilution	0 µL		
Pre-Dilution Rate	1				

REAGENT VOLUME

R1 (R1-1)	120 µL	Dilution	0 µL		
R1-2	µL	Dilution	µL		
R2 (R2-1)	45 µL	Dilution	10 µL		

WAVELENGTH

Primary	340 nm	Secondary	410 nm		

METHOD: FIXED

REACTION SLOPE: +

MEASURING POINT

Point 1:	First	14	Last	18
Point 2:	First		Last	

Linearity Limit %

Lag Time Check ☐Perform Lag Time Check

REACTION OD LIMIT

Min. OD	-2.0000	Max OD	3.0000

REACTION BLANK OD LIMIT

First: Low	-2.0000	High	3.0000
Last: Low	-2.0000	High	3.0000

ANALYTICAL MEASURING RANGE

Low	-999999.9	High	999999.9

MANUFACTURER FACTOR

A	1	B	0

REAGENT ONBOARD STABILITY: 8 Days 0 Hours

LIH INFLUENCE CHECK ☐Perform LIH Check

Lipemia	+
Icterus	+
Hemolysis	+

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
None	1	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type: AB

Formula: Y=AX+B

Calibrator Name: Add #

☐SLOPE CHECK

Slope Check: None

STABILITY AND INTERVAL

Reagent Blank Stability	8 Days	0 Hours	Interval	Lot	
Calibration Stability	8 Days	0 Hours	Interval	Lot	

CALIBRATION OD AND CONCENTRATION PARAMETERS

Counts: 2

☐Use highest calibrator for Upper AMR

MB Factor:

Positive Cutoff: 100.0

Number of Levels: 5

	Calibrator Name	Conc.	Factor Range Low	Factor Range High
Point 1	#	100.0*	-9999999	9999999
Point 2				
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

OD DELTA CHECK

☐Reagent Blank	0.0000
☐Calibration	0.0000

\# User Defined

PROZONE CHECK PARAMETERS

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Calibrator Name LZI Hydrocodone 300 Qualitative Calibrator Ref C68830

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☐Logic Check 1

Check Points		Decision Values	
Point 1	0	Value 1	0
Point 2	0	Value 2	0
Point 3	0	Value 3	0

Limit Points	
Limit 1	0
Limit 2	27

Check Pattern

Pattern	Pattern 1 ▼

☐Logic Check 2

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points	
Limit 1	0
Limit 2	27

☐Logic Check 3

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points	
Limit 1	0
Limit 2	27

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Reagent Name Hydrocodone 300 S/Q REF C68823 DxC 500 AU Urine Settings

Calibrator Name LZI Hydrocodone 300 Semi-Quantitative Calibrator Ref C68807, C68831

The information provided in this application sheet is intended as a supplement to the package insert.
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TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev		Discipline	Chemistry
Test ID	HYD300-			Calculated Result	☐
LIS Code	HYD300-			Result Type	Semi-Quantitative

UNITS AND RANGE SETTINGS

Urine

Use Settings from	None	Units	ng/mL	Decimal Places	x.x
Test Kind	General	Revision	01		☒ Multi Reagent Switch
Reagent Name	HYD	Reagent ID	249		☐ FSE Test
ABB Name	HYD2G	Parameter Long Name	Hydrocodone 300 S/Q C68823 HYD2G Urine		

Region ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME

Sample Volume	12	µL	Dilution	0	µL
Pre-Dilution Rate	1				

REAGENT VOLUME

R1 (R1-1)	120	µL	Dilution	0	µL
R1-2		µL	Dilution		µL
R2 (R2-1)	45	µL	Dilution	10	µL

WAVELENGTH

Primary	340	nm	Secondary	410	nm

METHOD: FIXED

REACTION SLOPE: +

MEASURING POINT

Point 1:	First	14	Last	18
Point 2:	First		Last	

Linearity Limit: %

Lag Time Check: ☐Perform Lag Time Check

REACTION OD LIMIT

Min. OD	-2.0000	Max OD	3.0000

REACTION BLANK OD LIMIT

First: Low	-2.0000	High	3.0000
Last: Low	-2.0000	High	3.0000

ANALYTICAL MEASURING RANGE

Low	150.0	High	800.0

MANUFACTURER FACTOR

A	1	B	0

REAGENT ONBOARD STABILITY: 8 Days 0 Hours

LIH INFLUENCE CHECK

☐Perform LIH Check

Lipemia	+
Icterus	+
Hemolysis	+

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	1	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type: 5AB

Formula: Polygonal

Calibrator Name: Add #

☒SLOPE CHECK Number of Levels: 5

Slope Check: +

STABILITY AND INTERVAL

Reagent Blank Stability	8	Days	0	Hours	Interval: Lot
Calibration Stability	8	Days	0	Hours	Interval: Lot

CALIBRATION OD AND CONCENTRATION PARAMETERS

Counts: 2

☐Use highest calibrator for Upper AMR

MB Factor:

Positive Cutoff: 300.0

	Calibrator Name	Conc.	Factor Range Low	Factor Range High
Point 1	#	0.0	-2.0000	3.0000
Point 2	#	150.0	-2.0000	3.0000
Point 3	#	300.0	-2.0000	3.0000
Point 4	#	500.0	-2.0000	3.0000
Point 5	#	800.0	-2.0000	3.0000
Point 6				
Point 7				

OD DELTA CHECK

☐Reagent Blank	0.0000
☐Calibration	0.0000

\# User Defined

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Calibrator Name LZI Hydrocodone 300 Semi-Quantitative Calibrator **Ref C68807, C68831**

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☐Logic Check 1

Check Points		Decision Values	
Point 1	0	Value 1	0
Point 2	0	Value 2	0
Point 3	0	Value 3	0

Limit Points	
Limit 1	0
Limit 2	27

Check Pattern

Pattern	Pattern 1 ▼

☐Logic Check 2

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points	
Limit 1	0
Limit 2	27

☐Logic Check 3

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points	
Limit 1	0
Limit 2	27