

Lin-Zhi International, Inc.

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Reagent Name Hydrocodone 100 C/O REF C68823 DxC 500 AU Urine Settings

Calibrator Name LZI Hydrocodone 100 Qualitative Calibrator Ref C68824

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

HYD100

Calculated Result

☐

LIS Code

HYD100

Result Type

Qualitative

UNITS AND RANGE SETTINGS

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

HYD1U

Parameter Long Name

Hydrocodone 100 C/O C68823 HYD1U Urine

Region

☒ US

☐ OUS

☐ AP

☐ JP

☐ EU

☐ Other

Urine

GENERAL PARAMETERS

SAMPLE VOLUME

Sample Volume

18

µL

Dilution

0

µL

REACTION OD LIMIT

Min. OD

-2.0000

Max OD

3.0000

REAGENT VOLUME

Pre-Dilution Rate

1

REACTION BLANK OD LIMIT

First: Low

-2.0000

High

3.0000

R1 (R1-1)

120

µL

Dilution

0

µL

Last: Low

-2.0000

High

3.0000

R1-2

µL

Dilution

µL

ANALYTICAL MEASURING RANGE

Low

-999999.9

High

999999.9

R2 (R2-1)

45

µL

Dilution

10

µL

MANUFACTURER FACTOR

A

1

B

0

WAVELENGTH

Primary

340

nm

Secondary

410

nm

REAGENT ONBOARD STABILITY

8

Days

0

Hours

METHOD

FIXED

LIH INFLUENCE CHECK

☐ Perform LIH Check

REACTION SLOPE

+

Lipemia

+

MEASURING POINT

Point 1: First

14

Last

18

Icterus

+

Point 2: First

µL

Last

µL

Hemolysis

+

Linearity Limit

%

Lag Time Check

☐ Perform Lag Time Check

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

Counts

2

Formula

Y=AX+B

MB Factor

Point 1

Point 2

Point 3

Point 4

Point 5

Point 6

Point 7

Calibrator Name

Add

#

Positive Cutoff

100.0

☐ SLOPE CHECK

Slope Check

None

Number of Levels

5

STABILITY AND INTERVAL

Reagent Blank Stability

8

Days

0

Hours

Interval

Lot

Calibration Stability

8

Days

0

Hours

Interval

Lot

OD DELTA CHECK

☐ Reagent Blank

0.0000

☐ Calibration

0.0000

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

Calibrator Name	Conc.	Factor Range Low	Factor Range High
#	100.0*	-9999999	9999999

User Defined



Reagent Name Hydrocodone 100 C/O REF C68823 DxC 500 AU Urine Settings

Calibrator Name LZI Hydrocodone 100 Qualitative Calibrator Ref C68824

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PROZONE CHECK PARAMETERS											
☐ Logic Check 1				☐ Logic Check 2				☐ Logic Check 3			
Check Points		Decision Values		Check Points		Decision Values		Check Points		Decision Values	
Point 1	0	Value 1	0	Point 1	0	Value 1	0	Point 1	0	Value 1	0
Point 2	0	Value 2	0	Interval	1	Value 2	0	Interval	1	Value 2	0
Point 3	0	Value 3	0								
Limit Points				Limit Points				Limit Points			
Limit 1	0			Limit 1	0			Limit 1	0		
Limit 2	27			Limit 2	27			Limit 2	27		
Check Pattern											
Pattern		Pattern 1 ▼									

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Reagent Name Hydrocodone 100 SQ REF C68823 DxC 500 AU Urine Settings

Calibrator Name LZI Hydrocodone 100 Semi-Quantitative Calibrator Ref C68807, C68825

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TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name

Test

Rev

Discipline

Chemistry

Test ID

HYD100-

Calculated Result

☐

LIS Code

HYD100-

Result Type

Semi-Quantitative

UNITS AND RANGE SETTINGS

Use Settings from

None

Units

ng/mL

Decimal Places

x.x

Urine

Test Kind

General

Revision

01

☒ Multi Reagent Switch

Reagent Name

HYD

Reagent ID

249

☐ FSE Test

ABB Name

HYD2U

Parameter Long Name

Hydrocodone 100 S/Q C68823 HYD2A Urine

Region

☒ US

☐ OUS

☐ AP

☐ JP

☐ EU

☐ Other

GENERAL PARAMETERS

SAMPLE VOLUME

Sample Volume

18

µL

Dilution

0

µL

REACTION OD LIMIT

Min. OD

-2.0000

Max OD

3.0000

REAGENT VOLUME

Pre-Dilution Rate

1

REACTION BLANK OD LIMIT

First: Low

-2.0000

High

3.0000

R1 (R1-1)

120

µL

Dilution

0

µL

Last: Low

-2.0000

High

3.0000

R1-2

µL

Dilution

µL

ANALYTICAL MEASURING RANGE

Low

25.0

High

300.0

R2 (R2-1)

45

µL

Dilution

10

µL

MANUFACTURER FACTOR

A

1

B

0

WAVELENGTH

Primary

340

nm

Secondary

410

nm

REAGENT ONBOARD STABILITY

8

Days

0

Hours

METHOD

FIXED

LIH INFLUENCE CHECK

☐ Perform LIH Check

REACTION SLOPE

+

Lipemia

+

MEASURING POINT

Point 1: First

14

Last

18

Icterus

+

Point 2: First

Last

Hemolysis

+

Linearity Limit

%

Lag Time Check

☐ Perform Lag Time Check

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

Counts

2

☐ Use highest calibrator for Upper AMR

Formula

Polygonal

MB Factor

Point 1

#

0.0

-2.0000

3.0000

Calibrator Name

Add

#

Positive Cutoff

100.0

Point 2

#

50.0

-2.0000

3.0000

☒ SLOPE CHECK

Slope Check

+

Number of Levels

5

Point 3

#

100.0

-2.0000

3.0000

STABILITY AND INTERVAL

Reagent Blank Stability

8

Days

0

Hours

Interval

Lot

Point 4

#

150.0

-2.0000

3.0000

Calibration Stability

8

Days

0

Hours

Interval

Lot

Point 5

#

300.0

-2.0000

3.0000

OD DELTA CHECK

☐ Reagent Blank

0.0000

☐ Calibration

0.0000

Point 6

Point 7

User Defined



Reagent Name **Hydrocodone 100 SQ REF C68823** **DxC 500 AU Urine Settings**
Calibrator Name **LZI Hydrocodone 100 Semi-Quantitative Calibrator** **Ref C68807, C68825**

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PROZONE CHECK PARAMETERS											
☐ Logic Check 1				☐ Logic Check 2				☐ Logic Check 3			
Check Points		Decision Values		Check Points		Decision Values		Check Points		Decision Values	
Point 1	0	Value 1	0	Point 1	0	Value 1	0	Point 1	0	Value 1	0
Point 2	0	Value 2	0	Interval	1	Value 2	0	Interval	1	Value 2	0
Point 3	0	Value 3	0								
Limit Points				Limit Points				Limit Points			
Limit 1	0			Limit 1	0			Limit 1	0		
Limit 2	27			Limit 2	27			Limit 2	27		
Check Pattern											
Pattern		Pattern 1 ▼									