

Reagent Name Fentanyl 5 C/O REF C68809 DxC 500 AU and DxC 500i Urine Settings

Calibrator Name LZI Norfentanyl Qualitative Calibrator Ref C68810

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	FEN5		Calculated Result	☐					
LIS Code	FEN5		Result Type	Qualitative ▼					
UNITS AND RANGE SETTINGS									
Use Settings from	None ▼	Units	None	Decimal Places	x.x ▼	Urine			
Test Kind	General ▼	Revision	05	☒ Multi Reagent Switch					
Reagent Name	FEN		Reagent ID	248		☐ FSE Test			
Region	ABB Name	FEN1N	Parameter Long Name	Fentanyl 5 C/O C68809 FEN1N URINE					
	☐ US	☒ OUS	☒ AP	☐ JP	☒ EU	☐ Other			

GENERAL PARAMETERS					
SAMPLE VOLUME		Sample Volume	15	μL	
		Pre-Dilution Rate	1		
REAGENT VOLUME		R1 (R1-1)	120	μL	
		R1-2		μL	
		R2 (R2-1)	45	μL	
WAVELENGTH		Primary	340	nm	
		Secondary	410	nm	
METHOD		FIXED			
REACTION SLOPE		+			
MEASURING POINT		Point 1: First	14	Last	19
		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	High	999999
		MANUFACTURER FACTOR			
		A	1	B	0
		REAGENT ONBOARD STABILITY			
		90	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

CALIBRATION OD AND CONCENTRATION PARAMETERS

Counts 2 ▼ ☐ Use highest calibrator for Upper AMR

MB Factor Point 1

Positive Cutoff 100.0 Point 2

5 Point 3

Point 4

Point 5

Point 6

Point 7

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

STABILITY AND INTERVAL

Reagent Blank Stability 14 Days 0 Hours

Calibration Stability 14 Days 0 Hours

Interval Lot ▼

Interval Lot ▼

OD DELTA CHECK

☐ Reagent Blank 0.0000

☐ Calibration 0.0000

User Defined



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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							

FEN (wash step), DxC 500 AU

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Contamination Parameter Configurations				
Test Name:		FEN		▼
Type:		Urine		▼
Operation:		Yes		▼
Test Name	Pre-Dispense Wash Count		Post-Dispense Wash Count	
	Detergent-1	Water	Detergent-1	Water
1. Fentanyl	0	0	3	0
2. X	x	x	x	x
3. X	x	x	x	x
4. X	x	x	x	x
5. X	x	x	x	x
6. X	x	x	x	x
7. X	x	x	x	x
8. X	x	x	x	x
9. X	x	x	x	x
10. X	x	x	x	x
11. X	x	x	x	x
12. X	x	x	x	x
13. X	x	x	x	x
14. X	x	x	x	x
15. X	x	x	x	x
16. X	x	x	x	x
17. X	x	x	x	x
18. X	x	x	x	x
19. X	x	x	x	x
20. X	x	x	x	x

Reagent Name Fentanyl 5 S/Q REF C68809 DxC 500 AU and DxC 500i Urine Settings

Calibrator Name LZI Norfentanyl Semi-Quantitative Calibrator Ref C68807, C68811

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TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name

Test

Rev

Discipline

Chemistry

Test ID

FEN5-

Calculated Result

LIS Code

FEN5-

Result Type

Semi-Quantitative

UNITS AND RANGE SETTINGS

Use Settings from

None

Units

ng/mL

Decimal Places

x.xx

Urine

Test Kind

General

Revision

05

Multi Reagent Switch

Reagent Name

FEN

Reagent ID

248

FSE Test

ABB Name

FEN2N

Parameter Long Name

Fentanyl 5 S/Q C68809 FEN2N Urine

Region

☐US

☒OUS

☒AP

☐JP

☒EU

☐Other

GENERAL PARAMETERS

SAMPLE VOLUME

Sample Volume

15

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

R2 (R2-1)

45

µL

Dilution

10

µL

Low

2.50

High

20.00

WAVELENGTH

Primary

340

nm

Secondary

410

nm

MANUFACTURER FACTOR

A

1

B

0

METHOD

FIXED

REAGENT ONBOARD STABILITY

90

Days

0

Hours

MEASURING POINT

Point 1: First

14

Last

19

LIH INFLUENCE CHECK

☐Perform LIH Check

Point 2: First

Last

Lipemia

+

Icterus

+

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	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

5AB

Counts

2

Formula

Polygonal

MB Factor

Point 1

Point 2

Point 3

Point 4

Point 5

Point 6

Point 7

Calibrator Name

Add

#

Positive Cutoff

5.00

☒Slope Check

Slope Check

+

Number of Levels

5

STABILITY AND INTERVAL

Reagent Blank Stability

14

Days

0

Hours

Interval

Lot

Calibration Stability

14

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.	OD Range Low	OD Range High
#	0.00	-2.0000	3.0000
#	2.50	-2.0000	3.0000
#	5.00	-2.0000	3.0000
#	10.00	-2.0000	3.0000
#	20.00	-2.0000	3.0000

User Defined



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☐ 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									

FEN (wash step), DxC 500 AU

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Contamination Parameter Configurations				
Test Name: FEN		Type: Urine		Operation: Yes
Test Name	Pre-Dispense Wash Count		Post-Dispense Wash Count	
	Detergent-1	Water	Detergent-1	Water
1. Fentanyl	0	0	3	0
2. X	x	x	x	x
3. X	x	x	x	x
4. X	x	x	x	x
5. X	x	x	x	x
6. X	x	x	x	x
7. X	x	x	x	x
8. X	x	x	x	x
9. X	x	x	x	x
10. X	x	x	x	x
11. X	x	x	x	x
12. X	x	x	x	x
13. X	x	x	x	x
14. X	x	x	x	x
15. X	x	x	x	x
16. X	x	x	x	x
17. X	x	x	x	x
18. X	x	x	x	x
19. X	x	x	x	x
20. X	x	x	x	x