



Fentanyl (qualitative), AU480

System Reagent: C68809

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.

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	FEN	<	>	Type:	Urine	Operation	Yes			
Sample Volume	15	μL	Dilution	0	μL	OD Limit				
Pre-Dilution Rate	1		Min. OD	-2.0000	Max.	3.0000				
Reagents Volume:	R1(R1-1)	120	μL	Dilution	0	μL	Reagent OD limit:			
							First Low	-2.0000	High	3.0000
							Last Low	-2.0000	High	3.0000
	R2 (R2-1)	45	μL	Dilution	10	μL	Dynamic Range Low	-999999.9	High	999999.9
Wavelength:	Pri.	340	nm	Sec.	410	nm	Correlation Factor A	1.0	B	0
Method:	FIXED									
Reaction slope:	+									
Measuring Point 1:	First	14	Last	19	LIH Influence Check					
Measuring Point 2:	First		Last		Lipemia					
Linearity:										
No Lag Time:										
							Factor for Maker A	1	B	0
							Onboard Stability	Day	Hour	
							Icterus			
							Hemolysis			

Specific Test Parameters																																																																																			
General		LIH	ISE	Range																																																																															
Test Name:	FEN	<	>	Type:	Urine																																																																														
Value/Flag:	Flag	Level L:	99.9	Level H:	100.0	Panic Value																																																																													
Specific Ranges:	<table border="1"> <thead> <tr> <th></th> <th>Sex</th> <th>Year</th> <th>Month</th> <th>Year</th> <th>Month</th> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> 1.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td><input type="checkbox"/> 2.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td><input type="checkbox"/> 3.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td><input type="checkbox"/> 4.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td><input type="checkbox"/> 5.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td><input type="checkbox"/> 6.</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> <td>#</td> </tr> <tr> <td colspan="7">7. No demographics</td> <td>#</td> <td>#</td> </tr> <tr> <td colspan="7">8. Not within expected values</td> <td>#</td> <td>#</td> </tr> </tbody> </table>										Sex	Year	Month	Year	Month	Low	High	<input type="checkbox"/> 1.	#	#	#	#	#	#	#	<input type="checkbox"/> 2.	#	#	#	#	#	#	#	<input type="checkbox"/> 3.	#	#	#	#	#	#	#	<input type="checkbox"/> 4.	#	#	#	#	#	#	#	<input type="checkbox"/> 5.	#	#	#	#	#	#	#	<input type="checkbox"/> 6.	#	#	#	#	#	#	#	7. No demographics							#	#	8. Not within expected values							#	#
	Sex	Year	Month	Year	Month	Low	High																																																																												
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8. Not within expected values							#	#																																																																											
Unit	Decimal Places		1																																																																																

Calibration Specific									
General		ISE							
Test Name:	FEN	<	>	Type:	Urine	<input type="checkbox"/> Use Serum Cal.			
Calibration Type:	AB	Formula:	Y=AX+B	Counts:	2	Slope Check			
<Calibrator Parameters>						None			
Point 1:	Calibrator	OD	Conc	Factor Range		Allowable Range Check			
	#		100.0*	Low	High	<input type="checkbox"/> Reagent Blank			
Point 2:				-9999999	9999999	<input type="checkbox"/> Calibration			
Point 3:						Advanced Calibration			
Point 4:						Operation			
Point 5:						Yes			
Point 6:						Interval (RB/ACAL)			
Point 7:						Lot / Lot			
Point 8:									
Point 9:									
Point 10:									
<Point Cal. For Master Curve>						Stability			
Point 1:	Calibrator	OD	Conc	OD Range		Reagent Blanks			
				Low	High	14 Day 0 Hour			
Point 2:						14 Day 0 Hour			
MB Type Factor:						1-Point Calibration Point			
						<input type="checkbox"/> With CONC-0			

User Defined

* The cutoff is normalized to 100. Positive samples are ≥ 100 and are flagged with a (P). LZI Norfentanyl Qualitative Calibrator Ref No.: C68810.



Fentanyl (semi-quantitative), AU480

System Reagent: C68809

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Specific Test Parameters												
General		LIH	ISE	Range								
Test Name:	FEN	<	>	Type:	Urine	Operation	Yes					
Sample Volume	15	μL	Dilution	0	μL	OD Limit						
Pre-Dilution Rate	1		Min. OD	-2.0000	Max.	3.0000						
Reagents Volume:	R1(R1-1)	120	μL	Dilution	0	μL	Reagent OD limit:					
							First Low	-2.0000	High	3.0000		
							Last Low	-2.0000	High	3.0000		
	R2 (R2-1)	45	μL	Dilution	10	μL	Dynamic Range Low	2.5	High	20		
							Correlation Factor A	1	B	0		
Wavelength:	Pri.	340	nm	Sec.	410	nm	Factor for Maker A	1	B	0		
Method:	FIXED											
Reaction slope:	+											
Measuring Point 1:	First	14	Last	19	LIH Influence Check							
Measuring Point 2:	First		Last		Lipemia							
Linearity:												
No Lag Time:												
						Onboard Stability					Day	Hour
						Icterus						
						Hemolysis						

Specific Test Parameters									
General		LIH	ISE	Range					
Test Name:	FEN	<	>	Type:	Urine				
Value/Flag:	#	Level L:	#	Level H:	#				
Specific Ranges:									
	Sex	Year	Month	Year	Month	Low	High	Panic Value	
<input type="checkbox"/>	1.	#	#	#	#	#	#	Low	High
<input type="checkbox"/>	2.	#	#	#	#	#	#	#	#
<input type="checkbox"/>	3.	#	#	#	#	#	#	#	#
<input type="checkbox"/>	4.	#	#	#	#	#	#	#	#
<input type="checkbox"/>	5.	#	#	#	#	#	#	#	#
<input type="checkbox"/>	6.	#	#	#	#	#	#	#	#
7. No demographics						#	#		
8. Not within expected values						#	#		
Unit	ng/mL*		Decimal Places	2					

Calibration Specific											
General		ISE									
Test Name:	FEN	<	>	Type:	Urine	<input type="checkbox"/> Use Serum Cal.					
Calibration Type:	5AB	Formula:	Polygonal	Counts:	2	Slope Check				+	
<Calibrator Parameters>											
Calibrator	OD	Conc	Factor Range		Allowable Range Check						
			Low	High	<input type="checkbox"/> Reagent Blank						
Point 1:	#	§*	-2.0000	3.0000	<input type="checkbox"/> Calibration						
Point 2:	#	†*	-2.0000	3.0000	Advanced Calibration						
Point 3:	#	†*	-2.0000	3.0000	Operation					Yes	
Point 4:	#	†*	-2.0000	3.0000	Interval (RB/ACAL)					Lot / Lot	
Point 5:	#	†*	-2.0000	3.0000							
Point 6:											
Point 7:											
Point 8:											
Point 9:											
Point 10:											
<Point Cal. For Master Curve>											
Calibrator	OD	Conc	OD Range		Stability						
			Low	High	Reagent Blanks						
Point 1:					14					Day	0
Point 2:					14					Day	0
MB Type Factor:			1-Point Calibration Point		None					<input type="checkbox"/> With CONC-0	

User Defined

§ LZI Universal Negative Calibrator Ref No.: C68807

† LZI Norfentanyl Semi-Quantitative Calibrator Set Ref No.: C68811

* Values set for working in ng/mL.

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For Sales Outside USA (OUS) Only

Fentanyl (qualitative and semi-quantitative wash setting), AU480

System Reagent: C68809

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Miscellaneous						
Checked Tests	Contamination Parameters			Data Check Parameters		
Contamination Prevention	Carry-Over Prevention (Type Changes)			Carry-Over Prevention (Test)		
Test Name	Pre-Dispense Wash Count			Post-Dispense Wash Count		
	Detergent-1	Detergent-2	Water	Detergent-1	Detergent-2	Water
1. Fentanyl	0	0	0	0	0	3
2. X	x	x	x	x	x	x
3. X	x	x	x	x	x	x
4. X	x	x	x	x	x	x
5. X	x	x	x	x	x	x
6. X	x	x	x	x	x	x
7. X	x	x	x	x	x	x
8. X	x	x	x	x	x	x
9. X	x	x	x	x	x	x
10. X	x	x	x	x	x	x
11. X	x	x	x	x	x	x
12. X	x	x	x	x	x	x
13. X	x	x	x	x	x	x
14. X	x	x	x	x	x	x
15. X	x	x	x	x	x	x
16. X	x	x	x	x	x	x
17. X	x	x	x	x	x	x
18. X	x	x	x	x	x	x
19. X	x	x	x	x	x	x
20. X	x	x	x	x	x	x