



Reagent Name Fentanyl 5 C/O REF C68809 DxC 500 AU 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 ID (FEN5), LIS Code (FEN5), UNITS AND RANGE SETTINGS, Use Settings from, Test Kind, Reagent Name (FEN), ABB Name (FEN1N), Region, Discipline, Chemistry, Calculated Result, Result Type (Qualitative), Units (None), Decimal Places (x.x), Revision (01), Multi Reagent Switch, FSE Test, Parameter Long Name (Fentanyl 5 C/O C68809 FEN1N URINE).

GENERAL PARAMETERS

SAMPLE VOLUME, REAGENT VOLUME, WAVELENGTH, METHOD, REACTION SLOPE, MEASURING POINT, REACTION OD LIMIT, REACTION BLANK OD LIMIT, ANALYTICAL MEASURING RANGE, MANUFACTURER FACTOR, REAGENT ONBOARD STABILITY, LIH INFLUENCE CHECK, Lag Time Check.

CALIBRATION PARAMETERS

Table with columns: Base Unit, Decimal Place, Unit1, Factor 1, Unit 2, Factor 2, Unit 3, Factor 3, Unit 4, Factor 4. Includes CALIBRATOR SPECIFIC, CALIBRATION OD AND CONCENTRATION PARAMETERS, STABILITY AND INTERVAL, and OD DELTA CHECK.

User Defined



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PROZONE CHECK PARAMETERS

<input type="checkbox"/> Logic Check 1		<input type="checkbox"/> Logic Check 2		<input type="checkbox"/> Logic Check 3	
Check Points	Decision Values	Check Points	Decision Values	Check Points	Decision Values
Point 1	<input type="text" value="0"/>	Point 1	<input type="text" value="0"/>	Point 1	<input type="text" value="0"/>
Point 2	<input type="text" value="0"/>	Interval	<input type="text" value="1"/>	Interval	<input type="text" value="1"/>
Point 3	<input type="text" value="0"/>	Value 1	<input type="text" value="0"/>	Value 1	<input type="text" value="0"/>
		Value 2	<input type="text" value="0"/>	Value 2	<input type="text" value="0"/>
Limit Points		Limit Points		Limit Points	
Limit 1	<input type="text" value="0"/>	Limit 1	<input type="text" value="0"/>	Limit 1	<input type="text" value="0"/>
Limit 2	<input type="text" value="27"/>	Limit 2	<input type="text" value="27"/>	Limit 2	<input type="text" value="27"/>
Check Pattern					
Pattern	<input type="text" value="Pattern 1"/>				

FEN (wash step), DxC 500 AU

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Contamination Parameter Configurations

Test Name: <input type="text" value="FEN"/>		Type: <input type="text" value="Urine"/>		Operation: <input type="text" value="Yes"/>	
Test Name	Pre-Dispense Wash Count		Post-Dispense Wash Count		
	Detergent-1	Water	Detergent-1	Water	
1. Fentanyl	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="3"/>	<input type="text" value="0"/>	
2. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
3. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
4. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
5. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
6. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
7. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
8. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
9. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
10. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
11. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
12. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
13. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
14. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
15. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
16. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
17. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
18. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
19. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	
20. X	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	<input type="text" value="x"/>	



Reagent Name Fentanyl 5 S/Q REF C68809 DxC 500 AU 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	<input type="checkbox"/>
LIS Code	FEN5-		Result Type	Semi-Quantitative
UNITS AND RANGE SETTINGS				
Use Settings from	None	Units	ng/mL	Decimal Places
Test Kind	General	Revision	00	x.xx
Reagent Name	FEN	Reagent ID	248	<input checked="" type="checkbox"/> Multi Reagent Switch
Region	ABB Name	Parameter Long Name	Fentanyl 5 S/Q C68809 FEN2N Urine	<input type="checkbox"/> FSE Test
	FEN2N			
	<input type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
		<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other	

GENERAL PARAMETERS

SAMPLE VOLUME		Sample Volume	15	µL	Dilution	0	µL	REACTION OD LIMIT	
REAGENT VOLUME		Pre-Dilution Rate	1					Min. OD	-2.0000
	R1 (R1-1)	120	µL	Dilution	0	µL	REACTION BLANK OD LIMIT	Max OD	3.0000
	R1-2		µL	Dilution		µL	First: Low	-2.0000	High
	R2 (R2-1)	45	µL	Dilution	10	µL	Last: Low	-2.0000	High
WAVELENGTH		ANALYTICAL MEASURING RANGE		MANUFACTURER FACTOR		REAGENT ONBOARD STABILITY		LIH INFLUENCE CHECK	
	Primary	340	nm	Secondary	410	nm	Low	2.50	High
	METHOD	FIXED		A		1		14	
	REACTION SLOPE	+		B		0		0	
MEASURING POINT		Point 1: First		Last		14		Days	
Linearity Limit		14		19				Hours	
Lag Time Check		<input type="checkbox"/> Perform Lag Time Check						<input type="checkbox"/> Perform LIH Check	
						Lipemia		+	
						Icterus		+	
						Hemolysis		+	

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	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 OD AND CONCENTRATION PARAMETERS																																																								
Calibration Type		5AB		Counts		2		<input type="checkbox"/> Use highest calibrator for Upper AMR																																																					
Formula		Polygonal		MB Factor				<table border="1"> <thead> <tr> <th>Calibrator Name</th> <th>Conc.</th> <th>OD Range Low</th> <th>OD Range High</th> </tr> </thead> <tbody> <tr> <td>#</td> <td>0.00</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>#</td> <td>2.50</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>#</td> <td>5.00</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>#</td> <td>10.00</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>#</td> <td>20.00</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point 1</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 4</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 5</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 6</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point 7</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		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	Point 1				Point 2				Point 3				Point 4				Point 5				Point 6				Point 7			
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Point 7																																																													
Calibrator Name		Add #		Positive Cutoff		5.00																																																							
<input checked="" type="checkbox"/> Slope Check		Slope Check		Number of Levels		5																																																							
STABILITY AND INTERVAL		Reagent Blank Stability		Interval		Lot		OD DELTA CHECK																																																					
		14 Days		Lot		Lot		<input type="checkbox"/> Reagent Blank																																																					
		0 Hours		0		0		0.0000																																																					
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PROZONE CHECK PARAMETERS											
<input type="checkbox"/> Logic Check 1				<input type="checkbox"/> Logic Check 2				<input type="checkbox"/> Logic Check 3			
Check Points		Decision Values		Check Points		Decision Values		Check Points		Decision Values	
Point 1	<input type="text" value="0"/>	Value 1	<input type="text" value="0"/>	Point 1	<input type="text" value="0"/>	Value 1	<input type="text" value="0"/>	Point 1	<input type="text" value="0"/>	Value 1	<input type="text" value="0"/>
Point 2	<input type="text" value="0"/>	Value 2	<input type="text" value="0"/>	Interval	<input type="text" value="1"/>	Value 2	<input type="text" value="0"/>	Interval	<input type="text" value="1"/>	Value 2	<input type="text" value="0"/>
Point 3	<input type="text" value="0"/>	Value 3	<input type="text" value="0"/>								
Limit Points				Limit Points				Limit Points			
Limit 1	<input type="text" value="0"/>			Limit 1	<input type="text" value="0"/>			Limit 1	<input type="text" value="0"/>		
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Check Pattern											
Pattern		<input type="text" value="Pattern 1"/>									

FEN (wash step), DxC 500 AU

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Contamination Parameter Configurations											
Test Name:		<input type="text" value="FEN"/>		Type:		<input type="text" value="Urine"/>		Operation:		<input type="text" value="Yes"/>	
Test Name	Pre-Dispense Wash Count			Post-Dispense Wash Count							
	Detergent-1	Water		Detergent-1	Water						
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6. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
7. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
8. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
9. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
10. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
11. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
12. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
13. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
14. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
15. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
16. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
17. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
18. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
19. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						
20. X	<input type="text" value="x"/>	<input type="text" value="x"/>		<input type="text" value="x"/>	<input type="text" value="x"/>						