

# FEN Q

## FENTANYL (Q) ENZYME IMMUNOASSAY

510(k) Cleared

### Liquid Homogeneous Enzyme Immunoassay

**Lin-Zhi International's** The LZI Fentanyl Enzyme Immunoassay is intended for the qualitative determination of norfentanyl in human urine at the cutoff value of 5 ng/mL when calibrated against norfentanyl. The reagent kit, calibrators, and controls are ready-to-use and have 18 months of real-time stability data. The results shown below were performed on the Beckman Coulter AU680.

### Precision

Qualitative - Results were measured in  $\Delta OD$ , mAU

5 ng/mL Cutoff		Within-Run (N=22)		Run-to-Run (N=88)	
Concentration	% of Cutoff	# Samples	EIA Result	# Samples	EIA Result
0 ng/mL	0 %	22	22 Neg	88	88 Neg
1.25 ng/mL	25 %	22	22 Neg	88	88 Neg
2.5 ng/mL	50 %	22	22 Neg	88	88 Neg
3.75 ng/mL	75 %	22	22 Neg	88	88 Neg
5 ng/mL	100 %	22	20 Neg/ 2 Pos	88	62 Neg/ 26 Pos
6.25 ng/mL	125 %	22	22 Pos	88	88 Pos
7.5 ng/mL	150 %	22	22 Pos	88	88 Pos
8.75 ng/mL	175 %	22	22 Pos	88	88 Pos
10 ng/mL	200 %	22	22 Pos	88	88 Pos

### Method Comparison

Qualitative Accuracy Study

	Neg	< 50 % of the Cutoff	Near Cutoff Neg	Near Cutoff Pos	High Pos	% Agreement
Pos	0	1	6	8	41	100.0%
Neg	21	19	5	0	0	86.5%

### Cross Reactivity

Fentanyl and Metabolites

Compounds	Concentration Tested (ng/mL)	% Cross Reactivity	Result
Fentanyl	3.2	156.25%	Positive
Norfentanyl	5	100.00%	Positive

### Structurally Related Compounds

Compounds	Concentration Tested (ng/mL)	% Cross Reactivity
4-Fluoro-isobutyryl Fentanyl	35	14.29%
9-HydroxyRisperidone	100,000	0.01%
Acetyl Fentanyl	7	71.43%
Acetyl Norfentanyl	100	5.00%
Acryl Fentanyl	3.5	142.86%
Alfentanil	100,000	0.01%
Butyryl Fentanyl	3.5	142.86%

### Structurally Related Compounds, continued

Compounds	Concentration Tested (ng/mL)	% Cross Reactivity
Carfentanil Oxalate		
Cis-d, I 3-Methylfentanyl		
Cyclopropyl Norfentanyl	20	25.00%
Despropionylfentanyl (4-ANPP)	100,000	0.01%
Furanyl Fentanyl	6	81.97%
Furanyl Norfentanyl	180	2.78%
( $\pm$ )- $\beta$ -Hydroxythiofentanyl	5	100.00%
Isobutyryl Fentanyl	20	25.00%
Isobutyryl Norfentanyl	400	1.25%
Labetalol Hydrochloride	100,000	0.01%
Methoxyacetyl Fentanyl	3.5	142.86%
MT-45	100,000	0.01%
N-Benzyl Furanyl Norfentanyl	12	41.67%
N-Benzyl Para-Fluoro Norfentanyl	4.2	119.05%
Norcarfentanil Oxalate	100,000	0.01%
Ocfentanil	3.5	142.86%
Para-Fluoro Butyryl Fentanyl (P-FBF)	5.5	90.91%
Para-Fluorofentanyl	3.1	163.93%
Remifentanil	100,000	0.01%
Risperidone	100,000	0.01%
Sufentanil	100,000	0.01%
Thienyl Fentanyl	3.5	142.86%
Thiofentanyl	3.2	156.25%
Trans-d, I 3-Methylfentanyl	6	83.33%
Trazodone	100,000	0.01%
U-47700	100,000	0.01%
Valeryl Fentanyl	95	5.26%
$\omega$ -1-Hydroxy Fentanyl	320	1.56%

For additional product performance details, see product insert.

### Ordering Information

Ref #	Product	Size
0310	Fentanyl EIA, small Kit	(R <sub>1</sub> /R <sub>2</sub> ) 100/37.5 mL
0311	Fentanyl EIA, large Kit	(R <sub>1</sub> /R <sub>2</sub> ) 1000/375 mL
0313	Fentanyl 5 ng/mL Cutoff Calibrator	5 mL
0317	Fentanyl 3.75 ng/mL Level 1 Control	5 mL
0318	Fentanyl 6.25 ng/mL Level 2 Control	5 mL

DA 10/23/2024

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ISO 13485:2016

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SAL/0104-1.FEN.Q.Rev.2

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