



CUSTOMER COMMUNICATION

AU480, AU680, AU5800 and DxC 700 AU Clinical Chemistry Analyzers Introducing: Lin-Zhi Fentanyl Reagent, Calibrator, and Controls for the United States

August 2021

Dear Beckman Coulter AU and DxC AU Customer,

We are pleased to introduce the new Lin-Zhi Fentanyl (Q) Enzyme Immunoassay for use on the AU480, AU680, AU5800 and DxC 700 AU clinical chemistry analyzers. This new assay expands Beckman Coulter's drugs of abuse menu used for in vitro diagnostic testing.

Currently, this assay is CLIA categorized on the AU480 and AU680. CLIA categorization for the DxC 700 AU and AU5800 is in progress. For the time being, customers who do not have an AU480 or AU680 may choose to run Fentanyl on the DxC 700 AU and AU5800 as an FDA modified clinical lab test.

The Lin-Zhi Fentanyl (Q) Enzyme Immunoassay is intended for the qualitative determination of norfentanyl, which is the primary metabolite of fentanyl, in human urine at the cutoff value of 5 ng/mL when calibrated against norfentanyl. The measurement of norfentanyl has greater clinical utility because it has a longer half-life, is more abundant in urine, and more sensitive than fentanyl (the parent analyte) measurements.^{1,2}

Fentanyl (Q) Enzyme Immunoassay features¹:

- > Liquid, ready-to-use reagent, calibrators and controls
- > Urine sample type
- > Cross-reactivity with fentanyl (156.25%) and norfentanyl (100%)

Ordering Information:

Product Description	REF	Kit Size	Instructions for Use, Application Sheet and Safety Data Sheet
LZI Fentanyl (Q) Enzyme Immunoassay	C68808	R1: 100 mL (liquid) R2: 37.5 mL (liquid)	Available for viewing, printing and download at: http://www.lin-zhi.com/BCI_Applications
LZI Norfentanyl (Q) Qualitative Calibrator	C68815	1x5 mL (liquid)	
LZI Norfentanyl Level 1 Control	C68821	1x5 mL (liquid)	
LZI Norfentanyl Level 2 Control	C68822	1x5 mL (liquid)	
OSR Bottle Kit, 20x30 mL	63094		
OSR Bottle Kit, 20x60 mL	63093		

Beckman Coulter recommends the Lin-Zhi Norfentanyl Level 1 and Level 2 Controls for quality control monitoring of the Fentanyl Enzyme Immunoassay. Each control level includes one 5 mL bottle of ready-to-use control and the recommended ranges.

Please share this information with your laboratory staff and retain this notification as part of your laboratory documentation.

If you have any questions regarding this product, please contact your local Beckman Coulter Representative, or use the link below for a listing of local contact information.

<https://www.beckmancoulter.com/en/support/contact-us>

Thank you for your continued support of Beckman Coulter products and services.

Sincerely,



Alisha Jones
Global Chemistry Product Management

1. *LZI Fentanyl (Q) Enzyme Immunoassay Instructions for Use, Lin-Zhi International, Inc., 2020.*
2. *DePriest, A., Heltsley, R., Black, D., Cawthon, B., Robert, T., Moser, F., . . . Cone, E. (2010). Urine Drug Testing of Chronic Pain Patients. III. Normetabolites as Biomarkers of Synthetic Opioid Use. Journal of Analytical Toxicology, 34, 447-448.*

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