LZI Norfentanyl Controls

For Beckman Coulter, Inc.

2-8°C

IVD For In Vitro Diagnostic Use Only

Lin-Zhi International, Inc.

REF		Description	Quantity
C68821	CONTROL –	**LZI Norfentanyl Level 1 Control**	
		NFEN Level 1 Control (3.75 ng/mL)	1 x 5 mL
C68822	CONTROL +	**LZI Norfentanyl Level 2 Control**	
		NFEN Level 2 Control (6.25 ng/mL)	1 x 5 mL

Intended Use

The LZI Norfentanyl Level 1 Control and LZI Norfentanyl Level 2 Control are for use as assayed quality control materials to monitor the precision of the LZI Fentanyl Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808 or C68809) on a number of automated clinical chemistry analyzers (1, 2).

Description of the Controls

The LZI Norfentanyl Controls are human urine-based liquids and ready-to-use. The constituent is a processed drug-free human urine matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The controls are prepared by spiking known concentrations of norfentanyl into the drug-free matrix.

*****Actual concentrations of these calibrators are confirmed by GC/MS or LC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (3).

Precautions and Warning

- *The LZI Norfentanyl Controls are for in vitro diagnostic use only. Harmful if swallowed.*
- *The controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing such liquids always flush with a large volume of water to prevent azide build-up (4).*
- *The controls are prepared from non-sterile human urine. They are not tested by licensed reagents for the presence of antibodies to human immunodeficiency viruses, the hepatitis antigens, and/or anti- hepatitis antibodies. They should be handled as potentially infectious. Always use good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the controls beyond their expiration dates.*
- Rx ONLY *For USA: Cautions: Federal law restricts this device to sale by or on the order of a physician.*

Preparation and Storage

The controls are ready-to-use. No reconstitution is required. Label the cap before removal to identify it with the original bottle. The controls should be stored refrigerated at 2-8ºC when not in use.

Stability

When stored refrigerated at 2-8ºC, the controls are stable either opened-recapped or unopened, until the expiration date printed on the vial label. Store controls tightly capped when not in use. Control solution dispensed in the sample cups and left on board a clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (3.75 ng/mL and 6.25 ng/mL) should be run daily to ensure proper assay performance. Additionally, run the controls with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Fentanyl Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808 or C68809) package insert (1, 2).

Limitations

The LZI Norfentanyl Controls are for use with the LZI Fentanyl Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808 or C68809) to detect norfentanyl in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Symbols Used

EC REP	Authorized Representative	COO	Country of Origin		Manufacturer	SDS	Safety Data Sheet
	Biological Risks		Date of Manufacture	Rx ONLY	Medical Prescription Only		Temperature Limits
CE	CE Mark	GTIN	Global Trade Item Number	CONTROL –	Negative Control	T.K.	Test Kit Number
	Consult Instructions for Use	IVD	*In Vitro* Diagnostic medical device	CONTROL +	Positive Control		Use-by Date
CONTENTS	Contents	LOT	Lot Number	REF	Reference Number		

Additional Information

Registered trademarks are the property of their respective owners.

Shipping Damage
Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

Bibliography

1. LZI Fentanyl Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68808) package insert.
2. LZI Fentanyl Enzyme Immunoassay for Beckman Coulter, Inc. (Ref# C68809) package insert. (For outside of U.S.)
3. Guidance for Industry and FDA Staff, Assayed and Unassayed Quality Control Material. U.S. Department of Health and Human Services. FDA, Document issued on June 7, 2007.
4. Sodium Azide. National Institute for Occupational Safety (NIOSH) Pocket Guide to Chemical Hazards Third Printing, September 2007. Available online at: https://www.cdc.gov/niosh/npg/default.html

Additions, deletions, or changes are indicated by a change bar in the margin.

Notice: Adulteration of reagents, use of instruments without appropriate capabilities, or other failure to follow instructions as set forth in this labeling can affect performance characteristics, and stated or implied label claims.

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