LZI Oxycodone Controls

2°C 8°C

IVD For In Vitro Diagnostic Use Only

Lin-Zhi International, Inc.

		Description	Quantity
0242b	CONTROL –	Oxycodone 75 ng/mL Level 1 Control	1 x 5 mL
0244b	CONTROL +	Oxycodone 125 ng/mL Level 2 Control	1 x 5 mL
0245b	CONTROL –	Oxycodone 225 ng/mL Level 1 Control	1 x 5 mL
0247b	CONTROL +	Oxycodone 375 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin –Zhi International, Inc. (LZI) Oxycodone Controls are for use as assayed quality control materials to monitor the precision of the LZI Oxycodone Enzyme Immunoassay (Ref# 0240b/0241b) on a number of automated clinical chemistry analyzers.

Description of the Controls:

The LZI Oxycodone 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 Oxycodone into the drug-free matrix. Controls are made from NIST traceable standards.

*****Actual concentrations of these calibrators are within ±10 % of the target value as determined 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 (2).

Precautions and Warning

- *The LZI Oxycodone 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.*
- *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 apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the controls beyond their expiration dates.*

Preparation and Storage

The controls are provided 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. Controls solution dispensed in the sample cups and left on board the clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (75 ng/mL and 125 ng/mL for the 100 ng/mL cutoff and 225 and 375 ng/mL for the 300 ng/mL cutoff) 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 Oxycodone Enzyme Immunoassay (Ref# 0240b/0241b) package insert (#).

Limitations

The LZI Oxycodone Controls are for use with the LZI Oxycodone Enzyme Immunoassay (Ref# 0240b/0241b) to detect oxycodone in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. 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.
3. LZI Oxycodone Enzyme Immunoassay (Ref# 0240b/0241b) package insert.

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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Printed in USA