LZI Oral Fluid Oxycodone Controls

2°C 8°C

FOR RESEARCH & DEVELOPMENT USE ONLY

Lin-Zhi International, Inc.

REF		Description	Quantity
S0247b	CONTROL -	LZI Oral Fluid Oxycodone 30 ng/mL Level 1 Control	1 x 5 mL
S0248b	CONTROL +	LZI Oral Fluid Oxycodone 50 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Oxycodone Controls are for use as controls in the qualitative and semi-quantitative calibration of the Lin-Zhi International, Inc. (LZI) Oral Fluid Oxycodone Enzyme Immunoassay (Ref# S0240b/S0241b) on a number of automated clinical chemistry analyzers. These are Non-FDA Approved Controls for Research & Development use only and should not be repackaged for IVD use.

Description of the Controls:

The LZI Oral Fluid Oxycodone Controls are in a negative synthetic oral fluid matrix, and ready to use. The constituent is a drug-free synthetic oral fluid 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 controls are within ±10% of the target value as determined by GC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (1).

Precautions and Warning

- *The LZI Oral Fluid Oxycodone Controls are Non-FDA approved and are for Research & Development use only. The LZI Oral Fluid Oxycodone Controls should not be re-packaged for in vitro diagnostic use.*
- *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 a non-sterile synthetic oral fluid matrix. 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 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 2-8 ºC when not in use.

Stability

When stored refrigerated at 2-8 ºC, 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 the clinical analyzer should be discarded after use.

Procedure and Results

Both levels of controls (30 ng/mL and 50 ng/mL) should be run daily to ensure proper assay performance. Additionally, run with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Oral Fluid Oxycodone Enzyme Immunoassay (Ref# S0240b/S0241b) package insert (2).

Limitations

The LZI Oral Fluid Oxycodone Controls are for use with the LZI Oral Fluid Oxycodone Enzyme Immunoassay to detect oxycodone in human oral fluid only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Bibliography

1. 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.
2. LZI Oral Fluid Oxycodone Enzyme Immunoassay (Ref# S0240b/S0241b) 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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