

# LZI Oral Fluid Cotinine II Calibrators



**Lin-Zhi International, Inc.**

**For Forensic Use Only**

<b>REF</b>	<b>Description</b>	<b>Quantity</b>
S0001	LZI Oral Fluid Negative Calibrator	1 x 5 mL
S0522	LZI Oral Fluid Cotinine 12.5 ng/mL Low Calibrator	1 x 5 mL
S0523	LZI Oral Fluid Cotinine 25 ng/mL Cutoff Calibrator	1 x 5 mL
S0524	LZI Oral Fluid Cotinine 50 ng/mL Intermediate Calibrator	1 x 5 mL
S0525	LZI Oral Fluid Cotinine 75 ng/mL High Calibrator	1 x 5 mL

## Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Cotinine II Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Cotinine II Enzyme Immunoassay (Ref# S0520/S0521) on a number of automated clinical chemistry analyzers. These are Non-FDA Approved Controls for Forensic Use Only and should not be repackaged for IVD use.

## Description of the Calibrators:

The LZI Oral Fluid Cotinine II Calibrators are in a negative synthetic oral fluid matrix, and ready to use. The LZI Oral Fluid Negative Calibrator is a drug-free synthetic oral fluid matrix containing buffers, stabilizers, and less than 0.1% of sodium azide. The calibrators are prepared by spiking known concentrations of cotinine into the LZI Oral Fluid Negative Calibrator.

\* 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 (1).

## Precautions and Warnings

- *The LZI Oral Fluid Cotinine II Calibrators are Non-FDA approved and are for Forensic Use Only. The LZI Oral Fluid Cotinine II Calibrators should not be repackaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *The calibrators contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing of such liquids, always flush with a large volume of water to prevent azide build-up (2).*
- *The calibrators are prepared from a non-sterile synthetic oral fluid matrix. Always apply good laboratory practices to avoid any skin contact or ingestion.*
- *Do not use the calibrators beyond their expiration dates.*

## Preparation and Storage

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

## Stability

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

## Procedure and Results

For qualitative calibration, use the 25 ng/mL as the cutoff calibrator. For semi-quantitative calibration, use all five calibrators. Recalibration should be performed after reagent bottle change, a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Oral Fluid Cotinine II Enzyme Immunoassay (Ref# S0520/S0521) package insert (3).

## Limitations

The LZI Oral Fluid Cotinine Calibrators are for use with the LZI Oral Fluid Cotinine II Enzyme Immunoassay (Ref# S0520/S0521) to detect cotinine in human oral fluid only.

## Symbols

LZI uses the symbols and signs listed on the symbol glossary on the website. Visit [www.lin-zhi.com/symbol-glossary](http://www.lin-zhi.com/symbol-glossary) for detailed information.

## **Bibliography**

1. Guidance for Industry, Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators. U.S. Department of Health and Human Services. FDA, Document issued on February 22, 1999.
  2. 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>
  3. LZI Oral Fluid Cotinine II Enzyme Immunoassay (Ref# S0520/S0521) package insert.
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| Additions, deletions, or changes are indicated by a change bar in the margin.

For technical assistance please call: (408) 970-8811

***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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