

LZI Oral Fluid Cotinine II Controls



Lin-Zhi International, Inc.

For Forensic Use Only

REF	CONTROL	Description	Quantity
S0526	CONTROL-	LZI Oral Fluid Cotinine II 18.75 ng/mL Level 1 Control	1 x 5 mL
S0527	CONTROL+	LZI Oral Fluid Cotinine II 31.25 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Cotinine II Controls are for use as Controls 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 Controls:

The LZI Oral Fluid Cotinine 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 cotinine 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 (1).

Precautions and Warning

- *The LZI Oral Fluid Cotinine II Controls are Non-FDA approved and are for Forensic Use Only. The LZI Oral Fluid Cotinine II 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 of such liquids always flush with a large volume of water to prevent azide build-up (2).*
- *The controls 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 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°C when not in use.

Stability

When stored refrigerated at 2-8°C, the controls are stable either opened and 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 (18.75 ng/mL and 31.25 ng/mL) should be run daily to ensure proper assay performance. Additionally, runs with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Oral Fluid Cotinine II Enzyme Immunoassay (Ref# S0520/S0521) package insert (2).

Limitations

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

Symbols

LZI uses the symbols and signs listed on the symbol glossary on the website. Visit www.lin-zhi.com/symbol-glossary for detailed information.

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. 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 inserts.
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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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