

LZI Oral Fluid Cannabinoids (THC) Controls



Lin-Zhi International, Inc.

For Forensic Use Only

REF		Description	Quantity
S0077		LZI Oral Fluid Cannabinoids (THC) 2 ng/mL Low Calibrator / Level 1 Control	1 x 5 mL
S0078		LZI Oral Fluid Cannabinoids (THC) 8 ng/mL Intermediate Calibrator / Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Cannabinoids (THC) Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Cannabinoids (THC) Enzyme Immunoassay (Ref# S0070/S0071) on a number of automated clinical chemistry analyzers.

Description of the Controls

The LZI Oral Fluid Cannabinoids (THC) 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 0.09% of sodium azide. The controls are prepared by spiking known concentrations of Δ^9 -THC into the drug-free matrix.

*Actual concentrations of these controls 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 Cannabinoids Controls should not be repackaged 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.*
- *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-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. See the expiration date on individual bottle labels.

Procedure and Results

Both levels of controls (2 ng/mL and 8 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 Cannabinoids (THC) Enzyme Immunoassay (Ref# S0070/S0071) package insert (2).

Limitations

The LZI Oral Fluid Cannabinoids (THC) Controls are for use with the LZI Oral Fluid Cannabinoids (THC) Enzyme Immunoassay to detect cannabinoids 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. LZI Oral Fluid Cannabinoids (THC) Enzyme Immunoassay (Ref# S0070/S0071) package insert.

| 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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