LZI Oral Fluid Methamphetamine Controls

IVD For In Vitro Diagnostic Use Only

2°C

Rx ONLY

Lin-Zhi International, Inc.

REF		Description	Quantity
S0056b	CONTROL -	LZI Oral Fluid Methamphetamine 37.5 ng/mL Level 1 Control	1 x 5 mL
S0057b	CONTROL +	LZI Oral Fluid Methamphetamine 62.5 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Methamphetamine Controls are for use as controls in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Methamphetamine Enzyme Immunoassay (Ref# S0050b/S0051b) on a number of automated clinical chemistry analyzers.

Description of the Controls:

The LZI Oral Fluid Methamphetamine 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 *d*-methamphetamine 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 Oral Fluid Methamphetamine 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 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 (37.5 ng/mL and 62.5 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 Methamphetamine Enzyme Immunoassay (Ref# S0050b/S0051b) package insert (2).

Limitations

The LZI Oral Fluid Methamphetamine Controls are for use with the LZI Oral Fluid Methamphetamine Enzyme Immunoassay to detect *d*-methamphetamine 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 Methamphetamine Enzyme Immunoassay (Ref# S0050b/S0051b) 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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