LZI Oral Fluid Amphetamine Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Rx ONLY

Lin-Zhi International, Inc.

REF	Description	Quantity
S0001	LZI Oral Fluid Negative Calibrator	1 x 5 mL
S0042b	LZI Oral Fluid Amphetamine 20 ng/mL Low Calibrator	1 x 5 mL
S0043b	LZI Oral Fluid Amphetamine 50 ng/mL Cutoff Calibrator	1 x 5 mL
S0044b	LZI Oral Fluid Amphetamine 100 ng/mL Intermediate Calibrator	1 x 5 mL
S0045b	LZI Oral Fluid Amphetamine 140 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Amphetamine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) on a number of automated clinical chemistry analyzers.

Description of the Calibrators:

The LZI Oral Fluid Amphetamine Calibrators are in a negative synthetic oral fluid matrix, and ready to use. The LZI Oral Fluid Negative Calibrator is a synthetic drug-free oral fluid matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The calibrators are prepared by spiking known concentrations of *d*-amphetamine into the LZI Oral Fluid Negative Calibrator. Calibrators are made from NIST traceable standards.

*****Actual concentrations of these calibrators 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 Warnings

- *The LZI Oral Fluid Amphetamine Calibrators are for in vitro diagnostic use only. Harmful if swallowed.*
- *The calibrators 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 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. Any calibrator solution dispensed into sample cups and left on board the clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the 50 ng/mL calibrator 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 Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) package insert (2).

Limitations

The LZI Oral Fluid Amphetamine Calibrators are for use with the LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) to detect *d*-amphetamine in human oral fluid only.

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. LZI Oral Fluid Amphetamine Enzyme Immunoassay (Ref# S0040b/S0041b) 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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