

LZI Oral Fluid Opiates Calibrators



| For Forensic Use Only

Lin-Zhi International, Inc.

REF	Description	Quantity
S0008	LZI Oral Fluid LIS Negative Calibrator	1 x 5 mL
S0022c	LZI Oral Fluid Opiate 20 ng/mL Low Calibrator	1 x 5 mL
S0023c	LZI Oral Fluid Opiate 40 ng/mL Cutoff Calibrator	1 x 5 mL
S0024c	LZI Oral Fluid Opiate 60 ng/mL Intermediate Calibrator	1 x 5 mL
S0025c	LZI Oral Fluid Opiate 80 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Opiate Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) on a number of automated clinical chemistry analyzers (1). These calibrators are for Forensic Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Calibrators:

The LZI Oral Fluid Opiates Calibrators are in a negative synthetic oral fluid matrix and ready-to-use. The LZI Oral Fluid LIS Negative Calibrator is a drug-free synthetic oral fluid matrix containing buffers, stabilizers, and 0.1 % of ProClin™ 300 as a preservative. The calibrators are prepared by spiking known concentrations of morphine into the LZI Oral Fluid LIS Negative Calibrator.

Precautions and Warnings

- *The LZI Oral Fluid Opiates Calibrators are for Forensic Use Only and should not be repackaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *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 40 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 Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) package insert (1).

Limitations

The LZI Oral Fluid Opiates Calibrators are for use with the LZI Oral Fluid Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) to detect morphine in human oral fluid only.

Bibliography

1. LZI Oral Fluid Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) 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.

Additions, deletions, or changes are indicated by a change bar in the margin.



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