

LZI Oral Fluid Methadone Controls



FOR RESEARCH & DEVELOPMENT USE ONLY



Lin-Zhi International, Inc.

REF	CONTROL	Description	Quantity
S0117c	CONTROL-	LZI Oral Fluid Methadone 10 ng/mL Low Calibrator / Level 1 Control	1 x 5 mL
S0118c	CONTROL+	LZI Oral Fluid Methadone 30 ng/mL Intermediate Calibrator / Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Methadone Controls are for use as controls in the qualitative and semi-quantitative calibration of the LZI Oral Fluid Methadone Enzyme Immunoassay (Ref# S0110c/S0111c) on a number of automated clinical chemistry analyzers. These are Non-FDA Approved Controls for Research & Development use only and should not be repackaged for IVD use.

Description of the Controls:

The LZI Oral Fluid Methadone 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 ProClin 300 as a preservative. The controls are prepared by spiking known concentrations of methadone into the drug-free matrix. Controls are made from NIST traceable standards.

*Actual concentrations of these controls are within $\pm 10\%$ 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 LZI Oral Fluid Methadone Controls are Non-FDA approved and are for Research & Development use only. The LZI Oral Fluid Methadone Controls should not be re-packaged for in vitro diagnostic use.*
- *Harmful if swallowed.*
- *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 °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.

Procedure and Results

Both levels of controls (10 ng/mL and 30 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 Methadone Enzyme Immunoassay (Ref# S0110c/S0111c) package insert (2).

Limitations

The LZI Oral Fluid Methadone Controls are for use with the LZI Oral Fluid Methadone Enzyme Immunoassay to detect methadone 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. LZI Oral Fluid Methadone Enzyme Immunoassay (Ref# S0110c/S0111c) package inserts.
2. 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.

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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