LZI Oral Fluid Opiates Controls

2°C 8°C

For Forensic Use Only

Lin-Zhi International, Inc.

REF		Description	Quantity
S0027c	CONTROL -	LZI Oral Fluid Opiates 30 ng/mL Level 1 Control	1 x 5 mL
S0028c	CONTROL +	LZI Oral Fluid Opiates 50 ng/mL Level 2 Control	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Oral Fluid Opiates Controls are for use as assayed quality control materials to monitor the precision of the LZI Oral Fluid Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) on a number of automated clinical chemistry analyzers (1). These controls are for Forensic Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Controls:

The LZI Oral Fluid Opiates 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 morphine into the drug-free matrix.

Precautions and Warning

- *The LZI Oral Fluid Opiates Controls are for Forensic Use Only and should not be repackaged 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 2-8ºC when not in use.

Stability

When stored refrigerated at 2-8ºC, 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 (30 ng/mL and 50 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 Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) package insert (1).

Limitations

The LZI Oral Fluid Opiates Controls are for use with the LZI Oral Fluid Opiates Enzyme Immunoassay (Ref# S0020c/S0021c) to detect morphine 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 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.

Manufacturer:
Lin-Zhi International, Inc.
2945 Oakmead Village Court
Santa Clara, CA 95051
USA
Tel: (408) 970-8811
Fax: (408) 970-9030
www.lin-zhi.com