# LZI Norbuprenorphine Controls

IVD For In Vitro Diagnostic Use Only

2°C 8°C

## *Lin-Zhi International, Inc.*

| REF | | | Description | Quantity |
|---|---|---|---|---|
| 0272 | CONTROL - | | Norbuprenorphine 3 ng/mL Level 1 Control | 1 x 5 mL |
| 0274 | CONTROL - | or CONTROL + | Norbuprenorphine 7 ng/mL Level 1/2 Control | 1 x 5 mL |
| 0276 | CONTROL + | | Norbuprenorphine 13 ng/mL Level 2 Control | 1 x 5 mL |

**Intended Use**

The Lin-Zhi International, Inc. (LZI) Norbuprenorphine Controls are for use as assayed quality control materials to monitor the precision of the LZI Norbuprenorphine Enzyme Immunoassay (Ref# 0270/0271) on a number of automated clinical chemistry analyzers.

**Description of the Controls:**

The LZI Norbuprenorphine Controls are human urine-based liquids, and ready to use. The constituent is a processed drug-free human urine matrix, containing buffers, stabilizers, and less than 0.1 % of sodium azide. The controls are prepared by spiking known concentrations of Norbuprenorphine into the drug-free matrix. Controls are made from NIST traceable standards.

*****Actual concentrations of these calibrators are determined by GC/MS or LC/MS. Values are provided only as guidelines and laboratories should determine the ranges based on their own test system and tolerance (2).

***Precautions and Warning***

- *The LZI Norbuprenorphine 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 non-sterile human urine. They are not tested by licensed reagents for the presence of antibodies to human immunodeficiency viruses, the hepatitis antigens, and/or anti- hepatitis antibodies. They should be handled as potentially infectious. 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 provided 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. Controls 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 (3 and 7 ng/mL for the 5 ng/mL cutoff and 7 and 13 ng/mL for the 10 ng/mL cutoff) should be run daily to ensure proper assay performance. Additionally, run the controls with each new calibration and after specific maintenance or troubleshooting procedures are performed. For interpretation of results, refer to the appropriate LZI Buprenorphine Enzyme Immunoassay (Ref # 0270/0271) package insert (3).

**Limitations**

The LZI Norbuprenorphine Controls are for use with the LZI Buprenorphine Enzyme Immunoassay (Ref# 0270/0271) to detect norbuprenorphine in human urine only. Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

**Symbols Used**

| | | | | | |
|---|---|---|---|---|---|
| EC REP | Authorized Representative | | Date of Manufacture | CONTROL - | Negative Control |
| | Biological Risks | GTIN | Global Trade Item Number | CONTROL + | Positive Control |
| CE | CE Mark | IVD | *In Vitro* Diagnostic medical device | REF | Reference Number |
| | Consult Instructions for Use | LOT | Lot Number | SDS | Safety Data Sheet |
| CONTENTS | Contents | | Manufacturer | | Temperature Limits |
| COO | Country of Origin | Rx ONLY | Medical Prescription Only | | Use-by Date |

**Bibliography**


1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
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.
3. LZI Buprenorphine Enzyme Immunoassay (Ref # 0270/0271) package insert.


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

***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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