LZI Norbuprenorphine Calibrators

IVD For In Vitro Diagnostic Use Only

2°C 8°C

Lin-Zhi International, Inc.

REF	Description	Quantity
A53687	Negative Calibrator	1 x 5 mL
A68826	Norbuprenorphine 5 ng/mL Low Calibrator	1 x 5 mL
A68827	Norbuprenorphine 10 ng/mL Cutoff Calibrator	1 x 5 mL
A68828	Norbuprenorphine 20 ng/mL Intermediate #1 Calibrator	1 x 5 mL
A68829	Norbuprenorphine 40 ng/mL Intermediate #2 Calibrator	1 x 5 mL
A68830	Norbuprenorphine 100 ng/mL High Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Norbuprenorphine Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Buprenorphine Enzyme Immunoassay with Beckman Coulter® Synchron DxC automated clinical system analyzers (1).

Description of the Calibrators

The LZI Norbuprenorphine Calibrators are human urine-based liquids and ready-to-use. The Negative Calibrator is a processed drug-free human urine matrix containing buffers, stabilizers, and less than 0.1 % of sodium azide. The calibrators are prepared by spiking known concentrations of norbuprenorphine into the Negative Calibrator.

*****Actual concentrations of these calibrators are within ±10% of the target value as determined by GC/MS or LC/MS. Values are provided only as guidelines and that laboratories should determine the ranges based on their own test system and tolerance (2).

Precautions and Warning

- *The LZI Norbuprenorphine 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 (3).*
- *The calibrators 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 calibrators beyond their expiration dates.*
- Rx only *For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.*

Preparation and Storage

The calibrators are provided 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 2-8ºC when not in use.

Stability

When stored refrigerated at 2-8ºC, the calibrators are stable either opened-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 of the clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the negative, cutoff, and high calibrators (0 ng/mL, 10 ng/mL, and 100 ng/mL). For semi-quantitative calibration, use all six calibrators (0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL, 40 ng/mL, and 100 ng/mL). Recalibration should be performed after reagent bottle change or if there is a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI Buprenorphine Enzyme Immunoassay for Beckman Coulter Synchron Systems (Ref # A53684) package insert (1).

Limitations

The LZI Norbuprenorphine Calibrators are for use with the LZI Buprenorphine Enzyme Immunoassay for Beckman Coulter Synchron Systems (Ref # A53684) to detect norbuprenorphine in human urine only.

Bibliography

1. LZI Buprenorphine Enzyme Immunoassay for Beckman Coulter® Synchron Systems (Ref # A53684) package insert.
2. 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.
3. Sodium Azide. National Institute for Occupational Safety (NIOSH) Pocket Guide to Chemical Hazards. Third Printing, September 2007. Available online at: https://www.cdc.gov/niosh/npg/default.html

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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