LZI Cannabinoids (cTHC) 25 Calibrators

IVD For In Vitro Diagnostic Use Only

2ºC 8ºC

Lin-Zhi International, Inc.

Outside USA Only

REF	Description	Quantity
0002c	LZI Cannabinoids (cTHC) Negative Calibrator	1 x 5 mL
0072c	LZI Cannabinoids (cTHC) Calibrator (12.5 ng/mL)	1 x 5 mL
0073c	LZI Cannabinoids (cTHC) Calibrator (25 ng/mL)	1 x 5 mL
0007c	LZI Cannabinoids (cTHC) Calibrator (37.5 ng/mL)	1 x 5 mL
0075c	LZI Cannabinoids (cTHC) Calibrator (50 ng/mL)	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) Cannabinoids (cTHC) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) on a number of automated clinical chemistry analyzers (1).

Description of the Calibrators

The LZI Cannabinoids (cTHC) Calibrators are human urine-based liquids and ready-to-use. The Cannabinoids (cTHC) Negative Calibrator is a processed drug-free human urine matrix containing buffers, stabilizers, and 0.09% of sodium azide. The calibrators are prepared by spiking known concentrations of 11-nor-Δ^9-THC-9-COOH into the Cannabinoids (cTHC) Negative Calibrator. Throughout this insert, cTHC is referenced as an abbreviation for 11-nor-Δ^9-THC-9-COOH.

*****Actual concentrations of these calibrators are confirmed 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 Cannabinoids (cTHC) 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 of 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, hepatitis antigens, and/or anti-hepatitis antibodies. They should be handled as potentially infectious. 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 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. See the expiration date on individual bottle labels.

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. Real-time open-recapped vial stability studies when stored refrigerated, indicate that expiration dates are at least 18 months from the production date. Real-time closed vial stability studies are currently at 60 days of storage and continue to be monitored. Accelerated studies for closed vial stability indicate that expiration dates should be at least 18 months from the production date. Store calibrators tightly capped when not in use. Calibrator solution dispensed in the sample cups and left onboard the clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the 25 ng/mL as your cutoff calibrator. For semi-quantitative calibration, use all five calibrators. 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 Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) package insert (4).

Limitations

The LZI Cannabinoids (cTHC) Calibrators are for use with the LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) to detect cannabinoids in human urine only.

Bibliography

1. Urine testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. Guidance for Industry and Food and Drug Administration Staff, The Abbreviated 510(k) Program. U.S. Department of Health and Human Services. FDA, Document issued on September 13, 2019.
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
4. LZI Cannabinoids (cTHC) Enzyme Immunoassay (Ref# 0070c/0071c) package insert.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

LZI uses the symbols and signs listed on the symbol glossary on the website. Visit www.lin-zhi.com/symbol-glossary for detailed information.

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

For technical assistance please call: (408) 970-8811

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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