LZI SPICE II (UR-144/XLR-11) Calibrators

2°C 8°C

For Forensic Use Only

Lin-Zhi International, Inc.

REF	Description	Quantity
0002c	THC Negative Calibrator	1 x 5 mL
0422	SPICE II (UR-144-N-(5-hydroxypentyl) metabolite) 10 ng/mL Calibrator	1 x 5 mL
0423	SPICE II (UR-144-N-(5-hydroxypentyl) metabolite) 20 ng/mL Calibrator	1 x 5 mL
0424	SPICE II (UR-144-N-(5-hydroxypentyl) metabolite) 35 ng/mL Calibrator	1 x 5 mL
0425	SPICE II (UR-144-N-(5-hydroxypentyl) metabolite) 50 ng/mL Calibrator	1 x 5 mL

Intended Use

The Lin-Zhi International, Inc. (LZI) SPICE II (UR-144/XLR-11) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI SPICE II (UR-144/XLR-11) Enzyme Immunoassay (Ref# 0420/0421) on a number of automated clinical chemistry analyzers (1). These calibrators are for Forensic Use Only and should not be repackaged for *in vitro* diagnostic use.

Description of the Calibrators:

The LZI SPICE II (UR-144/XLR-11) Calibrators are human urine-based liquids and ready-to-use. The LZI THC 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 UR-144-N-(5-hydroxypentyl) metabolite into the LZI THC Negative Calibrator.

Precautions and Warning

- *The LZI SPICE II (UR-144/XLR-11) Calibrators should not be repackaged for in vitro diagnostic use.*
- *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 (2).*
- *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 use good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the calibrators beyond their expiration dates.*

Preparation and Storage

The calibrators are 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 a clinical analyzer should be discarded after use.

Procedure and Results

For qualitative calibration, use the 20 ng/mL as the cutoff calibrator. For semi-quantitative calibration, use all five calibrators. Recalibration should be performed after reagent bottle change, a change in calibrators or reagent lot, and after instrument maintenance is performed. For interpretation of results, refer to the appropriate LZI SPICE II (UR-144/XLR-11) Enzyme Immunoassay (Ref# 0420/0421) package insert (1).

Limitations

The LZI SPICE II (UR-144/XLR-11) Calibrators are for use with the LZI SPICE II (UR-144/XLR-11) Enzyme Immunoassay (Ref# 0420/0421) to detect UR-144/XLR-11-type synthetic cannabinoids in human urine only.

Bibliography

1. LZI SPICE II (UR-144/XLR-11) Enzyme Immunoassay (Ref# 0420/0421) package insert.
2. 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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