

# Lin-Zhi International, Inc.



Dedicated to the development of  
innovative and quality products for  
clinical diagnostics.

January 24, 2017

## **RE: Customer Information Regarding LZI Product Use**

Dear Valued Customer,

In the efforts to maximize your assay success, we would like to provide the following recommendation regarding our products.

### **Use calibrators and controls in sequential lot numbers:**

An assay's calibrators and controls should be used together in sequential lot numbers because the bulk concentrations are made at the same time, tested together, and go through quality control together. An example of a sequential lot numbers would be 1404101, 1404102, 1404103, etc.

An example of calibrators/controls used together sequentially would be:

If a customer uses the Buprenorphine EIA Lot#1605001

They calibrate the reagent using:

Negative Calibrator – Lot#1402013

Low Calibrator – Lot#1501111

Cutoff Calibrator - Lot#1501113

Intermediate Calibrator - Lot#1501115

High Calibrator - Lot#1501116

They should run controls using:

Negative Control/Level 1 Control - Lot#1501112

Positive Control/Level 2 Control - Lot#1501114

Particularly for the lower concentration calibrators/controls, using non-sequential calibrator/control numbers could cause the negative control to run above the cutoff calibrator or the positive control run below the cutoff calibrator.

Customers can request specific lot numbers on their purchase orders, however, it is recommended that customers plan ahead when ordering (depending on the frequency of calibration and use of controls) in case older lots have been completely sold out.

Another option for customers is to order a whole new set of calibrators and controls on their next order.

### **Only LZI THC calibrators and controls should be used with the LZI THC EIA kit:**

For both LZI urine and oral fluid products, there is a special formulation to enhance the stability of the THC analyte. Due to the unique formulation, LZI has seen that the absorbance values of the THC calibrators and controls are increased as compared to the products of competitive suppliers.

LZI's EIA formulations are optimized to account for the higher absorbance rates. Use of other suppliers' calibrators and controls with LZI's THC EIA kit may lead to false negative results.

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## Explanation of product nomenclature:

LZI uses a certain nomenclature for its lot numbers: An 'R' stands for Replacement. This letter at the end of a lot number indicates that a **NEW** bulk was made for that specific concentration calibrator or control.

Replacements must match the specifications of the original calibrator/control and be separately GCMS qualified (within  $\pm 10\%$  of target concentration). Replacement bulks are given the same expiration date as the product it is replacing.

A 'K' stands for kitting. This letter at the end of the lot number indicates that there were multiple kitting events of this item from an initial bulk. All products with the same lot number followed by a 'K' come from the **SAME** bulk. A bulk may be kitted a certain number of times depending on the situation which are denoted by K2, K3, etc. These are the kitting events that follow the initial kitting.

If you have any questions or concerns regarding this notification please do not hesitate to contact us by e-mail at [customerservice@lin-zhi.com](mailto:customerservice@lin-zhi.com) or by phone at 408-970-8811.

Sincerely,

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