

Advisory Notice

Date Released: 2016-August-17

Posted By: Quality Control

Effective: Lot 1K5 Calibrator

Product Affected: hCG Extended Range (hCG-XR) Test System (ELISA) & (CLIA)

Brief Description of Advisory: Ready to use calibrators

To whom it may concern,

Recent product improvements by Monobind support the use of ready to use, liquid calibrators for its hCG Extended Range (hCG-XR) assays. Therefore hCG-XR calibrators starting with **LOT 1K5** will no longer require the reconstitutions of dried reagents.

In summary:

Reagent	Previous Format	New Format	Lots Affected
hCG-XR Calibrators (A-F)	Dried Serum	Liquid Serum	1K5 & Newer

These reagents are present in the following Monobind products:

- hCG-XR AccuBind® ELISA Item #: 8825-300
- hCG-XR AccuLite® CLIA Item #: 8875-300

The product Instructions for Use (IFU) have been updated to a new version to reflect this change and can be downloaded at <http://www.monobind.com/Support-Areas/product-inserts>

The Design Output has also been updated and is available by request.

As an official of the company, I verify this information to be true and correct.

Sincerely,

Anthony Shatola



Quality Control Director