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Advisory Notice

Monobind Inc.

orld Resource for Diagnostic Products

Date Released: 2018-December-4 Posted By: Quality Control Product Affected: Free Testosterone Brief Description of Advisory: Larger Measurement Range, Control Now Included, Antibody Plate, See Updated IFU

To whom it may concern,

Based on market feedback and customer request, Monobind has revised its Free Testosterone assays to have a larger measurement range (0-60 pg/ml from 0-37.5 pg/ml), a three-level control, as well as an antibody-coated plate which affects the following products:

•	Free Testosterone AccuBind [®] ELISA	ltem #: 5325-300
•	Free Testosterone AccuLite [®] CLIA	Item #: 5375-300

This applies all lots produced in December 2018 (going forward), specifically LOT 53K1L8 and later.

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

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

Product Price: There has been no price increase.

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

Sincerely,

Anthony Shatola

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Quality Control Director

Monobind Inc. ISO 13485 Certified Company