

www.monobind.com

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## **Advisory Notice**

Date Released: 2019-January-29 Posted By: Quality Control

**Product Affected: Troponin I Improvement** 

Brief Description of Advisory: More sensitive, lower cutoff, new IFU

To whom it may concern,

Based on market feedback and customer request, Monobind has improved its **Troponin I** (cTnI) assay to be more competitive with other systems on the market, including better low end-sensitivity and lower cut-off values. Changes are summarized below:

|                               | Previous cTnl System     | Improved cTnl System             |
|-------------------------------|--------------------------|----------------------------------|
| Calibrator Value              | 0, 1, 3, 6, 15, 30 ng/ml | 0, 0.4, 1.25, 2.5, 7.5, 20 ng/ml |
| Plate                         | Streptavidin Coated      | Antibody Coated                  |
| Cut off Range/ Expected Value | < 1.3 ng/ml              | < 0.4 ng/ml                      |

<u>All other aspects of the product remain unchanged</u>, including part number, general procedure and total assay time.

The product page has been updated on our website and a new product Instructions for Use (**IFU**) released and can be downloaded at <a href="http://www.monobind.com/Support-Areas/product-inserts">http://www.monobind.com/Support-Areas/product-inserts</a>

The **Design Output** is available by request.

**Product Price**: There has been no price increase.

Part Number: There is no change to product part number

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

Sincerely,

AShatola

Anthony Shatola Quality Control Director