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100 North Pointe Drive Lake Forest, CA 92630 TEL 949.951.2665 FAX 949.951.3539

Advisory Notice

Date Released: 2018-October-2 Posted By: Quality Control

Product Affected: Free beta hCG New System

Brief Description of Advisory: New Plate, Part Number/ IFU

To whom it may concern,

Based on market feedback and customer request, Monobind has released a new **Free beta hCG** assay to be more competitive with other systems on the market (including better correlation to Demeditec). The old assay system is discontinued immediately. Changes are summarized below:

	Discontinued Free beta hCG XR System	New Free beta hCG System
ELISA PN	10225-300	2025-300
CLIA PN	10275-300	2075-300
Calibrators Units	ng/ml	ng/ml
Calibrator Value	0, 5, 10, 25, 100, 250	0, 10, 25, 50, 100, 250
Conversion Factor	1 ng/ml = 1 mIU/ml	1 ng/ml = 1 mIU/ml
Plate	Streptavidin Coated	Antibody Coated
# of Reagents	Eight	Eight
ELISA Total Time	60 Minutes	60 Minutes
CLIA Total Time	45 Minutes	45 Minutes

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

The **Design Output** 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,

AShatola

Anthony Shatola Quality Control Director