

# Advisory Notice

**Date Released: 2018-September-17**

**Posted By: Quality Control**

**Product Affected: PAPP-A Improvement**

**Brief Description of Advisory: Shorter Procedure, New Part Number, Updated IFU**

To whom it may concern,

Based on market feedback and customer request, Monobind has released a new PAPP-A 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:

	<b>Discontinued PAPP-A System</b>	<b>New PAPP-A System</b>
ELISA PN	7925-300	12625-300
CLIA PN	7975-300	12675-300
Calibrators Units	mIU/L	µg/ml
Calibrator Value	0, 100, 500, 1,500, 5,000, 10,000	0, 0.64, 1.6, 3.2, 9.6, 32
Conversion Factor	Not provided	Multiply by 156.25 for mIU/L
ELISA Total Time	110 Minutes	75 Minutes
CLIA Total Time	80 Minutes	60 Minutes

Please note all other reagents and test procedure is unchanged other than reduced incubation time.

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.

**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  
Quality Control Director