

Advisory Notice

Date Released: 2020-May-26

Posted By: Quality Control

Product Affected: PAPP-A Improvement

Brief Description of Advisory: Plate and Reagent Change, Updated IFU

To whom it may concern,

Monobind has updated its PAPP-A assay to utilize an antibody-coated plate, thereby alleviating any potential biotin influence during prenatal testing. Only mega-dose supplementation (not commonly found in multivitamin or prenatal vitamin) will impact test results as detailed in Monobind [response](#) dated December 29, 2017.

Changes are summarized below:

	Discontinued PAPP-A System	New PAPP-A System
Plate Type	Streptavidin Based	Antibody Coated
Biotin Reagent	Biotin	None

Please note all other reagents and test procedure is unchanged other than elimination of biotin addition.

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