Monobind Inc.
The World Resource for Diagnostic Products

www.monobind.com

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

Advisory Notice

Date Released: 2017-June-12
Posted By: Quality Control
Effective Date: 2017-June-12
Product Affected: N-17OHP
Brief Description of Advisory: Alternate procedure to improve sensitivity & precision

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To whom it may concern,

Ongoing product development at Monobind has resulted in a significant performance-improvement of the N-17OHP ELISA Assay (#5525-300) by *delaying the addition of the Enzyme Reagent*. Note, there is no change in kit reagents or total time involved, and the previous procedure can still be utilized. However with the new procedure, Monobind found an increase to sensitivity and precision by greater than two-fold. The difference in reagent addition is summarized below:

Improved Method: Add the punched Dried Blood Dot, Biotin Reagent and Rotate for 30-minutes, then add the Enzyme Reagent and Rotate an additional 90-minutes (total 120-minutes Mix time)

Alternative/Existing Method: Add the punched Dried Blood Dot, Biotin Reagent, Enzyme Reagent and Rotate for 120-minutes

An updated UFU, with the term *Improved Performance,* has been issued as Rev 6 and can be found on the Monobind website and will be included with new shipments. We request this be communicated to users accordingly, so they may select the desired procedure as both are included in the IFU. Should you require any additional assistance, please do not hesitate to contact us.

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

Sincerely,

ASshatola

Anthony Shatola
Quality Control Director