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## **Advisory Notice**

Date Released: 2021-June-2 Posted By: Quality Control Product Affected: CK-MB ELISA

**Brief Description of Advisory: Wash Steps Increased** 

To whom it may concern,

Based on observed product performance, Monobind has decided to increase the number of wash steps for its CK-MB ELISA assays from three (3) to five (5). This will assist in <u>minimizing the background</u> seen in the assay results as washing serves as a critical aspect to product performance. All other aspects of the procedure and assay are unchanged.

The Instructions for Use (IFU) on the <u>CK-MB product page</u> as well as in our Support Area for <u>Product Inserts</u> are updated. This notice can also be found on our <u>Company Advisories</u> page.

Monobind will place a sticker on all CK-MB ELISA kits notifying users to increase the wash cycles. Any CK-MB ELISA product in the market can effectively be increased to five washes now. (Please note that CK-MB CLIA kits already include five (5) washes, as do all Monobind CLIA kits.)

## In Summary:

Effected Product/ Area	Details
CK-MB ELISA	2925-300
Wash Steps	Increase Wash Steps from (3) to (5)
IFU	Revision 5

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

Sincerely,

AShatola

Anthony Shatola Quality Assurance Director