

May 2015

Globally Harmonized System Update – Immunoassay Products

Dear Beckman Coulter Immunoassay Customer:

Beckman Coulter is in the process of updating our product labeling, Safety Data Sheets (SDS), and assay Instructions for Use (IFU) to align with the Globally Harmonized System (GHS). The GHS provides an internationally harmonized system for classification of substances and mixtures according to their health, environmental, and physical hazards. It also harmonizes requirements for communication on hazardous elements. The benefits of the GHS are a common approach to classifying chemicals, as well as communicating any related hazards to consumers, workers, and emergency responders. This letter gives you additional information on changes specific to the Beckman Coulter Access Family of Immunoassay Systems.

It is important to note that while there are changes to document and label formatting, there are ***no changes to our products***. Product performance, assay procedural steps, and instrument operating instructions are not impacted by the GHS update.

Labels: We have streamlined the information provided on the labels and simplified the outer packaging by eliminating labels from the tops of the Access boxes. The new label elements are consistent with the GHS requirements. Reagent, calibrator, and QC labels will be printed in black and white.

Instructions for Use: The Access reagent, calibrator, and QC IFUs have a new format which aligns with the IFUs for the Beckman Coulter AU and SYNCHRON Chemistry Systems. Section headings have been changed, and information has been rearranged to a standard order. However, the content of the IFUs remains the same. (Please note that Instrument IFUs and other manuals are not affected.)

Safety Data Sheets (formerly MSDS): The new SDS format contains 16 specific sections, ensuring consistency in presentation of important chemical information. The GHS label elements will be added to section 2 of the SDS.

All assay IFU and SDS documents available on our Beckman Coulter website will be updated by June 1, 2015.

Beckman Coulter encourages you to visit our webpage dedicated to GHS. There you will find information regarding the background of GHS, the impact of GHS on Beckman Coulter products, GHS pictograms, and web links to regulatory agency sites for further information. The GHS webpage also includes downloadable examples and guides related to Safety Data Sheets, Instructions for Use, and labels.

Beckman Coulter GHS Webpage: www.beckmancoulter.com/GHS

Regulations require that all products manufactured after June 1, 2015 must use the new GHS criteria. However, the regulations permit manufacturers to continue distribution of existing product inventory with the prior labeling system until December 1, 2015 in the U.S. and until June 1, 2017 outside the U.S. Please note that you may see a mixture of labeling styles on products through this transition period. Beckman Coulter is committed to maintaining a high level of compliance and quality through this transition. Ultimately, we believe the standardized GHS documents will make it easier for you, our customer, to access consistent information for our products.

If you have questions related to this transition, please contact our Customer Service team:

- > At our website: <https://www.beckmancoulter.com>
- > By phone, call 1-800-854-3633 in the United States and Canada.
- > Outside the United States and Canada, contact your local Beckman Coulter representative.

Thank you for your continued support of Beckman Coulter products and services.