**URGENT FIELD SAFETY NOTICE**

AQUIOS CL Flow Cytometry System (PN B30166)

Attention Beckman Coulter (BEC) Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

### ISSUE:
AQUIOS CL System will associate the wrong sample ID with results if the following sequence of events occurs:

- The STAT button is selected within AQUIOS CL Software and the user opens the single-tube loader door.
- User creates a test request when prompted, places a specimen tube in single tube loader, and closes the single-tube loader door.
- The STAT button is selected again and the user opens the single-tube loader door within 15 seconds or less of loading the first sample and before the “Details” column on Running screen changes to “Prepping” for that sample.
- User removes the first specimen tube and replaces with a different specimen tube.
  - If another request is entered for the new specimen and the single-tube loader door is closed, the new specimen tube will be prepared twice. Both test requests will be processed with 2nd specimen tube.
  - If another request is NOT entered for new specimen and the single-tube loader door is closed, the new specimen tube will be prepared once. The first test request will be processed with 2nd specimen tube.

### IMPACT:
If the above sequence of events is followed, it will result in sample mis-identification and erroneous results will be generated. The system will not identify or flag the erroneous results.

### ACTION:
Follow the steps outlined and review all warnings in AQUIOS CL Instructions for Use “Running a sample Using the Single-tube loader” (Chapter 5) when running STAT specimens to avoid sample mis-identification.

When running multiple specimens via the single tube loader, wait for the currently loaded specimen to be in the “Incubating” status in the “Details” column on the Running screen before selecting the STAT button or attempting to cancel the run (see AQUIOS CL Instructions for Use, section A-5 “Running Screen”).

### RESOLUTION:
Beckman Coulter will release the software correction for this issue by end of January, 2018. A Beckman Coulter Field Service Engineer will contact you soon after to schedule the installation of the software upgrade.
Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:
- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notification, please contact:
- From our website: http://www.beckmancoulter.com
- By phone: call 800-369-0333 in the United States and Canada.
- By email: LScustomerLetter@Beckman.com
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this has caused your laboratory.

Sincerely,

Nancy Nadler
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form