

URGENT FIELD SAFETY NOTICE
AQUIOS CL Flow Cytometry System (PN B30166)

Attention Beckman Coulter Customer,

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

ISSUE:	As a result of internal investigations, BEC has learned that an erroneous configuration setting during servicing may be possible on the AQUIOS CL instruments. If the incorrect configuration occurs, the probe may aspirate samples only from a single tube and will not aspirate samples from the remaining tubes in the cassette.
IMPACT:	The probe would repeatedly aspirate from a single tube position in the cassette, resulting in erroneous patient results for the remaining tubes in the cassette. This results in a mismatch between the test result and sample ID.
ACTION:	Quality Control samples must be run utilizing the control cassette and the autoloader. The controls will not pass if this issue exists on your unit, when run using the autoloader. If your controls do not pass, immediately contact your Beckman Coulter representative. BEC Service organization will be in contact with you to ensure that the configuration settings are correct.
RESOLUTION:	BEC will be implementing actions to prevent this configuration error from recurring.

The national competent authority has been informed of this field safety corrective action.

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.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact [insert local contact information];

- From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Enclosure: Response Form

FA-31696