September 28, 2017

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:	When AQUIOS CL systems are connected to a Laboratory Information System (LIS), the system may duplicate sample requests leading to sample mis-identification. For this to happen, the following conditions must be met: ⇒ The AQUIOS CL Flow Cytometer is connected to an LIS and ⇒ The AQUIOS CL system has the DEFAULT TEST enabled and ⇒ Host Query is enabled in LIS setup screen on system and ⇒ There are multiple cassettes in the Autoloader and ⇒ The LIS host query response is received in a brief time window before LIS response timeout occurs. When all of these conditions are met, a sample will follow two (2) paths of test request creation (LIS and DEFAULT TEST). All software versions (2.0, 2.0.1 and 2.1) in existence are impacted by this issue and all applications used on the AQUIOS CL are impacted by this issue.
IMPACT:	When this issue occurs: ▪ It will result in sample mis-identification and erroneous results will be generated. ▪ The system will not always identify or flag the erroneous results however, some erroneous results may be flagged with 'Sample ID reused'. ▪ The frequency will not be predictable – from the limited data set that BEC has analyzed, this random mis-identification occurred 24 times out of 92,000 runs. Once the duplicate test is created, the following events will occur: ▪ The software will continue to create multiple tests as long as there are tubes available (in the cassette in the Autoloader). ▪ The system may associate an incorrect sample ID with the run data.
ACTION:	Immediately perform an adjustment to the software options on your AQUIOS CL System by turning off the DEFAULT TEST. This will eliminate the issue and result in one sample producing one set of results (see **Attachment 1**). After doing this, samples with no LIS test requests will become entries in the incomplete tab (see **Attachment 2** for instructions on how to run samples after the DEFAULT TEST is turned OFF). BEC will contact your laboratory in the coming weeks and assist in determining if any samples previously run in your laboratory were impacted.
RESOLUTION:	Beckman Coulter is working on a permanent resolution to correct and eliminate this issue.

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,

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Quality Assurance and Regulatory Affairs Enclosure:
Response Form

Attachment 1

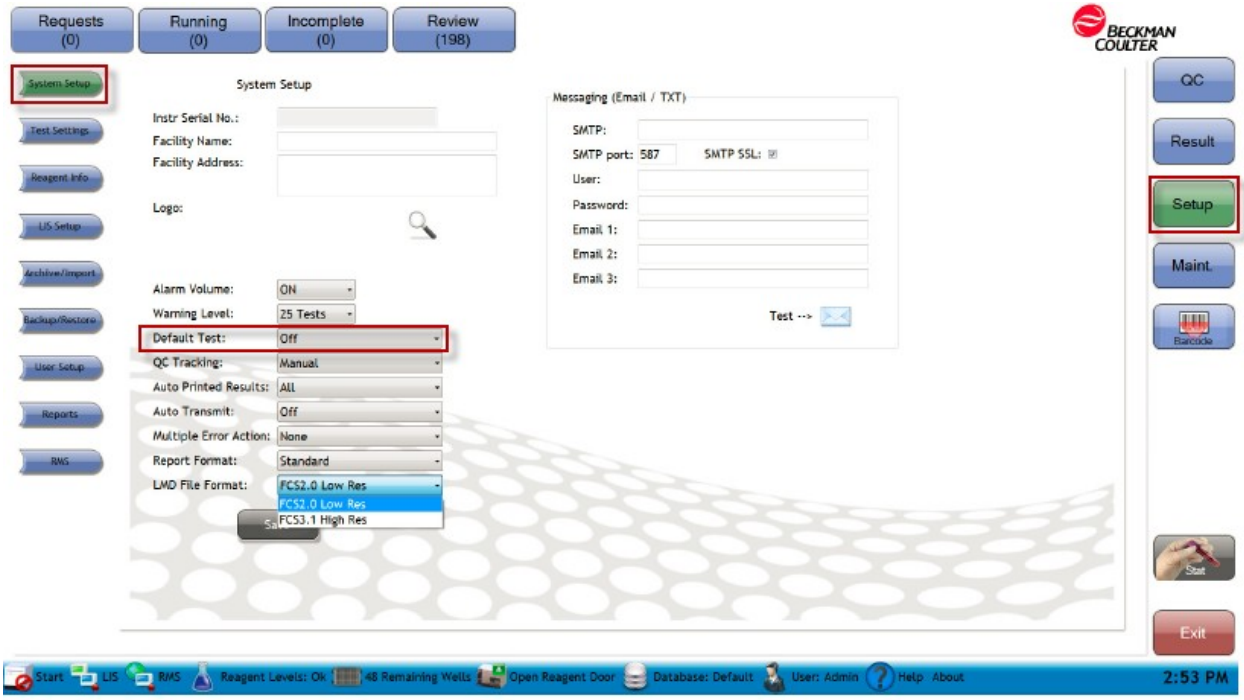
Instructions for Disabling the Default Test Feature

Please refer to the AQUIOS CL Instructions for Use, PN B21896, Chapter 8 – Setup for additional information. The Admin User is the user type which must perform this action.

1. Select 

from the right side of the screen, the software will open in the 

area.



2. Toggle the Default Test option to off.
3. Select Save on this screen prior to moving to any other areas of the software.

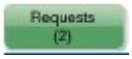
When the Default test is disabled, there are 4 potential ways in which the system can recognize test requests for samples, utilizing the internal barcode scanning process:

1. Tube barcode is scanned 1st time and there is an order in LIS – AQUIOS software creates the test request.
2. Tube barcode is scanned 2nd time and LIS is configured to return order again – AQUIOS software creates a test request.
3. Tube is scanned and there is no order in LIS – the sample information is placed in the “Incomplete” tab, and a manual test request needs to be created. Follow the instructions indicated below for manual test creation.
4. Tube is scanned 2nd time and LIS not configured to return order again - the sample information is placed in the “Incomplete” tab, and a manual test request needs to be created. Follow the instructions indicated below for manual test creation.

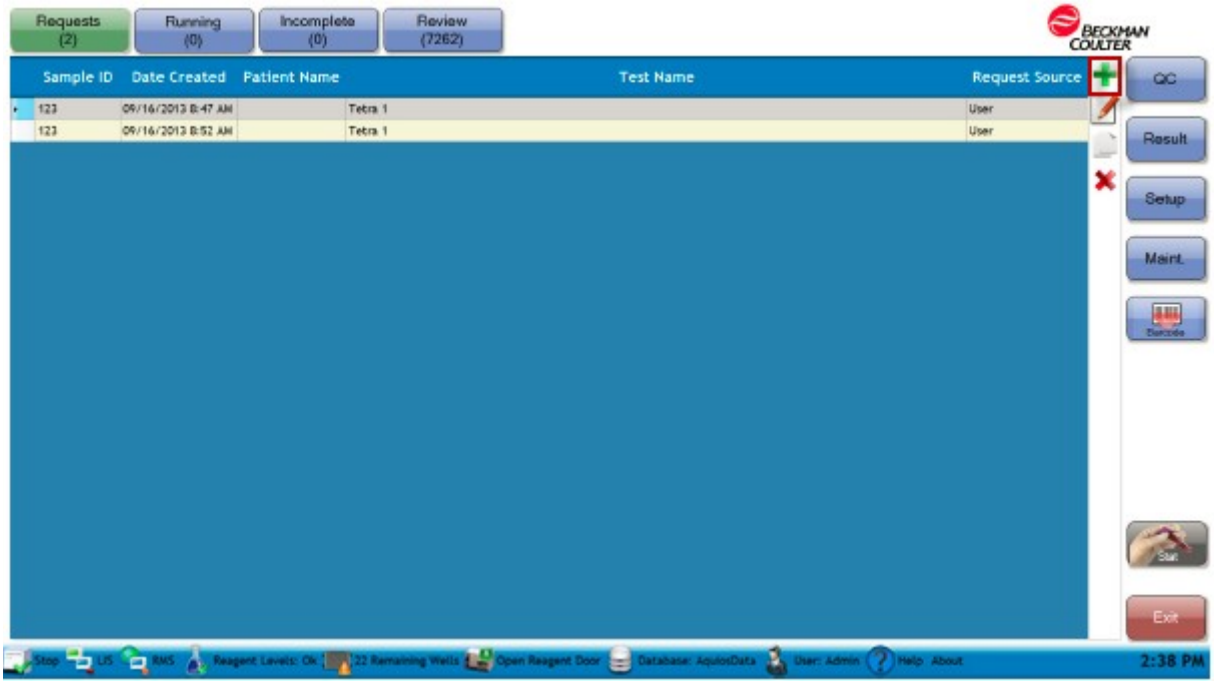
Attachment 2

Instructions for Manually Creating Test Requests on the AQUIOS CL

Please refer to the AQUIOS CL Instructions for Use, PN B21896, Chapter 5 – Sample Processing – Add Test Request for Patient Sample for additional information. The test request can be created before the tubes are ready to be loaded into the system. Once the test request is created, the request appears on the Request Details List.

1. Select 

from the Main Screen.
2. The following screen appears.



3. Select the  from the top right side of the screen.
4. The “Add Request” screen is obtained.

5. Ensure that the **Patient** radial is selected.
6. Enter the Sample ID using one of the following methods:
    - If the sample has a barcode, select the icon to turn on the external barcode reader, and scan the barcode. The barcode information will appear in the Sample ID field of the "**Add Request"** screen
    - Manually type the Sample ID into the field.
    - NOTE – Only samples with a barcode can be run via the autoloader.
7. Use the Test dropdown menu to select the desired test.
8. Enter any additional information to the Add Request screen, and select OK.
9. The sample can now be loaded into a cassette and placed on the autoloader, if a barcode is present. Alternatively, it can also be run via the single tube loader.
10. Refer to the AQUIOS IFU, PN B21896, Chapter 5 – Sample Processing for additional information on the Sample Processing options available on the AQUIOS CL System.