URGENT FIELD SAFETY NOTICE

AQUIOS CL Flow Cytometry System (PN B30166)
All Software Versions (2.0, 2.0.1 and 2.1)
All Applications

Attention Beckman Coulter (BEC) Customer,

This letter is an updated notification in follow-up to our previous communication that you received (dated September 28, 2017) concerning duplicate sample requests leading to sample mis-identification when using the AQUIOS CL systems connected to a Laboratory Information System (LIS). This letter contains important information that needs your immediate attention. The information in this letter replaces the instructions in the original notification dated September 28, 2017.

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<th>ISSUE:</th>
<th>Beckman Coulter is providing important updated information regarding this issue as follows:</th>
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| 1. **Host Query Error** | a) When AQUIOS CL systems are connected to a Laboratory Information System (LIS) directly or through middleware, the system may duplicate sample requests leading to sample mis-identification.  
   b) For this to happen, the following conditions must be met:  
   - The AQUIOS CL Flow Cytometer is connected to an LIS and  
   - Host Query is enabled in LIS setup screen on system and  
   - There are multiple cassettes in the Autoloader and  
   - An error occurs while processing your host query response  
   c) Sample ID duplications caused by errors with host query will be presented as **sequential** duplications. On the review and results screen, no other sample ID from same instrument (serial number) will be listed with a run time between duplicate sample ID entries. |
| 2. **Cassette Unloading Duplication** | a) All AQUIOS CL systems may duplicate sample requests if a cassette is not properly unloaded by the instrument. These sample duplications do **NOT** result in mis-identification.  
   b) Sample ID duplication caused by errors with cassette unloading will present as **non-sequential** duplications. On the review and results screen, one or more sample IDs from same instrument (serial number) will be listed with a run time between duplicate sample ID entries. |

Both issues described above are present in all software versions (2.0, 2.0.1 and 2.1) and all applications used on the AQUIOS CL are impacted.

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<th>IMPACT:</th>
<th>1. <strong>Host Query Error</strong></th>
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| 1. | When duplications are created by the host query error:  
   - 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.
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.

2. **Cassette Unloading Duplication**
   When duplications are created by the cassette unloading scenario:
   - There may be two or more correct results generated for the same sample.
   - There is no impact to samples in other cassettes in the Autoloader.

**ACTION:**

1. **Host Query Error**
   a) Immediately perform an adjustment to the software options on your AQUIOS CL System by disabling Host Query. Adjustments to your LIS or middleware configuration will be necessary to receive demographics and test requests from LIS after Host Query is disabled in the AQUIOS CL software (see FA-31978-B, Attachment 1).

   b) Per the instructions for use (IFU), if AQUIOS CL systems are sharing a database, the host database will only store one settings configuration which will be applied to all AQUIOS CL systems. **It is not possible to maintain different settings on different AQUIOS CL systems sharing a database.** Changes to the settings that are made on one instrument are not refreshed on other instruments until exiting and reentering the software. If AQUIOS CL systems sharing a database are configured with different settings, an instrument may not be utilizing intended settings. (See AQUIOS CL Instructions for Use, PN B21896 - Chapter 8 --System Setup Screen and LIS Setup Screen IFU).

   c) These adjustments will eliminate the issue and result in one sample producing one set of results.

   d) After Host Query has been disabled, the DEFAULT TEST setting no longer has any impact on sample duplication and generation of erroneous results. You may elect to re-enable the DEFAULT TEST setting to suit your Laboratory workflow.

2. **Cassette Unloading Duplications** - No further action is required on your part. No erroneous results are generated by this duplication event.

3. **BEC** will contact your laboratory in the coming weeks and assist in determining if any samples previously run in your laboratory were impacted by host query misidentifications.

4. Please review the attached data release consent form (**FA-31978-B, Attachment 2**) as a signed copy will be necessary before BEC may retrieve the data needed to review previous runs.

Consult with your Medical Director to determine if a retrospective review of results is warranted.

**RESOLUTION:** Beckman Coulter is working on a software upgrade to permanently correct and eliminate these issues.
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 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,

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form
Instructions for Disabling Host Query on AQUIOS CL Software

Please refer to the AQUIOS CL Instructions for Use, PN B21896, and Chapter 8 – LIS Setup Screen 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. Click the LIS setup Button

3. Uncheck “Use Host Query for Requests”.

4. Select “Save” on this screen prior to moving to any other areas of the software.

5. Click the LIS status icon on the bottom of the screen to bring up LIS information screen.
6. Click “OFF” to turn LIS connection off. Then click “ON” to turn the LIS connection back on.

7. If your AQUIOS CL system is directly connected to an LIS, contact your laboratory LIS support and ask for host query to be disabled.

8. If your AQUIOS CL system is connected to middleware, please contact middleware support and ask for host query to be disabled. Host query only needs to be disabled on the middleware system. The LIS system configuration does not need to be altered.

9. If you are using a Beckman Coulter supported Data Innovations Instrument Manager system, following steps outlined under “Disabling Host Query in Data Innovations Middleware” section. Host query only needs to be disabled on the Data Innovations Middleware system. The LIS system configuration does not need to be altered.

10. After Host Query has been disabled, the DEFAULT TEST setting no longer has any impact on sample duplication and generation of erroneous results. You may elect to re-enable the DEFAULT TEST setting to suit your Laboratory workflow.

**ADDITIONAL INFORMATION**

Once Host Query is disabled in AQUIOS software, the following will occur:

- Any samples on the autoloader which do not have a test request will not be processed and will become entries in the incomplete tab unless DEFAULT TEST is enabled.
- If DEFAULT TEST is enabled, samples on the autoloader without a test request will be prepared according to DEFAULT TEST setting.
- Test codes configuration and result upload procedure will not be impacted.
- AQUIOS CL software will not request an order upon scanning the barcode of a tube within the cassette.
- If Host Query is disabled in AQUIOS software but not LIS or middleware: Test requests and demographics entered in the LIS will not be available in AQUIOS CL software unless manually entered.
- If Host Query is disabled in AQUIOS software AND LIS or middleware: Test requests and demographics entered in the LIS will be sent to the AQUIOS Request screen when the LIS next communicates/upon next automatic LIS communication with the AQUIOS CL software.
Disabling Host Query in Data Innovations Middleware

1. On the DI workstation, open Instrument Manager.

2. Login as IM_ADMIN with no password

3. From the Main Menu at the top left of the screen, select “System”, then select “Status” from the drop down menu.

4. Right click on each AQUIOS instrument and select “Stop Selected Connection”. Wait until connection status changes to “OFF”.

5. Under “Configuration”, select “Configuration Editor”.

6. Select the Aquios configuration from the list and click “Properties.” The name and description are user-defined fields so any Aquios instrument may be listed by serial number or another lab designation for the instrument.
7. On the “Configuration Properties” screen, select “Driver Properties”.

8. If the Aquios Configuration screen does not open on screen, click on the task bar and select AQUIOS Configuration. On the Beckman Coulter AQUIOS Configuration screen under the Standard Configuration tab select “No” in the Query Mode.

9. Select “Close” on all Configuration screens.

10. If the status window is not open, from the Main Menu, select “System Menu”, then select “Status. Right click on each AQUIOS listed on and select “Start Selected Connection”.

11. If the Aquios system is ON, the status should change to ON. If the Aquios software is closed, the status will remain “connecting” until the software is opened.
FA-31978-B, Attachment 2

NOTICE TO CUSTOMERS AND CONSENT TO DATA COLLECTION

Customer: ____________________________________________________ (corporate entity name)

The safety of our products and health of our patients are our highest priority at Beckman Coulter. In accordance with our quality system and regulatory requirements, Beckman Coulter requests your laboratory’s consent to allow our engineering team to further investigate the data and system logs from the following instrument:

Aquios CL (“Instrument”)

The location(s) and serial number(s) for the Instrument are listed on Attachment A.

You should be aware that some of the information stored on the Instrument may be considered personal data under relevant data protection laws. This information will be transferred to the United States, where it will be analyzed for quality purposes. The data will not be used for any other purpose. Where necessary, there may be a need to report information to health authorities in the United States and other countries in accordance with applicable legal requirements.

We will transfer data from the Instrument database(s), which may include archives that are restored from the Instrument or other archive storage location.

The information that will be collected from the Instrument may include:

- Sample identification number
- Date the sample was collected
- Other: ____________________________________________________

Patient names will not be collected.

Appropriate administrative, technical, and physical measures will be used to safeguard the data collected. Beckman Coulter will restrict access to the data to those employees, agents and contractors who have a legitimate business need for such access in order to assist us in the performance of quality control and regulatory reporting activities.

As indicated, Beckman Coulter will transfer the data across borders for the purposes outlined in this Notice. The data will be stored in the United States and accessed by Beckman Coulter in the United States.

CONSENT TO DATA COLLECTION AND PROCESSING

I acknowledge that I have read the above Notice, and I understand and consent to the collection of data as described in this Notice. I understand that the data will be kept confidential in accordance with Beckman Coulter’s policies and local regulations.

Signature: ____________________________________________________

Name: _________________________________________________________

Title: _________________________________________________________

Date: ________________________________
ATTACHMENT A

Instrument Location and Serial Number

1. Aquios CL, serial number: _______________ location: __________________________

2. Aquios CL, serial number: _______________ location: __________________________

3. Aquios CL, serial number: _______________ location: __________________________