February 28, 2025

URGENT FIELD SAFETY NOTICE

DxC 500 AU Clinical Chemistry Analyzer

REF	UDI-DI	Serial Number	Software version
C63519	14987666545058	See Appendix B	V1.3, V1.4, V1.4.1, V1.4.2, V1.4.3
C63520	14987666545065		

Single Registration Number (SRN): US-MF-000010288

Attention Beckman Coulter Customer,

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

| ISSUE: | Beckman Coulter has determined that the DxC 500 AU Clinical Chemistry Analyzer might assign a test result to an incorrect sample ID under the following workflow conditions. After loading a barcoded sample tube (Sample A) onto the DxC 500 AU Clinical Chemistry Analyzer, all tests ordered for that barcoded sample tube are locked into the specific position of that barcoded tube on the analyzer (for example, the position on the DxLab Rack or position in the STAT table) until all tests are completed or cancelled for that sample tube._x000D_
 _x000D_
A problem might occur if, for any reason, all tests ordered for that barcoded sample tube (Sample A) are not completed or remain "in pending", and the operator attempts to analyze a second sample tube (Sample B) in that same position on the rack or STAT table. If the bar code for Sample B is not successfully scanned by the analyzer or if the sample tube is not labelled, the analyzer assumes the sample that previously occupied that position has been reloaded (Sample A). The analyzer will complete and report the pending tests associated with Sample A, using Sample B. No results will be reported for Sample B._x000D_
 _x000D_
This issue does not arise if all barcoded sample tubes are successfully scanned or if testing is complete for the first barcoded sample (Sample A). |
|---|---|
| IMPACT: | As outlined in the Sample Processing chapter of the DxC 500 AU IFU, *if the analyzer cannot run the tests due to missing or expired reagents, supplies, or calibrations, or if there is a problem with the placement of samples in racks, the system generates an event on the Sample Events page.* |

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	If an issue arises which impacts test completion of a sample, this will be evident on the analyzer through the generation of a sample event and will also be evident in the sample list on the Sample List page. If sample events and/or the sample list are not reviewed by the operator in real time when the event is triggered on the analyzer, or reviewed by the operator after the analyzer has completed testing and returns to standby AND the testing condition outlined in the Issue section is carried out, this might lead to false positive/high test results, false negative/low test results, or delayed results.
ACTION:	• Beckman Coulter recommends reviewing your laboratory workflow, sample labeling/label integrity and positioning to determine impact and sharing this with your laboratory and/or Medical Director. • The latest available system software (software V1.4.3) provides improved sample event information and real time reporting, identifying the specific location of the sample with tests that are not completed. This software will help in the management of this issue. • For current software version is V1.3, V1.4, V1.4.1, or V1.4.2 customers, contact your Beckman Coulter service representative at your earliest convenience to upgrade to software V1.4.3. To check the software version, follow the instructions in the Viewing Analyzer Version Information topic in the IFU: **Viewing Analyzer Version Information** You can view information about the current version of the analyzer software and hardware. 1 Select **Menu > About**. The analyzer displays the About dialog, with the analyzer software version, and telephone numbers for service and sales representatives. 2 For more detailed information, select **Details**. The analyzer displays the Product Version dialog with version information for software subsystems and the version of the IFU that is included in the System Help. 3 To exit each dialog, select the **X** in the upper right corner of the dialog. • Follow the attached appendix A Job Aid, which will prevent the operator workflow described in the ISSUE section. The Job Aid will outline how to use the sample list to manage the samples which have not completed. There is no requirement to reverify applications, for example, precision studies.
RESOLUTION:	• Beckman Coulter is working on implementing the countermeasure in the next software release. • Your Beckman Coulter Customer Service representative will contact your laboratory to schedule the software update when it is available.

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 our Customer Support Center: + 41 (0) 800 850 810.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

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Appendix A: DxC 500 AU Job Aid:
Managing Offboard Samples with a 'Presented' Status

When a sample is loaded for processing on the analyzer and meets the precheck conditions (sufficient consumables and reagents, and valid calibrations) to complete all the ordered tests on the sample, the sample will proceed through the following sample statuses on the Sample List:

- **Presented**: The analyzer has identified an order for the presented sample(s) and is waiting to aspirate the sample.
- **In Progress**: The analyzer has started aspirating the sample.
- **Completed**: The analyzer has finished processing the sample, and there are no pending tests with an 'Ordered' status in the sample order.

If there are ordered tests on the presented sample that did not run due to failed precheck conditions (insufficient consumables and reagents, or invalid calibration), the sample will remain in the 'Presented' state indefinitely on the Sample List, even after the analyzer returns to the *Running (Standby)* state. The 'Presented' sample will remain associated with the rack and position, or STAT table position, that the sample was processed on, until action is taken to complete or cancel the pending test orders on the 'Presented' sample.

Manage these samples that remain in a 'Presented' status on the Sample List by taking one of the following actions:

- Address the failed precheck conditions (load the insufficient consumable or reagent, calibrate the test, etc.) and reload and run the sample in the same load location and position (STAT table or DxLAB rack) that it was originally processed from.
- Cancel the ordered tests on the sample with the 'Presented' status using the **Cancel Tests** feature.

This job aid will provide procedures on:

- Managing 'Presented' Samples Processed in DxLAB Racks
- Managing 'Presented' Samples Processed in the STAT Table
- Canceling Ordered Tests on 'Presented' Samples

Managing 'Presented' Samples Processed in DxLAB Racks

Step	Title	Action
1	Confirm Sample Status	a. From the Home page, select the **Sample List** task indicator. b. Select **Active** in the upper left corner. Samples that have tests with a status of 'In Progress' or 'Presented' are displayed. c. Confirm the sample has a status of 'Presented'.
2	Confirm Rack Status (Software Version 1.4.3 and Higher)	a. Select **Menu** > **Advanced** > **Sample Racks**. b. Select **Offboard** or **Onboard** to verify the rack location. The rack will need to be **Offboard**. 📝 To complete processing for a presented sample, it must be loaded back on the instrument in the same rack and position as originally run.
3	Confirm Sample State	a. Confirm the sample volume is sufficient for all the tests ordered. b. Confirm the sample type is correct for the test(s). c. Confirm the sample has not evaporated. d. Confirm the bar code label on the sample container is in the correct location on the container, is visible through the slot in the rack and is not damaged. e. Confirm the correct sample container and the correct rack and position are being used to process the sample. f. Confirm calibrations are complete and valid. g. Confirm there are sufficient reagent tests available.
4	Complete Sample Processing	a. Place the rack in the sample handler. b. Close the sample handler door. The analyzer will start processing the sample. 📝 After reloading and running the sample, confirm the status is 'Completed' in the **All** view of the Sample List.

Managing 'Presented' Samples Processed in the STAT Table

Step	Title	Action
1	Confirm Status of the sample	a. From the Home page, select the **Sample List** task indicator. b. Select **Active** in the upper left corner. Samples that have tests with a status of 'In Progress' or 'Presented' are displayed. c. Confirm the sample displays 'STAT' in the Rack column and has a status of 'Presented' in the Status column. To complete processing for a presented sample, it must be loaded back in the STAT table in the same position as originally run.
2	Confirm Sample State	a. Confirm the sample volume is sufficient for all the tests ordered. b. Confirm the sample type is correct for the test(s). c. Confirm the sample has not evaporated. d. Confirm the bar code label on the sample container is in the correct location on the container, is not damaged and is facing outward on the STAT table. e. Confirm the correct sample container and the correct table position are being used to process the sample. f. Confirm calibrations are complete and valid. g. Confirm there are sufficient reagent tests available
3	Complete Sample Processing	a. Place the sample container in the appropriate position on the STAT table as identified on the Sample List. b. Close the STAT table cover. c. Select the START button in the STAT Table state area on the status bar and then select **Start STAT**. The analyzer will perform a STAT table check and start processing the sample. After reloading and running the sample, confirm the status is 'Completed' in the **All** view of the Sample List.

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Canceling Tests on 'Presented' Samples

If you are unable to address the precheck conditions and reload and run the pending tests for the sample to go to completion, you can cancel the tests on the sample in the 'Presented' state.

When canceling tests, the instrument must be in the *Running (Standby)* state. The **Cancel Tests** function is only used for samples which remain in 'Presented' after being initially loaded on the instrument.

Step	Title	Action
1	Cancel Tests (Software Version 1.4.2 and Higher)	a. Select **Menu** > **Advanced** > **Cancel Tests**. b. Select the appropriate sample**: Patient, Calibration or QC**. When performing this procedure, it cancels all samples of the selected sample kind that are marked as 'Presented'. c. Confirm the analyzer is the *Running (Standby)* state. d. Select **Cancel Tests**. e. View the status of the samples on the Sample List to confirm they are no longer in the 'Presented' state.

Appendix B: Affected Serial Number

Part Number	Serial Number
C63520	2024010028
C63520	2024060085
C63520	2024070116
C63520	2024080159
C63520	2023070009
C63520	2024070134
C63520	2024090172
C63520	2024090199
C63520	2023110023
C63520	2024010024
C63520	2024010025
C63520	2024080150
C63520	2024080152
C63520	2024080161
C63520	2024090163
C63520	2024090165
C63520	2024090167
C63520	2024060077
C63520	2024060082
C63520	2024100209
C63520	2024090197
C63520	2024010038
C63520	2024050066
C63520	2024010035
C63520	2024050072
C63520	2024040056
C63520	2024030049
C63520	2024020046
C63520	2024070111
C63520	2024030051
C63520	2024030052
C63520	2024010033
C63520	2024100215
C63520	2023090015
C63520	2024100222
C63520	2024100224
C63520	2024060103

C63520	2024060104
C63520	2024100207
C63519	2024060094
C63519	2024070114
C63520	2024060101
C63520	2024010029
C63520	2024100228
C63520	2024080146
C63520	2024080138
C63520	2024080145
C63520	2024060107
C63520	2024070113
C63520	2024090177
C63520	2024090179
C63520	2023080012
C63520	2024050068
C63520	2024040060
C63520	2024050074
C63520	2024020045
C63520	2024070128
C63520	2024070119
C63520	2024070115
C63520	2024020042
C63520	2024070120
C63520	2024070121
C63520	2024070123
C63520	2024070124
C63520	2024070125
C63520	2024070126
C63520	2024040062
C63520	2024010027
C63520	2024080148
C63520	2024010032
C63520	2024090181
C63520	2024010031
C63520	2024100226
C63520	2024020043
C63520	2024060099
C63520	2024010030
C63520	2024090176

C63520	2024090190
C63520	2024080141
C63520	2024040063
C63520	2024020047
C63520	2024060096
C63520	2024040059
C63520	2024060088
C63520	2024060075
C63520	2024060106
C63520	2024100230
C63519	2024090174
C63520	2025010246
C63520	2023100019
C63520	2024070109
C63520	2024080139
C63520	2024080142
C63520	2024070108
C63519	2024090170
C63520	2024030053
C63520	2024090185
C63520	2024080149
C63520	2024070136
C63520	2024090188
C63520	2024010034
C63520	2024070127
C63520	2023070010
C63520	2024070129
C63520	2024070130
C63520	2024080157
C63520	2024100205
C63520	2025010248
C63520	2024020041
C63520	2024100217
C63520	2024100219
C63520	2024030055
C63520	2024090183
C63520	2023060005
C63519	2024070118
C63520	2024010036
C63520	2024010037

C63520	2024070132
C63520	2024070131
C63520	2023100020
C63520	2024090192
C63520	2024090194
C63520	2024080153
C63520	2024080155
C63520	2024060102
C63520	2024100214
C63520	2025010250
C63520	2024050064
C63520	2024050070
C63520	2024100212
C63520	2024090195
C63520	2023090016
C63520	2023110022
C63520	2024070110
C63520	2024100201
C63520	2024080144

CUSTOMER RESPONSE FORM
DxC 500 AU Clinical Chemistry Analyzer

REF	Serial Number	Software Version
C63519 C63520	See Appendix A	V1.3, V1.4, V1.4.1, V1.4.2, V1.4.3

Check the appropriate box below:

☐ I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken, and records retained as part of our Laboratory Quality System documentation.

Or:

☐ We do not have this product. I have read and understood the information within the accompanying Beckman Coulter Notification and have retained this record as part of our Laboratory Quality System documentation.

Name and Address of Laboratory / Hospital / Organization / Institution:

_____

_____

Signed:_____   Date:_____

Name:_____   Title:_____

Tel: _____   Email: _____

Beckman Coulter is updating the customer address list for field action notifications. If the contact information on your notification is inaccurate, please update:

Customer Number:_____

Contact Name:_____   Title:_____

Tel: _____   Email: _____

Mailing Address:_____