



February 28, 2025

URGENT FIELD SAFETY NOTICE**DxC 500i Clinical Analyzer**

Product	Configuration	Analyzer Module	REF	UDI	Software
DxC 500i Clinical Analyzer	With ISE	DxC 500 AU Module w/ISE, DxC 500i	C63522	14987666545089	SW 1.3.0 and 1.3.2
		Access 2 Module, DxC 500i	C13252	15099590742331	
	Without ISE	DxC 500 AU Module, DxC 500i	C63521	14987666545072	
		Access 2 Module, DxC 500i	C13252	15099590742331	

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

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:	<p>Beckman Coulter has determined that the DxC 500i Clinical Analyzer might assign a test result to an incorrect sample ID under the following workflow conditions.</p> <p>After loading a barcoded sample tube (Sample A) onto the DxC 500i Clinical 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, Carousel Rack or position in the STAT table) until all tests are completed or cancelled for that sample tube.</p> <p>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 barcode 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.</p> <p>For chemistry test analysis on the DxC 500i analyzer, there is no real time sample event that alerts the operator when tests have not completed. Only</p>
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	<p>when the system returns to standby is the notification generated on the Sample Events page.</p> <p>For immunoassay test analysis on the DxC 500i analyzer, a sample event is generated immediately with details of the test that cannot be run.</p> <p>e.g. "Rack ID: 11039, Position 1, Insufficient reagent: PSA-Hyb, loaded"</p> <p>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).</p>
IMPACT:	<p>As outlined in the Sample Processing chapter of the DxC 500i 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.</p> <p>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 may lead to false positive/high test results, false negative/low test results, or delayed results.</p>
ACTION:	<ul style="list-style-type: none"> • 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. • Follow the attached 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. • Your Beckman Coulter service representative will contact you to schedule a software upgrade which will help in the management of this issue. This software upgrade will provide improved sample event information and real time reporting, identifying the specific location of the sample with tests that are not completed. • There is no requirement to reverify applications, for example, precision studies.
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter is working on implementing a fix for this issue. • Your Beckman Coulter 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;

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:
 Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 28-Feb-2025 | 3:11:22 PM PST
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President Quality & Regulatory Affairs

Enclosure: Response Form
Appendix A: DxC 500i Job Aid: Managing Offboard Samples with a 'Presented' Status

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

When a sample is loaded for processing on the analyzer and meets the precheck conditions to complete all ordered tests on the sample (sufficient consumables and reagents, and valid calibrations), 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 remains in the 'Presented' state indefinitely on the Sample List and does not go to the 'Completed' state, even after the analyzer returns to the *Running (Standby)* state. The 'Presented' sample will remain associated with the rack 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 incomplete 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.) for the incomplete tests and reload and run the sample in the same load location and position (STAT table, DxLAB rack, or carousel rack) that it was originally processed.
- 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 Carousel 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 the Sample Status	<ul style="list-style-type: none"> a. Select Home > Sample List task indicator. b. Select Active in the upper left corner of the Sample List to display samples with the statuses of 'Presented' or 'In Progress'. c. Confirm the sample displays the status of 'Presented'.
2	Confirm the Rack Status	<ul style="list-style-type: none"> a. Select Menu > Advanced > Rack Retrieval. b. Select Offboard or Onboard to verify the rack location. The DxLAB rack with the 'Presented' sample will need to be Offboard. d.  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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> a. Place the DxLAB rack in the sample handler. b. Close the sample handler door. e. The analyzer will start processing the sample. f.  After reloading and running the sample, confirm the sample has a status of 'Completed' in the All view of the Sample List.





Managing 'Presented' Samples Processed in Carousel Racks

Step	Title	Action
1	Confirm the Sample Status	<ul style="list-style-type: none"> a. Select Home > Sample List task indicator. b. Select Active in the upper left corner of the Sample List to display samples with the statuses of 'Presented' or 'In Progress'. c. Confirm the sample displays the status of 'Presented'.
2	Confirm the Rack Status	<ul style="list-style-type: none"> a. Select Menu > Advanced > Rack Retrieval. b. Select Offboard or Onboard to verify the rack location. The carousel rack with the 'Presented' sample will need to be Offboard. g.  To complete processing for a presented sample, it must be loaded back on the sample carousel in the same rack and position as originally run.
3	Confirm Sample State	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> a. Select Load Carousel in the status bar. b. Load the carousel rack in the sample carousel. c. Select Done in the dialog. h. The analyzer will start processing the sample. i.  After reloading and running the sample, confirm the sample has a status of 'Completed' in the All view of the Sample List.



Managing 'Presented' Samples Processed in the STAT Table

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




Canceling Ordered 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 1.3.2 and Higher)	<ol style="list-style-type: none"> Select Menu > Advanced > Cancel Tests. 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'. Confirm the analyzer is in the <i>Running (Standby)</i> state. Select Cancel Tests. View the status of the samples on the Sample List to confirm they are no longer in the 'Presented' state.