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To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 233 dated 29/10/2023 Regarding NCMDR Field Safety Corrective Action of Dxl 9000 Access Immunoassay Analyzer from (mfr: Beckman Coulter).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control





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Circular No. 233/ 2023

13 -04-1445 H

29 -10-2023

Field Safety Corrective Action of Dxl 9000 Access Immunoassay Analyzer from Beckman Coulter.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19734
Product	Dxl 9000 Access Immunoassay Analyzer.
Description	In-vitro diagnostics - equipment / products for clinical chemistry.
Manufacturer	Beckman Coulter.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	REF: C11137 Software Versions: 1.15 and below
Reason	The above analyzer may incorrectly identify samples under certain condition (see the attachment).
Action	1. Perform a retrospective review of all add on tests or rerun tests that were generated on a Dxl 9000 analyzer that is connected to a host system. 2. Retesting is recommended on Sample A. 3. Perform one of the following: - Option 1: Disconnect the Dxl 9000 Access Immunoassay Analyzer from the host system. You may continue ordering tests through the analyzer console. - Option 2: Follow the instructions provided in Appendix A. 4. Software version 1.15.2 will be released to prevent reporting an erroneous test result. 5. Software version 1.16 will be released also to resolve the analyzer issue. 6. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

Twitter: dgpa_dc Email: dg-padc@moh.gov.om



August 31, 2023

URGENT FIELD SAFETY NOTICE
Dxl 9000 Access Immunoassay Analyzer

REF	Software Versions
C11137	1.15 and below

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention. Patient results may be affected.

ISSUE:	<ul style="list-style-type: none"> • Beckman Coulter has determined that the Dxl 9000 Access Immunoassay Analyzer may incorrectly identify samples. • The issue only occurs under the following conditions: <ol style="list-style-type: none"> 1. The Dxl 9000 analyzer is connected to a host system (LIS or middleware). 2. Normal sample processing occurs through the host system. <ol style="list-style-type: none"> a) A sample (Sample A) with test orders is submitted from the host system and loaded onto the Dxl 9000 analyzer using a DxLAB sample rack. b) The analyzer completes the tests and transmits test results back to the host system for Sample A. 3. The host system sends the analyzer new information or test order updates for Sample A. This can happen immediately or days later. This action assigns Sample A to the previous rack and position it occupied during step 2b. 4. A new sample (Sample B) with tests orders is submitted from the host system and placed into the same rack and position to which Sample A was previously assigned, and the rack is loaded onto the Dxl 9000 analyzer. 5. The analyzer reads the tube barcode, but disregards the sample ID of Sample B and reverts to information for Sample A. <ol style="list-style-type: none"> a) Any pending tests for Sample A will be run using Sample B instead, resulting in an erroneous result for Sample A. In addition, the tests ordered for Sample B will not run, and no results will be reported for Sample B. Sample B will be offloaded with no notification to the user. b) If Sample A received a new information update (such as patient demographic information) from the host system but no test order updates, the tests ordered for Sample B will not run, and no results will be reported for Sample B. Sample B will be offloaded with no notification to the user.
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	<ul style="list-style-type: none"> Subsequent update messages from the host system for Sample A will initiate the sequence starting at Step 4. The sequence will occur each time that the host system submits additional test requests for Sample A while any other sample, not just Sample B, occupies the same rack and position that was initially occupied by Sample A. The issue only affects samples loaded using DxLAB sample racks loaded directly onto the sample handler of a DxI 9000 analyzer connected to a host system. This issue does not affect samples that are sampled from an automation line.
IMPACT:	<ul style="list-style-type: none"> An erroneous test result may be reported to a physician for Sample A. A delay in test results may occur for Sample B, because the analyzer does not process the test orders.
ACTION:	<ul style="list-style-type: none"> Perform a retrospective review of all add on tests or rerun tests that were generated on a DxI 9000 analyzer that is connected to a host system. Retesting is recommended on Sample A. Perform one of the following: Option 1: Disconnect the DxI 9000 Access Immunoassay Analyzer from the host system. You may continue ordering tests through the analyzer console. Option 2: Follow the instructions provided in Appendix A.
RESOLUTION:	<ul style="list-style-type: none"> Beckman Coulter has identified the root cause of this issue and will release system software version 1.15.2, which prevents reporting an erroneous test result. Test results will still be delayed whenever this issue occurs. This issue will be resolved with system software version 1.16. Your service representative will contact your laboratory to schedule both software upgrades when they are 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,



Vice President Quality & Regulatory Affairs
Beckman Coulter Inc.

Enclosure: Response Form

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Appendix A: FA-23038

Dxl 9000 Access Immunoassay Analyzer

These instructions will prevent the host system (LIS or middleware) from downloading test orders or sending new information updates to the analyzer but will allow the Dxl 9000 analyzer to upload test results to the host system.

A. If the Dxl 9000 analyzer in your laboratory is not connected to an automation line, follow these instructions:

1. Create a set of duplicate DxLAB sample racks. These will be used later in the instructions.
 - a. Label DxLAB sample racks with the same numbers that are already in use in your laboratory to create the duplicate set. Refer to *Placing Labels on a DxLAB Rack* topic in the System Help or IFU for more information.
 - b. Contact your local Beckman Coulter representative for additional DxLAB sample racks and DxLAB tube rack labels.
2. If your host system (LIS or middleware) is configured with rules to run reflex tests or rerun tests, configure the same reflex and rerun rules on the Dxl 9000 analyzer console. Refer to the *Configuring Reflex Tests*, *Configuring Reruns*, and *Configuring Reruns with Dilutions* topics in the System Help or IFU for more information.
3. Disable host system queries for each Dxl 9000 analyzer in your laboratory.
 - a. If your lab uses the REMISOL Advance Data Manager System, follow these instructions:
 - i. Access the Blocking Status menu by using the **Environment > Instrument Blocking** menu or when you click on the **Instrument Blocking** toolbar button. Refer to the *Instrument Blocking Status* topic in the REMISOL Advance Data Manager System IFU for more information.
 - ii. For each Dxl 9000 analyzer, clear the Download checkbox to disable all downloads to the Dxl 9000 analyzer.
 - iii. Validate the change by clicking on the OK button.
 - b. If your lab does not use the REMISOL Advance Data Manager System, follow these instructions:
 - i. From the Dxl 9000 analyzer console, select **Menu > System Configuration > LIS**.
The LIS page is displayed.
 - ii. In the General Settings section of the page, clear the **Issue host queries** checkbox to disable all host queries from the Dxl 9000 analyzer.
 - iii. Select **System Configuration** in the breadcrumb links to return to the System Configuration page.
 - iv. Select **Activate Draft**. Refer to the *Activating a Draft Configuration* topic in the System Help or IFU for more information.



NOTE: After the host system query setting is disabled, all test orders for the DxI 9000 analyzer must be ordered at the DxI 9000 analyzer console. Completed test results will upload to the host system.

4. Obtain a list of pending test requests for the DxI 9000 analyzer from the host system.
5. Order the pending test requests from the DxI 9000 analyzer console. Refer to the *Entering Test Orders* topic in the System Help or IFU for more information.
6. Perform the following steps when loading samples to ensure that the DxI 9000 analyzer accurately identifies the samples in the rack.
 - a. Find two racks with the same Rack ID.
 - b. Place ordered samples in one of the racks. Leave the other rack empty.
 - c. Load both racks in the Input Area with the empty rack on the left. Refer to the *Placing a Rack in the Input Area* topic in the System Help or IFU for more information.

NOTE: Loading the empty rack may cause the analyzer to generate a sample event with the description, "A sample is not onboard to run test" or "The container was not detected." The event can be dismissed.
 - d. Select the **Sample List** task indicator on the *Home* page of the user interface.
 - e. Select **Active** to view active samples.
 - f. Confirm that the samples you loaded on the instrument display in the Active Sample List and are assigned to the rack that you loaded.
 - g. Confirm that all test orders from the rack are complete before reusing the rack for different samples. Refer to the *Reviewing Results* topic in the System Help or IFU for more information.
 - If all test orders are complete, the rack may be reused for other samples.
 - If the analyzer automatically placed reflex or rerun test requests for any of the samples in the rack, reload the sample or cancel the pending test orders. Pending orders can be found on the Sample List page by selecting the Ordered or Active option. Refer to the Monitoring Sample Status topic in the System Help or IFU for more information.
7. Frequently review host system reports for any outstanding test orders to ensure the test orders are complete. Follow steps 4 through 7 to complete pending test orders.



B. If the Dxl 9000 analyzer in your laboratory is connected to an automation line, follow these instructions:

This issue does not affect samples that are loaded on automation lines; however, samples loaded from a DxLAB sample rack onto a Dxl 9000 analyzer connected to an automation line could be impacted.

1. Create a set of duplicate DxLAB sample racks. These will be used later in the instructions.
 - a. Label DxLAB sample racks with the same numbers that are already in use in your laboratory to create the duplicate set. Refer to *Placing Labels on a DxLAB Rack* topic in the System Help or IFU for more information.
 - b. Contact your local Beckman Coulter representative for additional DxLAB sample racks and DxLAB tube rack labels.
2. Any samples that need to be loaded onto the Dxl 9000 analyzer using a DxLAB sample rack must be ordered from the Dxl 9000 analyzer console prior to being loaded. Refer to the *Entering Test Orders* topic in the System Help or IFU for more information.
3. Perform the following steps when loading samples to be sure that the Dxl 9000 analyzer accurately identifies the samples in the rack.
 - a. Find two racks with the same Rack ID.
 - b. Place ordered samples in one of the racks. Leave the other rack empty.
 - c. Load both racks in the Input Area with the empty rack on the left. Refer to the *Placing a Rack in the Input Area* topic in the System Help or IFU for more information.
NOTE: Loading the empty rack may cause the analyzer to generate a sample event with the description, "A sample is not onboard to run test" or "The container was not detected." The event can be dismissed.
 - d. Select the **Sample List** task indicator on the *Home* page of the user interface.
 - e. Select **Active** to view active samples.
 - f. Confirm that the samples you loaded on the instrument display in the Active Sample List and are assigned to the rack that you loaded.
 - g. Confirm that all test orders from the rack are complete before reusing the rack for different samples. Refer to the *Reviewing Results* topic in the System Help or IFU for more information.
 - If all test orders are complete, the rack may be reused for other samples.
 - If the analyzer automatically placed reflex or rerun test requests for any of the samples in the rack, reload the sample or cancel the pending test orders. Pending orders can be found on the Sample List page by selecting the Ordered or Active option. Refer to the Monitoring Sample Status topic in the System Help or IFU for more information.