January 3, 2024

URGENT FIELD SAFETY NOTICE – FSN-23048

Dear 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.

DxI 9000 Access Immunoassay Analyzer

Issue Description and Scope	REF	Issue Number
Access Ultrasensitive Insulin users who configure SI units (pmol/L).	33410 APF 182	Please See Issue 1 Below
System provides numerical results that are below the lowest reportable result if laboratory chooses to report assay results in units of measurement other than the defined default units.	C11137	Please See Issue 2 Below
A result of "0" incorrectly reported when the system utilizes an expression that utilizes non-numerical symbols (e.g., ">" or "<") to derive a calculated test as part of result reporting.	C11137	Please See Issue 3 Below
Reserve volume is enabled and the assay LIS code is not the same as the assay Test ID.	C11137	Please See Issue 4 Below

Issue 1	
ISSUE:	• Beckman Coulter has determined that there is an issue with the Access Ultrasensitive Insulin assay protocol file (APF) for use with the DxI 9000 Access Immunoassay Analyzer (APF 182 test definition version 6.7 and below). • The Access Ultrasensitive Insulin APF applies an incorrect conversion factor when converting from system default units of µIU/mL to the International System of Units (SI units) of pmol/L.
IMPACT:	• Users who configure SI units (pmol/L) for the Access Ultrasensitive Insulin assay on the DxI 9000 Access Immunoassay Analyzer will have an incorrect conversion factor applied to the results. The Access Ultrasensitive Insulin results reported in SI units (pmol/L) will be approximately 40,000 times lower than expected. The incorrect results are typically below the limit of detection of the Access Ultrasensitive Insulin assay. • Results reported in default units are not affected. • All quality control and patient results reported in SI units (pmol/L) are affected.

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ACTION:	• Configure the Access Ultrasensitive Insulin assay to the system default units (µIU/mL). Refer to the appropriate system manuals for instructions. • To manually convert concentrations to SI units (pmol/L), multiply µIU/mL by a multiplication factor of 7.0.
RESOLUTION:	• Beckman Coulter has identified the root cause of this issue and will release an updated Access Ultrasensitive Insulin APF on the DxI 9000 analyzer that includes the correct conversion factor for SI units (pmol/L). • Your Beckman Coulter representative will contact you when the updated APF is available.

Issue 2	
ISSUE:	• If your laboratory chooses to report any Access assay results in units of measurement other than the defined default units, Beckman Coulter has determined that the DxI 9000 Access Immunoassay Analyzer will provide numerical results that are below the lowest reportable result defined in the assay protocol file (APF). The DxI 9000 Access Immunoassay Analyzer system software does not convert the lowest reportable result in the APF to the units chosen by the user. The analyzer uses the lowest reportable result in the default units instead and then appends the units chosen to that numerical value.
IMPACT:	• This issue only affects Access assays that are configured to report results in any unit of measurement other than the defined default units. • This issue does not affect non-dilution Access assays. • If your laboratory chooses to report Access assay results in units of measurement other than the defined default units, this issue may cause an erroneous but believable high or low result when the DxI 9000 analyzer performs a dilution.
ACTION:	• If the DxI 9000 Access Immunoassay Analyzer is connected to a host system, you can configure the host system to convert results from the system default units to the desired reporting units. • If the DxI 9000 analyzer is not connected to a host system, revert all Access assays to their system default units to be sure the analyzer accurately reports dilution assay test results. • Perform a retrospective review of all dilution assay test results that were reported in units other than the system default units.
RESOLUTION:	• Beckman Coulter is investigating the root cause of this issue will implement a correction with a future software release. • Your Beckman Coulter service representative will contact you to schedule the software upgrade when it is available.

Issue 3	
ISSUE:	• The DxI 9000 System incorrectly provides a “0” result when the system utilizes a calculation created by the user that includes non-numerical symbols (e.g., “>” or “<”) to derive a calculated test as part of result reporting. • For example, a test result that exceeds the analytical measuring range reports the result with an expression that includes “>”. If used in a calculated result along with another assay, it causes the formula to not be used and report “0”.

IMPACT:	• An example where this can occur is the onboard calculation of percent free PSA. The calculated result will be reported as “0” when the Total PSA result exceeds the analytical measuring range or is below the onboard dilution range. • An erroneously calculated result of “0” may be reported to the physician.
ACTION:	• Discontinue using the calculated result feature on the DxI 9000 user interface. Calculations can be performed manually or at the host system. • For assay results that have already been run, if a calculated result of “0” was obtained, perform a retrospective review to ensure none of the assay results contained a “>” or “<” result. If any of the assay results contained a “>” or “<” then the calculated result interpretation should be corrected to “no result”.
RESOLUTION:	• Beckman Coulter is investigating the root cause of this issue and will implement the correction with a future software release. • Your service representative will contact you to schedule your software upgrade when it is available.

Issue 4	
ISSUE:	• Beckman Coulter has determined that the DxI 9000 Access Immunoassay Analyzer may not aliquot a reserve volume for assays configured to do so if the configured assay LIS code is different than the assay Test ID. • To verify: 1. Select **Menu > System Configuration > Test Menu**. 2. On the **Test Configuration** tab, the assay LIS code must be the same as the assay Test ID to perform reserve volume aliquoting. • If the LIS code is different than the Test ID, the DxI 9000 analyzer does not recognize that reserve volume is enabled. • This could lead to a delay in reflex testing.
IMPACT:	• If reserve volume is enabled and the assay LIS code is not the same as the assay Test ID: 1. The DxI 9000 analyzer will not aliquot a reserve volume. 2. The assay rule conditions (including reruns, reflexes, and rule-based dilutions) will still initiate a reserve volume order. 3. The order will not run automatically because the necessary reserve volume was not aliquoted. ○ The following sample event will occur for the affected sample: “**A sample is not onboard to run test:”** followed by the impacted test(s) 4. A delay in patient test result reporting could occur. • There is no impact if the assay LIS code and assay Test ID are the same.
ACTION:	• If a reserve volume order is not run automatically as identified by a sample event notification, reload the sample to complete the ordered test. • Alternatively, to ensure reserve volume is aliquoted, on the **Menu > System Configuration > Test Menu** screen, reenter the assay LIS code to match the assay Test ID shown on screen.

RESOLUTION:	• Beckman Coulter is investigating the root cause of this issue and will release a DxI 9000 Access Immunoassay Analyzer system software update that correctly aliquots a reserve volume even if an assay LIS code is not the same as the assay Test ID. • Your Beckman Coulter representative will contact you when the system software update 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 note, there are four issues communicated within this notice. Ensure you have reviewed this letter in full prior to completing the response form.

Please complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologise for the inconvenience that this caused your laboratory.

Yours sincerely,

Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe

Enclosed: Vigilance Response Form