Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution onthis issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please informus about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Affairs Specialist

Contact person of this notification	...Alice Wong.....
Department	... Marketing.....
Telephone	...6012-296 0320.....
Fax	...603 7772 0551.....
E-mail	... awong02@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
No 18, Jalan Tandang 51/205A,
Seksyen 51, 46050 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Tel : (603) 77728256
Fax : (603) 77720551
Website : www.beckmancoulter.com

November 21, 2024

IMPORTANT PRODUCT NOTICE
DxI 9000 Access Immunoassay Analyzer

REF	Software Versions
C11137	1.17.0 and prior

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the DxI 9000 Access Immunoassay Analyzer Duplicate Test Order issue. Patient results may be affected.

ISSUE:	• Beckman Coulter has determined that DxI 9000 Access Immunoassay Analyzers running with the system software versions listed above may cancel ordered tests that are in progress if any of the following scenarios occur:
	  ○ An operator configures reflex or rerun criteria for Test A.
	  ○ An operator requests Test A and B for a sample.
	  ○ The DxI 9000 analyzer produces a result for Test A and that result triggers the reflex or rerun criteria.
	• When the reflex or rerun requirements are met, the replicates for Test B are treated in the following ways:
	  ○ Any Complete or In Progress replicates for Test B are not affected.
	  ○ If Test B has not begun sample processing, it will be cancelled.

IMPACT:	• If this issue occurs the affected test result is displayed as the Sample Not Onboard sample event message and is cancelled. • This issue may delay reporting test results to the physician, which could delay patient treatment.
ACTION:	Rerun any samples that were cancelled.
RESOLUTION:	The software release notes for software versions 1.17.2 and above provide labeling for this issue.

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 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 any inconvenience that this caused your laboratory.

Sincerely,

Signed by:
Cartha Donovan
Signer Name: Cartha Donovan
Signing Reason: I approve this document
Signing Time: 21-Nov-2024 | 7:15:48 AM PST
FC8790FF4BB84911B7E9B8C4F430830A

Cartha Donovan
Senior Director, Quality & Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

phone: 952.448.4848
fax: 800.232.3828
www.beckmancoulter.com