CORE DIAGNOSTICS
Abbott Laboratories
Diagnostics Division
Abbott Park, IL, 60064 USA

Single Registration Number (SRN): N/A

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued March 14, 2023

Product

Product Description	List Number	Serial Number	Impacted Firmware version	UDI
a3600 Storage and Retrieval Module 15K (SRM)	06P46-21	See Attachment A	All	N/A
	06P46-22			
	06P72-02			
*a*3600 Storage and Retrieval Module 9K (SRM)	06P46-01		All	N/A
	06P46-02			
*a*3600 Alinity h Interface Module (HSQ)	04V85-01		All	N/A
	04V86-01			
Accelerator *a*3600 Input Output Module (IOM)	06P33-01		Prior to version 2.3.0	N/A

Explanation

Core Diagnostics has received the attached letter from Inpeco, the manufacturer of ACCELERATOR *a*3600. The firmware of the modules listed above has the potential to mis-associate sample IDs leading to (a) Delayed results due to lost sample location (b) Incorrect results at modules not equipped with the barcode reader prior to aspiration. See appendix A for the list of Modules not equipped with the barcode reader.

There has been one reported incident of delayed results for this issue on the storage module and no reported incidents of incorrect results.

Impact on Donor/Patient Results

See “Risk to Health” section in the attached Inpeco letter.

Necessary Actions to be Taken by Customer

Refer to “Actions to be taken by the user” section in the attached Inpeco letter.

For impacted modules, a representative from Abbott will contact you once the firmware is available.

Please complete the included Abbott Customer Reply Form. It is not necessary to complete the Inpeco Customer Reply.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

Appendix A

Module	Description
AQM	Aliquoter
ATL	ACL TOP LAS
CEN	Centaur
C16	c16000
LIA	Liaison
250	Phadia 250
I1K	Phadia 1000
VIS	Vista
ACH	Advia Chemistry XPT
CS5	CS-5100
AIA	AIA 2000
G8	G8
LXL	Liaison XL
WBB	Carrier Buffer
MG2	Maglumi
DXI	DXI 800
HA8	HA-8180
HV8	Helena V8
BP2	Bioplex 2200
CP3	CP3000
ALQ	Aliquoter Module
ICQ	Alinity ci