Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

DIAGNOSTICS

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

Date Issued October 23, 2019

Product All previous lots are impacted by this issue. The lots listed below are in-date lots.

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
Alinity c Carbon Dioxide Reagent Kit	07P7230	54449UQ03	31MAY2020	(01)00380740121600 (17)200531(10)54449UQ03
	07P7220	54454UQ03	31MAY2020	(01)00380740121594 (17)200531(10)54454UQ03

Explanation

This letter is to inform you that Abbott internal studies have determined that atmospheric Carbon Dioxide (CO_2) can be absorbed into the Alinity c Carbon Dioxide reagent, resulting in the potential for incorrect results. This testing demonstrated that the amount of CO_2 absorbed is higher with increased reagent carousel rotation and when the volume of reagent in the cartridge is reduced. This phenomenon can be detected as a shift in QC. The shift is predictive in both direction and magnitude of the potential impact to patient results. Refer to **Appendix A** for *CO_2 Study Summary* for expected shift in results.

Three actions are being taken:

1. Product Recall for Alinity c Carbon Dioxide Reagent Kit **LN 07P7230 (15000 test kit), lot number 54449UQ03.**
2. Quality control procedure change for Alinity c Carbon Dioxide Reagent Kit **LN 07P7220 (3000 test kit), lot number 54454UQ03**.
3. Reagent cartridge fill volume increase for Alinity c Carbon Dioxide Reagent Kit **LN 07P7220 (3000 test kit)** will occur with the next lot of production, beginning with lot number **55731UQ09,** to allow usual quality control procedure to resume.

Patient Impact There is the potential to generate incorrect patient results.

Necessary Actions

The following actions are requested by your laboratory:

Alinity c Carbon Dioxide Reagent Kit (LN 07P7230) – Kit size 15000 tests
Immediately discontinue use of the reagent lot number 54449UQ03. **Destroy any remaining** inventory according to your laboratory procedures. *Since existing modes of control are not effective in minimizing the effect of atmospheric CO_2 absorbed into the reagent, this product will no longer be available.* Contact your local Abbott representative for alternative replacement product.

Alinity c Carbon Dioxide Reagent Kit (LN 07P7220) – Kit size 3000 tests
For lot number **54454UQ03, two levels of CO_2 controls must be run every hour, instead of every 24 hours, and assay calibration performed as needed** to minimize the potential to generate incorrect results. --- Beginning with lot number **55731UQ09** of LN 07P7220, the reagent cartridge fill volume will be increased from 12.7 mL to 20.7 mL. Abbott studies have confirmed that increasing the volume of reagent in the cartridge reduces the amount of atmospheric CO_2 absorbed and mitigates the potential for incorrect results. **The usual QC procedure of testing two levels of CO_2 controls every 24 hours may be resumed.**

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Complete and return the Customer Reply Form.

Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this issue may cause. If you or any of the health care providers you serve have any 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
CO_2 Study Summary

The data below was generated over a continuous 8-hour period to simulate user environment at various levels of instrument test throughput. The data demonstrates the increase in CO_2 results observed for a sample over time using various carousel rotation frequencies (tests/hour) and cartridges with different volumes of remaining reagent.

	Small Cartridge (3000 tests per kit)		
Reagent Remaining	**Maximum CO_2 increase observed, mEq/L**		
	900 Tests/Hour	300 Tests/Hour	100 Tests/Hour
100%	2	1	0
50%	3	2	1
10%	5	3	2

	Large Cartridge (15000 tests per kit)		
Reagent Remaining	**Maximum CO_2 increase observed, mEq/L**		
	900 Tests/Hour	300 Tests/Hour	100 Tests/Hour
100%	3	2	1
50%	4	3	1
10%	8	5	3

For example: When using a small Alinity c cartridge (3000 tests per kit), and the reagent volume is 50% depleted, a maximum increase of 2 mEq/L from the expected value was observed when an instrument is performing 300 tests/hour over an 8-hour period.

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Customer Reply

Immediate Action Required

[redacted]

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Abbott Diagnostics Product Recall letter dated October 23, 2019

Instructions: Please provide a copy of the accompanying Product Recall Letter to the laboratory manager/supervisor responsible for Alinity c Carbon Dioxide Reagent Kit.

The laboratory manager/supervisor should complete the information below acknowledging receipt of the Product Recall Letter and **fax the Customer Reply Form, prior to November 6, 2019 via FAX #: 1-800-777-0051 or email QAGCO@abbott.com. Even if you no longer have the instrument(s), please return the completed Customer Reply Form so that we can appropriately update our customer database.**

Thank you for your cooperation.
Abbott Diagnostics
Quality Assurance for Global Commercial Operations

Were the necessary actions as stated in the Product Recall letter understood and completed?

___ **Yes**

List Number	Lot Number	Number of Kits Destroyed
07P7230	54449UQ03	

NOTE: Credit will be based upon the total number of kits destroyed

___ **No** (If answered NO, an Abbott Representative will contact you).

___ **Action is <u>not applicable</u>**. No longer have instrument.

_____ _____

Customer Number Serial Number(s)

_____

Name of Institution

_____ _____

Address Phone Number

_____ _____ _____

City State Zip Code

_____ _____

Name (print) Title/Position

_____ _____

Signature Date