SENTINEL
DIAGNOSTICS

Field Safety Notice
Iron

Product Name	Reference number REF	Lot Number	Expiration Date	UDI
IRON	6K95-41	30610Y600	2025-01-31	(01)00380740010928(17)250131 (10)30610Y600
IRON	6K95-30	21058Y600	2024-10-31	(01)00380740010911(17)241031 (10)21058Y600
		21101Y600	2024-10-31	(01)00380740010911(17)241031 (10)21101Y600
		30918Y600	2025-01-31	(01)00380740010911(17)250131 (10)30918Y600
Alinity c Iron Reagent Kit	08P3920	21046Y600	2024-09-30	(01)00380740136253(17)240930 (10)21046Y600
		21118Y600	2024-10-31	(01)00380740136253(17)241031 (10)21118Y600
		30227Y600	2024-11-30	(01)00380740136253(17)241130 (10)30227Y600
		30302Y600	2024-12-31	(01)00380740136253(17)241231 (10)30302Y600

SRN – Manufacturer
IT-MF-000012556

Date: September 29, 2023

Details on affected devices:

The purpose of this letter is to inform you of a product recall for IRON for use with ARCHITECT REF 6K95-41, REF 6K95-30 and Alinity c Iron Reagent Kit REF 08P3920. Sentinel has identified a performance issue for the reagent lots listed above. Please review the information below carefully and follow the necessary actions.

Description of the problem:

It has been identified that when using the ARCHITECT and Alinity c Iron products for the lots listed above, variable results can be obtained for quality control and patient samples. Based on internal testing, it has been confirmed that a positive shift of approximately 15% for Alinity c Iron products and approximately 30% for IRON for use with ARCHITECT products can be observed.
To date, no harm or injuries to patients have been reported with abnormal test results.

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Patient Impact:

- There is a potential for the delay in reporting patient results due to the quality control failures.
- There is also a potential for falsely elevated results.

Actions to be taken:

- Discontinue the use of and destroy any remaining inventory of the affected lots listed above of IRON for use with ARCHITECT REF 6K95-41, REF 6K95-30 and Alinity c Iron Reagent Kit REF 08P3920 according to your laboratory procedures.
- Review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results. Results should always be assessed in conjunction with the patient's medical history, clinical examination and other biochemical tests as suggested by clinical guidelines.
- Complete and return the Abbott Customer Reply Form.
- Please retain this letter for your laboratory records.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

Reference person:

If you or any of your customers have any questions regarding this information, please contact your local area Abbott Customer Service.

We are highly committed to solve the issue and apologize for the inconvenience this may cause.

Best Regards.

Marco Buonaguidi
Head of Marketing and Sales
29/9/'23

Patricia Dupé
Head of Quality System
Sept. 29, 2023