Abbott Laboratories
200 Abbott Park Road
CP1/3rd Flr, Dept 09YF
Abbott Park, IL 60064

January 26, 2024

Dear Valued Abbott Customer,

We have reviewed our customer notification files for the labeling update regarding Alinity i PM, Alinity c PM, ARCHITECT c4000 PM, Alinity s System, CELL-DYN Ruby, and CELL-DYN Sapphire for Product Correction letter (FA19OCT2023) that we sent to your facility dated October 19, 2023. To date, we have not received a customer reply form from your facility. The customer reply form is used to meet regulatory requirements, providing documentation that each customer has received the communication.

We would like to confirm that your facility received this letter and that all necessary actions were followed. We understand the value of your time and effort in this matter. For your convenience, we have attached a copy of the original communication and a new customer reply form.

Please review the attached letter. Complete the customer reply form and fax it back to 1-800-777-0051 or e-mail it to PMS@abbott.com by Monday, February 12, 2024. **Even if you no longer have the reagent, please complete the reply form so that we can appropriately update our customer database.**

Abbott considers you a valuable customer, and we thank you in advance for your cooperation and assistance.

Sincerely,

Amy Edmondson
Post Market Surveillance
Core Diagnostics

CORE DIAGNOSTICS

Abbott Laboratories
Diagnostics Division
Abbott Park, IL, 60064 USA

Urgent Medical Device Correction

Immediate Action Required

Date Issued October 19, 2023

Product

This Product Correction is for instruments distributed in US and Brazil only.

Product Description	List Number (LN)	Serial Number	UDI	Single Registration Number
Alinity s System	06P16	All	(01)00380740138479(21)*	US-MF-000017778
Alinity c Processing Module	03R67	All	(01)00380740137380(21)*	US-MF-000017777
Alinity i Processing Module	03R65	All	(01)00380740137366(21)*	US-MF-000017777
ARCHITECT c4000 Processing Module	02P24-01	All	(01)00380740003746(21)*	US-MF-000017777
	02P24-02		(01)00380740081225(21)*	
	02P24-40		(01)00380740003753(21)*	
	01R24-56		(01)00380740116026(21)*	
	01R25-56		(01) 00380740116064(21)*	
CELL-DYN Sapphire Analyzer	08H00	All	(01)00380740017170(21)*	US-MF-000023583
CELL-DYN Ruby Analyzer	08H67	All	(01)00380740017170(21)*	US-MF-000023583

*All serial numbers

Explanation

A labeling update is required for the products listed above to meet US regulatory requirement 21 CFR 801.437 (User labeling for devices that contain natural rubber) and Brazilian requirement RDC 37/2015 (medical devices and IVDs to include in the label a Standardized Latex Warning in Portuguese "CONTAIN NATURAL LATEX. MAY CAUSE ALLERGIES"). According to our records, one or more of these products are present in your laboratory.

These Abbott products include internal hardware parts and/or subassemblies that contain dry natural rubber (latex) which may cause allergic reactions, but do not include the required precautionary label.

Additionally, the Alinity s System Solid Waste Container Rubber Band (LN 04U97-01), used to secure the biohazard bag to the solid waste container, contains dry natural rubber (latex).

To date, there are no documented occurrences of operator injury attributed to dry natural rubber (latex).

Explanation continued	A precautionary label indicating the presence of dry natural rubber (latex) will be applied to your product(s). Your local Abbott representative will schedule a service visit when the instrument label is available for application. In addition, the precautionary language regarding dry natural rubber (latex) will be added to a future version of each product's Operator/Operations Manual in the Technical Library and/or Online Help.
Impact to User Safety	There is potential for operator injury if a user with hypersensitivity to dry natural rubber (latex) interacts with these components.
Necessary Actions to be Taken by Customer	Follow good laboratory practice by wearing impervious gloves and other personal protective equipment when working on the above listed Abbott product(s). Complete and return the Customer Reply Form. If you have forwarded the product(s) listed above to other laboratories, please inform them of this Product Correction and provide 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). 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 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.

CORE DIAGNOSTICS

Abbott Laboratories
Diagnostics Division
Abbott Park, IL, 60064 USA

Customer Reply

Immediate Action Required

Core Diagnostics Product Correction letter dated October 19, 2023 – FA19OCT2023

Product

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	02P24-40		(01)00380740003753(21)*	
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*All serial numbers

Instructions

1. Please provide a copy of the accompanying Product Correction letter to the laboratory manager, supervisor or health professional responsible for the impacted product.
2. Please complete all sections and return this Customer Reply Form to the Abbott contact prior to **12FEB2024**. Even if you no longer have the instrument(s)/reagent(s), this form is required for the reconciliation of our records.

Abbott contact

- E-mail: PMS@abbott.com
- Fax: 1-800-777-0051

Acknowledgement	By completing and signing this document I confirm that the Product Correction Letter was understood and that the necessary actions for the customer were completed. If not, please choose one of the options below. ☐ No, I would like to be contacted by an Abbott Representative. ☐ Not Applicable, Please Explain (e.g. no longer have the instrument): _____		
Customer number		**Serial Number(s)**	
Facility Name(s)			
Address			
City		**State**	
Phone Number		**E-mail**	
Name (print)		**Title/Position**	
Signature		**Date**	