REMINDER
URGENT: MEDICAL DEVICE RECALL

Alere INRatio®/INRatio®2 PT/INR Monitoring System

December 16, 2016

Dear Valued Customer:

Our records indicate that you had previously registered the Alere INRatio® or Alere INRatio®2 PT/INR Monitoring System as part of our Cleaning and Disinfection Surveillance program.

Beginning in July 2016, Alere San Diego, Inc. issued an Urgent Medical Device Recall notice regarding the Alere INRatio®/INRatio®2 PT/INR Monitoring System. Enclosed is a copy of the Urgent Medical Device Recall notice that is being sent to all registered users.

Our records indicate that we have not yet received your completed URGENT MEDICAL DEVICE RECALL: REPLY FORM. We request that you please complete and return the enclosed URGENT MEDICAL DEVICE RECALL: REPLY FORM as soon as possible to confirm that you have received the notice and have completed the required actions requested in the notification.

Please disregard this request if you have already received and replied to a prior notice from the 2016 Urgent Medical Device Recall regarding the Alere INRatio®/INRatio®2 PT/INR Monitoring System.

Should you have any questions about the information contained in this notice, please contact the Alere INRatio® Recall Hotline by phone at 1-866-723-2535. Additionally, we have established a website providing information about the recall and answers to frequently asked questions at www.inr-care.com.

Sincerely,

Rodney D. Mell
Vice President of Quality Assurance and Compliance
Alere San Diego, Inc.

URGENT: MEDICAL DEVICE RECALL

Alere INRatio®/INRatio®2 PT/INR Monitoring System

August 2, 2016

Dear Healthcare Professional:

The purpose of this notification is to inform you that Alere San Diego, Inc. is initiating a voluntary removal of the Alere INRatio®/INRatio®2 PT/INR Monitoring System. This removal includes both the Alere INRatio®/INRatio®2 PT/INR Monitors as well as Alere INRatio® Test Strips that collectively constitute the "Alere INRatio® System".

Our records indicate that you have received at least one Alere INRatio® or Alere INRatio®2 PT/INR Monitoring System manufactured by Alere San Diego, Inc.

The Alere INRatio®/INRatio®2 PT/INR Monitoring System is used for the quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The Alere INRatio®/INRatio®2 PT/INR Monitoring System is intended for use outside the body (in vitro diagnostic use). The Alere INRatio®/INRatio®2 PT/INR Monitoring System is intended for professional and home use by people taking warfarin who need to monitor the clotting time of their blood. The Alere INRatio®/ INRatio®2 PT/INR Monitoring System is not intended to be used for screening purposes.

In December 2014, Alere initiated a voluntary correction to inform users of the Alere INRatio® System that patients with certain medical conditions should not be tested with the system. Alere identified this issue through internal investigations associated with the recall of the Alere INRatio®2 PT/INR Professional Test Strip in April 2014, which was initiated based on the potential, in certain cases, of the Alere INRatio® System to provide an INR result that was significantly lower than a result obtained using a laboratory INR system. As part of its commitment to ensuring the safety of patients, Alere proactively reported these device concerns to the U.S. Food and Drug Administration (the "FDA") and began conducting a thorough investigation into these events.

Alere has recently decided to voluntarily remove the Alere INRatio® System from the market and to discontinue manufacturing the product line. Alere will continue manufacturing and distributing the Alere INRatio® Test Strips for a period of time to allow patients to safely transition to another monitoring method.

Alere's focus, as always, is on the safety of patients. Alere recommends that patients have periodic verification of their INR using a laboratory INR method. Any patient having significant discrepant low results on the Alere INRatio®/INRatio®2 System as compared to the plasma-based laboratory INR method should immediately be transitioned to an alternate method for monitoring their INR. Significant discrepancy in INR results may lead to a delay in an urgent medical decision to reverse a supratherapeutic INR level, particularly when the erroneous INR result is within the therapeutic range but the actual value is supratherapeutic, i.e., when the actual INR value is 6 or greater. For example, discrepancies in which the laboratory INR value is 6 or greater and the Alere INRatio® INR value is 3 or less are of particular concern. In such cases, actions should be taken not only to reverse the high INR, but also to transition the patient from the Alere INRatio® System to an alternative INR monitoring method. You may also consider discrepancies of a lower magnitude to be significantly discrepant, including discrepancies of 1 or 2 INR units compared to the laboratory INR value, based on your professional judgment and medical practice.

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Until such time that your facility has transitioned to an alternate method of PT/INR testing, you should continue to use the Alere INRatio® System as long as you ensure that you and your patients (either patients being tested at your facility or your patients who self-test at home) adhere to the precautions and recommendations found in the Medical Device Correction Notification of December 2014 and current product insert labeling. These are available at www.inr-care.com. If you have questions, please contact the Alere INRatio® Recall Hotline at 1-866-723-2535.

Alere sincerely apologizes for the difficulty that this action may cause to you and your facility. We greatly value our relationship with you. We appreciate your attention and timely cooperation in this matter.

Sincerely,

Rodney D. Mell
Vice President of Quality Assurance and Compliance
Alere San Diego, Inc.

CUSTOMER REQUIRED ACTION

1. Customers who currently have one or more Alere INRatio®/INRatio®2 PT/INR Monitoring Systems should **transition as soon as possible to an alternate method to perform PT/INR testing**, such as a plasma-based laboratory INR method or a point-of-care monitoring system from a different manufacturer.
2. After transitioning to an alternate PT/INR testing method, customers must:

   Dispose of all Alere INRatio®/INRatio®2 PT/INR **Monitors** in your possession in compliance with the instructions set forth in the enclosed Reply Form (Option A)

   OR

   Return all Alere INRatio®/INRatio®2 PT/INR **Monitors** in your possession to Alere San Diego, Inc. using the instructions described in the enclosed Reply Form (Option B). Prior to shipment of monitor(s), please follow the Cleaning and Disinfecting instructions per the User Guide.

   AND

   Dispose of all unused Alere INRatio® **Test Strips** in your possession and document on the enclosed Reply Form. Alere recommends that you cut the test strips prior to disposal.
3. You must ensure that you and your staff have read, understood and implemented the actions listed above.
4. If you have forwarded product to other customers, please provide a copy of this letter to them.
5. Please **complete and fax or e-mail the enclosed Reply Form within 10 business days** to confirm your receipt of this notice. If you have questions regarding this notification, please contact the Alere INRatio® Recall Hotline at **1-866-723-2535**. Additionally we have established a website providing information and frequently asked questions: www.inr-care.com.

Please fax or e-mail the completed Reply Form to:
Alere San Diego, Inc.
Fax: 1-888-656-6380, Email: Alere5191@stericycle.com

URGENT: MEDICAL DEVICE RECALL

Please complete this form even if you do not have any involved product and fax back to 1-888-656-6380 or email to Alere5191@stericycle.com within 10 business days.

URGENT MEDICAL DEVICE RECALL: REPLY FORM

I have been notified by Alere San Diego, Inc. of the removal of the Alere INRatio®/INRatio®2 PT/INR Monitoring System.

Please check the appropriate boxes:

☐ I have no record of receipt of this product and therefore will take no further actions.

☐ I have read the letter and confirm that users of the Alere INRatio®/INRatio®2 PT/INR Monitoring System in my facility's possession have transitioned or will safely transition to an alternate method of PT/INR testing upon consultation with their healthcare provider.

☐ **Monitor Disposition Option A:** I confirm that I have disposed of or will dispose of all Alere INRatio®/INRatio®2 PT/INR Monitors in my possession by delivering the monitors to a local, electronic hazardous waste facility.

Product	Serial Number(s)	Quantity Disposed of
Alere INRatio®/INRatio2® PT/INR Monitor		

☐ **Monitor Disposition Option B:** I confirm that I have returned or will return all Alere INRatio®/INRatio®2 PT/INR Monitors in my possession to Alere San Diego, Inc. using the pre-paid return label provided with this notification package.

Product	Serial Number(s)	Quantity to Return
Alere INRatio®/INRatio®2 PT/INR Monitor		

☐ I confirm that I have disposed of or will dispose of the following quantity of Alere INRatio® PT/INR Test Strips and/or kits in my possession (If you do not currently possess any of test strips listed, please indicate zero (0) in the "Quantity Disposed of" field below).

Product	Strip Lot #(s)	Quantity Disposed of	Units
Alere INRatio® PT/INR Test Strips			12 Pack Kits
			48 Pack Kits
			Individual Strips

☐ I have distributed the Alere INRatio® System to others. I have forwarded this notification to the impacted entities/individuals.

☐ I have read, understood and have implemented the actions listed above.

Please complete the following information:

DATE: _____

AUTHORIZED SIGNATURE: _____

PRINT NAME: _____

TITLE: _____ **DEPARTMENT:** _____

INSTITUTION: _____

ADDRESS: _____

CITY: _____ **STATE:** _____ **PHONE:** _____

POSTAL CODE: _____ **COUNTRY:** _____

EMAIL: _____

DISTRIBUTOR: _____

Please fax the completed form to 1-888-656-6380 or email a PDF to Alere5191@stericycle.com.

To satisfy requirements for regulatory reporting, please complete and return this form within 10 business days of receipt.

5191_31_04AS_V1.1 52302256/179799

Ship STERICYCLE
To:
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
ID: 52302256
Event: 5191
Seq.# 179799

IN 462 9-01

UPS GROUND
TRACKING #: 1Z E38 010 06 9900 0779

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All follow-up will be based on this shipping information.

TRACKING: 1Z E38 010 06 9900 0779

ID 52302256 Event 5191
CREIGHTON MEDICAL ASSOCIATE

GTY-04-12