



Alere Inc.
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May 19, 2014

National Distribution and Contracting Inc.
402 BNA Dr, Ste 500
Nashville, TN 37217-2551

Re: Sales of Alere INRatio[®] 2 PT/INR Professional Test Strips

To Whom It May Concern:

We are writing because we have become aware that some distributors have been selling the Alere INRatio[®] 2 PT/INR Professional Test Strip (PN 99008G2) into the over-the-counter (OTC) market to consumers for home use. The Alere INRatio[®] 2 PT/INR Professional Test Strip has 510(k) clearance from the FDA only for use by or on the order of a licensed medical professional. These strips do not have OTC clearance and therefore should not be sold or distributed directly to consumers for home use. Such distribution may be in violation of the Federal Food, Drug, and Cosmetic Act and other laws.

As you may be aware via our press release or other means, Alere Inc. (NYSE:ALR) has recently initiated a voluntary Class 1 recall in the U.S. of the Alere INRatio[®] 2 PT/INR Professional Test Strip. FDA defines Class 1 recall as recalls where there is a reasonable probability that the use of, or exposure to, a device will cause serious adverse health consequences or death. If you have sold the Alere INRatio[®] 2 PT/INR Professional Test Strip into the OTC market to consumers for home use, you **must contact those consumers** that have received this product and instruct them to immediately return all unused product. In addition, Alere requires that you provide **complete accountability and traceability** of all product shipped to consumers. You may use the attached forms for this purpose. Completed forms should be sent to Alere Technical Service at Fax Number **1-858-805-8457** or email to **Responses.ts@alere.com**.

In order to facilitate the return of the Alere INRatio[®] 2 PT/INR Professional Test Strips that you may have inappropriately shipped to consumers, please use the following language in your correspondence to affected consumer customers:

We have previously shipped you the Alere INRatio[®] 2 PT/INR Professional Test Strip (PN 99008G2). These are products that the FDA has cleared only for use by or on the order of medical professionals and are not cleared by FDA for sale or distribution directly to consumers. Please be aware that Alere has initiated a voluntary Class 1 recall in the U.S. of this product based on complaints received of patients who had a therapeutic or near therapeutic INR with the Alere INRatio[®] 2 PT/INR Professional Test Strip but a significantly higher INR (outside of therapeutic range) when performed by a central laboratory. This type of event may lead to a patient becoming over anti-coagulated based on a false low test result being reported. This over anti-coagulated state can result in bleeding, with complications that can range from minor to severe or life-threatening. Consequently, it is important for you to take the following steps:

- *Confirm you are in possession of the Alere INRatio[®] 2 PT/INR Professional Test Strip (PN 99008G2) by inspecting the product packaging as shown in Figure 1.*
- *If confirmed, immediately **STOP using** the Alere INRatio[®] 2 PT/INR Professional Test Strips (PN 99008G2).*
- *Contact _____ to arrange for a return of **all unused Alere INRatio[®] 2 PT/INR Professional Test Strips (PN 99008G2)** and an alternative means for testing. It is imperative that **all unused product** be immediately returned to _____.*
- *If there is reason to believe a recent INR result obtained using an Alere INRatio[®] 2 PT/INR Professional Test Strip may not have been accurate (e.g., symptoms such as bleeding or bruising when an INR value is low), you should immediately consult with your doctor and arrange for an alternative means for testing.*
- *If you have obtained an unexpected result or experienced other issues related to the use of your Alere INRatio[®] 2 PT/INR Professional Test Strips, please contact Alere Technical Services at 1-844-292-5373.*



Thank you for your prompt attention to this matter. Please contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Jonathan Gothorpe". The signature is fluid and cursive, with a large loop at the beginning and a long, sweeping tail.

Jonathan Gothorpe
Senior Counsel, North America & LAMARCIS





Figure 1: Visual Reference Guide

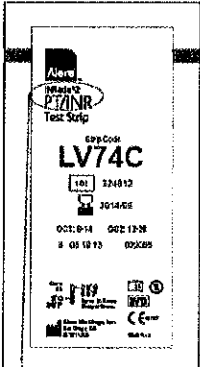
Recalled Test Strip

Alere INRatio[®]2 PT/INR Professional Test Strip

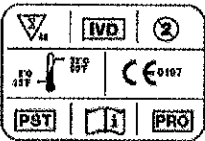
Side of Product Box



Strip Pouch



Alere INRatio [®] 2 PT/INR Test Strip	
Exp. Code	
LV74C	
Lot	324812
Lot	301466
Oct: 0-14	002: 13-18
2: 03 18 15	005C05



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PIN: 26366G2 Rev. A 2013-05

INRatio[®]2
Test Strip

REF 99008G2

99008G2



URGENT: MEDICAL DEVICE RECALL

Please complete this form if affected product was further distributed to *professional customers/consignees/sub-distributors*. Please return all forms to Alere Technical Services by Fax at 1-858-805-8457 or email to Responses.ts@alere.com.

Use multiple forms as necessary

Include pagination information at the bottom of the form

URGENT MEDICAL DEVICE RECALL: REPLY FORM (For Professional/Sub-Distributor Distributed Product)

Account Name	Account Contact Info	QTY Shipped	QTY returned	QTY Consumed
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
	Ph: Email:	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips

DATE: _____

PRINT NAME: _____

COMPANY/DISTRIBUTOR NAME: _____

AUTHORIZED SIGNATURE: _____

Please FAX the completed forms along with any attachments to 1-858-805-8457 or email a PDF to Responses.ts@alere.com.

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



URGENT: MEDICAL DEVICE RECALL

Please complete this form if affected product was distributed to end use (patient self-test) customers. Please return all forms to Alere Technical Services by Fax at 1-858-805-8457 or email to Responses.ts@alere.com.

Use multiple forms as necessary

Include pagination information at the bottom of the form

URGENT MEDICAL DEVICE RECALL: REPLY FORM (For Patient Self-Test Distributed Product)

Customer Identifier*	Strip Lot #	QTY Shipped	QTY returned	QTY Consumed
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
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		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips
		<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips	<input type="checkbox"/> Kits <input type="checkbox"/> Strips

* Use non-personally identifiable information such as an assigned account number or shipment date. Do not use names or other personal information such as SSN, telephone number, address, or date of birth.

DATE: _____

PRINT NAME: _____

COMPANY/DISTRIBUTOR NAME: _____

AUTHORIZED SIGNATURE: _____

Please FAX the completed forms along with any attachments to 1-858-805-8457 or email a PDF to Responses.ts@alere.com.

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