URGENT: MEDICAL DEVICE CORRECTION

Alere™ INRatio® PT/INR Monitor System

December 5, 2014

Dear Valued Customer,

This letter contains important information concerning the Alere™ INRatio® PT/INR Monitor system (INRatio® Monitor or INRatio® 2 Monitor and INRatio® Test Strips) that has been prescribed to you for monitoring your blood clotting time (PT/INR) while you are on warfarin therapy. A complete list of the affected INRatio® products is attached to this notice (Appendix A). You should discuss this information with your doctor.

In certain cases an INRatio® PT/INR Monitor system may provide an INR result that is significantly lower than a result obtained using a laboratory INR system. The plasma-based laboratory INR method is considered the most accurate and reliable INR method.

This issue can arise if you have certain medical conditions. The INRatio® PT/INR Monitor system should NOT be used if you have any of the medical conditions listed below. **You should contact your doctor to determine if any of these medical conditions apply to you:**

- Anemia (low hemoglobin or low red blood cell count). Your hematocrit should be between 30 – 55%
- Any conditions associated with elevated fibrinogen levels (Note: fibrinogen is the protein from which a clot is formed)
    - acute inflammatory conditions (for example viral or bacterial infections such as pneumonia or flu)
    - chronic inflammatory conditions (for example rheumatoid arthritis, Crohn's disease, ulcerative colitis, infectious liver diseases such as hepatitis, or inflammatory kidney diseases such as diabetic nephropathy and glomerulonephritis)
    - severe infection (for example sepsis)
    - advanced stage cancer or end stage renal disease requiring hemodialysis
- any bleeding or unusual bruising

If you have any of these conditions your doctor should immediately switch you to a laboratory INR method for monitoring your INR and warfarin therapy. If you are unsure whether you have one of these conditions, you should consult your doctor.

Incorrect results can also occur if you do not carefully follow the instructions for performing the test. Please ensure you take the following precautions to reduce the risk of this issue occurring:

- If your INRatio® INR result falls within the therapeutic range, but you have symptoms of delayed clotting such as bleeding or bruising, you should consult your doctor immediately and arrange for testing by an alternate method.
- Only use the Alere INRatio® PT/INR Monitor system if your hematocrit is within a range of 30% to 55%. **You should contact your doctor to arrange for a hematocrit measurement (a red blood cell anemia test), if such a test has not been recently performed** or there are any signs or symptoms of blood loss.

- Apply **ONLY** one large drop of blood immediately to the test strip. Never add more blood to a test strip after the test has begun. Applying additional sample may result in a discrepant result. **If in doubt, repeat the test with a fresh drop of blood from a new fingerstick site using a new lancet on a fresh test strip**.
- The monitor should be on a stable surface during the test. Do not move the monitor during the test.

In addition to the precautions described above, Alere recommends that you **arrange with your doctor to have your INR measured using a laboratory INR method.** The plasma-based laboratory INR method is considered the most accurate and reliable INR method. Your doctor will adjust your warfarin therapy if necessary at this time according to the degree of the difference between the Alere device and laboratory method. Also, your doctor has received a notification to investigate whether you have any of the conditions that can lead to these falsely low INR results. Testing is recommended to ensure you do not have conditions that could result in the INRatio® PT/INR Monitor system giving a result that is much lower than the laboratory INR method. If a much lower result is observed, your doctor should immediately switch you to an alternative method for monitoring your INR and warfarin therapy.

As part of its commitment to ensuring the safety of patients, Alere has reported these device concerns to the U.S. Food and Drug Administration and is conducting a thorough investigation into these events.

Customers with questions regarding this issue can contact Alere INRatio Recall Hotline at 1-877-929-2579. For additional information customers should go to www.inr-care.com.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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CUSTOMER REQUIRED ACTION

- **Ensure you have discussed this letter with your doctor**.
- Ensure you have read and understand the precautions described in the current product labeling (Alere INRatio® PT/INR Test Strip Package Insert; Alere INRatio®2 PT/INR Home Monitoring System User Guide; INRatio® Self Test User Guide) and the additional precautions in this notice describing medical conditions that may increase the risk of obtaining a lower than expected INR result. Note: if you need an additional copy of the product labeling, please contact1-877-866-5313.
- Do not use the INRatio® PT/INR Monitor system (INRatio® Monitor or INRatio® 2 Monitor and INRatio® Test Strips) if you have any of the medical conditions described in this notice.
- **Speak to your doctor about performing a hematocrit measurement (red blood cell anemia test) and periodic comparisons with a laboratory INR method.**
- Please complete the enclosed Reply Form (Appendix B – the last page of this notice) and **return it within 10 days** to confirm receipt of this notice, using one of the following methods:
    - Return the response via US Postal Service in the enclosed postage paid envelope

      OR
    - FAX the response to **1-877-929-2580**

      OR
    - E-mail the response to Alere4319@stericycle.com
- If you have questions regarding this notification, please contact Alere INRatio Recall Hotline by phone at 1-877-929-2579. Additionally we have established a website providing information and frequently asked questions. www.inr-care.com.

We apologize for any inconvenience that this may cause you. We appreciate your attention and cooperation in this important matter.

Sincerely,

Keith McLain, VP Quality Alere San Diego

Appendix A: Product List

Product	Ref Number	Product Description
INRatio® Test Strips	0100071	Alere INRatio® PT/INR Test Strips, Box of 12
	0100139	Alere INRatio® PT/INR Test Strips, Box of 48
INRatio® Monitors	0100004	Alere INRatio® PT/INR System Professional
	0100007	INRatio® Prothrombin Time (PT) Monitoring System
INRatio®2 Monitors	0200431	Alere INRatio®2 PT/INR Professional Testing System
	0200432	Alere INRatio®2 PT/INR Home Monitoring System
	55128A	Alere INRatio®2 PT/INR Professional Monitoring System
	55130	Alere INRatio®2 PT/INR Monitor

If you would like to receive an additional copy of the labeling for your product, please contact Alere at 1-877-866-5313.

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Appendix B: Reply Form

This is a sample Urgent Medical Device Correction. Please use the barcoded Reply Form included with the Urgent Medical Device Correction you receive in the mail. You may also call 1-877-929-2579 or send an email to Alere4319Web@stericycle.com if you have additional questions regarding this notice.