Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 10, 2014

TO: All Local Health Departments
Attn: Chief,Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Alere Inc. - RECALL [Medical Device]

AFFECTED PRODUCT: **Alere INRatio® and INRatio®2 PT/INR Monitor system**

SUMMARY: **Unclassified Recall; The recall has been initiated because in certain cases an INRatio® and INRatio®2 PT/INR Monitor system may provide an INR result that is clinically significantly lower than a result obtained using a reference INR system (laboratory method). This issue can arise if the patient has certain medical conditions or can occur if the instructions in the labeling for performing the test are not followed.**

The affected products are the INRatio® Monitor or INRatio®2 Monitor and INRatio® Test Strips.

The product was distributed in the United States.

SUGGESTED ACTION: **For consumer inquiry only. Customers with questions regarding this recall can contact Alere at 1-877-929-2579. For additional information on the recall, including a list of product part numbers affected by the recall, customers should go to www.inr-care.com.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Alere Initiates Voluntary URGENT CORRECTION for Use of Alere INRatio® and INRatio®2 PT/INR Monitor System Healthcare Professionals and Patient Self-Testers Should Not Use the INRatio® and INRatio®2 PT/INR Monitor System with Certain Medical Conditions

Contact:
Consumer:
1-877-929-2579

Media Contact:
Jackie Lustig
Director, Corporate Communications
Jackie.lustig@alere.com
781.341.4009

FOR IMMEDIATE RELEASE – December 8, 2014 – WALTHAM, Mass. – Alere Inc. (NYSE:ALR) has initiated a voluntary correction to inform U.S. users of the Alere INRatio® and INRatio®2 PT/INR Monitor system of certain medical conditions that should not be tested with the system (INRatio® Monitor or INRatio®2 Monitor and INRatio® Test Strips). In certain cases an INRatio® and INRatio®2 PT/INR Monitor system may provide an INR result that is clinically significantly lower than a result obtained using a reference INR system (laboratory method). This issue can arise if the patient has certain medical conditions or can occur if the instructions in the labelling for performing the test are not followed.

The INRatio® and INRatio®2 PT/INR Monitor system should not be used on patients with any of the following conditions:

- Anemia of any type with hematocrit less than 30%
- Any conditions associated with elevated fibrinogen levels including:
  - Acute inflammatory conditions (examples may include acute viral or bacterial infections such as pneumonia or influenza)
  - Chronic inflammatory conditions (examples may include 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 (e.g., sepsis)
  - Chronically elevated fibrinogen for any reason
  - Hospitalized or advanced stage cancer or end stage renal disease patients requiring hemodialysis
- Any bleeding or unusual bruising, clinically observed or reported by the patient

Patients with any of the conditions listed above should immediately be transitioned to a laboratory INR method for monitoring their INR and warfarin therapy.

In addition, healthcare professionals and patient self-testers should adhere to the following precautions in order to obtain the most accurate results:

In addition to the precautions outlined above, Alere also recommends that patients have periodic verification of their INR using a laboratory INR method. Any patient having a significant discrepant low result on the INRatio® and INRatio®2 monitor system as compared to the plasma-based laboratory INR method should immediately be transitioned to an alternative method for monitoring their INR and warfarin therapy. Significant discrepancy in INR results may lead to a delay in an urgent medical decision to reverse a supratherapeutic INR level following the established guidelines for monitoring warfarin therapy. Such discrepancies are of particular concern 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.

Alere also recommends that patients be tested to verify that their hematocrit falls within the range of 30% to 55%. Patients with hematocrit outside this range should be immediately transitioned to a plasma-based laboratory INR monitoring method.

Alere is working on an improvement to the current INRatio® and INRatio®2 meter, which will serve to mitigate further the potential for these discrepant results.

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 recall can contact Alere at 1-877-929-2579. For additional information on the recall, including a list of product part numbers affected by the recall, 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About the Alere INRatio® and INRatio®2 PT/INR Professional Monitoring System
The Alere INRatio® and INRatio®2 PT/INR Professional Monitoring System, consisting of the Alere INRatio® and INRatio®2 PT/INR Monitor and the Alere™ INRatio® Test Strip, is intended for use in the quantitative determination of International Normalized Ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio® and INRatio®2 PT/INR Professional Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio® and INRatio®2 PT/INR Monitoring System is not intended to be used for screening purposes and is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

For more information on Alere, please visit www.alere.com.

Media Contact:
Jackie Lustig
Director, Corporate Communications
Jackie.lustig@alere.com
781.341.4009

Investor Contact:
Juliet Cunningham
Vice President, Investor Relations
Jackie.lustig@alere.com
858.805.2232

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