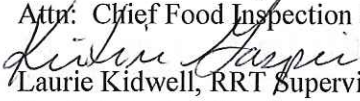




**DATE:** May 7, 2014

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

**FROM:**   
Laurie Kidwell, RRT Supervisor  
Food Protection Program

**SUBJECT:** Alere Inc. - RECALL [Drug]

**AFFECTED  
PRODUCT:** Alere INRatio2 PT/INR Professional Test Strips

**SUMMARY:** Class I Recall; The recall is due to complaints of patients who had a therapeutic or near therapeutic INR with the Alere INRatio2 PT/INR Professional Test Strip but a significantly higher INR (outside of therapeutic range) when performed by a central laboratory.

The recalled product is Alere INRatio2 PT/INR Professional Test Strips (PN 99008G2).

The product was distributed nationwide.

**SUGGESTED  
ACTION:** For consumer inquiry only. Customers with questions regarding this recall or requiring replacement product can contact Alere at 844-292-5373. For additional information on the recall customers should go to [www.inr-care.com](http://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 Product Recall of Alere INRatio®2  
PT/INR Professional Test Strips**

**Healthcare Professionals Should Stop Using Strips**

**Contact:**

Consumer:  
844-292-5373

**Media:**

Jackie Lustig  
781-314-4009  
[Jackie.Lustig@alere.com](mailto:Jackie.Lustig@alere.com)

**FOR IMMEDIATE RELEASE** - May 6, 2014 - WALTHAM, Mass. – Alere Inc. (NYSE:ALR) has initiated a voluntary Class 1 recall in the U.S. of the Alere INRatio2 PT/INR Professional Test Strips (PN 99008G2). This action is a result of complaints of patients who had a therapeutic or near therapeutic INR with the Alere INRatio2 PT/INR Professional Test Strip but a significantly higher INR (outside of therapeutic range) when performed by a central laboratory.

Alere has received nine serious adverse event reports, three of which described bleeding associated with patient deaths. The reason for the adverse event reports was significantly different test results between the Alere INRatio2 PT/INR Professional Test Strip and the local laboratory plasma INR test. The Alere INRatio2 PT/INR Professional Test Strip results were between 3.1 – 12.2 INR units lower than the laboratory result.

The root cause for this issue has not yet been determined; therefore Alere cannot determine the patient conditions or circumstances that may contribute to the discrepancy. Given these reports, Alere is concerned that the Alere INRatio2 PT/INR Professional Test Strips may report an inaccurately low INR result. Therefore, Alere has notified customers of the discrepant results and has advised them to immediately STOP using the Alere INRatio2 PT/INR Professional Test Strips and use an alternative method to perform PT/INR testing, such as a plasma-based laboratory INR test, an alternative Alere product, or an alternative point-of-care monitoring system from a different manufacturer. Alere has requested that customers return unused product to the company.

Alere will transition customers from the current Alere INRatio2 PT/INR Professional Test Strip to the Alere INRatio PT/INR Test Strip (PN 100139). The voluntary recall does not include the Alere INRatio PT/INR Test Strip (PN 100071), which is utilized by patient self-testers for home INR monitoring.

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

Customers with questions regarding this recall or requiring replacement product can contact Alere at 844-292-5373. For additional information on the recall customers should go to [www.inr-care.com](http://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](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax** Download form [www.fda.gov/MedWatch/getforms.htm](http://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®2 PT/INR Professional Monitoring System**

The Alere INRatio2 PT/INR Professional Monitoring System, consisting of the Alere INRatio2 PT/INR Monitor and the Alere INRatio2 PT/INR Professional 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 INRatio2 PT/INR Professional Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio2 PT/INR Professional 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.

**About Alere**

By developing new capabilities in near-patient diagnosis, monitoring and health information technology, Alere enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on infectious disease, toxicology, cardiology and diabetes. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit [www.alere.com](http://www.alere.com) .

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