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# Alere San Diego Inc., Alere INRatio and INRatio2 PT/INR Monitor System (Professional and Prescription Home Use) - Falsely Low INR Test Results

**Recall Class:** Class I

**Date Recall Initiated:** December 5, 2014

**Devices:**

- Alere INRatio and INRatio2 PT/INR Monitor System (Professional and Prescription Home Use)
  - INRatio Monitor or INRatio2 Monitor
  - INRatio Test Strips
- Manufacturing and Distribution Dates: April 1, 2008 to December 4, 2014

Related Class I Recall for Professional INRatio2/INR Test Strips

**Use:** The Alere INRatio and INRatio 2PT/INR Monitor System and INRatio Test Strips measure how quickly a patient's blood clots (Prothrombin Time) when taking warfarin, a blood-thinning medicine. The International Normalized Ratio (INR) test is used to compare the results of the patient's

Prothrombin Time (PT).
Healthcare professionals and trained patients or their caregivers use the Alere INRatio and INRatio 2PT/INR Monitor System and INRatio Test Strips to monitor patients' anti-coagulation status while taking warfarin.

**Recalling Firm:**
Alere San Diego, Inc.
9975 Summers Ridge Road
San Diego, California 92121

**Reason for Recall:** The Alere INRatio Monitor System (INRatio Monitor or INRatio2 Monitor and INRatio Test Strips) may provide an INR result that is lower than expected result obtained using a laboratory INR method. Incorrect results can also occur if a patient has certain medical conditions. These conditions include, anemia, conditions associated with elevated fibrinogen levels, or unusual bleeding or bruising. Incorrect results can also occur if the instructions in the labeling for performing the test are not followed. (See Healthcare Professional letter or Patient letter).

Use of the affected devices may delay treatment and cause severe or life-threatening injuries, including death.

Alere received 18,924 reports of incidents in which the device has malfunctioned, including 14 serious injuries. According to the firm, all affected devices may fail.

This recall is not expected to cause a device shortage.

**Public Contact:** For questions about this recall, call the Alere INRatio Recall Hotline at 1-877-929-2579 or use Alere's contact form to submit an inquiry at http://www.inr-care.com/ww/index/contact-us.html .

**FDA District:** Los Angeles District Office

**More Information about this Recall:**

Alere sent patients and healthcare professionals an Urgent Medical Device Correction letter dated December 5, 2014. The letter identified the problem, the actions to be taken, and the specific products affected by the recall.

**Patients**:

- Read and discuss the correction letter with your doctor.
- Stop using the INRatio and INRatio2 PT/INR Monitor System (INRatio Monitor or INRatio2 PT/INR Monitor and INRatio Test Strips) if you have any of the conditions detailed in the correction letter.

Be sure you understand the precautions described in the current product labeling. Also understand the additional precautions outlined in the correction letter describing medical conditions in which the Monitor System should not be used because of increased risk of obtaining a lower than expected INR result.

- Talk to your doctor about having a red blood cell anemia test and periodic comparisons with a laboratory INR method.
- Complete and return the reply form enclosed with the letter within 10 days of receiving it to confirm receipt of the recall letter; either by postage-paid envelope, or FAX the reply form to Alere San Diego, Inc. at 1-877-929-2580, or email the form to Alere4319@stricycle.com.

**Healthcare Professionals:**

- Read the correction letter.
- Understand the precautions described in the current product labeling. Also understand the additional precautions outlined in the correction letter describing medical conditions that may increase the risk of obtaining a (falsely or erroneously) lower than expected INR result. The Monitor System should NOT be used if your patients have any of the outlined medical conditions.
- Verify that your patient has hematocrit within the range of 30-55%. If a patient has a hemocrit of less than 30%, immediately transition your patient to an alternate INR monitoring method.
- Perform INR verification testing for your patients using a laboratory INR test method. Immediately transition any patient with a clinically significant lower result on the Monitor System to an alternative INR monitoring method to monitor their INR and warfarin therapy.
- Only patients who have already been stabilized on warfarin should be tested with the Monitor System.
- Provide a copy of this letter to another customer if you forwarded a recalled product to them.
- Complete and fax or email the reply form enclosed with the letter within 10 days to confirm receipt of the letter; FAX the completed reply form to Alere San Diego, Inc. at 1-877-929-2580, or email the form to Alere4319@stericycle.com .

**Products Being Recalled:**

**Alere INRatio and INRatio2 PT/INR Monitoring System**

| 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 |
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|---|---|---|
| INRatio Monitors | 0100004 | Alere INRatio PT/INR System Professional |
| | 0100007 | INRatio Prothrombin Time (PT) Monitoring System |
| INRatio2 Monitors | 0200431 | Alere INRatio 2PT/INR Professional Testing System |
| | 0200432 | Alere INRatio PT/INR Home Monitoring System |
| | 55128A | Alere INRatio PT/INR Professional Monitoring System |
| | 55130 | Alere INRatio PT/INR Monitor |

## About Class I Recalls

Class I recalls are the most serious type of recall. They involve situations when it is likely that use of these devices will cause serious health problems or death.

Health care professionals and consumers may report bad reactions or faulty problems they had using the device to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

### Additional Resources

- Firm Press Release
- Patient Self-Tester Information - Voluntary Urgent Correction Information
- Healthcare Professional Information - Voluntary Urgent Correction Information

Page Last Updated: 01/08/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.



**U.S. Food and Drug Administration**
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA