

Patients Put At Risk By Faulty Home Blood Test Bring Class-Action Suit

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The lives of patients on blood thinners depend on accurate coagulation tests. Alere's home-based tests were inaccurate, threatening the health and life of patients.

Anticoagulants like warfarin require constant monitoring and adjustment of dosages to strike the balance between dangerously low coagulant levels that could lead to uncontrollable bleeding and dangerously high levels that could lead to deadly clots.

Alere, a diagnostics firm, sold a number of home blood coagulation test systems prescribed by physicians to help patients maintain that precise balance. But the U.S. Food and Drug Administration discovered that the company had failed to report known instances in which the blood testing device produced significantly inaccurate results. When the company failed to respond to the FDA's warning letter, the FDA intervened and the company issued a "voluntary" Class 1 Recall of its INRatio Monitors, INRatio2 Monitors and INRatio Test Strips.

Class 1 recalls are rare, issued only when there is a significant and immediate danger of death or other serious injury from using the recalled product. Despite the seriousness of the recall, Alere didn't ensure that all patients relying on these systems received recall notices. In addition, the company hasn't offered to refund the costs of the monitoring systems to anyone.

Two plaintiffs – J.E. from Alexandria, Virginia, and J.D. from Tucson, Arizona – have brought a class-action lawsuit against Alere. They are represented by John Roddy and Elizabeth Ryan of Bailey Glasser's Boston, Massachusetts, office, David Selby of the firm's Birmingham, Alabama, office, and Todd Wheelles and Jeremy Knowles with Morris, Haynes, Wheelles, Knowles & Nelson.

Neither plaintiff – identified only by their initials in the complaint in order to protect confidential medical information – received a recall notice from Alere. Both learned of the products' inaccuracy after searching the Internet. Neither has received any refund, even though J.D. paid approximately \$1,700 out-of-pocket for Alere products.

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Tens of thousands of Alere customers are potentially members of the class covered by this lawsuit. Alere continues to advertise the system for sale to the public, despite the acknowledged flaws, and it has refused to provide refunds to customers.

The lawsuit was filed in the U.S. District Court for Massachusetts.