MedicalXpress

US regulators recall 10-minute Ebola test

April 23 2015

US regulators have issued an international recall for a 10-minute Ebola blood test made by a California-based company, saying it has not been proven to work and could put lives at risk.

"A recall has been issued for the LuSys Laboratories, Inc., Ebola Virus One-Step Test Kits because the FDA has not cleared or approved the kits for use or sale," said the Food and Drug Administration in a statement emailed to reporters on Thursday.

"The results obtained from these test kits have not demonstrated to be accurate and should not be used as in vitro diagnostic tests for Ebola infection."

The recall was initially issued in mid-March and applies to test kits exported to Denmark, Sierra Leone and Canada between October 2014 and January 2015.

The FDA did not say how many tests were sent out.

The recall is described as a Class I, "the most serious type of recall and involve(s) situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death," the FDA said.

"A false positive result may be life-threatening by potentially placing the patient in an isolation cohort with Ebola-infected patients."

Contacted by AFP, a company representative in San Diego said early trials have shown the test to be 86 percent accurate.

The problem with the FDA came down to a labeling error, he said. The equipment had not been properly labeled "for research purposes only."