

U.S. Food and Drug Administration
Protecting and Promoting Your Health

LuSys Laboratories, Inc., Ebola Virus One-Step Test Kits - Not Cleared for Marketing

Recall Class: Class I

Date Recall Initiated: March 13, 2015

Product: Ebola Virus One-Step Test Kits

Product Codes and Lot Numbers:

Catalog Number	Device
I-100	Ebola VP 40 IgX Serum/Plasma/Blood Cassette
I-101	Ebola GP IgX Blood, Serum/Plasma Cassette
I-102	Ebola VP IgG/IgM (Dual Strip) Blood/Serum/Plasma Cassette
I-103	Ebola GP IgG/IgM (Dual Strip Blood/Serum/Plasma Cassette
I-123(A)	Ebola Virus Antigen Blood
I-123(B)	Ebola Virus Antigen Nasal
I-104	Ebola Accessories assembled, self-contained package

All lots of the Ebola Virus One-Step Test kits are affected by this recall.

The affected devices were sold in California and exported internationally to Sierra Leone, Canada, and Denmark between October 2014 and January 2015.

These devices do not have FDA clearance or [Emergency Use Authorization \(//MedicalDevices/Safety/EmergencySituations/ucm161496.htm#ebola\)](http://www.fda.gov/medicaldevices/safety/emergency_situations/ucm161496.htm#ebola) (EUA) for in vitro diagnostic detection of Ebola virus.

Use: The tests are intended for use as an aid in the diagnosis of Ebola Virus infection.

Recalling Firm:

LuSys Laboratories, Inc.
10054 Mesa Ridge Court, Suite 118
San Diego, CA 92121

Reason for Recall: The FDA has not cleared or approved the Ebola Virus One-Step Test Kits for use or sale. 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. A false positive result may be life-threatening by potentially placing the patient in an isolation cohort with Ebola infected patients. A false negative test result may be life-threatening by causing a lack or delay in treatment of the patient and risking infecting healthcare providers, family and other close contacts.

Public Contact: Questions should be directed to LuSys Laboratories, Inc. at 858-546-0902 (Monday – Friday, 9am – 5:30 PT).

FDA District: Los Angeles District Office

More Information about this Recall:

On March 13, 2015, LuSys Laboratories, Inc. sent an Urgent Voluntary Medical Device Recall to all affected customers. The letter identified the product, problems, and the following actions for customers:

- Stop use of the Ebola Virus One-Step Test Kits
- Return the test kits to LuSys Laboratories, Inc.
- Fax the Acknowledgement and Receipt form to LuSys Laboratories, Inc. at: 858-866-1688

About Class I Recalls:

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.