



California Medical Device Recall Information



Recall Name

LuSys Laboratories Recalls Ebola Virus One-Step Test Kits Because Products are Not Cleared for Marketing

Recall Date	Product Description	Recalling Firm	Recall Reason
3/13/15	Ebola Virus One-Step Test Kits <ul style="list-style-type: none"> Catalog #-100: Ebola VP 40 IgX Serum / Plasma / Blood Cassette Catalog #-101: Ebola GP IgX Blood, Serum / Plasma Cassette Catalog #-102: Ebola VP IgG/IgM (Dual Strip) Blood / Serum / Plasma Cassette Catalog #-103: Ebola GP IgG/IgM (Dual Strip Blood / Serum / Plasma Cassette Catalog #-123(A): Ebola Virus Antigen Blood Catalog #-123(B): Ebola Virus Antigen Nasal Catalog #-104: Ebola Accessories assembled, self-contained package 	LuSys Laboratories, Inc. San Diego, CA	<p><i>The FDA has not cleared or approved the Ebola Virus One-Step Test Kits for use or sale.</i></p> <p><i>The results obtained from these test kits have not been demonstrated to be accurate.</i></p>

Recall Class	Product Identification	Distribution	Affected Dates
I	ALL Lots	CA, international	Sold between: Oct. 2014 & Jan. 2015

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm444162.htm>