



California Medical Device Recall Information



Recall Name

Alere San Diego Recalls Triage Rapid Diagnostic Test System Products Due to Significantly Decreased Precision

Recall Date	Product Description	Recalling Firm	Recall Reason
5/22/12	Triage® Rapid Diagnostic Test System Products	Alere San Diego, Inc. San Diego, CA	<i>Increased frequency of false positive or false negative results</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Triage CardioProfiler <ul style="list-style-type: none"> • Panel PN 97100CP Triage Cardiac Panel <ul style="list-style-type: none"> • Panel PN 97000HS Triage Profiler SOB <ul style="list-style-type: none"> • Panel PN 97300 Triage BNP <ul style="list-style-type: none"> • PN 98000XR Triage D-dimer <ul style="list-style-type: none"> • PN 98100 <u>Lot Numbers.</u> Printed on each product: <u>Product List</u>	CA , nationwide	Approximate ship dates October, 2011 through June, 2012

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm311387.htm>