



California Medical Device Recall Information



Recall Name

**Atossa Genetics Recalls ForeCYTE Breast Health Test and
Mammary Aspiration Specimen Cytology Test (MASCT)
Due to Potential for False Results**

Recall Date	Product Description	Recalling Firm	Recall Reason
10/04/13	ForeCYTE Breast Health Test and Mammary Aspiration Specimen Cytology Test (MASCT)	Atossa Genetics Seattle, WA	<i>The FDA has not approved the MASCT device for the screening or diagnosis of breast cancer, or the ForeCYTE Breast Health Test for any indication. The devices may report false positive or false negative results, and do not replace screening mammograms, diagnostic imaging tests, or biopsies.</i>

Recall Class	Product Identification				Distribution	Affected Dates
	Product Code	Part #	Description	Lot #		
TBD	AG-MASCT	9002528	MASCT System Kits	All	CA, nationwide	Distributed: 02/01/13 to 09/13/13
	AG-MASCT	9002528MD	MASCT System Kits	All		
	DTG-MASCT	9002587	Clarity System Kits	All		
	AG-FC5	9002513	MASCT Patient Sample Kits	All		
	AG-FC5	9002513MD	MASCT Patient Sample Kits	All		
	DTG-FC5	9002614	Clarity Patient Sample Kits	All		
	NRLBH-5	9002717MD	Nipple Aspirate Fluid Laboratory Kit	All		

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm370782.htm>