

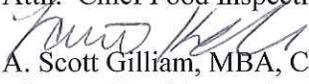


Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** October 17, 2013

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:**   
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** Atossa Genetics Inc. [Medical Device]

**AFFECTED PRODUCT(S):** ForeCYTE Breast Health Test  
Mammary Aspiration Specimen Cytology Test (MASCT)  
See the attached list for more detailed product information.

**SUMMARY:** Voluntary Recall; Atossa Genetics Inc. (NASDAQ: ATOS) initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the U.S. Food and Drug Administration (FDA). This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States. Distributors and customers should stop using affected products and return them to Atossa immediately.

**SUGGESTED ACTION:** Recommend notification of affected parties via phone, fax, or e-mail. Distributors and customers should be directed to contact Atossa at 800-351-3902 to obtain instructions on how to return these products. Customers with questions may contact the company via telephone at 1-888-219-4629 at any time. Any problems experienced with the use of this product may be reported to the FDA: at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> Online (form available to fax or mail), or call FDA 1-800-FDA-1088

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### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



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To promote and provide  
essential public health services.

## **ForeCYTE Breast Health Test; Mammary Aspiration Specimen Cytology Test (MASCT)**

**Contact:**

Consumer:

1-800-351-3902

1-888-219-4629

**FOR IMMEDIATE RELEASE** - October 4, 2013 -Atossa Genetics Inc. (NASDAQ: ATOS) initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States. Distributors and customers should stop using affected products and return them to Atossa immediately.

Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the U.S. Food and Drug Administration (FDA) in a warning letter received by Atossa in February 2013. The FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. Atossa will remove existing product from the market until FDA's concerns are addressed.

The MASCT device has been cleared by the FDA for use as a sample collection device, with the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-cancerous, and cancerous cells. The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE Breast Health Test has not been cleared or approved by the FDA for any indication. The ForeCYTE Breast Health Test and the MASCT device are not a replacement for screening mammograms, diagnostic imaging tests, or biopsies. Patients should follow the recommendations and instructions of their physician with respect to breast cancer screening and diagnosis.

To date, Atossa is unaware of any adverse incidents or injuries associated with the use of the ForeCYTE Breast Health test and the MASCT device or the processing method currently identified in the IFU. Additionally, Atossa is unaware of any risk to health or injury for clinicians or the patient population that have used these devices. However, these devices may produce false positive or false negative results. Although not cleared or intended for this use, if these devices are used as a substitute for recommended screening or diagnosis of breast cancer, FDA is concerned that patients may choose to forgo recommended mammograms and necessary biopsies.

Atossa is working with the FDA on this matter and this voluntary recall. Atossa is notifying its distributors and customers by certified mail and is arranging for the return of all recalled product(s). Products affected by this recall are listed in the table below (table 1):

<b>Product Code</b>	<b>Part Number</b>	<b>Description</b>	<b>Lot Number</b>
AG-MASCT	9002528	MASCT System Kits	All
AG-MASCT	9002528MD	MASCT System Kits	All

<b>DTG-MASCT</b>	9002587	Clarity System Kits	All
<b>AG-FC5</b>	9002513	MASCT Patient Sample Kits	All
<b>AG-FC5</b>	9002513MD	MASCT Patient Sample Kits	All
<b>DTG-FC5</b>	9002614	Clarity Patient Sample Kits	All
<b>NRLBH-5</b>	9002717MD	Nipple Aspirate Fluid Laboratory Kit	All

### **MASCT System Kit**

1. MASCT Breast Pump
2. Instructions for Use (IFU)
3. Heating Pad
4. Timer
5. Saccomono's Fixative
6. Nu Prep Gel
7. Welcome and Training Materials Coversheet
8. MASCT System Order Form
9. ForeCYTE Training Video DVD
10. MASCT System Instructions with pictures - pink

### **Patient Sample Kit**

1. Two (2) flower assemblies (e.g., filter, filter retainer, and filter holder),
2. Instructions for Use (IFU)
3. Two (2) specimen collection devices,
4. Two (2) breast bags for transporting the specimen collection container
5. Barcode labels
6. Saccomono's Fixative
7. Nu Prep Gel
8. MASCT System package insert
9. ForeCYTE Test Requisition Form
10. Patient Information Sheet
11. Atossa Patient Information
12. FED EX Clinical PAK
13. MASCT System Order Form
14. FED EX Pouch
15. FED EX Airbill

Distributors and customers should contact Atossa at 800-351-3902 to obtain instructions on how to return these products. Customers with questions may contact the company via telephone at 1-888-219-4629 at any time.

Any problems experienced with the use of this product may be reported to the FDA: at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

Online (form available to fax or mail), or call FDA 1-800-FDA-1088

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