Urgent Field Safety Notice

sona Aspergillus GM Lateral Flow Assay (Ref# AF2003 Lot# L106296)
FSCA # 1627497-2019-00002
Field Safety Corrective Action

October 31, 2019

Dear sona Aspergillus GM LFA Customer,

Details on affected devices:
The purpose of this letter is to advise you that IMMY is voluntarily performing a Field Safety Corrective Action (FSCA) on the sona Aspergillus GM Lateral Flow Assay (LFA) (**Ref #: AF2003, Lot #: L106296**), which were distributed by IMMY to users or distributors between June 10, 2019 and July 12, 2019. Our records indicate you have received the affected lot.

Reason for the FSCA:
As part of post-market surveillance activities, the above device was found to cause weak false-positive results. We have received 3 complaints associated with this issue. There have been no reports of patient injury or death.

This FSCA does not affect any other batches/lots/versions of Aspergillus GM LFA.

Risk to Health:
In the case of false-positives, clinicians who use the LFA results alone may unnecessarily treat patients. The results of any sample that ran negative using this lot of antigen should NOT be affected. In other words, the negative predictive value of this lot has not changed from previous lots.

How to recognize that the device may fail:
If the negative control (Running Buffer Ref# AFLFRB) runs positive, the results of testing will be compromised. If the negative control is not run each day of testing, it will not be possible to tell if positive results are true positive.

Actions to be taken by you, the customer:

- Please **immediately** check your inventory and destroy affected lot.
- Please **immediately** complete the attached Acknowledgement and Receipt Form (pages 3 and 4 below) even if you do not have any affected stock remaining. Note: The form is a fillable PDF. You can save it to your computer, fill out electronically and attach to an email. Return the completed form to IMMY using one of the methods below:

    - Email: customerservice@immy.com
    - Mail to:
      Attn: Joy Pelfrey
      IMMY
      2701 Corporate Centre Dr
      Norman, OK USA 73069

- Ensure relevant staff members are informed of this FSCA, including relevant clinicians.
- If you have supplied any potentially affected product to another organization, please advise that organization of this recall and contact us so we can follow up with them.
- In case product is in transit, display this letter in a prominent place for one month.

To request a free-of-charge replacement , please notify IMMY's Customer Service (customerservice@immy.com) and a new lot of Aspergillus GM LFA (Ref# AF2003) will be shipped as quickly as possible.

Before contacting customer service, please have the following information available: approval to receive a no-charge replacement and/or a no-charge PO and the shipping information, including an attention line.

Other Information:
If you have any questions, do not hesitate to contact IMMY's Quality Assurance Department by calling 1-405-360-4669 Monday through Friday 8:30 AM to 5:00 PM Central Standard Time or emailing IMMY's VP of Regulatory Affairs & Quality Assurance, Joy Pelfrey at joy-pelfrey@immy.com.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Authorized by:

Name: (Print): Joy Pelfrey

Signature: _____

Title: VP of Regulatory Affairs & Quality Assurance

sona Aspergillus GM LFA Field Safety Corrective Action
Ref #: AF2003 Lot# L106296
Acknowledgement and Receipt Form
Response is Required

Customer Information:

Lab Name: _____

Account Name: _____
(used by your purchasing group)

Ship to Address: _____

City, State, Country: _____

Zip Code: _____

Special Shipping Instructions _____

Person Completing Form: _____

I have read and understand the FSCA instructions provided in the October 31, 2019 letter. Yes ☐ No ☐

I will need replacement kits. Yes ☐ No ☐

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

_____

_____

_____

Affected Product Information: Include information that is applicable for affected product.

Product/Brand Names	IMMY's Product Catalog Number	Quantity of Kits Received	Quantity of Kits remaining in inventory & destroyed	# of Kits to be replaced
sona Aspergillus GM LFA	AF2003			

Return Response Box:

Please provide any additional information, if applicable.

Special Instructions for Distributors:

☐ I have checked my stock and have notified IMMY that I have stock remaining.

☐ I have identified and notified *all* of my customers that were shipped or may have been shipped this product; Note: Please notify all customers before November 11, 2019 and send IMMY a list of customers and quantities each customer received

<or>

☐ Attached is a list of customers (Name and contact information) who received this product. Please notify my customers.

Acknowledgement

I have received the Field Safety Notice for Aspergillus GM LFA, Ref #: AF2003. I have ensured that all personnel have been notified of the potential defects, how to identify a defect, and what to do when a defect is identified.

Signature _____ Date: _____

Name/Title	
Telephone	
Email address	

Please **immediately** complete even if you do not have any affected stock and return it to IMMY using any of the methods below:

- Email: customerservice@immy.com
- Mail to:
  Attn: Joy Pelfrey
  IMMY
  2701 Corporate Centre Dr
  Norman, OK, USA 73069