Urgent Field Safety Notice

Cryptococcal Antigen Lateral Flow Assay (CrAg® LFA)

Ref# CR2003, Lot #s F1011097, F1011096, F1011095, F1011094, and F1011093
FSCA #: 1627497-2022-001a

Field Safety Corrective Action

January 3, 2022

Dear CrAg® LFA Distributor,

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 Cryptococcal Antigen Lateral Flow Assay (Ref# CR2003, Lot #s F1011097, F1011096, F1011095, F1011094, and F1011093), which were distributed to customers between November 12, 2021 and December 27, 2021. Our records indicate you have received one or more of the affected lots.

Reason for the FSCA:
As part of post-market surveillance activities, the above devices were found to have reduced specificity (90% now versus 99% before). There have been no complaints, reports of patient injury or death.

This FSCA does not affect any other lots of the CrAg® LFA (Ref# CR2003).

Risk to Health:
The health risk only applies to patients with positive test results. A small number of samples with positive test results may be false positives, which may cause some patients to initiate unnecessary anti-fungal therapy.

Samples with negative test results are NOT affected. The negative predictive value remains high at nearly 100%.

How to recognize that the device may fail:
It is not possible to distinguish between a true positive and false positive result.

Actions to be taken by you, the distributor:

1. **Immediately** identify and segregate any affected kits you have in your inventory to prevent them from being shipped to your customers. As soon as possible, discard your affected inventory.
2. **Immediately** notify your affected customers of this FSCA.
3. Send your customers the "IMMY CR2003 Int'l Field Safety Notice_20220103_End User_Fillable)" document provided by IMMY and request that they complete the Acknowledgement and Receipt Form found on pages 3 & 4 of the letter. **A copy of all completed "Acknowledgement and Receipt Forms" must be sent to IMMY.**

4. Complete the attached Distributor Acknowledgement and Receipt Form (pages 3 and 4 below) even if you do not have any affected stock remaining in your possession. 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, Inc.
      2701 Corporate Centre Dr
      Norman, OK USA 73069

5. Complete the provided "CR2003 Distributor Shipping Records Form" and return to IMMY. This **must** be returned to IMMY even if you have not distributed any of the affected product. *Note: IMMY will not be able ship replacement product if this form has not been returned to IMMY.*

Product Replacement:

To request a free-of-charge replacement, please notify IMMY's Customer Service (customerservice@immy.com) and a new lot of CrAg® LFA (Ref# CR2003) will be shipped as quickly as possible. **Note: IMMY will not be able to ship replacement product until we have received the completed "Distributor Acknowledgement Form" and the completed "CR2003 Distributor Shipping Records Form" from you.**

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.

Type of Action by the IMMY:

IMMY is immediately notifying all users of the decrease in specificity. The source for the false-positive has been identified and is being remediated.

Other Information:

If you have any questions, do not hesitate to contact IMMY by calling 1-405-360-4669 Monday through Friday 8:30 AM to 5:00 PM Central Standard Time or emailing customerservice@immy.com.

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

Authorized by:

Name: Joy Pelfrey, MPH

Signature: _____

Title: VP of Regulatory Affairs & Quality Assurance

IMMY

IMMY CrAg® LFA Field Safety Corrective Action
Ref #: CR2003
Distributor Acknowledgement and Receipt Form

Response is required before replacements can be sent.

Distributor Information:

Company Name: _____

Address: _____

City, State, Country: _____

Phone Number: _____

Affected Inventory Records:

*Please complete the table below. Report **YOUR** inventory for each lot number you have that is affected as well as the number of kits you shipped to your customers.*

Product Name	IMMY's Ref #	Lot Number(s) Received	Quantity of kits still in inventory	Quantity of kits you will destroy	Quantity of kits shipped to end-users
CrAg® LFA	CR2003				

Replacements:

Please indicate if you will require replacement kits and if yes, the number of kits required and where to ship them.

☐ I will need replacement kits. Please send me _____ (qty of kits).

○ Send the kits to the same address as all other orders.

○ Send to a different address:

☐ I will NOT need replacements.

Incidences:

Are you aware of any incidences associated with the affected product? Yes ☐ No ☐

If yes, please explain:

_____

_____

_____

_____

Additional Response:

Please provide any additional information, if needed.

Acknowledgement

I have read and understood the Field Safety Notice for the CrAg® LFA (Ref #: CR2003) including the "Actions to be taken by you" section. I have ensured that all personnel, both within our company and external end-users, 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