URGENT: Field Safety Notice

Cryptococcal Antigen Lateral Flow Assay (CrAg LFA)

FSCA ID: 1627497-2016-00002

(Ref# CR2003, Lot #s 161028142817JH, 161019161504NZ, 161013081750KH, 161003112913JG, 161007110553JG, and 161010145035NZ)

Date: 04 January 2017

Attention CrAg LFA Customer:

The purpose of this letter is to advise you that IMMY is voluntarily recalling the Cryptococcal Antigen Lateral Flow Assay (Ref# CR2003, Lot #s 161028142817JH, 161019161504NZ, 161013081750KH, 161003112913JG, 161007110553JG, and 161010145035NZ), which were distributed to customers between October 3rd, 2016 and December 16, 2016. This recall does not affect any other lots of the Cryptococcal Antigen Lateral Flow Assay (Ref# CR2003). Our records indicate you have received one or more of the affected lots.

Description of the problem:
The affected lots' negative predictive value remains unchanged and is nearly 100%. It is only the positive predictive value that is affected. Thus, you may choose to continue to use the affected lots to report negative results and perform alternative confirmatory testing on all positive specimens. However, there are risks associated with this choice. The CrAg LFA is the most sensitive, commercially-available test for cryptococcal antigen. The risk associated with confirming all positive specimens with a less sensitive test is that true, low titer specimens may be negative using a less sensitive test method. Thus, a true, low titer positive specimen may be incorrectly reported as negative. Clinical evidence must be used in conjunction with test results.

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 reports of patient injury or death.

Risk to Health:
The health risk only applies to patients with positive test results. A small number of samples with positive test results may not be true 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%.

Actions to be taken by you, the customer/user:

- Determine if you will choose to continue using the affected lot as described above. If you are not, destroy all your inventory.
- Please **immediately** complete the attached Acknowledgement and Receipt Form (pages 3 and 4 below) even if you do not have any affected stock and return it to IMMY using one of the methods below:

    - Fax: 1-405-364-1058
    - Scan and Email: joy-pelfrey@immy.com

- Mail to:
  Attn: Joy Pelfrey
  IMMY
  2701 Corporate Centre Dr
  Norman, OK 73069

- Ensure relevant staff members are informed of this recall, including relevant clinicians.
- If you have supplied any potentially affected product to another organisation please advise that organisation 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.

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected lots have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Other Information:
If you require free-of-charge replacement, indicate the number of kits needed in the attached Acknowledgement and Receipt Form and they will be shipped out as soon as possible.

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 joy-pelfrey@immy.com.

Authorized by:

Name: (Print): Joy Pelfrey _____

Signature: _____

Title: Director of Regulatory Affairs & Quality Assurance _____

Cryptococcal Antigen Lateral Flow Assay (CrAg LFA) Field Safety Notice
Ref# CR2003

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Lab: _____

Person Completing Form: _____

I have read and understand the recall instructions provided in the December 29th, 2016 letter. 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	Lot Number Received	Quantity in inventory	Quantity destroyed	Quantity Requested to be replaced
Immy Cryptococcal Antigen Lateral Flow Assay (CrAg LFA)	CR2003				

[☐] *We are choosing to continue to use the affected lots and will perform confirmatory testing on all positive results.*

Return Response Box:

Please provide any additional information, if applicable.

Acknowledgement

I have received the Recall Notification Letter for Cryptococcal Antigen Lateral Flow Assay (CrAg LFA), Ref # CR2003. I have either chosen to continue using the affected lot or ensured that all inventory of my affected lots have been destroyed.

Signature _____ Date: _____

Name/Title	
Telephone	
Email address	
Complete Mailing Address	

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

- Fax: 1-405-364-1058
- Scan and Email: joy-pelfrey@immy.com
- Mail to:
  Attn: Joy Pelfrey
  IMMY
  2701 Corporate Centre Dr
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Cryptococcal Antigen Lateral Flow Assay (CrAg LFA)

FSCA ID: 1627497-2016-00002

(Ref# CR2003, Lot #s 161028142817JH, 161019161504NZ, 161013081750KH, 161003112913JG, 161007110553JG, and 161010145035NZ)

Date: 04 January 2017

Attention CrAg LFA Distributor:

Details on affected devices:
The purpose of this letter is to advise you that IMMY is voluntarily removing *the* Cryptococcal Antigen Lateral Flow Assay (Ref# CR2003, Lot #s 161028142817JH, 161019161504NZ, 161013081750KH, 161003112913JG, 161007110553JG, and 161010145035NZ), which were distributed to customers between October 3rd, 2016 and December 16, 2016. This recall does not affect any other lots of the Cryptococcal Antigen Lateral Flow Assay (Ref# CR2003).

Description of the problem:
The affected lots' negative predictive value remains unchanged and is nearly 100%. It is only the positive predictive value that is affected. Thus, you may choose to continue to use the affected lots to report negative results and perform alternative confirmatory testing on all positive specimens. However, there are risks associated with this choice. The CrAg LFA is the most sensitive, commercially-available test for cryptococcal antigen. The risk associated with confirming all positive specimens with a less sensitive test is that true, low titer specimens may be negative using a less sensitive test method. Thus, a true, low titer positive specimen may be incorrectly reported as negative. Clinical evidence must be used in conjunction with test results.

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 reports of patient injury or death.

Risk to Health:
The health risk only applies to patients with positive test results. A small number of samples with positive test results may not be true 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%.

Actions to be taken by you, the distributor:

1. Please **immediately** check your stock and destroy affected stock on hand to prevent further use.
2. Please **immediately** complete the attached Acknowledgement and Receipt Form (pages 3 and 4 below) even if you do not have any affected stock and return it to IMMY using one of the methods below:

    - Fax: 1-405-364-1058
    - Scan and Email: joy-pelfrey@immy.com

- Mail to:
  Attn: Joy Pelfrey
  IMMY
  2701 Corporate Centre Dr
  Norman, OK 73069

3. **Identify all your customers that you have shipped the affected lots to and send them this FSCA Notification and Acknowledgment Form. Alternatively, you can send us a list of the customers with their contact information and we will contact them directly.**
4. **Instruct your customers to either have confirmatory testing done on all positive samples when using the affected lots or destroy affected lots. The end user needs to complete an Acknowledgement and Receipt form and return to you. Send a copy to IMMY using one of the methods described above**.
5. **Send IMMY a list of all customers you shipped the affected lots to and how many you shipped to them**.

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected lots have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Other Information:
If you require free-of-charge replacement, indicate the number of kits needed in the attached Acknowledgement and Receipt Form and they will be shipped out as soon as possible.

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 joy-pelfrey@immy.com.

EC REP
MDSS
Schiffgraben 41
175 Hannover, Germany

Authorized by:

Name: (Print): Joy Pelfrey

Signature: _____

Title: Director of Regulatory Affairs & Quality Assurance

Cryptococcal Antigen Lateral Flow Assay (CrAg LFA) Field Safety Notice
Ref# CR2003

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Company: _____

Person Completing Form: _____

I have read and understand the recall instructions provided in the January 4, 2017 letter. 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	Lot Number Received	Quantity in inventory	Quantity destroyed	Quantity Requested to be replaced
Immy Cryptococcal Antigen Lateral Flow Assay (CrAg LFA)	CR2003				

[☐] *We are choosing to continue to use the affected lots and will perform confirmatory testing on all positive results.*

Return Response Box:

Please provide any additional information, if applicable.

Special Instructions for Distributors:

I have checked my stock and have destroyed inventory consisting of _____ kits.

[ ] I have identified and notified *all* of my customers that were shipped or may have been shipped this product. I will send that list of customers to IMMY;
< or >
[ ] Attached is a list of customers (Name and contact information) who received this product. Please notify my customers.

Acknowledgement

I have received the Recall Notification Letter for Cryptococcal Antigen Lateral Flow Assay (CrAg LFA), Ref # CR2003. I have either chosen to continue using the affected lot or ensured that all inventory of my affected lots have been destroyed.

Signature _____ Date: _____

Name/Title	
Telephone	
Email address	
Complete Mailing Address	

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

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