May 9th, 2016

# URGENT: MEDICAL DEVICE RECALL

## Histoplasma Yeast Complement Fixation Antigen Dilute (Ref# H30150, Lot #111WH3)

Dear H30150 Customer/Distributor,

The purpose of this letter is to advise you that IMMY is voluntarily recalling *Histoplasma Yeast Complement Fixation Antigen Dilute (Ref# H30150, Lot # 111WH3).*

**Reason for the Voluntary Recall:**
As part of post-market surveillance activities, the above device was found to have bacterial contamination. We are aware of one customer complaint associated with this problem, across multiple bottles of this lot. There have been no reports of patient injury or death.

This recall does not affect any other batches/lots/versions of Histoplasma Yeast Complement Fixation Antigen Dilute. This batch/lot/version has been distributed to customers since February 19, 2016.

**Risk to Health:**
The health risk associated with this issue is highly dependent on your laboratory's complement fixation methods. The contamination can lead to false positives or to an artificial increase in titers for positive samples. Any sample that ran negative using this lot of antigen should NOT be affected. In the case of increased titers, clinicians who use complement fixation titers to follow response to therapy may continue therapy longer than necessary. In the case of false positives, clinicians who use complement fixation results alone may unnecessarily treat patients.

**How to recognize that the device may fail:**
Using either a positive control (e.g. IMMY's Histoplasma Yeast CF Positive Control - Ref# H40110), a negative control (e.g. IMMY's Negative Control Serum - Ref# N80110) or Antigen Anti-Complementary (AC) controls, or any combination of the 3, can be used to determine failure. If the Negative Control runs positive, the antigen may be failing. IMMY's positive control should titer 1:32 ± 1 dilution. If IMMY's positive control titer exceeds 1:64, the antigen may be failing. If you are running different positive controls, if you see significant increase in their titers, the antigen may be failing. If the Antigen AC controls are outside of the acceptable range, the antigen may be failing.

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

- Please **immediately** check your stock and destroy affected stock on hand to prevent further use
- 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
      2700 Technology Place
      Norman, OK 73071

- 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.

If you require free-of-charge replacement, indicate the number of vials needed in the attached Acknowledgement and Receipt Form and they will be shipped out as soon as possible. Note: We will also send you free product if you require repeat testing on any samples that were reported positive using this lot.

**Product and Distribution Information:**

| Product and Distribution Information Table | | | | | |
|---|---|---|---|---|---|
| **Product Names, Unique Device Identifier (if applicable)** | **Manufacturer's Product Number/Catalog Number** | **Lot/Serial Number** | **Distribution Dates** | **Expiration Date (YYYY/MM/DD)** | **Quantity** |
| Histoplasma Complement Fixation Antigen Dilute | H30150 | 111WH3 | February 19, 2016 – April 29, 2016 | 2018-12-02 | 3 |

**Type of Action by the IMMY:**
IMMY is immediately removing all material from the market. The source for the contamination has been identified and remediated.

**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 joy-pelfrey@immy.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

**Authorized by:**

Name: (Print……_____

Signat[redacted]_____

Title: _____

**MEDICAL DEVICE RECALL RETURN RESPONSE**
**Acknowledgement and Receipt Form**
*Response is Required*

# Histoplasma Yeast Complement Fixation Antigen Dilute (Ref# H30150)

**Lot/Serial numbers: 111WH3**

I have read and understand the recall instructions provided in the May 9, 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.**

| **Affected Product Information Table** | | | | | | |
|---|---|---|---|---|---|---|
| Product/Brand Names | Manufacturer's Product Number/Catalog Number | Lot Number shipped to Customer | Number of positive test results reported using Lot | Quantity in inventory | Quantity destroyed | Quantity Requested to be replaced |
| Histoplasma Yeast Complement Fixation Antigen | H30150 | 111WH3 | | | | |

**Return Response Box:**

| |
|---|
| *Please provide any additional information, if applicable.* |

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|---|
| *Special Instructions for Distributors:*<br><br>I have checked my stock and have destroyed inventory consisting of _____ vials.<br><br>[ ] I have identified and notified my customers that were shipped or may have been shipped this product by May 11th, 2016;<br><or><br>[ ] Attached is a list of customers who received/may have received this product. Please notify my customers. |

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**Acknowledgement**

I have received the Recall Notification Letter for Histoplasma Yeast CF Antigen Dilute, Ref # H30150 Lot# 111WH3. I have ensured that all inventory has been destroyed.

Signature_____ Date: _____

| | |
|---|---|
| Name/Title | |
| Telephone | |
| Email address | |
| Complete Mailing Address | |

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

- Fax: 1-405-364-1058
- Scan and Email: .
- Mail to:
  Attn: ……..
  IMMY
  2700 Technology Place
  Norman, OK, USA 73071