PN# NCR 14104

**URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE**

**Commercial name of the affected product:** LABType HD DRB1 Typing Test
**FSCA-identifier:** NCR14104
**Type of action:** Review Test Results

**19 January 2015**

**Attention:** Distributors and Users

The purpose of this letter is to advise you that One Lambda, Inc., part of ThermoFisher Scientific, is conducting a recall/correction of the *LABType HD DRB1 Typing Test.*

**Reason for the Voluntary Recall (Description of the problem):** The following allele specificities are missing from the lot-specific user documents and catalog file for the *LABType HD DRB1 Typing Test* (catalog ID RSSOH2B1, Lot 009, batches 1-16): DRB1*03:12, DRB1*03:16, DRB1*04:23, DRB1*04:25, DRB1*04:32, DRB1*04:52, DRB1*11:40, DRB1*14:142, DRB1*15:06:02, DRB1*15:74, DRB1*15:85, DRB3*03:02, DRB4*01:05, DRB4*01:08. This may cause a mistype for DRB1*04:52. A sample with DRB1*04:52 would be typed as DRB1*04:03:01/03:03/03:05/03:07~03:08 without indicating an ambiguity with DRB1*04:52.

**Risk to Health:** There is low risk to the patient or end user as a result of this problem. Clinical decisions for transplant are based on multiple sources. This product is not used as the sole source for typing analysis. Overall risk to the patient is low. In addition, test results will be further investigated by the HLA specialist during confirmatory testing per ASHI and EFI regulations.

**Product and Distribution Information:**
Catalog ID: RSSOH2B1, Lot Number: 009, Batch Numbers 1-16 Expiration Dates: 12/2015 to 03/2016

**Action to be taken by the user or distributor:** Review test results generated with the above-mentioned products using the corrected lot-specific user documents and catalog file; if there is an assignment of DRB1*04:03:01/03:03/03:05/03:07~03:08 a secondary check for confirmation of that allele is required.

> **End User:** Please complete the attached **Acknowledgement Form** and return to One Lambda, Inc.
>
> **Distributors** – our records indicate that you may have purchased products for re-sale. Please complete the **Acknowledgement Form** in regards to inventory you have received and/or is still in stock. In addition, please contact your affected customers, advise them of the situation and provide them with a copy of this letter. Please insert your information onto the **Acknowledgement Form** and have your end users return the **Acknowledgement Form** back to you.

**Type of Action by the Manufacturer:** RSSOH2B1 Lot 009 lot-specific user documents corrected: RSSO-H2B1-009-WS3-00 Rev. 3 Effective 07Jan15; RSSO-H2B1-009-WS-00 Rev. 3 Effective 07Jan15; RSSO-H2B1-009-LIM-00 Rev. 3 Effective 07Jan15; RSSO-H2B1-009-BPI-00 Rev. 3 Effective 07Jan15. RSSOH2B1 Lot 009 lot-specific catalog file corrected: RSSO-H2B1-0009-CAT-00 Rev. 3 Effective 07Jan15.

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

**Contact reference person:** If you have additional questions or concerns regarding this matter, you may contact One Lambda's Customer Support team for assistance at Email: techsupport@onelambda.com or Phone: +1 (818) 702-0042. You may also contact our authorized representative in Germany: MDSS GmbH, Tel.: +49 511 62628630, vigilance@mdss.com

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

The undersigned confirms the appropriate Regulatory Agencies have been advised of this Field Safety Notice.

[redacted]

Angela Estany
Regulatory Affairs Manager

*Document ID: TEMP-OLI-0008*

# Field Safety Notice Return Response
# ACKNOWLEDGEMENT FORM

**Customer Information (Please Complete)**
**Name:**
**Address:**

Product:
Catalog ID: RSSOH2B1, Lot Number: 009, Batch Numbers 1-16 Expiration Dates: 12/2015 to 03/2016

I have read and understand the attached Field Safety Notice and instructions **and have taken appropriate actions to review test results**: _____ **(initial)**
Any adverse events associated with the recalled product? ____ **Yes** _____ **No**
If yes please explain:

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|---|
| |

**Return Response: (please provide additional information if applicable)**

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|---|
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**DISTRIBUTORS:**

I have checked my stock and have quarantined inventory consisting of N/A – inventory does not need to be quarantined. Action is to review test results with revised documentation.

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter by [specify date and method of notification – attach additional sheets if necessary]: _____
_____
_____.

**Please sign and date below indicating that all transmission actions have been taken and that this information has been disseminated to all required individuals. Return to One Lambda via fax +1 818-702-6956 or email bradley.young@thermofisher.com**

**Signature of Receipt by End User/Distributor:**

_____ _____
Signature Date

**Print: (please complete)**

| | |
|---|---|
| Name/Title: | |
| Telephone: | |
| Email Address: | |