

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE**Commercial name of the affected product:** Lambda Cell Tray™**FSCA-identifier:** CR 150163**Type of action:** Review Test Results**27 May 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 of the Lambda Cell Tray™.

Reason for Notice: High background may be seen on these products which may cause negative reactions to appear positive. This issue is detectable as the negative control serum tested will alert the end user to the false reaction.

Risk to Health: There is very low/negligible risk of death or serious harm to the patient as a result of this problem because false reactions will not be reported and will be detected. The negative control failure will alert the end user to the product failure.

Product and Distribution Information:

Catalog ID: LCT1W30, Lot Number: 027, batches 030-038
LCT1W60, Lot Number: 027, batches 059-063

Expiration Dates: 5/2015, 7/2015, 9/2015 & 10/2015
Expiration Dates: 9/2015 & 10/2015

Action to be taken by the user or distributor: Review test results generated with the above mentioned products, impacted test results may need to be further investigated by HLA Laboratory Director. Products on hand should be discarded. A new lot of product is in the process of manufacture and will be supplied as a replacement free of charge.

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: An investigation as to the root cause of the issues is underway and new lot of each catalog ID is in the process of manufacture.

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.

Angela Estany
Regulatory Affairs Manager

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE
ACKNOWLEDGEMENT FORM

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

Product: Lambda Cell Tray™

Catalog ID: LCT1W30, Lot Number: 027, batches 030-038

LCT1W60, Lot Number: 027, batches 059-063

Expiration Dates: 5/2015, 7/2015 & 9/2015

Expiration Dates: 9/2015 & 10/2015

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:

| |
|--|
| |
|--|

Return Response: (please provide additional information if applicable)

| |
|--|
| |
|--|

DISTRIBUTORS:

I have checked my stock and have quarantined inventory consisting of:

| |
|--|
| |
|--|

| |
|--|
| |
|--|

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: | |