One Lambda, Inc.
A Thermo Fisher Scientific Brand
22801 Roscoe Blvd.
West Hills, CA 91304
Tel (800) 822-8824
Fax (747) 494-1001
www.onelambda.com

ONE LAMBDA
A Thermo Fisher Scientific Brand

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE

PN# 2022-0593

Commercial name of the affected product: LinkSēq HLA Typing Kits
FSCA-identifier: PN# 2022-0593
Type of action: Field Safety Corrective Action

Date: September 29, 2022

Attention: Distributors and Users of LinkSēq™ HLA Typing Kits

Intended Use: For the DNA typing of HLA Class I and Class II alleles.

Reason for the Voluntary Recall (Description of the problem): Assays **LSDQB-008.1 and LSDQB-009.1** may generate a heterozygous DQB1*04 DQB1*05 for a homozygous DQB1*05 sample or a No Call when one of the alleles is a DQB1*05:04 due to high peak ratio. Confirmatory testing with a secondary method is required to resolve a heterozygous DQB1*04 DQB1*05 result.

The following SKUs may generate incorrect results without software warnings: 1550C, 1554C, 1551C, 1575C, 1861C, and 1862C. False reactions without software warnings would result in a heterozygous DQB1*04 and DQB1*05 assignment instead of a homozygous DQB1*05 assignment.

The following SKUs may generate incorrect results with software warnings encompassing rare / no call / haplocheck: 1580C and 2301C. Incorrect test results may lead to serological misassignment if confirmatory testing with secondary method is not performed as required.

Risk to Health: There is a risk of incorrect test results assigned to patient sample. Transplants require confirmatory testing derived from multiple sources to determine donor suitability. A transplant decision will not be made solely on the results of the test in question being either positive or negative.

Product and Distribution Information:

SKU	Lot #
1054C-ABS	K3932-AC
1054C-RLC	K3933-CC
1550C	K4123-AC, K3992-FC, K4209-AC, K3992-AC, K3992-BC, K3992-DC
1551C	K4158-AC, K4168-AC, K4158-BC, K4168-BC, K4189-AC, K4027-BC, K4104-AC
1554C	K4083-BC, K4103-AC, K4157-AC, K4167-AC, K4184-AC, K4184-BC, K3886-CC, K3886-DC, K4026-BC, K4026-DC, K4026-EC, K4083-AC
1575C	K4066-BC, K4066-CC, K4113-AC, K4113-BC, K4114-AC, K3942-BC, K4141-AC, K4147-AC, K4148-AC, K4149-AC, K4174-AC, K4183-AC, K4224-AC, K4227-AC, K4235-AC, K4236-AC, K4237-AC, K3922-AC, K3931-BC, K3931-CC, K3940-AC, K3940-BC, K3942-AC, K3974-AC, K3974-CC, K3976-AC, K4030-BC, K4066-AC
1580C	K3989-CC, K4064-AC, K4133-AC, K4132-AC, K4134-AC, K4132-BC, K4135-AC, K4142-AC, K4140-AC, K4145-AC, K4146-AC, K4151-AC, K4152-AC, K4154-AC, K4172-AC, K4175-AC, K4173-AC, K4204-AC, K4205-AC, K4207-AC, K4173-AC, K4217-AC, K4218-AC, K4230-AC, K4231-AC, K4233-AC, K4234-AC, K4253-AC, K3883-CC, K3883-DC, K3930-AC, K3930-BC,

ONE LAMBDA
A Thermo Fisher Scientific Brand

SKU	Lot #
	K3943-BC, K3944-AC, K3971-BC, K3972-CC, K3972-DC, K3973-AC, K3989-BC, K4019-AC, K4019-BC, K4023-AC, K4024-BC, K4065-AC, K4073-AC
1861C	K4109-AC, K4214-AC, K4214-BC, K4212-BC, K3956-DC
1862C	K3955-EC, K4110-AC, K4110-BC, K4110-CC, K4215-AC, K3955-CC, K3955-DC
2301C	K4131-AC, K4192-AC, K4025-AC, K4076-AC

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. Confirmatory testing with a secondary method may be required to confirm testing results.

- **Distributors**: – Our records indicate that you may have purchased products for re-sale. Please complete the **Acknowledgement Form** in regards to the 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.

- **End Users:** Please complete the attached **Acknowledgement Form** and return to One Lambda, Inc.

Type of Action by the Manufacturer: Users of impacted products are notified to review the results. The primers for impacted assays LSDQB-008.1 and LSDQB-009.1 will be updated in future lots of the impacted SKU's to prevent false positive assignment.

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 the One Lambda Customer Support team for assistance at 1Lambda-techsupport@thermofisher.com or +1 (747) 494-1000.

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

Angela Estany

Sr. Director, Regulatory and Quality

ONE LAMBDA
A Thermo Fisher Scientific Brand

Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM

PN# 2022-0593

Customer Information (Please Complete)

Name:
Address:
Product:
Catalog ID:

I have read and understand the attached Field Safety Notice and instructions and have taken appropriate actions: **_____ (initial)**

Any patient death or injury associated with the recalled product? **____ Yes _____ No**

If yes, please explain:

Return Response: (please provide additional information if applicable)

DISTRIBUTORS:

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter: **____ Yes _____ No**

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 (+1 747-494-1001) or email (tdx-postmarket@thermofisher.com).

Signature of Receipt by End User/Distributor:

_____ _____
Signature Date

Print: (please complete)

Name/Title:	
Telephone:	
Email Address:	