Linkage Biosciences™

890 Dubuque Avenue, South San Francisco, CA 94080, USA Phone: +1.415.346.5262 Fax +1.415.346.5360

URGENT FIELD SAFETY NOTICE

Commercial name of the affected product: LinkSēq HLA ABCDRDQA1DQB1 384 Typing Kit - 1550C, LinkSēq HLA ABCDRDQDP+ 384 - 1575C, LinkSēq HLA ABCDRDQDP SABR 384 Typing Kit - 1580C, LinkSēq HLA DRDQDP 384 - 1861C, and LinkSēq HLA DRDQDP 384 - 1862C

FSCA-identifier: MW 18-003
Type of action: Review Test Results

24 October 2018

Attention: Distributors and Users
The purpose of this letter is to advise you that Linkage Biosciences, Inc. is conducting a correction of the following LinkSēq HLA ABCDRDQA1DQB1 384 Typing Kit - 1550C, LinkSēq HLA ABCDRDQDP+ 384 - 1575C, LinkSēq HLA ABCDRDQDP SABR 384 Typing Kit - 1580C, LinkSēq HLA DRDQDP 384 - 1861C, and LinkSēq HLA DRDQDP 384 - 1862C.

Reason for the Voluntary Recall/Correction (Description of the problem): The above mentioned products contain primer LSDQA-005.1. We were aware of one case where the primer LSDQA-005.1 produced a false negative when in the presence of DQA1*01 DQA1*05 sample and generated an erroneous homozygous DQA1*01 typing when used with specific lots of DNA Polymerase including; T1701, T1702, T1703, T1704, T1705, T1706, T1707, T1709, T1710, T1711, T1801, T1802, and T1803.

Risk to Health: There is low risk to the patient or end user as a result of this problem because of the following: The LinkSēq™ HLA Kits Instruction for Use (LHLA-PI.3-EN) states that this product should not be used as the sole basis for making a clinical decision. In addition, clinical decisions for transplant are based on multiple sources and all homozygous results must be confirmed.

Product and Distribution Information: See Annex 1
Product Type: 1550C, 1575C, 1580C, 1861C, and 1862C

Action to be taken by the user or distributor:
Users should review all results from the affected products prior to determining the DQA locus result when the well is negative at this primer location. In particular, please review the results of this primer when the DQA locus result is DQA1*01 homozygous to confirm if the DQA1*05 is incorrectly excluded.

> **End User:** Please complete the attached **Acknowledgement Form** and return to Linkage Biosciences, Inc.
>
> **Distributors** – our records indicate that you may have purchased products for re-sale. Please complete the **Acknowledgement Form** in regard 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: Current products lots contain new lots of DNA Polymerase and future lots of product will contain an update to the DQA locus primer to mitigate this specificity issue.

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 Linkage Biosciences Customer Support team for assistance at Email: support@linkagebio.com or Phone: +1 (415) 346-5262. You may also contact our authorized representative in the Netherlands: Emergo Europe, emergovigilance@ul.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.

Linkage Biosciences™

890 Dubuque Avenue, South San Francisco, CA 94080, USA Phone: +1.415.346.5262 Fax +1.415.346.5360

Eric Mitchell
Manager, Regulatory Affairs & Quality

Annex 1

Cat ID: 1862C
Kit Lot
NA – no affected lots distributed

Cat ID: 1861C		
Kit Lot		
K3487-DC	K3487-FC	K3566-BC

Cat ID: 1550C	
Kit Lot	
K3480-AC	K3480-DC
K3480-BC	K3480-EC

Cat ID: 1575C	
Kit Lot	
K3467-BC	K3521-GC
K3467-DC	K3521-HC
K3470-CC	K3536-AC
K3471-CC	K3549-AC
K3488-AC	K3549-BC
K3488-BC	K3552-AC
K3488-CC	K3552-BC
K3518-AC	K3552-CC
K3518-BC	K3569-AC
K3518-EC	K3569-BC
K3519-AC	K3569-GC
K3519-CC	K3570-AC
K3520-AC	K3570-BC
K3520-EC	K3612-BC
K3521-DC	K3612-EC

Cat ID: 1580C		
Kit Lot		
K3469-BC	K3508-BC	K3548-BC
K3469-FC	K3508-EC	K3548-DC
K3476-BC	K3508-FC	K3548-EC
K3476-CC	K3476-CC	K3508-HC
K3476-EC	K3476-EC	K3508-JC
K3492-AC	K3509-AC	K3567-BC
K3492-BC	K3509-BC	K3567-CC
K3492-CC	K3509-CC	K3568-AC
K3492-DC	K3509-DC	K3568-BC
K3492-FC	K3524-AC	K3568-CC
K3492-GC	K3524-BC	K3568-DC
K3499-AC	K3524-CC	K3571-AC
K3499-BC	K3525-BC	K3571-BC
K3499-EC	K3525-CC	K3611-BC
K3507-AC	K3525-DC	K3611-CC
K3507-BC	K3534-AC	K3634-AC
K3507-CC	K3534-BC	K3634-EC
K3508-AC	K3548-AC	

Linkage Biosciences™

890 Dubuque Avenue, South San Francisco, CA 94080, USA Phone: +1.415.346.5262 Fax +1.415.346.5360

Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM

Customer Information (Please Complete)

Name:

Address:

Product: LinkSēq™ HLA Kit

Cat ID: 1862C
Kit Lot
NA – no affected lots distributed

Cat ID: 1861C		
Kit Lot		
K3487-DC	K3487-FC	K3566-BC

Cat ID: 1550C	
Kit Lot	
K3480-AC	K3480-DC
K3480-BC	K3480-EC

Cat ID: 1575C	
Kit Lot	
K3467-BC	K3521-GC
K3467-DC	K3521-HC
K3470-CC	K3536-AC
K3471-CC	K3549-AC
K3488-AC	K3549-BC
K3488-BC	K3552-AC
K3488-CC	K3552-BC
K3518-AC	K3552-CC
K3518-BC	K3569-AC
K3518-EC	K3569-BC
K3519-AC	K3569-GC
K3519-CC	K3570-AC
K3520-AC	K3570-BC
K3520-EC	K3612-BC
K3521-DC	K3612-EC

Cat ID: 1580C		
Kit Lot		
K3469-BC	K3508-BC	K3548-BC
K3469-FC	K3508-EC	K3548-DC
K3476-BC	K3508-FC	K3548-EC
K3476-CC	K3476-CC	K3508-HC
K3476-EC	K3476-EC	K3508-JC
K3492-AC	K3509-AC	K3567-BC
K3492-BC	K3509-BC	K3567-CC
K3492-CC	K3509-CC	K3568-AC
K3492-DC	K3509-DC	K3568-BC
K3492-FC	K3524-AC	K3568-CC
K3492-GC	K3524-BC	K3568-DC
K3499-AC	K3524-CC	K3571-AC
K3499-BC	K3525-BC	K3571-BC
K3499-EC	K3525-CC	K3611-BC
K3507-AC	K3525-DC	K3611-CC
K3507-BC	K3534-AC	K3634-AC
K3507-CC	K3534-BC	K3634-EC
K3508-AC	K3548-AC	

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)

890 Dubuque Avenue, South San Francisco, CA 94080, USA Phone: +1.415.346.5262 Fax +1.415.346.5360

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 Linkage Biosciences, Inc., via fax +1 415 346 5360 or email quality@linkagebio.com

Signature of Receipt by End User/Distributor:

_____ _____
Signature Date

Print: (please complete)

Name/Title:	
Telephone:	
Email Address:	