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 ABCDRDQDP SABR 384 Typing Kit, 1580C and LinkSēq HLA ABCDRDQDP+ 384, 1575C

FSCA-identifier: MW 18-001
Type of action: Review Test Results

26 July 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 ABCDRDQDP SABR 384, 1580C and LinkSēq HLA ABCDRDQDP+ 384, 1575C

Reason for the Voluntary Recall/Correction (Description of the problem): We were aware of one case where the primer LSA-004.1 produced a false negative when in the presence of A1 A11 sample and generated an erroneous homozygous A11 typing. No adverse events were reported.

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 Rev06) 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. Overall risk to the patient is low.

Product and Distribution Information: See Annex 1
Product Type: 1580C and 1575C

Action to be taken by the user or distributor:
Users should review all results from the affected product LSA-004.1 prior to determining the A locus call when the well is negative at this location. In particular, please review this primer when the A locus call is A11 homozygous to confirm if the A1 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: Future products lots will contain an additional A locus primer set 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.

Eric Mitchell
Manager, Regulatory Affairs and Quality

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Annex 1

1580C			
Kit Lot			
K3420-FC	K3492-AC	K3525-CC	K3611-CC
K3423-CC	K3492-BC	K3525-DC	K3611-DC
K3423-DC	K3492-DC	K3534-AC	K3611-FC
K3434-CC	K3499-AC	K3534-AC	K3612-EC
K3434-DC	K3499-BC	K3534-BC	K3634-AC
K3434-HC	K3499-EC	K3534-DC	K3634-BC
K3434-IC	K3507-AC	K3548-AC	K3634-DC
K3441-AC	K3507-BC	K3548-BC	K3635-AC
K3441-CC	K3507-CC	K3548-DC	
K3441-DC	K3508-FC	K3567-AC	
K3441-FC	K3508-HC	K3567-BC	
K3442-AC	K3508-JC	K3567-CC	
K3442-EC	K3509-AC	K3568-AC	
K3442-FC	K3509-BC	K3568-BC	
K3469-BC	K3509-CC	K3568-CC	
K3476-BC	K3509-DC	K3568-DC	
K3476-CC	K3524-AC	K3571-AC	
K3476-DC	K3524-BC	K3571-BC	
K3476-EC	K3524-DC	K3611-AC	
K3476-EC	K3525-BC	K3611-BC	

1575C		
Kit Lot		
K3417-AC	K3470-CC	K3569-GC
K3417-BC	K3471-CC	K3569-HC
K3419-AC	K3488-AC	K3570-AC
K3419-CC	K3488-BC	K3570-BC
K3431-AC	K3488-CC	K3570-CC
K3431-CC	K3518-AC	K3570-DC
K3432-EC	K3518-BC	K3612-AC
K3433-AC	K3518-EC	K3612-BC
K3433-CC	K3519-AC	K3612-DC
K3433-DC	K3519-CC	K3623-BC
K3433-EC	K3520-AC	K3623-CC
K3433-FC	K3521-EC	K3636-BC
K3438-BC	K3521-GC	
K3438-CC	K3523-CC	
K3440-BC	K3536-AC	
K3466-CC	K3549-AC	
K3466-DC	K3549-BC	
K3466-EC	K3552-AC	
K3467-BC	K3552-BC	
K3467-DC	K3569-AC	

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Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM

Customer Information (Please Complete)

Name:

Address:

Product: LinkSēq™ HLA Kit

1580C			
Kit Lot			
K3420-FC	K3492-AC	K3525-CC	K3611-CC
K3423-CC	K3492-BC	K3525-DC	K3611-DC
K3423-DC	K3492-DC	K3534-AC	K3611-FC
K3434-CC	K3499-AC	K3534-AC	K3612-EC
K3434-DC	K3499-BC	K3534-BC	K3634-AC
K3434-HC	K3499-EC	K3534-DC	K3634-BC
K3434-IC	K3507-AC	K3548-AC	K3634-DC
K3441-AC	K3507-BC	K3548-BC	K3635-AC
K3441-CC	K3507-CC	K3548-DC	
K3441-DC	K3508-FC	K3567-AC	
K3441-FC	K3508-HC	K3567-BC	
K3442-AC	K3508-JC	K3567-CC	
K3442-EC	K3509-AC	K3568-AC	
K3442-FC	K3509-BC	K3568-BC	
K3469-BC	K3509-CC	K3568-CC	
K3476-BC	K3509-DC	K3568-DC	
K3476-CC	K3524-AC	K3571-AC	
K3476-DC	K3524-BC	K3571-BC	
K3476-EC	K3524-DC	K3611-AC	
K3476-EC	K3525-BC	K3611-BC	

1575C		
Kit Lot		
K3417-AC	K3470-CC	K3569-GC
K3417-BC	K3471-CC	K3569-HC
K3419-AC	K3488-AC	K3570-AC
K3419-CC	K3488-BC	K3570-BC
K3431-AC	K3488-CC	K3570-CC
K3431-CC	K3518-AC	K3570-DC
K3432-EC	K3518-BC	K3612-AC
K3433-AC	K3518-EC	K3612-BC
K3433-CC	K3519-AC	K3612-DC
K3433-DC	K3519-CC	K3623-BC
K3433-EC	K3520-AC	K3623-CC
K3433-FC	K3521-EC	K3636-BC
K3438-BC	K3521-GC	
K3438-CC	K3523-CC	
K3440-BC	K3536-AC	
K3466-CC	K3549-AC	
K3466-DC	K3549-BC	
K3466-EC	K3552-AC	
K3467-BC	K3552-BC	
K3467-DC	K3569-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)

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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:	

Diese Bestellung wurde durch die GHX Europe übermittelt.

Direktion Management Services
Abteilung Einkauf
Freiburgstrasse
3010 Bern

INSELGRUPPE

Bestellung

Linkage Biosciences
Dubuque Avenue 890
94080 South San Fransisco

Bestellnummer	**4500556630**
Datum	27. 07. 2018
Ihre Lieferantennummer	722200
Unsere Kundennummer	1000
Ihre Telefonnummer	866 575 89 15
Kontakt Insel Gruppe	Loeffel Beatrice
Telefon	031 632 0333
Fax	031 6322 83 81
Email	Beatrice.Loeffel@insel.ch
Unsere MwSt-Nr.	CHE-433.951.246

Bitte liefern Sie an:
Inselspital Bern
Hauptanlieferung (HAV), Rampe 35B
Freiburgstrasse 16A
via Friedbühlstrasse
3008 Bern

Bitte Rechnung an
Insel Gruppe AG
Kreditorenbuchhaltung
Freiburgstrasse 18
3010 Bern

Lieferbedingungen: CIP Bern
Zahlungsbedingungen: innerhalb von 30 Tagen ohne Abzug

Es gelten die Allgemeinen Einkaufsbedingungen der Insel Gruppe AG.

Für folgende Position(en) erwarten wir Ihre Auftragsbestätigung innerhalb 1 Arbeitstag an die obenstehende E-Mail Adresse.

Pos	Material-Nr. Bezeichnung Mengenfaktor	Bestellmenge	Einheit	Preis/Einheit	Nettowert CHF
10	10088225 HLA – ABCDRDQDP SABR 384 Kits Ihre Materialnummer 1580C 1 Set <=> 1 SET **Lieferdatum:** 17. 08. 2018 Bruttopreis	18	Set	2400.00 CHF 1 SET	43200.00
				Bezugsnebenkosten:	**0.00 CHF**

Gesamtnettowert exkl. Mwst CHF	43200.00
Gesamtnettowert inkl. Mwst CHF	43200.00

Die Medizinprodukte müssen der Medizinprodukteverordnung (MepV) entsprechen und die grundlegenden Anforderungen der zutreffenden EG-Richtlinie 93/42/EWG oder 90/385/EWG erfüllen.