Life Technologies
9099 N. Deerbrook Trail
Brown Deer, WI 53223
www.lifetechnologies.com

Urgent Recall/Field Safety Notice

DMR0000741 **Date of Issue:** 09-Feb-2015

Attention: Distributors and Users

Reason for Notice*:*

The primer mix in Lane 6 (Primer Mix R13-51B) of the following products may cause a DRB1*13:50 allele to be typed as a DRB1*13:14 allele. These alleles occur very rarely. This issue is due to limited sequence information available for this allele at the time of release. Due to the recent availability of a sample exhibiting the DRB1*13:50 allele, a new lot-specific comment has been added to the Quality Control Comments alerting users to the possibility of a false negative in lane 6 with the DRB1*13:50 allele.

Details on Affected Devices:

Item Number	Lot/Serial	Description	Expiration Date
450804	015 1511957	DRB1-13 SSP UNITRAY® 12 TESTS	10/2015
450804	015 1322626	DRB1-13 SSP UNITRAY® 12 TESTS	11/2014
450814	015 1511957 / 1632888	DRB1-13 SSP UNITRAY® W/TAQ 12 TESTS	8/2015
54270D	015 1446996	ALLSET+™ GOLD DRB1-13 HIGH RES	6/2015
54270D	015 1589779	ALLSET+™ GOLD DRB1-13 HIGH RES	10/2015
54270D	015 1608927	ALLSET+™ GOLD DRB1-13 HIGH RES	3/2016

Risk to Patient Health*:*

There is low risk of death or serious harm to the patient or end user as a result of this problem because of the following: The alleles impacted by the mistype occur very rarely in the population, clinical decisions for transplant are based on multiple sources, this product is not used as the sole source for typing analysis, and test results will be further investigated by the HLA specialist during confirmatory testing.

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Action to be taken by the User:

Please take the following actions:

If a DRB1*13:14 result is obtained with continued use of these products, it is recommended to repeat the typing with a secondary method. In addition, all previous DRB1*13:14 results should be reviewed in light of this new information. As internal investigation showed the potential for the false negative to be sample-specific, the reactivity of the primer mix (R13-51B) in lane 6 was not changed.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

For confirmation that this notice was received and read, we kindly ask that you return a completed copy of the Customer Confirmation form provided with this notice. Instructions for returning the form are provided on the form itself.

Action taken by Life Technologies:

Urgent Recall/Field Safety Notice DMR0000741 has been issued. The Version 2. lot-specific comment on the Quality Control Comments document for the affected products have been updated with the statement that a false negative is possible with DRB1*13:50:01 samples and alleles with like patterns. For your convenient review, a single copy of an AllSet+™ kit and a single copy of UniTray® kit revised Quality Control Comments have been included.

Contact Reference Person:

For users worldwide, if you should have any questions,
please contact your local Life Technologies Representative or

e-mail: *HLATechSupport@lifetech.com* or call *1-888-821-4443 Option #2*

Thank you for your continued support. We appreciate your immediate attention to this notification and apologize for any inconvenience this may have caused. Should you require further assistance, please contact us using the above-mentioned contact information.

Sincerely,
Life Technologies
9099 N. Deerbrook Trail
Brown Deer, WI 53223

Submit via Email

DMR0000741

CUSTOMER CONFIRMATION

For all users worldwide, please fill out and return this confirmation form back to Life Technologies HLA Technical Support by using the "Submit via Email" button at the top right corner of this page OR complete and fax to our US Fax Number: +1 414-214-4001.

It is important to us that we are able to confirm that you have received the information in the Customer Notification that accompanies this form. By checking the box below, you are acknowledging and representing that you have received the Customer Notification referenced in the top left of this form and that you understand and have taken the necessary actions recommended in the Customer Notification.

☐ I acknowledge and agree with the above statement. Checking this box constitutes as my signature.

Institution Name:

Address:

Phone Number:

Director/Supervisor Name:

Date:

Email Address: