



URGENT: PRODUCT CORRECTION

Date: 31 January 2018

URGENT: PRODUCT CORRECTION

FA #:18-01 ~ EU FA#18-02

Dear LIFECODES® Customer,

Our records indicate you received one of the following LIFECODES HLA-A SSO Typing Kits or LIFECODES HLA-A eRES SSO Typing Kits and utilize the MATCH IT! DNA software:

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	02017A	31 DEC 2018
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	06206B	30 APR 2018
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	3006227	15 OCT 2019
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	02017B	31 DEC 2018
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	06206C	30 APR 2018
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	12076X	31 MAR 2018

Issue Details:

As a result of a complaint investigation, we have determined that when using MATCH IT! DNA software v1.2.3 (with the Pairwise functionality turned OFF) on a Win 7 32-bit computer to analyze HLA-A typing, the software does not correctly load the suggested assignment table when navigating between samples that contain complex numbers of HLA-A allele-string pairs. When the user navigates from one sample to the next, the software does not automatically assign a typing into the Assigned View field when the auto assign feature is activated in preferences. If the user attempts to make a manual assignment to the Assigned View field, the software will crash.

It has also been determined that there is a possibility of a mistype when using MATCH IT! DNA software v1.2.4 (with the Pairwise functionality turned OFF) on a Win 7 32-bit computer to analyze HLA-A typing. If the user navigates from one sample to the next sample, the software can maintain the previous sample typing in the Assigned View field in addition to the Suggested Assignments. If the user attempts to make a manual assignment, the software will freeze. There is no warning that the typing in Assigned View is incorrect.

Product Impact:

There is no impact to the HLA-A and HLA-A eRES SSO typing kits. These kits are performing as expected.

The MATCH IT! DNA Software has the potential for a mistype with the A2 homozygous typing or typing with an A2 in the pair of alleles.

Previous results generated using MATCH IT! DNA software with an HLA-A or HLA-A eRES SSO typing kit using Pairwise OFF should be reviewed in relation to the mistype potential.



Our Actions Taken:

Immucor has determined that this issue does not occur with 64-bit operating systems or any other Immucor HLA SSO typing kit. It is isolated to 32-bit computers with the Pairwise functionality turned OFF.

Customer Actions to Be Taken:

- If you are utilizing a WIN 7 32-bit operating system with the MATCH IT! DNA software, please turn ON the Pairwise functionality in the software as instructed in the MATCH IT! DNA User Manual. Pairwise ON is the default and when Pairwise is ON, no other action is necessary. The MATCH IT! DNA software User's Manual is available on the Immucor website.



Please complete the Response Form included on page 4 of this communication. Return the response form by fax to +44 (0)330 333 8749 OR email to vigilance.eu@immucor.com

We appreciate the trust and confidence you place in our products. Please contact your National Product Support Specialist should you need additional information or lifecodestechsupport@immucor.com.

We apologize for inconveniences this issue may have caused.

Sincerely,

Allison Stray
Senior Director, Quality and Regulatory Affairs



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FA#18-01 ~ EU FA # 18-02

Response Form

I verify that our facility was made aware of the voluntary field action of MATCH IT! DNA SOFTWARE v1.2.3 and v1.2.4 LIFECODES HLA-A SSO Typing Kit Lot: 3006227, 02017A, 06206B LIFECODES HLA-A eRES SSO Typing Kit Lot: 02017B, 06206C, 12076X	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	



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Dear Distributor of LIFECODES® Products,

Our records indicate you received one of the following LIFECODES HLA-A SSO Typing Kits or LIFECODES HLA-A eRES SSO Typing Kits and your customers utilize the MATCH IT! DNA software:

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	02017A	31 DEC 2018
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	06206B	30 APR 2018
LIFECODES HLA-A SSO Typing Kit	628911	10888234400394	3006227	15 OCT 2019
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	02017B	31 DEC 2018
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	06206C	30 APR 2018
LIFECODES HLA-A eRES SSO Typing Kit	628913	10888234400011	12076X	31 MAR 2018

Issue Details:

As a result of a complaint investigation, we have determined that when using MATCH IT! DNA software v1.2.3 (with the Pairwise functionality turned OFF) on a Win 7 32-bit computer to analyze HLA-A typing, the software does not correctly load the suggested assignment table when navigating between samples that contain complex numbers of HLA-A allele-string pairs. When the user navigates from one sample to the next, the software does not automatically assign a typing into the Assigned View field when the auto assign feature is activated in preferences. If the user attempts to make a manual assignment to the Assigned View field, the software will crash.

It has also been determined that there is a possibility of a mistype when using MATCH IT! DNA software v1.2.4 (with the Pairwise functionality turned OFF) on a Win 7 32-bit computer to analyze HLA-A typing. If the user navigates from one sample to the next sample, the software can maintain the previous sample typing in the Assigned View field in addition to the Suggested Assignments. If the user attempts to make a manual assignment, the software will freeze. There is no warning that the typing in Assigned View is incorrect.

Product Impact:

There is no impact to the HLA-A and HLA-A eRES SSO typing kits. These kits are performing as expected.

The MATCH IT! DNA Software has the potential for a mistype with the A2 homozygous typing or typing with an A2 in the pair of alleles.

Previous results generated using MATCH IT! DNA software with an HLA-A or HLA-A eRES SSO typing kit using Pairwise OFF should be reviewed in relation to the mistype potential.



Our Actions Taken:

Immucor has determined that this issue does not occur with 64-bit operating systems or any other Immucor HLA SSO typing kit. It is isolated to 32-bit computers with the Pairwise functionality turned OFF.

Customer Actions to Be Taken:

- If you are utilizing a WIN 7 32-bit operating system with the MATCH IT! DNA software, please turn ON the Pairwise functionality in the software as instructed in the MATCH IT! DNA User Manual. Pairwise ON is the default and when Pairwise is ON, no other action is necessary. The MATCH IT! DNA software User's Manual is available on the Immucor website.



Distributor Actions to Be Taken:

This notice also contains a response verification form that we have prepared for customers. As a field correction to our action, we ask that you distribute the attached notice to your customers or provide them with a reasonable translation. The response verification is intended to assist you and us in determining if the customer received and understood this notification.

As a distributor of Immucor products, you are responsible for notifying the regulatory agencies of countries where you have distributed the product, as required, and to maintain records of field actions and effectiveness checks.

We apologize for inconveniences this issue has caused. If you have any questions, please contact Technical Support.



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Sincerely,

Allison Stray
Senior Director, Quality and Regulatory Affairs



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Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	