



URGENT: FIELD SAFETY NOTIFICATION

Date: 17 February 2021

EU FA #21-01 - FA-WKS-21-001

Dear Valued Customer,

Our records indicate that you have received one of Immucor GTi Diagnostics' LIFECODES® MATCH IT! DNA Software versions indicated below.

Product Code	Product Name	Lot Number
888623	MATCH IT! DNA Software v1.2	V1.2
888623CE	MATCH IT! DNA Software v1.3	V1.3
888623	MATCH IT! DNA Software v1.3	V1.3

Manufacturer

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USA
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www.immucor.com

EU Authorized Representative

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Robert-Bosch-Str. 32
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Issue details:

As a result of a complaint investigation, we have determined that MATCH IT! DNA Software version 1.2 and version 1.3 have a maximum character limit of 4000. The character limit affects the ability to import all possible alleles that particular reactivity patterns can generate when a lot specific exp file is imported into the software. If there are more alleles for a particular reactivity pattern than the maximum character limit, these MATCH IT! DNA software versions will not report out some alleles. Therefore, samples that generate patterns with this anomaly will produce strings of alleles without all possible allele combinations. The software anomaly does not cause a change in serological typing but could result in a mistype if a single pair of alleles is reported. There are no specific conditions that could contribute to a clinical situation that could expose humans to a health hazard, therefore the risk is deemed low.

The investigation concluded this issue only occurs when analyzing samples with the LIFECODES HLA-A Typing Kit, LIFECODES HLA-A eRES Typing Kit, LIFECODES HLA-B eRES Typing Kit and LIFECODES HLA-CeRES Typing Kit.

Product Impact:

There is no impact to the LIFECODES HLA-A Typing Kit, LIFECODES HLA-A eRES Typing Kit, LIFECODES HLA-B eRES Typing Kit and LIFECODES HLA-CeRES Typing Kits. The Typing Kits performance is as expected.

As indicated in the Specific Performance Characteristics Section of the LIFECODES HLA-SSO Typing Kits Product Insert (LC1436IVDEN Revision K), the product performance level is based on the percent agreement for HLA-A Alleles when comparing HLA typing results for the first two data fields. The correct serological 1 field typing (e.g. A*01) is not impacted by this character limit and will be reported. Data for the additional fields are provided for information only but are in scope for the current performance characteristics.

The Product Insert, LC1436IVDEN Revision K, Results Section, also states MATCHIT! DNA Software is intended as an aid in analysis of LIFECODES SSO Typing Kits.

The frequency with which the character limit is estimated to impact availability of allele reporting is estimated as follows:

- Of the Common Alleles impacted, the highest frequency observed is 0.13% for A*02:22:01G (a grouping comprised predominantly of A*02:22:01:01), with the next highest of 0.10% for A*02:60:01.
- Both of these alleles are detected for HLA-A, but are missing when joined with HLA-A eRES. The highest frequency observed for HLA-A alone is 0.03% for A*02:30 (comprised predominantly of A*02:30:01).

Our Actions Taken:

Immucor is working on a software update to correct the issue described above. The software update is expected to be released April 9, 2021.

Immucor will issue a second communication notifying customers the software update is available. The software update will be available on a cd and will be mailed to customers. Upon receipt and implementation of the software update, Immucor will require customers to complete and return an acknowledgement form.

Your Actions to Be Taken:

- 1) Please complete the Response Form included on page 5 of this communication. Return the response form by fax to +49 6103 8056 6393, email to vigilance.eu@immucor.com or mail to: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Germany.
- 2) Until the software revision is released, please follow the directions below for assignments allele pairs impacted by this issue.

You may also use the directions below if you deem it necessary to reanalyze previous results generated using MATCH IT! DNA software v1.2 or v1.3 with a LIFECODES HLA-A Typing Kit, LIFECODES HLA-A eRES Typing Kit, LIFECODES HLA-B eRES Typing Kit and LIFECODES HLA-CeRES Typing Kit.

The alleles impacted differs depending on the loci, both CWD (Common Well Documented) alleles and rare alleles. Table 1 below identifies suggested assignments or allele strings that are impacted with the current software anomaly.

If you have observed results in the Suggested Assignment Column, use the results in the Assigned Serological Typing column.

Table 1: Anomaly Identified by Suggested Assignments

LIFECODES SSO Typing Kit	Suggested Assignment	Assigned Serological Typing
P/N: 628911, LIFECODES HLA-A SSO Typing Kit	A*01:01:01:01	A*01:XX
	A*02:01:01:01	A*02:XX
	A*24:02:01:01	A*24:XX
P/N: 628913, LIFECODES HLA-A eRES Typing Kit*	A*01:01:01:01	A*01:XX
	A*02:01:01:01	A*02:XX
	A*03:01:01:01	A*03:XX
	A*11:01:01:01	A*11:XX
	A*24:02:01:01	A*24:XX
P/N: 628917, LIFECODES HLA-B eRES Typing Kit**	B*07:02:01:01	B*07:XX
	B*35:01:01:01	B*35:XX
P/N: 628921, LIFECODES HLA-C eRES Typing Kit	C*04:01:01:01	C*04:XX
	C*07:01:01:01	C*07:XX
	C*07:02:01:01	C*07:XX

*The standard result of HLA-A when containing suggested assignments that include A*03:01:01:01 or A*11:01:01:01 is only impacted after the merge with eRES results.

**The standard result of HLA-B when containing suggested assignments that include B*07:02:01:01 or B*35:01:01:01 is only impacted after the merge with eRES results.

- 3) Customers may also manually interpret results using the LIFECODES HLA-SSO Typing Kits Product Insert, LC1436IVDEN Revision K, Results Section.



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We appreciate the trust and confidence you place in our products. Please contact your local Technical Support personally or at +1.855.IMMUCOR (US and Canada), for assistance or additional instructions should you need further support.

We apologize for inconveniences this issue may have caused.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Wilhelmi". The signature is fluid and cursive, with a long, sweeping tail on the final letter.

Maria Wilhelmi
Director RA/QA Europe



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FSCA: EU FA #21-01 - FA-WKS-21-001

Customer Response Form

I verify that our facility was made aware of the Field Safety Corrective Action for LIFECODES MATCH IT! DNA Software Versions 1.2 and 1.3, _____	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	