

Date: 21 April 2023**EU FA 23-02 - FA-WKS-23-001**

Dear Valued Customer,

Our records indicate you received the following LIFECODES® HLA-DQA1/B1 SSO Typing Kit:

Product Name	Product Code	UDI-DI	Lot Number	Manufacturing Date
LIFECODES HLA-DQA1/B1 SSO Typing Kit	628930	10888234400462	3012778	30AUG2022

Manufacturer

Immucor GTI Diagnostics, Inc.
20925 Crossroads Cir Ste 200
Waukesha, WI, 53186-4054
USA
+1 855.466.8267
www.immucor.com

EU Authorized Representative

Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Str. 32
63303 Dreieich
Germany
+49 (0) 6103 80560
www.immucor.com

Issue Details:

Immucor GTI Diagnostics, Inc has determined that threshold set for LIFECODES HLA-DQA1/B1 SSO Typing Kit probe DQA207 lot 3012778 threshold was artificially elevated. This may result in a false negative assignment for probe DQA207.

The investigation concluded this issue is isolated to LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778 probe DQA207.

Product Impact:

There is no impact to the LIFECODES HLA-DQA1/B1 SSO Typing Kit. The Typing Kits performance is as expected.

Probe DQA207 is specific for DQA1*02 alleles. If DQA207 has a false negative assignment, if using MATCHIT! DNA for analysis, the software will give a "Review Probes" sample result. This would signal further evaluation by user for determination of patient type as this means the sequence specific oligonucleotide reaction patterns do not match exactly with any pair of DQA1 alleles. 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 risk to the patient is considered low due to the additional risk reduction achieved through application of the requirements and limitations described in the product insert. Results from these kits are not to be used as the sole basis upon which a clinical decision affecting the patient is made. Due to the complex nature of HLA typing, qualified personnel should review data interpretation and typing assignments, as per the Limitations of the Procedure section of the product insert.

Our Actions Taken:

Immucor GTI Diagnostics, Inc. has corrected and uploaded the lot specific documentation affected for LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778 to the Customer Center on 14-Apr-2023.

Product Information	Initial lot specific files	Corrected lot specific files
LIFECODES HLA-DQA1/B1 SSO Typing Kit Lot: 3012778 Expiration: 2024-03-18 Part #: 628930	DQA1_B1_RS_EN_3012778_EXP_2024-03-18.pdf 3012778 3012433-DQAB_3_46_0.exp 3012778 3012433-DQAB_3_48_0.exp 3012778 3012433-DQAB_3_50_0.exp	DQA1_B1_RS_EN_3012778_EXP_2024-03-18v2.pdf 3012778 3012433-DQAB_3_46_0v2.exp 3012778 3012433-DQAB_3_48_0v2.exp 3012778 3012433-DQAB_3_50_0v2.exp

Customer Actions to Be Taken:

- 1) The correction is made by replacing the initial LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778 EXP file by importing the revised MATCHIT! DNA EXP file. The revised file can be accessed at the Customer Center.
- 2) A message will display asking for confirmation to overwrite the existing EXP file. Click Yes. A message will display stating that the file was imported successfully. At this time, any assay can be analyzed with the revised EXP.
- 3) (OPTIONAL) Re-analyze LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778 data by performing either step a or b if the results of analysis noted Review Probes of DQA207:
 - a. Manually re-import a csv file. In this case, you will be prompted to rename the batch since it already exists in the database. Both sets of data will now be present.
 - b. Delete a current batch and then re-import a csv file under the new lot. In this case, your previous data will be removed from the database.
- 4) There is no requirement to re-test any samples.
- 5) There is no requirement to return any kits.
- 6) Please complete the Response Form included on page 4 of this communication. Return the response form by 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.

We appreciate the trust and confidence you place in our products. Please contact your local Technical Support under +49 (0) 6103 8056-100 or at tech.support.eu@immucor.com or reach out to your local Technical Sales Specialist for assistance or additional instructions should you need further support.

We apologize for inconveniences this issue may have caused.

Sincerely,

DocuSigned by Maria Wilhelmi
 *Maria Wilhelmi* | I approve this document
21-Apr-2023 | 9:53:59 AM EDT
6158156DCC844B7DAC3E215F80772834

Maria Wilhelmi
Sr. Director RA/QA

**FSCA: EU FA #23-02 - FA-WKS-23-001
Customer Response Form**

I verify that our facility was made aware of the Field Safety Corrective Action for LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	