



URGENT: FIELD CORRECTION

Date: 21 April 2023

FA #:FA-WKS-23-001

Dear Distributor of products manufactured by Immucor, GTI Diagnostics, Inc.,

Our records indicate you received the following:

Product Name	Product Number	UDI Number	Lot Number	Manufacturing Date
LIFECODES® HLA-DQA1/B1 SSO Typing Kit	628930	10888234400462	3012778	30 AUG 2022

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 21 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

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 3 of this communication. Return the response form by email to kbarber@immucor.com OR fax to +1.262.754.1078

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 appreciate the trust and confidence you place in our products. Please contact Technical Support should you need additional information +1.855.IMMUCOR (US and Canada), or International Technical Support on +49-0-61038056100 or reach out to your local Technical Sales Specialist.

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

Sincerely,

DocuSigned by Leon Lambry



Leon Lambry

I am the author of this document
21-Apr-2023 | 3:26:38 PM EDT

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Leon Lambry

Senior Director, Quality and Regulatory Affairs

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Response Form

I verify that our facility was made aware of the voluntary field action of LIFECODES HLA-DQA1/B1 SSO Typing Kit lot 3012778	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution:	
Regulatory Agency Notification Required? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, Name and Country of Agency Notified:	Date Notified: