

URGENT: Field Safety Notice

Date: April 29, 2016

Attention: All customers using LIFECODES HLA-C eRES SSO Typing Kit
Part Number 628921
Lot Number 10235B

Issue: Possible false negative Probe result for HLA-C eRES Probes 380, 382, 384 and 385

Action: Correction

- Issued a revised EXP file
- Issued a revised threshold table
- **Users are required to download the revised files at www.immucor.com and follow the instructions provided in this notice.**

Affected Products and Lot Numbers:

Product Name	Product Number	Lot Number	Expiration Date
LIFECODES HLA-C eRES SSO Typing Kit	628921	10235B	30-SEP-2017

Description of the Issue and Associated Risk:

We have determined that the threshold set for HLA-C eRES Probes 380, 382, 384 and 385 are set high and may result in false negative probe results. The probes resolve the following CWD alleles Probe 380 resolves C*03:06, Probe 382 resolves C*12:13, Probe 384 resolves C*01:08 and Probe 385 resolves C*08:06.

The risk to the patient is considered low due to the low frequency of the alleles that are detected by these probes, the serological typing is not effected and 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.

Allele frequencies based on (www.allelefreqencies.net)

Actions to be taken by End Users (Correction Instructions):

1. The correction is made by replacing the old HLA-C eRES MATCHIT! EXP file by importing the revised MATCHIT! EXP file. The file can be accessed at

Global Site - <http://www.immucor.com/Global/Products/Pages/LIFECODES-Transplant-Products.aspx>

US Site - <http://www.immucor.com/en-us/Products/Pages/LIFECODES-Transplant-Products.aspx>

2. A message will appear asking to overwrite the existing file, click Yes. At this time, data can be analyzed with the revised EXP.

3. (OPTIONAL) Re-analyze HLA-C eRES data by performing either step a or b:

a. Manually re-import a csv file. In this case, you will be prompted to rename the session since it already exists in the database. Both sets of data are now 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.



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- 5. There is no requirement to return any kits.
- 6. Please complete Customer Response Form and Return to lifecodestechsupport@immucor.com

FILES

OLD EXP Files	REVISED EXP Files
10235B 08035C-Ce_3_21_1.exp	10235B 08035CA-Ce_3_21_1.exp
10235B 08035C-Ce_3_23_0.exp	10235B 08035CA-Ce_3_23_0.exp
OLD Threshold Table	REVISED Threshold Table
LC1235.4 HLA-C eRES Threshold Table lot 10235B	LC1235.4 HLA-C eRES Threshold Table lot 10235B Rev 1

Should you have any questions or concerns, please contact Technical Support at 855.IMMUCOR (US/CAN) or 777.225.8790 (International) or lifecodestechsupport@immucor.com. For Europe, please contact Christine Heylen at cheylen@immucor.com. We value your continued support of LIFECODES® products.

Thank you,



Susan L. Leary
Director, Quality and Regulatory Affairs