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QMS 11.18		Statement-No.: FSN-20230503 Date: 03.05.2023

Field Safety Notice

Product:	HLA-FluoGene ^{NX} Match	HLA-FluoGene ^{NX} ABCDRDQ
Lot No./ Serial No.:	T830123	T820322
Attn.:	End-User / Distributor	

Dear Ladies and Gentlemen,

The purpose of this letter is to inform you, that we created new kit files for the above-mentioned product lots.

Reason:

It was observed that the mix NX-C-41-M2 (position G11 in plate A in HLA-FluoGene^{NX} Match and HLA-FluoGene^{NX} ABCDRDQ) showed a false positive reaction in presence of the homozygous genotype C*06:02:01:01. This leads to the wrong heterozygous result C*06:02:01:01 / C*12:04:01. The latter is according to CWD-2.0 a well-documented allele.

The investigation of the cause gave the following result:

In quality controls, the affected mix has been tested more than 100 times for correct negativity. Only occasionally low background signals were observed.

Nevertheless, a complaint and internal tests later on showed high background signals with a tendency to false positivity.

Field Safety Corrective Action (FSCA):

As a correction, we changed the expected reaction behavior of the allele C*06:02:01:01 in the affected primer-probe-mix from negative to questionable in the FluoGene software. Doing this we created new kit files for the above-mentioned lots.

Direction for the user / general statement:

For further evaluation of the above-mentioned products with the respective lots, the use of the relevant new kit file is necessary.

Import of the revised kit file:

Please import the new kit file (see below) in the FluoGene Software as usual. Thereupon only the revised lot number is available to create a new job. The previous version is automatically set to inactive. Already processed analyses with the previous kit file remain untouched in the FluoGene Software.

For the Use with FGSW 1.7	Previous kit file	New kit files
HLA-FluoGene ^{NX} Match Lot T830123	T830123	T830123-1-cross-030523-HLA-NX-Match
HLA-FluoGene ^{NX} ABCDRDQ Lot T820322	T820322-3	T820322-4-cross-030523-NX-ABCDRDQ

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Impact of the new kit file on previous analyses:

In case you observed one of these results:

C*06:02:01:01 / C*12:04:01 (WD)

C*18:01:01:01 / C*12:04:01 (WD)

it is recommended to re-analyze the sample again with the new kit file. Previous analyses are not affected by the new kit file.

Distribution of this statement:

This note must be distributed to everyone who needs to be informed in their organizations and further on, to all who received the potential affected product(s).

Risk assessment:

Due to this occasionally false positive reaction in mix NX-C-41-M2, samples carrying the allele C*06:02:01:01 may be typed wrongly in case one of the above-mentioned allele combinations is displayed. In combination with other alleles, no result will be obtained.

The risk to the patient is considered low due to the low frequency of this event, 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.

Contact:

In case of questions please contact the technical support department of **inno-train** by e-mail: support@inno-train.de or by phone: +49 (0) 6173/6079-30.

We apologize for any inconvenience this may cause and thank you for your understanding.

inno-train Diagnostik GmbH



Sabine Scholz
Quality Manager



Dr. Sabrina König
Product Manager

 inno-train <small>DIAGNOSTIK GMBH</small> Niederhöchstädter Str. 62 D-61476 Kronberg / Taunus T: +49-6173-60 79 30 / F: -50	Field Safety Notice	Page 3 of 3
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Confirmation of receipt

To be filled out by the user and returned to **inno-train** within 72 hours per e-mail: order@inno-train.de or fax: +49 6173 60 79 50.

We hereby confirm the receipt of the Field Safety Notice and its comprehensibility released to

Product	Lot
HLA-FluoGene ^{NX} Match	T830123
HLA-FluoGene ^{NX} ABCDRDQ	T820322

Name: _____

Signature: _____

Title: _____

Date: _____

Institute: _____