Diagnostic Grifols, S.A
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August 8th, 2024

URGENT FIELD SAFETY NOTICE

Potential risk exists for Crossmatch results to be assigned to an incorrect recipient when using the *'Duplicate the Recipient-Donor profile assignment'* feature.

Dear Sir / Madam:

The purpose of this notification is to inform you about a potential risk identified in the Erytra-Eflexis analyzer with Software versions from 1.2.0 to 3.1.0 (included).

Product description

The following table provides detailed information about the impacted product:

Impacted Product	Product Code	Unique Device Identifier
Erytra Eflexis	210600	08436583730942

Issue description

The functionality *'Duplicate the Recipient-Donor profile assignment'* () feature is accessible from within the *Donor assignment* button (). This manual feature allows the operator to duplicate the recipient – donor(s) assignment, for the purpose of re-assigning the same donor profiles to a different recipient. Under the following specific conditions, the potential exists for the crossmatch results to be assigned to the incorrect recipient:

1. A crossmatch test has been previously executed for a recipient and at least one donor.
2. The "Duplicate the Recipient-Donor Profile Assignments" button was used to repopulate the crossmatch programming window and change the recipient information.
3. The crossmatch test result(s) for the previous recipient was/were in “Pending Validation,” “Validated,” or “Exported” status at the time the crossmatch test(s) was/were ordered for the new recipient.

When these specific conditions are met, the crossmatch test ordered for the latest recipient-donor(s) pairing will not be queued. Instead, the results from that first recipient-donor will be removed and assigned to the latest recipient-donor(s) pairing.

Risk assessment

The analyzer has the potential to assign incorrect Crossmatch results when *the 'Duplicate the Recipient-Donor profile assignment'* feature is used. An incorrect assignment of results could lead to a serious incident if a transfusion would be performed based on the incorrect results.

Crossmatch testing executed from a LIS request or any other manual assignation method are NOT

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affected. The error can only arise when the *'Duplicate the Recipient-Donor profile assignment'* feature is used to duplicate a Crossmatch test which is either in "Pending_to_validate", "Validated" or "Exported" status. If the crossmatch results of the first recipient are exported and the first recipient is no longer available on the instrument, the error does not occur.

The probability of an incorrect assignment of results in a Crossmatch test is very low as it is unusual for a Crossmatch test result to remain in the "Pending_to_Validate" or "Validated" status for an extended period of time, especially for customers utilizing the auto-validation and auto-exportation functions. Additionally, the use of *'Duplicate Recipient-Donor profile assignment'* feature is considered a minor feature because crossmatching the same donors to different recipients occurs infrequently.

This remote probability is further supported by the fact that the software versions in which it is possible for this issue to occurs have been installed in the worldwide market for 6 years and the error has never been reported.

The source of the error affecting this feature is already resolved in software version 3.2.0

Advise on action to be taken

Diagnostic Grifols recommends operators to not use the *'Duplicate the Recipient-Donor profile assignment'* feature () when running Erytra Eflexis, if version 3.2.0 is not installed.

Transmission of this Field Safety Notice

This notice needs to be provided to all individuals/stakeholders requiring awareness within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and any resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

Contact information

Please contact Grifols Technical Support or your local Technical Service representative if you have any questions or concerns regarding this communication.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

We apologize for any inconvenience that this action might cause to your laboratory.

[redacted]

Marta Genís
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Diagnostic Grifols, S.A.

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FIELD SAFETY NOTICE ACKNOWLEDGEMENT OF RECEIPT

Potential exists for Crossmatch results to be assigned to an incorrect recipient when using the 'Duplicate the Recipient-Donor profile Assignment' feature.

August 8th, 2024

Please confirm acknowledgment of this Field Safety Notice:

□ I have read and understood the contents and instructions provided in the notification letter.

Please provide the following information:

Name:_____

Position:_____

Company:_____

Address:_____

_____

Signature and Date:

PLEASE RETURN COMPLETED ACKNOWLEGDMENT FORM TO

To: Quality Compliance Department of Diagnostic Grifols

Location: Parets del Vallès, Spain

e-mail: CTSTechnical_Documentation@grifols.com