Field Safety Corrective Action (FSCA)

Reagent for ABO-RH1 grouping and RH-K phenotyping in E.M.®Technology microplate

DuoLys Kit - Lot N°468 000/ 469 000

Immediate actions required

Diagast's Ref: FSCA/2024/13 EN
April 19th 2024

Attention to: QWALYS® Users

Dear valued customer,

The following safety notice advises you with the immediate action on DuoLys kit Ref 79960 identified in the table used to determine ABO-RH1 grouping and RH-Kell phenotyping on the QWALYS® automated system.

	Lot Number	Expiration date
DuoLys kit Ref 79960	**468 000**	**31/03/2025**
	469 000	**31/03/2025**

Defect description

DIAGAST identified a failure of the brightness at the imaging level allowing the detection of empty wells on one of its production lines from 29/09/2023 until 23/02/2024. At this stage, this anomaly impacts all batches produced with the exception of batch 478000.

The incidence occurrence (empty wells) has been defined at 0.4% of microplates.

Risk for the Donors and Receivers

In the unlikely event of an empty well, the agglutination reaction can't happen due to antibody absence, therefore may potentially give a false negative reaction.

- **For ABO-RH1**, the configuration of the assay includes the forward and reverse test and the IFU states the need for the concordance between reverse and forward tests to determine the ABO group without doubt. In case of discordance, the results must not be reported. As a consequence, these lots can be used as long as the instructions in the package leaflet, and the laboratory's procedures are followed.

- **For RH-KEL phenotyping**
  - When DuoLys is used to process receiver samples, our risk analysis concluded that there is an absence of allo-immunisation risk: a false negative result would lead to a transfusion of an antigen-negative red-cell concentrate bag.
  - When DuoLys is used for blood bag group qualification, a residual risk in the RH-KEL phenotyping determination cannot be excluded. A false negative RH-KEL phenotyping result may lead to risks in case of transfusion if the antibody

screening test is negative (risk of allo-immunisation or transfusion incident for an already immunized patient).

Immediate actions

All the instructions stated in the current IFU must be followed.

- For Receivers

The microplates included in the DuoLys kits lot N° 468 000, 469 000 can be used, however:

1. For known patients, results for RH1 and RH-KEL phenotyping must match the RH1 and RH-KEL phenotype previously obtained with another lot of microplates or another technique.
2. For patient without anteriority, with only one determination with the impacted microplates:
    - Either the negative RH1 and RH-KEL are confirmed with another technique, to the lab manager's discretion. In particular, for RH1, a weak D test can be performed.
    - Or we recommend you to flag the result in your LIS regarding a potential false negative result
3. With regards to the results previously obtained with the impacted microplates, the person responsible for validating the analysis must take into account the occurrence of a potentially false negative result. We recommend to flag this result in your LIS in case of potential future discordance with the second determination.
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- For Donors

The microplates included in the DuoLys kits lot N° 468 000, 469 000 can be used if and only if :

For known donors, the previously obtained RH1 and RH-KEL phenotype results with different microplate lots or another technique MUST match with RH-KEL phenotype results obtained with the impacted microplates

Or

For new donors without historical results, the result of the RH1 and RH-KEL phenotype with the impacted microplates MUST be confirmed with another technique. Furthermore, in case RH1 negative results, a weak D test MUST be performed.

If the above requirements are not fulfilled, do not use anymore the microplates included in the DuoLys kits lot N° 468 000, 469 000 for the Donors.

For previous Donors results performed with the identified DuoLys lots, new testing MUST be carried out in case of an RH-KEL determination without historical phenotyping results or double determination performed with an another technique or another lot of microplates.

Our local Diagast representative will contact you to discuss alternative testing solutions and commercial issues on case-by-case basis.

In order to ensure the continuity of supply, other batches impacted by this safety notice will be delivered with an additional instruction integrated into the kits.

Please fill the enclosed Field Safety Corrective Action (FSCA) Response form immediately and return it by email to *hotline@diagast.com*

Our team will be at your disposal for any technical questions to +33 (0)3 20 96 53 65 or by email to *hotline@diagast.com*

Transmission of this Field safety corrective action
Please provide a copy of this notice to all individuals within your organization, as well as to any third parties with whom you interact, who may have access to or knowledge of concerned reagent.

The French Health Authorities (ANSM) has been informed with the FSCA

We fully regret any inconvenience that this action may have caused to you or your staff.

Yours faithfully,

Olivier BROLLI
DIAGAST Chief Executive Officer

Encl: hereafter, the FSCA Response Form

Field safety Corrective action (FSCA)
Response Form

Note: please fill the form even if you don't have any concerned reagents and send it back to hotline@diagast.com

Diagast's Ref°: FSCA/2024/13EN
Date: April 19th 2024

Concerned Device

Designation	Reference	Lot N°
DuoLys	**79960**	**468 000** **469 000**

Customer Information

Customer Account	
Organization Name	
Manager Name	
Adress	
Email	

We acknowledge:

- the receipt of the FSCA referenced above
- the shared information with all users of the concerned devices within our organization, as well as with any third parties to whom we may have transferred any concerned devices.

Date: Signature and organization stamp: