Field Safety Corrective Action (FSCA)

Reagent for ABO-RH1 grouping in E.M.®Technology microplate

ABD-LYS Kit – N° 281000 / 282000 / 284000 / 286000 / 287000

Immediate actions required

Diagast's Ref: FSCA/2024/14 EN
April 19th 2024

Attention to: QWALYS® Users

Dear valued customer,

The following safety notice advises you with the immediate action on **ABD-Lys** kit REF 79967 identified in the table below used to determine ABO grouping and RH1 phenotyping on the QWALYS® automated system.

Lot Number	Expiration date
281000	31/03/2025
282000	31/03/2025
284000	30/04/2025
286000	30/04/2025
287000	30/06/2025

Defect description

DIAGAST identified a failure of the brightness at the imaging level allowing the detection for 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 288000.

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.

When ABD-Lys 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 ABD-Lys is used for blood bag group qualification, a residual risk in the group determination cannot be excluded in the rare case of concordance between the reverse and forward typing reactions for a A2 group or for any other weak A group. The risk is increased with the absence of the specific anti-AB well in the ABD-Lys microplates.

Immediate actions

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

- For Receivers

The microplates included in the ABD-Lys kits lot N° 281000 / 282000 / 284000 / 286000 / 287000 can be used, however:

1. For known patients, the results of the determination of ABO and RH1 obtained with the concerned microplates must correspond to the historical results of the determination of ABO and RH1 obtained with different batches of microplates or another technique

2 For patients without prior history and for whom a single determination would be made with the impacted microplates
   - Either the ABO-RH1 results can be confirmed by another technique at the discretion of the biologist. In particular, for RH1, a weak D test can be performed.
   - or we recommend that you flag the result in your LIS regarding a potential false negative result.

3 With regard to the results previously obtained with the impacted microplates, the person responsible for validating the analysis must take into account the occurrence of this potentially false negative result. We recommend that you flag the results in your LIS to include a comment mentioning a potential false negative result for the sample, to facilitate interpretation in the event of a potential future discrepancy with the second determination.

- For Donors

The microplates included in the ABD-Lys kits lot N° 281000 / 282000 / 284000 / 286000 / 287000 can be used if and only if:

- For known donors, the historical ABO and RH1 determination results obtained with different Microplate lots match with ABO and RH1 determination results obtained with the concerned microplates or another technique

or

- Another technique is performed to confirm the blood bag group before any transfusion,

and

- A Cross Match test able to detect the ABO incompatibility between donor and receiver is performed

Furthermore, in case of RH1 negative result, a weak D test MUST be performed.

If the above requirements are not fulfilled, do not use anymore the microplates included in the ABD-Lys kits lots N° 281000 / 282000 / 284000 / 286000 / 287000 for the Donors.

In the specific case of the historical group results coming solely from a test performed with one of the impacted ABD-Lys lots, with no other data, no other determination with another technique and no group confirmation practices for blood bags, new testing MUST be carried out.

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.

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

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/2024/14EN
Date: April 19th 2024

Concerned Device

Designation	Reference	Lot N°	GMDN
ABD-Lys	79967	**281000** **282000** **284000** **286000** **287000**	45308

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: