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DIAGAST

Field Safety Corrective Action (FSCA)

ADDITIONAL INSTRUCTIONS OF IFU DIA04312

Reagent for ABO-RH1 grouping

E.M.®Technology microplate – Groupa 2 Lys 79964

Immediate actions required

Diagast's Ref: add - FSCA/2024/16
April 26th 2024

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.

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**, 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, the lot can be used as long as the instructions in the package leaflet, and the laboratory's procedures are followed.

- **For RH1**, the configuration of the assay includes two wells with different anti-D. The IFU states that if there is no agglutination, the absence of weak or partial D -RH1 antigen must be confirmed with a weak D test:

  - When Groupa 2 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 Groupa 2 Lys is used for blood bag group qualification, a false negative RH1 phenotyping result may lead to risks in case of transfusion to a RH1 negative patient

By this information added in the packaging, we would like to inform you that the following batch of Groupa 2 Lys 79964

Lot N°	Expiry date
105000	**30/06/2025**

can be used if the additional instructions of IFU DIA04312 are applied as followed:

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Immediate actions

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

➢ For Receivers

The microplates included in the Groupa 2 Lys kits **lot 105000** can be used, however:

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

2. For patients without history and for whom a single determination would be made with the concerned microplates, and both results with the anti-D are negative
   - Either the RH1 results can be confirmed with others reagents, at the discretion of the biologist, intended in the search of antigens weak D.
   - Or we recommend you to include a comment in your LIS regarding a potential false negative result.

3. With regards to the results previously obtained using the impacted batch, 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 with 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 Groupa 2 Lys kits **lot 105000** can be used if and only if :

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

or

- For new donors without historical results, in case of negative results with both anti-D, the results MUST be confirmed with others reagents intended in the search of antigens weak D.

In the specific case of the historical group results coming solely from a test performed with the impacted Groupa 2 Lys kits, with no other data, no other tests with another technique in case of negative results with both anti-D, new testing MUST be carried out for the donors.

If the above requirements are not fulfilled, do not use the microplates included in Groupa 2 Lys kits lot 105000 anymore for the Donors

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

Our team will be at your disposal for any technical questions by email to hotline@diagast.com

Instruction available in your language with this QR code

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Instrucciones disponibles en tu idioma con este código QR

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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*/2024/16-EN*
Date: April 26th 2024

Concerned Device

Designation	Reference	Lot N°
Groupa 2 Lys	79964	**105 000**

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:

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