



DIAGAST

ADDITIONAL INSTRUCTIONS OF IFU DIA04312

Reagent for ABO-RH1 grouping and RH-KEL phenotyping

E.M.®Technology microplate - DUOLYS 79960

Immediate actions required

Diagast's Ref: add - FSCA/2024/13- ICN FR

Monday, April 22nd 2024

Following the FSCA/2024/13 – ICN FR about the following batches of DUOLYS reference 79960:

Lot N°	Expiry dates
468 000	31/03/2025
469 000	31/03/2025

By this information added in the packaging, we would like to confirm you that the following batch of DUOLYS

Lot N°	Expiry dates
476000	30/06/2025
477000	31/07/2025

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

➤ For Receivers

- 1) For known patients, the results of the determination of RH1 and RH-KEL phenotyping obtained with the impacted microplates must match with the historical results of the determination of RH1 and RH-KEL phenotyping 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 RH1 and RH-KEL results are 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, using 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 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

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- 1) For known donors, the historical RH1 and RH-KEL determination results obtained with different microplate lots must match with RH1 and RH-KEL determination results obtained with the concerned microplates or another technique

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 of RH1 negative result, a weak D test **MUST** be performed.

If the above requirements are not fulfilled, do not use these impacted DUOLYS microplates anymore.

- 2) For previous Donors results performed with the identified DUOLYS lots, new testing **MUST** be carried out in case of RH-KEL determination without historical phenotyping results or second determination performed with an another technique or another batch of microplates.

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

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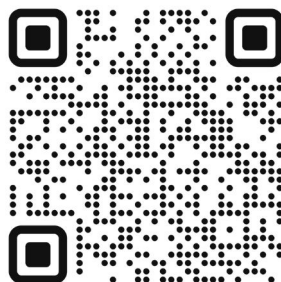
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