Diasorin

Urgent Field Notice

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Commercial name of the affected product: LIAISON® Rubella IgM

FCA-identifier FN-200326

Type of action: Field Corrective Action

Date: 2026-03-20

Details on affected device:
Product: LIAISON® Rubella IgM
Part number: 310730
Lot: 316026 (exp. date: 2027-04-29)

Description of the problem:

Our records indicate that you have received lot 316026 of the LIAISON® Rubella IgM product.

DiaSorin has identified a documentation omission related to the lot mentioned above: the Note for the User (NFTU) 300/001-554, which should have been included inside the kit packaging, was missing.
The NFTU provides the dedicated ranges to be applied when "LIAISON® Rubella IgM kit lot is used in conjunction with LIAISON® Control Rubella IgM ([REF] 310731) lot No. 058054, 058055, 058056 and lot No. 058057".

If the standard label ranges are applied instead of the ones implemented with NFTU, there is a potential risk of obtaining Positive Control results out-of-range low. In case of an Invalid Run, patients' results cannot be reported.

Therefore, no patient health risk is associated with this omission.

To avoid the inconvenience of potential invalid runs, the NFTU document is attached to this notification for your immediate reference and use.

Advise on action to be taken by the user:

Please refer to the appropriate ranges for the relevant kit-controls combinations as reported in the NFTU attached to this notification.

No retesting of patients' samples is required.

Transmission of this Field Notice:

Please forward this communication to all those required individuals within your organisation or to any organisation where the potentially affected devices have been distributed.

Please send a confirmation e-mail that all your customers have been informed.

Contact reference person:

Name:

Organisation:

Address:

Contact details:

Signature _____