Urgent Field Notice

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Commercial name of the affected product:
LIAISON® 25 OH Vitamin D TOTAL Assay (REF310600)
LIAISON® 25 OH Vitamin D TOTAL Assay 200 (REF318360)

FCA-identifier: 2023-03

Type of action: Field Corrective Action

Date: 3 Mar 2023

Attention: Distributor

Details on affected device:

LIAISON® 25 OH Vitamin D TOTAL Assay
LIAISON® 25 OH Vitamin D TOTAL Assay 200

Part Number 310600/318360
Lot Numbers: All lots
Expiry Date: N/A

Description of the problem:

DiaSorin has determined that the bias between plasma and serum samples is greater than stated in the Instructions for Use (IFU) for the LIAISON® 25 OH Vitamin D TOTAL Assays, REF 310600 and REF 318360. The IFU includes a statement in Section 8.0, Specimen Collection and Preparation, that “Human plasma collected in EDTA or lithium heparin tube types reported a mean bias of 22% versus serum.”

Impact:

- The use of EDTA-plasma or lithium heparin plasma specimen types will be removed from the LIAISON® 25 OH Vitamin D TOTAL kit Instructions for Use.
- The risk to health is considered to be low as the likelihood of adverse health consequences is remote. Healthcare providers take into account the patient history, clinical examination and all available test results when making diagnosis and management decisions related to Vitamin D status and associated conditions.

Advise on action to be taken by the user:

- **Do not test specimens collected in EDTA-plasma or lithium heparin plasma tube types using the LIAISON® 25 OH Vitamin D TOTAL kits.**
- Serum specimens can continue to be used to test and report patient results.

- Please share this information with your Laboratory Medical Director and anyone in your facility that may be impacted by this notice.

- Due to the low health risk, retesting of previously reported results from samples collected in EDTA-plasma or lithium heparin plasma tube types is not recommended.

Transmission of this Field Notice: (if appropriate)

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

Maintain a record of this notice and associated actions for an appropriate period to ensure effectiveness of the corrective action.

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