Urgent Field Notice

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Commercial name of the affected product: LIAISON® Aldosterone

FCA-identifier: FN- 2023-04

Type of action: Field Corrective Action

Date:

Details on affected device:
LIAISON® Aldosterone
REF 310450
Lot 136062, 136062A
Expiry date: 2023-07-07

Description of the problem:

DiaSorin has become aware that the above lots may produce a positive shift in patient results and additionally, invalid calibrations due to a failing Geometric Curve Check (GCC) may occur.

- For samples reading within the normal range (less than 39.2 ng/dL), an average increase of 2.66 ng/dL was observed.
- For samples reading above the normal range (> 39.2 ng/dL), an increase of 11% was observed.
- The Passing-Bablok slope is 1.06 against DiaSorin assigned means when using all samples.

Our records indicate that you have received one or more of these kits.

Impact:

The risk to health is low as it is not likely to cause adverse health consequences and healthcare providers use LIAISON® Aldosterone assay results in conjunction with information obtained from the patients' clinical evaluation and other diagnostic procedures.

Action to be Taken:

- Please stop using the affected lots. DiaSorin will provide replacement product.
- Due to low health risk, review of previously reported results is not recommended.

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.

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

Contact reference person:

Name

Organisation

Address

Contact details

Signature _____