

Urgent Field Safety Notice

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Commercial name of the affected product: LIAISON® 1-84 PTH Assay

FSCA-identifier-: FSN-271120

Type of action: Advice provided by the manufacturer regarding the use of the product already on the market

Date: November 25, 2020

Details on affected device:

- LIAISON® 1-84 PTH Assay
- Part No. 310630
- Lot No. 134909, 134909A and 134909B
- Expiry date: February 24, 2021

Description of the problem:

DiaSorin has confirmed that the LIAISON® 1-84 PTH Assay (REF 310630) lot numbers 134909, 134909A and 134909B, may produce falsely elevated patient results. The affected lots were performing as expected upon release. The performance of the assay has changed over time and customers may not have experienced any shift in patient results. The probability of temporary adverse health consequences is remote.

DiaSorin continues to investigate this problem, which is believed to be isolated to a specific lot of raw material. No other lots of the LIAISON® 1-84 PTH Assay have used this lot of raw material or have exhibited this problem.

Advise on action to be taken by the user:

Recommended actions:

- Stop using the LIAISON® 1-84 PTH Assay (REF 310630) lot numbers 134909, 134909A, 134909B, and destroy any remaining inventory. A new lot is available.
- No recommendation with respect to review and follow up of patient results is provided due to the low risk to patient. Laboratories should follow their own procedures and policies for the review and evaluation of previous results.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Contact reference person:

Name: Kym Pieper Director, Quality Assurance

Organisation: DiaSorin Inc.

Address: 1951 Northwestern Avenue P.O. Box 285, Stillwater MN 55082

Contact details: Office: 651-351-5861, Fax: 651-351-5669 kym.pieper@diasorin.com

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Signature *Kym Pieper* 25 NOV 2020



The section B has to be filled in by the customer and returned to DiaSorin Inc. US

SECTION A

RETURN TO THE e-mail/fax: kym.pieper@diasorin.com

ATTN: Kym Pieper

OR RETURN BY MAIL TO: DiaSorin Inc.

ATTN: Kym Pieper

1951 Northwestern Ave. P.O. Box 285

Stillwater, MN 55082-0285

Product: _____

Kit Lot: _____

NAME: _____

INSTITUTION: _____

No Kits you should have received: _____

SECTION B (Please use capital letters)

KITS USED, No: _____

KITS REMAINING, No _____ KITS DESTROYED, No _____

KITS SENT BACK TO _____, No _____

DATE: _____

SIGNATURE: _____

SEAL: _____