DiaSorin

Urgent Field Safety Notice

Commercial name of the affected product: LIAISON® Measles-IgM (318820)

FCA-identifier (e.g. date): FN-200731

Type of action (e.g. definition of a FSCA):
Stop using the 174026 lot on the LIAISON® Analyzer family.

Date: 2020.07.31

Attention:

Details on affected device: LIAISON® Measles IgM
Catalog Number: 318820
Lot Number: Lot 174026 - **Expiry date:** 2021/08/08

Description of the problem:

DiaSorin S.p.a. internal testing confirmed, for the lot in object, a reduction of index value of samples. Such decrease could lead to the risk of False Negative results classification in a limited number of tests on samples having low Measles virus IgM concentration, closer to the assay Cut-Off (i.e. Index 1.0).

The root cause of the problem has not yet been clearly identified, but DiaSorin S.p.a. is actively working to solve the issue and a new lot of LIAISON® Measles IgM, performing within specifications, will be soon available.

Advise on action to be taken by the user:

We recommend that you, please, **stop using this lot of LIAISON® Measles IgM kit on LIAISON Analyzer Family and destroy any remaining inventory.**
A new LIAISON® Measles-IgM (318820) Lot will be soon available for free of charge replacement.

Due to the qualitative determination of the Measles IgM, obtained positive results are not affected. There is no risk to patient health since even in case of reported negative classification: a negative result for Measles IgM does not always rule out acute measles virus infection.
Based on previous statement, no action is required for previously reported results.

As reported in the § 14 INTERPRETATION OF RESULTS of the product IFU, *the infection could be in its very early stage and the patient may be still unable to synthesize measles virus specific IgM. If clinical exposure to measles virus is suspected despite a negative finding, a second sample should be collected and tested no less than one or two weeks later*.

Please, contact your DiaSorin Representative for further information.

Transmission of this Field Notice: (if appropriate)
Please forward this communication to all the 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 and send us Page 3/3 that has to be filled in by the customer.

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

Contact reference person:

Name:

Organization:

Address:

Contact details:

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

Signature _____

The section B has to be filled in by the customer and returned to _____
(please indicate your site)

SECTION A

RETURN TO THE e-mail/fax: _____

(please indicate e-mail/fax address of the person in charge of collecting the info).

ATTN: _____(Please indicate the name of the person in charge of collecting the info)

OR RETURN BY MAIL TO:_____ (please indicate your site).

ATTN: _____ (Please indicate the name of the person in charge)

_____

(please indicate your site address)

Product: _____

Kit Lot: _____

NAME: _____

INSTITUTION: _____

Number of Kits you should have received : _____

SECTION B (Please use capital letters)

KITS USED, Number: _____

KITS REMAINING, Number: _____. **This kits quantity has been destroyed.**

DATE: _____

SIGNATURE: _____

SEAL: _____