DiaSorin The Diagnostic Specialist

DiaSorin S.p.A.
Via Crescentino, snc
13040 Saluggia (VC) Italy
tel. +39 / 0161.487093
fax +39 / 0161.487628
www.diasorin.com

Urgent Field Safety Notice

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Commercial name of the affected product: LIAISON® Borrelia IgG

FSCA-identifier (e.g. date): FSN-181114-1

Type of action (e.g. definition of a FSCA): In Field Safety Corrective Action to remove the affected device.

Date: **November 18 th, 2014**

Attention: Stop the use and remove the affected devices.

Details on affected device:
Type of device: In Vitro Diagnostic Medical Device
Model name: **LIAISON® Borrelia IgG**
Part number: **310880**
Batch/serial number: **089054X, 089054X/1, 089054X/2**
Expiry date: ***January 9, 2016 for all three lots***

Description of the problem:
Invalid calibrations may be obtained with the above mentioned lots due to the Calibrator 1 Deviation percentage [%] out of the high limit or due to the GCC (Geometrical Curve Check) out of range.
As a consequence the calibration cannot be validated and the testing with these lots on the analyzer cannot be performed.
Results obtained with a valid calibration have to be considered reliable; therefore, review of past patients results is not deemed necessary.

Advise on action to be taken by the user:
- We recommend to stop using the affected product lots.
- The affected lots must be identified and discarded.
- Fill the confirmation form to be sent back to the manufacturer

DiaSorin is offering free of charge replacement product.

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.

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Contact reference person:

Name: Rita Maffei

Organisation: DiaSorin S.p.A

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13040 Saluggia (VC) Italy

Contact details: E-mail: rita.maffei@diasorin.it
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature _____

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

Product: _____

Kit Lot: _____

RETURN TO FAX No: +xx.xxxx.xxx.xxx
ATTN: _____
(Please indicate the name of the person in charge)

RETURN BY MAIL TO: _____ (please indicate your site).
ATTN: _____ (Please indicate the name of the person in charge)
_____ (please indicate your site address)
_____ (please indicate your site address)

(Please use capital letters)

NAME: _____

INSTITUTION: _____

KITS USED, No: _____

KITS REMAINING, No _____

□ KITS DESTROYED, No _____

□ KITS SENT BACK TO _____, No _____

DATE: _____

SIGNATURE: _____

SEAL: _____