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

The Diagnostic Specialist

Urgent Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected product: LIAISON® Tg
FSCA-identifier: July 10th, 2014

Type of action (e.g. definition of a FSCA): In Field Safety Corrective Action to destroy remaining inventory

Date: **July 10th, 2014**

Attention: Immediately stop using the below reported device and destroy any remaining inventory.

Details on affected device:
Type of device: In Vitro Diagnostic Medical Device
Model name LIAISON® Tg *Catalog* – 311861
Batch/serial number 344161X
Expiry date: 2015-03-30

Description of the problem:
Internal testing showed that with LIAISON® Tg (311861) Lot 344161X an overestimation on thyroidectomized patient samples can be observed.

Advise on action to be taken by the user:
- Stop using the device
- Identify and dispose the device.
- Fill the confirmation form to be sent back to the manufacturer.
- This notice should be reviewed with the facility's laboratory director or medical director.

Transmission of this Urgent 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: Antonella Fassio

Organisation: DiaSorin S.p.A

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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 DiaSorin

Product: _____

Kit Lot: _____

RETURN TO FAX No:

RETURN BY MAIL TO:

(Please use capital letters)

NAME: _____

INSTITUTION: _____

KITS USED, No: _____

KITS REMAINING, No _____

- ☐ KITS DESTROYED, No _____
- ☐ KITS SENT BACK TO DiaSorin S.p.A, No _____

DATE: _____

SIGNATURE: _____

SEAL: _____