

Urgent Field Safety Notice

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Commercial name of the affected product: LIAISON[®] Calprotectin

FSCA-identifier: FSN-090315-1

Type of action: Customer notification of error in the German language Instructions for Use

Details on affected device:

LIAISON[®] Calprotectin

Part Number – 318960

Lot Number – 131747XA

Expiry Date – 2015/11/04

Description of the problem:

The German language translation of the Instructions for Use contains an error in Section 13. SPECIMEN EXTRACTION, METHOD 1: Weighing Protocol, procedure step number 9. The quantity of extraction buffer required is incorrect. The German translation states 800 µl instead of 850 µl of extraction buffer for the final dilution step. The diagram for the Stool Weigh Method on page 13 is correct in the German language Instructions for Use. Results obtained using Method 1 to extract the specimen are incorrect while results obtained using Method 2 are considered reliable.

Advise on action to be taken by the user:

- Please inspect your inventory for the affected kit lot.
- A corrected Instructions for Use (IFU) is attached.
- Complete the confirmation form and return to the manufacturer.
- Patient results obtained using Method 1 Weighing Protocol, in the German language Instructions for Use should be retested.

Transmission of this Field Safety Notice: (if appropriate)

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

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

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

The logo for DiaSorin, consisting of the word "DiaSorin" in white text on a blue square background.

Contact reference person:

Name: Rita Maffei

Organisation: DiaSorin S.p.A

Address: Via Crescentino s.n.c.
13040 Saluggia (VC) Italy

Contact details: E-mail: rita.maffei@diasorin.it
Tel. +39.0161.487.849

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: _____

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: _____