
Urgent Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected product: LIAISON® Control anti-HBc
FSCA-identifier (e.g. date): December 18th, 2013

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

Date: December 18th, 2013

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® Control anti-HBc Catalog – 310131

Batch/serial number 068033X and 068033X/1

Expiry date: February 18th, 2014

Description of the problem:

Internal testing confirmed that an increased frequency of control positive values recovering out of the defined limit may occur when running the LIAISON® Control anti-HBc lot n. 068033X. As a consequence the run cannot be validated.

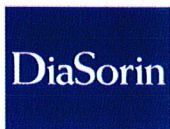
Advise on action to be taken by the user:

- Stop using the device
- Identify and dispose the device.
- Fill the confirmation form to be sent back to the manufacturer

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.



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

Contact reference person:

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Organisation: DiaSorin S.p.A

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13040 Saluggia (VC) Italy

Contact details: E-mail: antonella.fassio@diasorin.it
Tel. +39.0161.487.849

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 S.p.A.

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: _____