
Urgent Field Safety Notice

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Commercial name of the affected product: LIAISON® XL Murex HBsAg Quant

FSCA-identifier (e.g. date): September 9th, 2013

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

Date: September 9th, 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® XL Murex HBsAg Quant Catalog – 310250

Batch/serial number #132014X, 132014X/1, 132014X/2

Expiry date: December 17th, 2013

Description of the problem:

Through internal testing, DiaSorin has confirmed that one component of the kit lot, usable on the LIAISON® XL Analyzer only, may show a cloudy appearance.

Advise on action to be taken by the user:

- Stop using the device
- Identify and dispose the device
- Based on internal testing and a health risk assessment, review of initially reactive patient results is not considered necessary if the diagnostic algorithm prescribed in the Instruction For Use has been followed.
- 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.

Contact reference person:

Name: Antonella Fassio

Organisation: DiaSorin S.p.A

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

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: _____