
Field Safety Notice

Field Safety Notice**Commercial name of the affected product: Liaison[®] Biotrin Control Parvovirus B19 IgM****Part No: 317011****FSCA-identifier: November 22, 2013**

Type of action : When LIAISON[®] Biotrin Control Parvovirus B19 IgM (317011 - lots n°130010X, 130010X/1, 130011X, 130011X/1, 130012X, 130012X/1 and 130012X/2 are used on Liaison XL platform in combination with Liaison[®] Biotrin Parvovirus B19 IgM (317010) kit lots n° 129019X and 129019X/1 adopt a new Negative Control range reported in the revised Certificate of Analysis.

Date: November 22, 2013

Attention: When LIAISON[®] Biotrin Control Parvovirus B19 IgM (317011 - lots n°130010X, 130010X/1, 130011X, 130011X/1, 130012X, 130012X/1 and 130012X/2 are used on Liaison XL platform in combination with Liaison[®] Biotrin Parvovirus B19 IgM (317010) kit lots n° 129019X and 129019X/1 adopt a new Negative Control range reported in the revised Certificate of Analysis. The revised Certificate of Analysis are attached and have been loaded on the Dialog area of the www.diasorin.com web-site.

Details on affected device:*Type of device: In Vitro Diagnostic Medical Device**Model name: Liaison[®] Biotrin Parvovirus B19 IgM, kit lot Catalog – 317011**Batch/serial number: 130010X, 130010X/1, 130011X, 130011X/1, 130012X, 130012X/1 and 130012X/2**Expiry date: December 1st, 2013 for lots 130010X, 130010X/1, 130011X, 130011X/1
October 2nd, 2014 for lot 130012X, 130012X/1, 130012X/2***Description of the problem:**

Internal investigation confirmed that the Certificates of Analysis of the Liaison[®] Biotrin Control Parvovirus B19 IgM (P/N 317011), lots n° 130010X, 130010X/1, 130011X, 130011X/1, 130012X, 130012X/1 and 130012X/2 are reporting an incorrect Negative Control range for the LIAISON XL application, when used in combination with Liaison[®] Biotrin Parvovirus B19 IgM (317010) kit lots n°129019X and 129019X/1.

The Negative Control range for these lots of Liaison[®] Biotrin Control Parvovirus B19 IgM should be 0.0-0.5 Index instead of 0.0-0.3 Index as previously reported in the incorrect Certificate of Analysis.

Advise on action to be taken by the user:

- The affected lots can confidently be used on Liaison platform without any change of the Negative Control range

- We recommend to modify the Negative Control range of LIAISON® Biotrin Control Parvovirus B19 IgM (317011) kit lot n° 130010X, 130010X/1, 130011X, 130011X/1, 130012X, 130012X/1 and 130012X/2 when used in combination with LIAISON® Biotrin Parvovirus B19 IgM (317010, lots n°129019X and 129019X/1 on Liaison XL platform. Negative Control range should be 0.0-0.5 Index instead of 0.0-0.3 Index. The revised Certificates of Analysis are attached and loaded in the Dialog area of the www.diasorin.com web site.
- Fill the following confirmation form to be sent back to the manufacturer

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.

Contact reference person:

Name: Antonella Fassio

Organisation: DiaSorin S.p.A

Address: Via Crescentino s.n.c.
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 _____



The Diagnostic Specialist

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www.diasorin.com

This section has to be filled in by the customer and returned to DiaSorin

RETURN TO FAX No:

RETURN BY MAIL TO:

(Please use capital letters)

NAME: _____

INSTITUTION: _____

Acknowledgement of receipt

Of the Field Safety Corrective Action dated **November 22, 2013** for the adoption of modified Controls range on LIAISON XL platform only.

LIAISON[®] Biotrin Control Parvovirus B19 IgM *Catalog* 317011

Lot No. _____

DATE: _____

SIGNATURE: _____

SEAL: _____