Rev 1: September 2018

FSN Ref: FSN-050625 FSCA Ref: FSN-050625

Date: 05.06.2025

Urgent Field Safety Notice
LIAISON® Biotrin Parvovirus B19 IgM

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
LIAISON® Biotrin Parvovirus B19 IgM
Potential False Negative Results

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Immunoassay for the qualitative determination of specific IgM antibodies to parvovirus B19 in human serum or plasma samples.
1.	2. Commercial name(s)
	LIAISON® Biotrin Parvovirus B19 IgM
1.	3. Unique Device Identifier(s) (UDI-DI)
	08056771101165
1.	4. Primary clinical purpose of device(s)*
	The LIAISON® Biotrin Parvovirus B19 IgM assay uses chemiluminescence immunoassay (CLIA) technology for the in vitro qualitative determination of specific IgM antibodies to parvovirus B19 in human serum or plasma samples. The assay is intended as an aid to determine the serological status of individuals including pregnant women and children younger than 14 years and as an aid in the diagnosis of acute and past Parvovirus infection.
1.	5. Device Model/Catalogue/part number(s)*
	317010
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Lot 129080 (expiry date: 14.12.2025)
1.	8. Associated devices
	The test has to be performed on the LIAISON® Analyzer family.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Invalid calibrations or Positive Control out of range Low due to a drop in integral reactivity (signal, RLU). If after obtaining a valid calibration and a valid run by testing calibrators and Kit Controls right after integral shaking as per IFU, the kit is stored on-board of the instrument, there is a potential risk for obtaining False Negative results on daily routines.
2.	2. Hazard giving rise to the FSCA*
	The severity for False Negative results is Critical as there is the potential for delayed or no treatment for a not recognized hazardous status. In particular, an acute infection would be not recognized, therefore no further treatment of patient, particularly severe in case of Parvovirus B19 IgM negative result on pregnant women, where it could lead to fetal hydrops / severe anemia, on immunocompromised patients or individuals with underlying haemolytic disorders.
2.	3. Probability of problem arising
	The probability is considered Occasionally, as the reactivity drop could occur every time the integral is stored on-board of the instrument, but it can be mitigated when the users run Kit Controls alongside samples on the same integral.
	4. Predicted risk to patient/users
	The False Negative result severity is considered critical; the probability of occurrence is occasionally. The overall resulting risk is therefore considered MAJOR.

2.	5. Further information to help characterise the problem
	n.a.
2.	6. Background on Issue
	The root cause is under investigation and it is probably linked to a decreased reactivity of the component Conjugate.
2.	7. Other information relevant to FSCA
	n.a.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Destroy Device (Stop to use) ☒ Follow patient management recommendations ☐ Other ☐ None Re-evaluate the negative results obtained with this lot of product, considering that, as reported in the IFU, a negative result for IgM antibodies to parvovirus B19 generally indicates that the patient has not been infected, but does not exclude the possibility of acute parvovirus B19 infection.	
3.	2. By when should the action be completed?	The re-evaluation of the negative results should be done as soon as possible, but not later than one month from the notification.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes If clinical exposure to parvovirus B19 is suspected despite a negative finding, a retest with a different lot should be evaluated, especially on pregnant women, immunocompromised patients or individuals with underlying haemolytic disorders.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☒ Product quarantine ☐ Other ☐ None The residual stock of the impacted lot still at manufacturer's warehouse was quarantined. The distributed units are to be recalled.	
3	6. By when should the action be completed?	The quality hold of the residual stock was already done. The recall action has to be completed within one month from the notification.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	DiaSorin Italia S.p.A.
	b. Address	Via Crescentino snc, 13040 Saluggia (VC) Italy
	c. Website address	https://int.diasorin.com/en
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.