FSCA ID Ref: FSN-110324

Date: 11.03.2024

Urgent Field Safety Notice
LIAISON® BRAHMS PCT® II GEN

For Attention of*: Final customer

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

Urgent Field Safety Notice (FSN)
LIAISON® BRAHMS PCT® II GEN (318040)
Instructions For Use (IFU) error on matrices list

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Immunoassay for the in vitro quantitative determination of Procalcitonin in human serum and plasma specimens.
1.	2. Commercial name(s)
	LIAISON® BRAHMS PCT® II GEN
1.	3. Unique Device Identifier(s) (UDI-DI)
	08056771101301
1.	4. Primary clinical purpose of device(s)*
	LIAISON® BRAHMS PCT® II GEN assay uses chemiluminescence immunoassay (CLIA) technology for the in vitro quantitative determination of Procalcitonin in human serum and plasma specimens. Used in conjunction with other laboratory findings and clinical assessments, LIAISON® BRAHMS PCT® II GEN assay is intended for use as follows: – The early detection and differential diagnosis of clinically relevant bacterial infections.– The assessment of the degree of severity and the prognosis of the outcome of systemic bacterial infection, sepsis, severe sepsis and septic shock.– Identifying patients that benefit from antibiotic treatment.– Monitoring of antibiotic therapy within the measuring range.– The assessment of successful antibiotic therapy in patients with suspected or confirmed bacterial infection.
1.	5. Device Model/Catalogue/part number(s)*
	318040
1.	6. Software version
	n.a.
1.	7. Affected serial or lot number range
	Lot 239036; expiry date: 24.09.2025
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*
	In the Istructions for Use (IFU) associated to the lot 239036 there is an error in the list of the validated matrices that can be used with this assay; in particular potassium oxalate and sodium heparin plasma are erroneously indicated as possible matrices.
2.	2. Hazard giving rise to the FSCA*
	Regarding sodium-heparin, the counter ions of the heparin salt are not considered to have a significant impact on the assay functionality; on the contrary, we cannot exclude any residual risk of an incorrect result obtained with the potassium-oxalate matrix. Although assay results should be interpreted taking into consideration the patient's history and other diagnostic evidence, we cannot exclude that a potentially incorrect dose may have limited health consequences for patients' results. Therefore, a safety action in field is deemed necessary to ensure that Customers repeat testing of all patients whose samples were collected in potassium-oxalate tubes and that they should refer to the available correct version of the IFUs.

2.	3. Probability of problem arising
	The probability is rarely since no events nor requests of information on the matrices list were registered in field.
2.	4. Predicted risk to patient/users
	The Incorrect dose severity is considered critical; the probability of occurrence is rarely. The overall resulting risk is therefore considered LOW.
2.	5. Further information to help characterise the problem
	n.a.
2.	6. Background on Issue
	The root cause of the issue is under investigation and is probably linked to a human error that occurred during the documentation revision of the IFUs.
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*** ☒ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) If some tests were performed on potassium oxalate samples, repeat the tests on a patient sample taken with a correct matrix.		
3.	2. By when should the action be completed?	The verification of potential results obtained on potassium oxalate samples should be done by the customer within 1 month from the notification. At the same time the acknowledgement to refer to the new IFUs has to be done also within 1 month.	
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Only related to results obtained with the potassium oxalate matrix		
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes	
3.	**5. Action Being Taken by the Manufacturer** ☒ IFU or labelling change Correct IFUs available on Dialog		
3	6. By when should the action be completed?	Already done	
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:	Correct version of the IFUs
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.