FSCA ID Ref: FSN-2024-02

Date: 29Jul2024

Urgent Field Safety Notice
LIAISON® Testosterone xt

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

Urgent Field Safety Notice (FSN)

LIAISON® Testosterone xt

Serious injury could occur due to the failure mode associated with this recall

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	A direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL Analyzer
1.	2. Commercial name(s)
	LIAISON® Testosterone xt
1.	3. Unique Device Identifier(s) (UDI-DI)
	80567713184105D
1.	4. Primary clinical purpose of device(s)*
	The assay is intended for in vitro diagnostic quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL Analyzer.
1.	5. Device Model/Catalogue/part number(s)*
	Part Number: 318410
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	136248, 136663, 136663A, 136842, 136981, 136981A, 136981B
1.	8. Associated devices
	LIAISON® XL Analyzer.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	DiaSorin has determined that the affected kit lots of LIAISON® Testosterone XT may produce falsely low results in samples below 2 ng/mL. Median values below 2 ng/mL show a negative bias to the median values listed in the IFU. The negative bias in samples below 2 ng/mL may impact interpretation of results relative to the reference range claims for the adult female populations and pediatric populations.
2.	2. Hazard giving rise to the FSCA*
	Samples below 2 ng/mL show a negative bias causing the potential for false low patient test results.
2.	3. Probability of problem arising
	All of the affected lots have the potential to exhibit the product problem.
2.	4. Predicted risk to patient/users
	A falsely low patient result may cause serious adverse health consequences but the probability is remote. The risk to health is considered low due to intervention by healthcare providers who take into account patient history, clinical examination and other studies to make diagnoses and patient management decisions. Other testing may be conducted to rule out possible alternative diagnoses, especially if symptoms are unusual, debilitating and/or prolonged.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Customer complaints were received alleging failed external quality control samples and unexpected low patient test results. Diasorin's internal investigation confirmed that samples below 2 ng/mL have a negative bias which is outside of the expected performance of the assay for the identified kit lots.
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*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Patient test results below 2ng/mL should be reviewed.	
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 ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None All remaining inventory of the affected kits lot has been quarantined at the manufacturing site and Diasorin distributor sites.	
3	6. By when should the action be completed?	Immediately
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.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Diasorin Inc.
	b. Address	1951 Northwestern Ave. Stillwater MN 55082
	c. Website address	Diasorin.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	Kym Pieper Director, Quality Assurance
		[redacted]

	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.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2024-02
FSN Date*	29Jul2024
Product/ Device name*	LIAISON® Testosterone xt
Product Code(s)	318410
Batch/Serial Number (s)	136248, 136663, 136663A, 136842, 136981, 136981A, 136981B

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	

☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	29Aug2024

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.