Date: 17OCT2025

Urgent Field Safety Notice
LIAISON® C. difficile Toxins A&B

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

Company Name/Logo

Urgent Field Safety Notice (FSN)
LIAISON® C. difficile Toxins A&B
Temporary or medically reversible adverse health consequences.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The DiaSorin LIAISON® C. difficile Toxins A&B Assay is a chemiluminescent immunoassay (CLIA) intended for the qualitative determination of Clostridium difficile toxins A and B in human feces on the LIAISON® Analyzer family
1.	2. Commercial name(s)
	LIAISON® C. difficile Toxins A&B
1.	3. Unique Device Identifier(s) (UDI-DI)
	08056771600477
1.	4. Primary clinical purpose of device(s)*
	Qualitative determination of Clostridium difficile toxins A and B in human feces
1.	5. Device Model/Catalogue/part number(s)*
	Part Number 318900
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot Number 137454
1.	8. Associated devices
	LIAISON Analyzer Family

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The potential for false positive patient test results.
2.	2. Hazard giving rise to the FSCA*
	A false positive test result may cause the patient to receive the incorrect treatment. Patients may not be tested for other causes of their symptoms or receive unnecessary treatment with antibiotics.
2.	3. Probability of problem arising
	The probability of occurrence of a false positive test result is medium – can happen but not frequently
2.	4. Predicted risk to patient/users
	The severity of the harm is serious - Results in reversible injury or impairment requiring professional medical intervention. The likelihood of harm is low - Unlikely to happen, rare, remote. Patient risk is low.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Customer complaints alleging false positive patient results were reported.
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

All positive test results obtained with the affected kit lot should be confirmed using an alternative method.

3.	2. By when should the action be completed?	Specify where critical to patient/end user safety The action should be completed immediately upon receipt of this FSN

3. 3. Particular considerations for: IVD

Is follow-up of patients or review of patients' previous results recommended?
No
Review of past patient test results is not recommended for this Field Safety Notice (FSN). The risk to patients is low. Some positive results from the affected test lot may be false positives, but others may be correct. Clinical judgment is important when interpreting test results.
Healthcare providers usually consider the patient's medical history, physical examination, and results from several tests when diagnosing gastrointestinal symptoms. If a false positive result for *C. difficile* occurred, follow-up care and continued evaluation usually help to make the correct diagnosis.
No delays in treatment are expected. In most cases, healthcare providers have already made the correct treatment decisions based on the patient's symptoms and condition. Antibiotic treatment may begin based on symptoms or a positive test result. In general, the risks of using antibiotics are lower than the risks of not treating a *C. difficile* infection.

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

The issue is being investigated at Diasorin Inc.

3	6. By when should the action be completed?	7. Users should begin confirming positive patient test results using an alternative method as soon as they receive this notice.

3.	8. Is the FSN required to be communicated to the patient /lay user?	No

3 9. 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	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 Avenue, Stillwater MN 55082**
	c. Website address	**www.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:	N/A
4.	10. Name/Signature	**Kym Pieper** **Director, Quality Assurance**

	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.