FSN Ref: FSN_RAL Diagnostics_23/007
FSCA Ref: Manufacturer's FSCA_RAL Diagnostics_23/007

Date: March 1st 2023

Urgent Field Safety Notice
Recall pH = 7.0 buffer solution for SP automated systems (References 75050SX5000)

For Attention of*
:The local reactovigilance correspondent and/or the manager of the laboratory and/or the Director of the establishment and/ or RAL Diagnostics' partner distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Recall pH = 7.0 buffer solution for SP automated systems (Références 75050SX5000)

1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Buffer
1.	**2. Commercial name(s)**
	MC pH = 7.0 buffer solution for SP automated systems – for Wright staining and May-Grünwald-Giemsa staining
1.	**3. Primary clinical purpose of device(s)***
	The buffer solutions thus make it possible to maintain a stable pH during staining.
1.	**4. Device Model/Catalogue/part number(s)***
	75050SX5000
1.	**5. Software version**
	Not applicable
1.	**6. Affected serial or lot number range**
	L01232; L03432
1.	**7. Associated devices**
	Not applicable.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	Two concordant alerts have been reported on these product batches. The product has a yellowish color and a sulfur smellAn internal non-conformity has been opened and investigations are in process.Samples from the retention stock have been analyzed.The incriminated products were returned for analysis (physicochemical, microbiological and biological). The results of the analysis of this non-conformity, and in particularly the microbiological analyses, demonstrate a significant bacterial contamination preventing the reading of the colored slide. Therefore, we are recalling the pH = 7.0 Buffer solution for SP automated systems - Reference 75050SX5000 - lots: L01232 and L03432. According to our information, you have one or more of these products.
2.	**2. Hazard giving rise to the FSCA***
	This problem can cause non-compliant staining by causing a lack of readability on blood smears. As a result, we are recalling the affected products...
2.	**3. Probability of problem arising**
	2 incidents recorded on 2504 units of these batches put on the market.
2.	**4. Predicted risk to patient/users**
	No patient/user risks.
2.	**5. Further information to help characterise the problem**
	Not applicable
2.	**6. Background on Issue**
	N/A
2.	**7. Other information relevant to FSCA**
	RAL Diagnostics was notified through a customer complaint received on 06/01/2023 for a yellowish coloration of the product and a sulfur smell.

	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

Provide further details of the action(s) identified.

Option 1: Return devices:
- quarantine the products, do not make them available on the market and/or put them into service.
- Complete and return the response form (FSN reply - see Annex 02).
- send the products concerned to your distributor who, once all the incriminated products have been received, will return them to RAL Diagnostics.

Option 2: Destruction of the devices:
- If the incriminated batches are destroyed by the users, return the certificate of destruction to your distributor - see Annex 03)

- The distributor undertakes to return all the certificate(s) of destruction completed by the final users to RAL Diagnostics

2. If you no longer own the products concerned:

- complete and return the response form (FSN reply - see Appendix 02).

The RAL Diagnostics commercial teams will assist you in the procedure of return of products.

3.	**2. By when should the action be completed?**	June 1st ,2023
3.	**3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)**	Yes

3. **4. Action Being Taken by the Manufacturer**

☒ Product Removal ☒ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

Provide further details of the action(s) identified.

3.	**5. Is the FSN required to be communicated to the patient /lay user?**	Yes
3	**6. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?**	
	Yes Appended to this FSN	

	4. General Information*	
4.	**1. FSN Type***	New
4.	**2. Further advice or information already expected in follow-up FSN? ***	No
4.	**3. Manufacturer information** (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	RAL Diagnostics
	b. Address	2 rue Jacques Monod Site Montesquieu 33650 Martillac France
	c. Website address	https://www.cellavision.com/
4.	**4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. ***	Yes
4.	**5. List of attachments/appendices:**	Appendix 01: Information letter to distributors Appendix 02: FSN Reply Form Appendix 03: Certificate of Destruction
4.	**Name/Signature**	

	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.