FSN Ref: FSN_RAL Diagnostics_23/042
FSCA Ref: Manufacturer's FSCA_RAL Diagnostics_23/042

Date: May 23th, 2023

Urgent Field Safety Notice

Information for users
Buffer solution for SP automated systems
(References 75050SX5000; 75040SX5000)

For Attention of*
:The local vigilance 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.)*
Mail : **RAL Diagnostics** Regulatory Affairs Department ralregulatory@cellavision.com

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RAL Diagnostics

Urgent Field Safety Notice

Information for users
Buffer solution for SP automated systems
(References 75050SX5000; 75040SX5000)

1. Information on Affected Devices*

1. 1. Device Type(s)*

Buffer

1. 2. Commercial name(s)

pH = 7.0 buffer solution for SP automated systems (75050SX5000) for Wright and May-Grunwald-Giemsa staining
pH = 6.8 buffer solution for SP automated systems (75040SX5000) for Wright and May-Grunwald-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 ; 75040SX5000

1. 5. Software version

Not applicable

1. 6. Affected serial or lot number range

Reference	Commercial name	Batch number
75050SX5000	pH = 7.0 buffer solution for SP automated system	M41707
75050SX5000	pH = 7.0 buffer solution for SP automated system	M28606
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27506
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27105
75050SX5000	pH = 7.0 buffer solution for SP automated system	M26105
75050SX5000	pH = 7.0 buffer solution for SP automated system	M24905
75050SX5000	pH = 7.0 buffer solution for SP automated system	M17103
75050SX5000	pH = 7.0 buffer solution for SP automated system	M10203
75050SX5000	pH = 7.0 buffer solution for SP automated system	L83648
75050SX5000	pH = 7.0 buffer solution for SP automated system	L62643
75050SX5000	pH = 7.0 buffer solution for SP automated system	L52141
75050SX5000	pH = 7.0 buffer solution for SP automated system	L00732
75050SX5000	pH = 7.0 buffer solution for SP automated system	L86229
75050SX5000	pH = 7.0 buffer solution for SP automated system	L78827

75040SX5000	pH = 6.8 buffer solution for SP automated system	L12035	

1. 7. Associated devices

Not applicable.

2. Reason for Field Safety Corrective Action (FSCA)*

2. 1. Description of the product problem*

The user observes the presence of bacilli on blood smears, customer complaints have been reported internally.

2. 2. Hazard giving rise to the FSCA*

Results obtained with affected lots may be altered.
If on microscopic observation of the stained blood smear user observe the presence of bacilli, discard the product, perform a decontamination procedure (as described below) and use a new bottle.
If there is any doubt about the diagnosis (i.e. following the results of the upstream counters), repeat the staining using a new bottle.
If the user detects contamination, sending us the batch number concerned and proceeding with Stop 2-type maintenance on the SP automated system. If the problem persists despite the Stop 2 and the user still identifies bacterial contamination on the blood smear, we then recommend contacting the local Sysmex representative to have a technician intervene and proceed with the decontamination of the automated system.

The tests performed with the incriminated batches did not have to be repeated with new bottles - the technician could have been disturbed by the presence of bacteria when using these incriminated batches, but he could then repeat the staining. If the technician was able to make a diagnosis, it is because the presence of bacteria did not interfere with the interpretation of the slid reading. It is therefore not necessary to repeat the tests on the concerned slides.

Therefore, the potential hazards are minimal and the laboratory that performed tests with the affected lots should not inform the treating physician.

2. 3. Probability of problem arising

2 incidents recorded on 17 708 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 has been notified through customer complaints.

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 6th ,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 Production shutdown; Blocking of all stock for microbial contamination control; Audit and disinfection of production and packaging equipment.
3.	**5. Is the FSN required to be communicated to the patient /lay user?** — Yes to lay user
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 Appendix 01 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**	Sandrine SAUVIGNON QHSE Director

	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.

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RAL Diagnostics

Safety information for customers

Martillac,23rd May 2023

FAO:
Customers of RAL Diagnostics

Re: Letter sent by e-mail with acknowledgement of receipt

Dear Sir or Madam,

Further to feedback from users, please be informed that staining performed with the products listed below may be contaminated; bacilli may be observed in the blood smears.

Reference	**Brand name**	**Lot number**
75050SX5000	pH = 7.0 buffer solution for SP automated system	M41707
75050SX5000	pH = 7.0 buffer solution for SP automated system	M28606
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27506
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27105
75050SX5000	pH = 7.0 buffer solution for SP automated system	M26105
75050SX5000	pH = 7.0 buffer solution for SP automated system	M24905
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75050SX5000	pH = 7.0 buffer solution for SP automated system	L00732
75050SX5000	pH = 7.0 buffer solution for SP automated system	L86229
75050SX5000	pH = 7.0 buffer solution for SP automated system	L78827
75040SX5000	pH = 6.8 buffer solution for SP automated system	L12035

We are therefore proceeding with the recall of the 15 batches in question as requested by the ANSM.

According to our information, you are in possession of one or more of these products. It must be removed from your inventory and that of your clients.

We therefore ask that you inform all your clients who have received these batches not to use them. In addition, you must ask your clients to send any bottles still in their possession back to you or to complete the disposal certificate.

The products returned or disposed of by the users as well as those that you have in stock will be exchanged for you as soon as possible. We ask you to please excuse us for the inconvenience that this situation could cause.

With this letter, we ask you to please return the duly completed attached response form (FSN Reply Form) to us before 06 June 2023.

Your sales contact is at your disposal for any additional information.

Please know that we are invested in resolving this problem and satisfying our clients.

RAL Diagnostics
Regulatory Affairs Department
ralregulatory@cellavision.com

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Safety notice – Batch recall

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	23/042
FSN Date*	May 23rd, 2023
Product/ Device name*	pH = 7.0 buffer solution for SP automated systems pH = 6.8 buffer solution for SP automated systems
Product Code(s)	75050SX5000 75040SX5000

Batch/Serial Number (s)

Reference	Brand name	Lot number
75050SX5000	pH = 7.0 buffer solution for SP automated system	M41707
75050SX5000	pH = 7.0 buffer solution for SP automated system	M28606
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27506
75050SX5000	pH = 7.0 buffer solution for SP automated system	M27105
75050SX5000	pH = 7.0 buffer solution for SP automated system	M26105
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75050SX5000	pH = 7.0 buffer solution for SP automated system	L62643
75050SX5000	pH = 7.0 buffer solution for SP automated system	L52141
75050SX5000	pH = 7.0 buffer solutin for SP automated system	L00732
75050SX5000	pH = 7.0 buffer solution for SP automated system	L86229
75050SX5000	pH = 7.0 buffer solution for SP automated system	L78827

Reference	Brand name	Lot number
75040SX5000	pH = 6.8 buffer solution for SP automated system	L12035

2. Distributor details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	

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Safety notice – Batch recall

Distributor Reply Form

3. Return acknowledgement to Sender	
Email	
Distributor Helpline	
Postal Address	2 rue Jacques Monod Site Montesquieu 33650 Martillac France
Web Portal	https://www.cellavision.com/
Deadline for returning the Distributor reply form*	June 6th ,2023

4. Action taken by distributor (and its customers) – Tick all that apply		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	
☐	I have completed all actions prescribed in the FSN.	

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Safety notice – Batch recall

Distributor Reply Form

☐	I have received confirmation of reply from all identified customers			
☐	The required information and actions have been communicated to all affected users and have been completed.			
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty :	Lot / serial number :	Return date (MM/DD/YY):
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty :	Lot / serial number :	Return date (MM/DD/YY):
		Qty :	Creditt ☐ Replacement ☐	
		Comments:		
☐	Neither I nor any of my customers has any affected devices in inventory			
☐	No affected product can be returned / destroyed			
☐	Other action (specify):			
☐	I have a request, please contact me. (e.g. the product needs to be replaced).			
Name*:				
Signature*				
Date*				

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.

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CERTIFICAT DE DESTRUCTION
DISPOSAL CERTIFICATE

Fait par / made by :

SOCIÉTÉ/*COMPANY :* _____ **Date :** / /

Je soussigné(e), _____ atteste avoir détruit les produits suivants :

I undersigned, _____. certify that the following products have been disposed of.

PRODUIT / *PRODUCT*	REFERENCE	QUANTITES / *QUANTITY*	LOT / *BATCH*

Signature et cachet de l'entreprise :
Signature and stamp of the Company: