

Date: April 20<sup>th</sup>, 2023

**Urgent Field Safety Notice**

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

For Attention of\*  
:The RAL Diagnostics' partner distributor

Contact details of local representative (name, e-mail, telephone, address etc.)\*

Mail :

**RAL Diagnostics**

Regulatory Affairs Department

[ralregulatory@cellavision.com](mailto:ralregulatory@cellavision.com)

**Urgent Field Safety Notice**

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**(References 75050SX5000; 75040SX5000)**

<b>1. Information on Affected Devices*</b>			
<b>1.</b>	<b>1. Device Type(s)*</b>		
	Buffer		
<b>1.</b>	<b>2. Commercial name(s)</b>		
	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		
<b>1.</b>	<b>3. Primary clinical purpose of device(s)*</b>		
	The buffer solutions thus make it possible to maintain a stable pH during staining.		
<b>1.</b>	<b>4. Device Model/Catalogue/part number(s)*</b>		
	75050SX5000 ; 75040SX5000		
<b>1.</b>	<b>5. Software version</b>		
	Not applicable		
<b>1.</b>	<b>6. Affected serial or lot number range</b>		
	<b>Reference</b>	<b>Commercial name</b>	<b>Batch number</b>
	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	
<b>1.</b>	<b>7. Associated devices</b>			
	Not applicable.			

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>	
<b>2.</b>	<b>1. Description of the product problem*</b>
	The user observes the presence of bacilli on blood smears, customer complaints have been reported internally.
<b>2.</b>	<b>2. Hazard giving rise to the FSCA*</b>
	This problem may cause staining with artifacts that may interfere with the interpretation of blood smears. As a result, we are recalling the affected products.
<b>2.</b>	<b>3. Probability of problem arising</b>
	2 incidents recorded on 17 708 units of these batches put on the market.
<b>2.</b>	<b>4. Predicted risk to patient/users</b>
	No patient/user risks.
<b>2.</b>	<b>5. Further information to help characterise the problem</b>
	Not applicable
<b>2.</b>	<b>6. Background on Issue</b>
	N/A
<b>2.</b>	<b>7. Other information relevant to FSCA</b>
	RAL Diagnostics has been notified through customer complaints.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<b>1. Action To Be Taken by the User*</b>
	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other <input type="checkbox"/> None  Provide further details of the action(s) identified. <b>Option 1: Return devices:</b> - 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.  <b>Option 2: Destruction of the devices:</b> - 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.	<b>2. By when should the action be completed?</b>	June 6th ,2023
3.	<b>3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</b>	Yes
3.	<b>4. Action Being Taken by the Manufacturer</b>  <input checked="" type="checkbox"/> Product Removal <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None  Provide further details of the action(s) identified.	
3.	<b>5. Is the FSN required to be communicated to the patient /lay user?</b>	Yes
3	<b>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?</b> Yes      Appended to this FSN	
	<b>4. General Information*</b>	
4.	<b>1. FSN Type*</b>	New
4.	<b>2. Further advice or information already expected in follow-up FSN? *</b>	No
4.	<b>3. Manufacturer information</b> (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	<a href="https://www.cellavision.com/">https://www.cellavision.com/</a>
4.	<b>4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *</b>	Yes
4.	<b>5. List of attachments/appendices:</b>	Appendix 01: Information letter to distributors Appendix 02: FSN Reply Form Appendix 03: Certificate of Destruction
4.	<b>Name/Signature</b>	Sandrine SAUVIGNON QHSE Director

**Transmission of this Field Safety Notice**

<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>
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Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.

Martillac, 20<sup>th</sup> April, 2023

FAO:

Partner distributors 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	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](mailto:ralregulatory@cellavision.com)

## Safety notice – Batch recall

### Distributor Reply Form

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1. Field Safety Notice (FSN) information			
FSN Reference number*	23/042		
FSN Date*	April 20 <sup>th</sup> , 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
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	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*	



## Safety notice – Batch recall

### Distributor Reply Form

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

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

## Safety notice – Batch recall

### Distributor Reply Form

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<input type="checkbox"/>	I have received confirmation of reply from all identified customers			
<input type="checkbox"/>	The required information and actions have been communicated to all affected users and have been completed.			
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty :	Lot / serial number :	Return date (MM/DD/YY):
		Comments:		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty :	Lot / serial number :	Return date (MM/DD/YY):
		Qty :	Credit <input type="checkbox"/>	Replacement <input type="checkbox"/>
		Comments:		
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory			
<input type="checkbox"/>	No affected product can be returned / destroyed			
<input type="checkbox"/>	Other action (specify):			
<input type="checkbox"/>	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.

# 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:*