FSN Ref: FSN_RAL Diagnostics_23/012_22-02-23
FSCA Ref: Manufacturer's FSCA_RAL Diagnostics_23/012_02-22-23

Date: February 22th, 2023

Urgent Field Safety Notice
Recall MCDh 1
Reference 313590-2500

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

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mail : sandrine.sauvignon@cellavision.com Téléphone : +33 05 57 96 04 09 Fax : +33 05 57 96 04 05

FSN Ref: FSN_RAL Diagnostics_23/012_22-02-23
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Urgent Field Safety Notice (FSN)
Recall MCDh 1
Reference 313590-2500

1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Staining
1.	**2. Commercial name(s)**
	MCDh 1
1.	**3. Primary clinical purpose of device(s)***
	Fixation and differential staining of cellular structures
1.	**4. Device Model/Catalogue/part number(s)***
	313590-2500
1.	**5. Software version**
	Not applicable
1.	**6. Affected serial or lot number range**
	L84428; L25918; K42236; L14135
1.	**7. Associated devices**
	Not applicable.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	Three concordant signals were reported on these batches of products, internal non-conformities were opened, and investigations are in process. The results of the analysis of these non-conformities and in particular the biological analyses performed on the incriminated batches demonstrate that the products are non-conforming. Therefore, we are proceeding to a recall of MCDh 1 - batches: L84428; L25918; K42236; L14135. According to our information, you are the owner of one or more of these products.
2.	**2. Hazard giving rise to the FSCA***
	Staining may be altered, with a lighter or darker coloration being obtained. This problem may cause a delay in the delivery of expected results. As a consequence, we are proceeding to a recall of the affected products..
2.	**3. Probability of problem arising**
	4 incidents recorded on 3659 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**
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2.	**7. Other information relevant to FSCA**
	RAL Diagnostics was notified through a customer complaint received on 01/26/2023 for a colouring defect.

	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?** — April 26th, 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.ral-diagnostics.fr/
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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Information letter to distributors

Reactovigilance : N/A NC : 23/012 Page : **1** /**1**

At Martillac, February 22th , 2023

For the attention:
RAL Diagnostics' partner distributors

Subject: Electronic mail with acknowledgement of receipt

Dear Sir or Madam

Following feedback from users, we inform you that the colorations performed with the MCDh 1 stain (batches L84428; L25918 ; K42236 ; L14135), may be altered (lighter or darker coloring).

These batches of MCDh 1 were sold in 2.5 liter sizes under the reference 313590-2500.

Thus, we are proceeding with a recall of MCDh 1 lots: L84428; L25918; K42236; L14135.

The vigilance division of your national competent authority has been informed of this action.

According to our information, you are in possession of one or more of these products. It is to be removed from your stock and that of your customers. We therefore ask you to inform all your customers, having been delivered of this batch, not to use it anymore and to send it back to you or to complete the certificate of destruction.

The products returned or destroyed by the users as well as those you have in stock will be exchanged as soon as possible. We apologize for any inconvenience this may cause.

We kindly ask you to return the enclosed FSN Reply Form duly completed before April 26th, 2023.

Your sales correspondent is at your disposal for any further information.

Please be assured that we are committed to solving this problem and to the satisfaction of our customers.

Sandrine SAUVIGNON
Directeur Qualité, Hygiène, Sécurité et Environnement
Quality, Health, Safety and Environment Director

Visa :

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RAL Diagnostics

Safety notice – Batch recall

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	23/012
FSN Date*	02/22/2023
Product/ Device name*	MCDh 1
Product Code(s)	313590-2500
Batch/Serial Number (s)	L84428 ; L25918 ; K42236 ; L14135

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

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*	April, 26th 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: