FSN 26/121
FSCA Ref: 26/121

Urgent Field Safety Notice
RAL Stainer and RAL TB Stainer
References 405000 and 414195

Date:14-09-2026

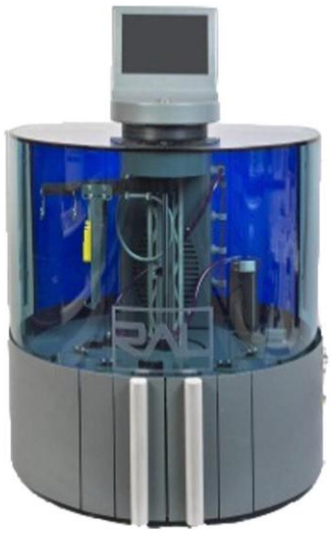
For Attention of*
:The local reactovigilance correspondent And/or the manager of the laboratory And/or the Director of the establishmentAnd/ or RAL Diagnostics' partner distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mail : RALregulatory@cellavision.com Téléphone : +33 (0)5 57 96 04 04

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1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Automated instrument intended to be used by laboratory professional users. 
1.	**2. Commercial name(s)**
	RAL Stainer and accessories – RAL TB Stainer and accessories
1.	**3. Primary clinical purpose of device(s)***
	RAL Stainer and RAL TB Stainer are automated instruments intended to be used, in combination with Kit RAL Stainer kits, by laboratory professional users to perform staining sequences.
1.	**4. Device Model/Catalogue/part number(s)***
	405000 and 414195
1.	**5. Software version**
	N/A
1.	**6. Affected serial or lot number range**
	Serial: 2224 to 2423
1.	**7. UDI-DI**
	RAL Stainer – ref. 405000: 376017719405000HP RAL TB Stainer – ref.414195: 376017719414195K5
1.	**8. Associated devices**
	360200-0000 Kit RAL Stainer MCDh 360220-0000 Kit RAL Stainer Gram-Nicolle 360225-0000 Kit RAL Stainer Gram-Nicolle slide counting 360230-0000 Kit RAL Stainer Fluo-RAL 760230-0000 Kit Stainer Fluo-RAL 360240-0000 Kit RAL Stainer Cold ZN 760240-0000 Kit Stainer Cold ZN 360210-0000 Kit RAL Stainer Gram- Hücker 360215-0000 Kit RAL Stainer Gram- Hücker, slide counting 360250-0000 Kit RAL Stainer 555 360255-0000 Kit RAL Stainer 555, slide counting

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1.	**9. Type of end user(s)**
	Laboratory professional users

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	The cap intended to be fitted on the kit reagent bottle may be difficult to position correctly.
2.	**2. Hazard giving rise to the FSCA***
	No risk for users, patient or others
2.	**3. Probability of problem arising**
	The trend analysis demonstrate that the occurrence of similar cases is limited, with 0,02% of the products affected over the last five years.
2.	**4. Predicted risk to patient/users**
	No risk for users, patient or others
2.	**5. Further information to help characterise the problem**
	Check the serial number of the instrument to determine whether it is affected by this issue.If the issue is observed, check whether the affected component interferes with the instrument's moving parts and may potentially cause blockage or damage to components such as the instrument arm, slide holder, or drain mechanism, or result in unusual noise during operation. In such cases, contact the Technical Service Department for assistance.
2.	**6. Background on Issue**
	The manufacturer became aware of this issue through several non-conformities (NCs) identified and recorded internally during the investigation of reported instrument malfunctions. The investigation was conducted internally, including an assessment of instruments returned by customers for investigation. The issue has not been observed on all instruments. Based on the information currently available, only a limited number of instruments appear to be potentially affected.
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
	Provide further details of the action(s) identified.

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	1. Check whether the instrument is potentially affected Identify the serial number of the RAL Stainer instrument and verify whether it is included in the list of serial numbers potentially affected by this Safety Notice. **2. Contact the local distributor** Contact your local distributor to obtain technical assistance and the appropriate corrective action. The replacement of the cover seal responsible for the improper fit between the cover and the bottle will be performed by the local distributor, in accordance with the instructions provided by the manufacturer.	
3.	**2. By when should the action be completed?**	Q4-2026
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 Replacement of spare-part ref. S4055100A and/or ref. S4055200A by local distributor assisted by RAL Diagnostics team	
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

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4.	**5. List of attachments/appendices:**	*Appendix 01: Information letter to distributors* *Appendix 02: FSN Reply Form (for distributors)*
4.	**Name/Signature**	Sandrine SAUVIGNON *Director Sr Compliance & Support*  Sandrine Sauvignon

	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.