Erba Lachema s.r.o.

Company Name/Logo

Rev 1: September 2018

FSN Ref: FSN 2024_01 FSCA Ref: FSCA 2024_01

Date: 15.05.2024

Urgent Field Safety Notice (FSN)
HDL C 160, HDL 80, HDL 360 XL-1000

For Attention of*:Customers of Erba Lachema s.r.o. who bought the affected products

Contact details of local representative (name, e-mail, telephone, address etc.)*
Anna Jonášová, Erba Lachema s.r.o. , Karásek 2219/1d, 621 00 Brno, Czech Republic, a.jonasova@erba.com, phone: +420 771 230 894

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Diagnostic reagents: HDL C 160 (cat. no. XSYS0043), HDL 80 (cat. no. BLT00028) and HDL C 360 XL-1000 (cat. no. XSYS0078)
1.	2. Commercial name(s)
	HDL C 160, HDL 80, HDL C 360 XL-1000
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not available
1.	4. Primary clinical purpose of device(s)*
	HDL C 160, HDL 80 and HDL C 360 XL-1000 are diagnostic reagents for in vitro determination of HDL cholesterol in human serum and plasma.
1.	5. Device Model/Catalogue/part number(s)*
	HDL C 160: catalogue number XSYS0043, HDL 80: catalogue number BLT00028, HDL C 360 XL-1000: catalogue number XSYS0078
1.	6. Software version
	Not relevant
1.	7. Affected serial or lot number range
	HDL C 160: 2308001, 2307007, 2306014, 2302002, 2302001, 2301148; 2212025, HDL 80: 2305153, 2303103, 2212039, HDL C 360 XL-1000: 2212026
1.	8. Associated devices
	XL analyzers, Chem 7, Chem 5 or competitors biochemistry analysers

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	According to our internal testing and post market surveillance data, we have confirmed that the reagents (affected batches mentioned above) do not reach the expected performance – the performance characteristic as accuracy, limit of quantification and reproducibility can be affected by the high factor results.
2.	2. Hazard giving rise to the FSCA*
	The affected performance characteristics of reagents may affect results during the daily internal process in a laboratory (especially high results of factor). The functionality of reagents can be limited in general with potential patient risks, however, the parameter is only one of the parameters

	measured and the given deviations should not put the patient's health at risk. No repeated measurement is needed. The given issue is not risky for users.
2.	3. Probability of problem arising
	This issue is expected to happen repeatedly during measurement of affected batches. Quality control measurement is expected to show high factor.
2.	4. Predicted risk to patient/users
	The high factor can affect results of quality control or patient samples. This issue may influence the patient health according to decisions of the doctor and patient´s health background.
2.	5. Further information to help characterise the problem
	Not available.
2.	6. Background on Issue
	Erba Lachema s.r.o. received reagent bulks from a supplier, 11 internal batches were produced from the supplier bulks (affected batches mentioned above) and all internal quality tests were acceptable at the release time. During the expiry, customer claims were received, and internal retesting of reference samples confirmed the issue with the reagents within time (the high factor). Pieces remaining in our stock were blocked and the supplier was contacted, the investigation is still ongoing.
2.	7. Other information relevant to FSCA
	Not applicable

	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

- Identify, locate, and send all affected pieces of these products in your stock to Erba Lachema s.r.o. if possible. If not possible, please discard all affected pieces of these products.
- The already opened vials are not to be used for measurements and should be destroyed.
- Contact Erba as soon as possible in order to report number of blocked pieces on your stock using Confirmation of receipt form at the end of this document. You will receive replacement free of charge.
- Use other lots of the said reagents in your stock until the affected lots will be replaced.
- If you have already shipped the affected LOT to any customer, please immediately inform them about this Field Safety Notice and instruct them to follow above-described rules.
- Also forward this notice to all those who need to be aware within your organization.

	• We ask customers outside the EU to handle necessary announcements to authorities in their countries. • We would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send back filled confirmation to Erba Lachema s.r.o. by e-mail until **30th of June 2024**.	
3.	2. By when should the action be completed?	**30.06.2024**
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No The functionality of this reagent can be limited in general with potential patient risks, however, the parameter is only one of the parameters measured and the given deviations should not put the patient's health at risk. The physician should take into account all other results.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Recall of affected batched from customers	
3	6. By when should the action be completed?	30.06.2024
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	**3.** For Updated FSN, key new information as follows:	

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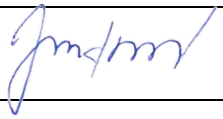
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Erba Lachema s.r.o.
	b. Address	Karásek 2219/1d, 621 00 Brno, Czech Republic
	c. Website address	www.erbalachema.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Confirmation form for customer
4.	10. Name/Signature	Anna Jonášová
		

	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.