Rev 1: September 2018

FSN Ref.: FSN_2024_06_LDH-P

FSCA-Ref.: FSCA_2024_06_LDH-P

Date: 2024-06-24

Urgent Field Safety Notice

LDH-P, opt. DGKC

(Destruction)

For Attention of*: all distributors, end users, medical practitioners using concerned reagent or results obtained with concerned reagent

Contact details of local representative (name, e-mail, telephone, address etc.)*
DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. IZ-NOE Sued, Hondastrasse, Objekt M55 2351 - Wr. Neudorf, AUSTRIA **Contact:** **Lorenz Miller (Reporting Officer in order of the PRRC)** **E-Mail: safety@dialab.at** **Phone: +43-2236-660910-48** **Website: www.dialab.at**

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Urgent Field Safety Notice (FSN)
LDH-P, opt. DGKC

Risk of falsified results

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in human serum or plasma on photometric systems.
1.	2. Commercial name(s)
	LDH-P, opt. DGKC
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	LDH-P, opt. DGKC is a diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in human serum or plasma on photometric systems. Lactate dehydrogenase (LDH) is an enzyme, consisting of five different isoenzymes which catalyse the interconversion of Lactate and pyruvate. LDH is present in the cytoplasm of all human tissues with higher concentrations in liver, heart and skeletal muscle, and lower values in erythrocytes, pancreas, kidney and stomach. Increased LDH activities are found in a variety of pathological conditions such as kardial infarction, cancer, diseases of liver, blood or muscle. However, because of the lack of organ specificity, determination of its isoenzymes or other enzymes such as alkaline phosphatase or GPT (ALT) / GOT (AST) is necessary for differential diagnosis.
1.	5. Device Model/Catalogue/part number(s)*
	D00657, D00658, D0432917, D76911, D94651, DA0836, DT1036.
1.	6. Software version
	-
1.	7. Affected serial or lot number range
	Expiry date 2024-10-04: Lot. 4857/34008; **Expiry date 2025-01-11: Lot. 01230203, 01230204, 01230205, 01230206, 01230207, 01230264.**

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In course of investigations in the context with a specific Lot. of raw material used for LDH-P, it was shown that LDH-P, opt. DGKC produced with this component showed a significant decrease of blank absorbance during product shelf life. This is associated with a risk of falsified results. Tests with patient samples showed an increase of LDH results of up to 15% when compared to results obtained with a reference batch of reagent.
2.	2. Hazard giving rise to the FSCA*
	A possible patient risk by falsified results cannot be ruled out.

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2.	3. Probability of problem arising
	The product of all items in the lot numbers mentioned is to be regarded as impaired.
2.	4. Predicted risk to patient/users
	LDH is a parameter associated with differential diagnosis in context with different pathological conditions (please see at point 4). Since LDH is usually tested together with other parameters and falsely increased results might lead to further patient investigation, the patient risk was assumed as rather low. However, a possible influence on patient treatment decisions cannot be ruled out.

	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 All Users: **- Ensure that the Field Safety Notice for this FSCA reaches all affected customers and end users.** **- Make sure that LDH-P of the mentioned Lot. numbers is no longer sold or used: Destruction of the product** Final customers: **- Discontinue further measurements with LDH-P reagent of the affected Lot. numbers immediately.**	
3.	2. By when should the action be completed?	2024-07-05
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes **Review of previous patient results measured with affected products to determine whether falsified results (internal tests showed results with deviations of up to 15%) could have influenced the treatment of patients. In case of doubt, it is recommended to repeat the measurement as far as possible or to clarify the further procedure with the responsible doctor.**	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, reply until 2024-07-05

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	**Annex 1: Customer Reply Form**
4.	5. Name/Signature	**Lorenz Miller, MSc.**

	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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