Rev 1: September 2018

FSN Ref.: FSN_2024_07_GPT (ALT)

FSCA-Ref.: FSCA_2024_07_GPT (ALT)

Date: 2024-08-06

Urgent Field Safety Notice

GPT (ALT), mod. IFCC

(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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Risk of falsified results

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Diagnostic reagent for quantitative in vitro determination of GPT (ALT) in human serum or plasma on photometric systems.
1.	2. Commercial name(s)
	GPT (ALT), mod. IFCC
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	GPT (ALT) is a Diagnostic reagent for quantitative in vitro determination of GPT (ALT) in human serum or plasma on photometric systems. Alanine Aminotransferase (ALAT/ALT), also called Glutamic Pyruvic Transaminase (GPT) and Aspartate Aminotransferase (ASAT/AST), formerly called Glutamic Oxalacetic Transaminase (GOT) are the most important representatives of a group of enzymes, the aminotransferases or transaminases, which catalyse the conversion of α-keto acids into amino acids by transfer of amino groups. As liver specific enzyme GPT is only significantly elevated in hepatobiliary diseases, Increased GOT levels, however, can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Parallel measurement of GPT and GOT is therefore applied to distinguish liver from heart or skeletal muscle damages. The GOT/GPT ratio is used for differential diagnosis in liver diseases. While ratios < 1 indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases.
1.	5. Device Model/Catalogue/part number(s)*
	REF: D00640, D0428917, D73911, D94620, DA0830, DB20323, DT1030.
1.	6. Software version
	-
1.	7. Affected serial or lot number range
	All Product with Expiry date 2025-03-17: **Kit Lot. No. 01230595, 01230596, 01230598, 01230599, 01230801, 01230802, 01230804, 01230806.** **Components:** **Reagent R1, Lot. No. 01230507** **Reagent R2, Lot. No. 01230343**

2 Reason for Field Safety Corrective Action (FSCA)*

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Managing Director | Geschäftsführer Murat Estelik, Dipl. Ing. Marlene Ramsey FN 108 078p | Landesgericht Wr. Neustadt UID/VAT: ATU 150 136 06 | DVR: 0130885
Raiffeisen Regionalbank Moedling BIC / SWIFT: RLNWATWWGTD IBAN €: AT97 3225 0000 0070 6739 IBAN USD: AT52 3225 0301 0070 6739

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2.	1. Description of the product problem*
	In course of a customer complaint, it was confirmed with tests of retained samples, that GPT (ALT) reagent of the named Lot. numbers with Expiry Date 2025-03-17 shows signs of impaired product quality. Data obtained with retain samples confirmed a falsified increase of GPT results.The ratio GOT/GPT is used for differential diagnosis in liver diseases. While ratios < 1 indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases. Falsified increased results of GPT, if not identified by routine testing of quality controls, would lead to a falsified decrease of the GOT/GPT ratio and could result in an increased risk for missing the detection of patients with severe liver disease. Concerned product must be removed from the market and destroyed. Moreover, it is required to consider a repeat of measurements of those patients whose treatment may have been affected by use of concerned reagent.
2.	2. Hazard giving rise to the FSCA*
	A possible patient risk by falsified results cannot be ruled out.
2.	3. Probability of problem arising
	The product of all items in the lot numbers mentioned is to be regarded as concerned.
2.	4. Predicted risk to patient/users
	There is a risk for falsified results resulting in misdiagnosis.

	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 GPT(ALT) of the mentioned Lot. numbers is no longer sold or used: Destruction of the product** Final customers: **- Discontinue further measurements with GPT (ALT) reagent of the affected Lot. numbers immediately.**	
3.	2. By when should the action be completed?	2024-09-03

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3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes **It is highly recommended to review and confirm previous results that were obtained by the affected lot.**	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, reply until 2024-09-03

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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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Confirmation Form

Product Name: GPT (ALT), mod. IFCC

FSCA-Identifier: FSCA_2024_07_ GPT (ALT)

◉ **Destruction** ○ **Return** ○ **Modification** ○ **others:** ○

Distributor/Customer Details:

Company Name:	
Address:	

Total Quantity:

Please list each of your concerned REFs, Lot- / Serial number(s) and the counts of concerned units:

All Customers: Kits, received from Dialab:	
Distributors: Kits in your storage for destruction:	
Distributors: Kits in your storage already destructed:	
Distributors: Kits already distributed to your customers:	

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End customers: Kits, currently in stock, for destruction:	
End customers: Kits, already destroyed:	
End customers: Kits already used up:	

The undersigned confirms that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice.

Completed By	
Telephone / E-Mail	
Date	
Original Signature	

Please complete this form and send it via e-mail until 3/9/24 to safety@dialab.at.

Thank you for your efforts!