Rev 1: September 2018

FSN Ref: FSN_GOT+GPT_2022_01 FSCA Ref: FSCA_2022_01_GOT+GPT

Date: 11:JAN:2022

Urgent Field Safety Notice

GOT (AST) mod. IFCC,
GPT (ALT) mod. IFCC

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 (safety officer)** **E-Mail: safety@dialab.at** **Phone: +43-2236-660910-48**

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Phone: +43(0)2236 660910-0 Fax: +43(0)2236 660910-30 Mail: office@dialab.at www.dialab.at
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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GOT (AST) mod. IFCC,
GPT (ALT) mod. IFCC

Risk of falsified patient results

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	GOT (AST) mod. IFCC: Diagnostic reagent for quantitative in vitro determination of GOT (AST) in human serum or plasma on photometric systems. GPT (ALT) mod. IFCC: Diagnostic reagent for quantitative in vitro determination of GPT (ALT) in human serum or plasma on photometric systems.
1.	2. Commercial name(s)
	GOT (AST) mod. IFCC; GPT (ALT) mod. IFCC
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	Diagnostic reagent for quantitative in vitro determination of GOT (AST) / GPT (ALT) in human serum or plasma on photometric systems. As liver specific enzyme GPT (ALT) is only significantly elevated in hepatobiliary diseases. Increased GOT (AST) 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 < 1indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases.
1.	5. Device Model/Catalogue/part number(s)*
	REF-No.: GOT (AST) mod. IFCC: D00678, D03115B, D0427917, D72911, D94610, D98616, D98617, DA0829, DE1829, DT1029. GPT (ALT) mod. IFCC: D00640, D03116B, D0428917, D73911, D94620, D98624, DA0830, DE1830, DT1030.
1.	6. Affected serial or lot number range
	GOT (AST) mod. IFCC: 130621, Exp. 2023-01-03 GPT (ALT) mod. IFCC: 120621, Exp. 2023-01-03

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2	**Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	In course of customer complaints it was detected that the concerned two product lots are affected by falsified results.
2.	2. Hazard giving rise to the FSCA*
	An influence by use of concerned reagent on patient decisions under consideration of GOT- or GPT- results cannot be excluded.
2.	3. Probability of problem arising
	all product of the named lots is regarded as concerned
2.	4. Predicted risk to patient/users
	Falsified patient and controls results. This situation could lead to delayed differentiation of liver, heart or skeletal muscle damages/diseases.

	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:

- Assure that the Field Safety Notice gets forwarded to all concerned distributors, customers, final users and medical practitioners.
- Separate and destroy all (opened and unopened) reagent of concerned lots, you get replacement/credit note by DIALAB.
- Undersign in the confirmation form attached to this FSN (Annex 1): You undersign, that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice. Send the filed out signed form to safety@dialab.at

Final users:
- Stop immediately any further use of reagent of the concerned product lots.

- Repeat, where possible, testing of GOT / GPT reagent with non-concerned product or with a comparable test.

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	- in cases where a misdiagnosis or improper medical treatment decision is regarded as possible as a consequence of the concerned product and no stable sample is available: Please repeat the sampling and measurement with non-concerned product or a comparable GOT / GPT test.	
3.	2. By when should the action be completed?	2022-02-04
3.	3. Considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Repeat analysis where the described influence may have resulted in wrong patient decision	
3.	4. Is customer Reply Required? * Please use the attached customer reply form	Yes
3.	5. Is the FSN required to be communicated to the patient /lay user?	N/A

	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 from**
4.	5. Name/Signature	[redacted]

	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

GOT (AST) mod. IFCC / GPT (ALT) mod. IFCC

FSCA-Identifier: FSCA_2022_01_GOT+GPT

Destruction

Distributor/Customer Details:

Company Name	
Address	

Total Quantity:

Received	
Distributed	

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 **2022-02-04** to safety@dialab.at.

Thank you for your efforts!

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