generi biotech

FSN Ref: FSCA_UGT1A1_02_2022
FSCA Ref: FSN_UGT1A1_02_2022

Date: 19.12.2022

Urgent Field Safety Notice
gb PHARM UGT1A1

For Attention of*: Customers and distributors.

Contact details of local representative	
Name of local representative:	[redacted]
e-mail:	
phone:	+420 734 334 449
Manufacturer address:	GENERI BIOTECH s.r.o. Machkova 587/42500 11 Hradec Králové 11 – Třebeš Czech Republic

A. Information on Affected Devices*	
1.	Device Type(s)*
	IVD kit, non-sterile
2.	Commercial name(s)
	gb PHARM UGT1A1
3.	Unique Device Identifier(s) (UDI-DI)
	N/A
4.	Primary clinical purpose of device(s)*
	Given mutations in the UGT1A1 gene affect the activity of UDP glucuronosyltransferase, the major enzyme of bilirubin metabolism. The examinations are used to confirm the diagnosis of Gilbert's syndrome, or before the administration of irinotecan drug and other drugs metabolised by UGT. The kit is intended for in vitro diagnostics.
5.	Device Model/Catalogue/part number(s)*
	3253-025, 3253-050
6.	Software version
	N/A
7.	Affected serial or lot number range
8.	200086008 200087011 200087012
9.	Associated devices

	N/A

B. Reason for Field Safety Corrective Action (FSCA)*	
1.	Description of the product problem*
	The detected signal for the 6TA/7TA allele (heterozygote) shows a relative shift in values (the 7TA peak is approximately half the height of the 6TA peak), which may lead to misinterpretation of the results. The 6TA/7TA heterozygote may be misidentified as a 6TA homozygote (wild-type).
2.	Hazard giving rise to the FSCA*
	Confusion of genotype 6/7TA (heterozygote) with genotype 6TA (wild-type).
3.	Probability of problem arising
	The likelihood is very high.
4.	Predicted risk to patient/users
	An incorrectly determined genotype may affect the confirmation or exclusion of Gilbert syndrome. Based on the genotype determined, the indication of the drug to the patient (e.g. irinotecan) may be adjusted.
5.	Further information to help characterise the problem
	N/A
6.	Background on Issue
	Customer complaint.
7.	Other information relevant to FSCA
	N/A

C. Type of Action to mitigate the risk*	
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.* Do not use the kit further and dispose of it. For analyses performed, review the data obtained and re-evaluate the determined 6TA genotype. Use manual evaluation of the shape of the melting curves to analyse the data. Automatic data analysis may evaluate the signal for the 7TA allele as sub-threshold, which may lead to a false determination of the 6TA genotype (wild-type) instead of the 6TA/7TA

	genotype (heterozygote). If in doubt, re-analyse the sample using the gb GENETIC Gilbert kit (will be sent free of charge on request).	
2.	By when should the action be completed?	Immediately.
3.	Particular considerations for:	IVD
	Is follow-up of patients or review of patients' previous results recommended? *Provide further details of patient-level follow-up if required or a justification why none is required*	Yes For analyses performed, review the data obtained and re-evaluate the determined 6TA genotype. Use manual evaluation of the shape of the melting curves to analyse the data. Automatic data analysis may evaluate the signal for the 7TA allele as sub-threshold, which may lead to a false determination of the 6TA genotype (wild-type) instead of the 6TA/7TA genotype (heterozygote). If in doubt, re-analyse the sample using the gb GENETIC Gilbert kit (will be sent free of charge on request).
4.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Use form: Reply_form_UGT1A1_02_2022_EN
5.	**Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None *Provide further details of the action(s) identified.* The batches in question will be disposed of and will no longer be placed on the market.	

6.	By when should the action be completed?	Immediately
7.	Is the FSN required to be communicated to the patient /lay user?	No
	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	Not appended to this FSN

	D. General Information*	
1.	FSN Type*	New
2.	For updated FSN, reference number and date of previous FSN	N/A
3.	For Updated FSN, key new information as follows	N/A
4.	Further advice or information already expected in follow-up FSN? *	No
5.	If follow-up FSN expected, what is the further advice expected to relate to:	N/A
6.	Anticipated timescale for follow-up FSN	N/A
7.	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**GENERI BIOTECH s.r.o.**
	b. Address	**Machkova 587/42500 11 Hradec Králové 11 – Třebeš, Czech Republic**
	c. Website address	**www.generi-biotech.com**
8.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
9.	List of attachments/appendices:	N/A
10.	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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Date: 19.12.2022

Reply form to FSN

FSN No.: FSN_UGT1A1_02_2022_EN
For Attention of: Customers and distributors.

Please, confirm that the customer information below has been received by your facility.

Product name: gb PHARM UGT1A1
Catalogue. No.: 3253-025 and 3253-050

Herewith I confirm that we have received above mentioned customer notification and that all required actions have been implemented and all concerned parties have been informed about this Field Safety Notice:

- Do not use the kit further and dispose of it.
- For analyses performed, review the data obtained and re-evaluate the determined 6TA genotype. Use manual evaluation of the shape of the melting curves to analyse the data. Automatic data analysis may evaluate the signal for the 7TA allele as sub-threshold, which may lead to a false determination of the 6TA genotype (wild-type) instead of the 6TA/7TA genotype (heterozygote).
- If in doubt, re-analyse the sample using the gb GENETIC Gilbert kit (will be sent free of charge on request).

I request free sample of kit gb GENETIC Gilbert: Yes / No
If yes, provide your address:

Customer/company name: _____

Confirmed by: _____
(name and position)

Date and signature: _____

Please complete this form and send it back via email until 31.01.2023.

Thank you for your efforts.

[redacted]
Quality Assurance Department

Manufacturer address:	GENERI BIOTECH s.r.o. Machkova 587/42 500 11 Hradec Králové 11 – Třebeš Czech Republic
e-mail:	info@generi-biotech.com