generi biotech

FSN Ref: FSCA_UGT1A1_01_2022
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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:	Jitka Kašparová
e-mail:	jitka.kasparova@generi-biotech.com
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.	200086006 200086007 200086008

	200087009 200087010 200087011 200087012
9.	Associated devices
	N/A

B. Reason for Field Safety Corrective Action (FSCA)*	
1.	Description of the product problem*
	The list of PCR cyclers in the User Manual contains incorrect information about the possibility of using the Rotor-Gene PCR cycler, which is not compatible for use with the gb PHARM UGT1A1 kit because the evaluation of the 5TA allele is not reliable.
2.	Hazard giving rise to the FSCA*
	The use of the Rotor-Gene 3000 and Rotor-Gene 6000 is not compatible with the gb PHARM UGT1A1 kit. The use of these cycles with the kit leads to invalid results. There is no direct impact on patients as the results cannot be evaluated.
3.	Probability of problem arising
	The likelihood is very high.
4.	Predicted risk to patient/users
	There is no direct impact on patients as the results cannot be evaluated.
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 with the Rotor-Gene PCR cyclers.	
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*	No
4.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
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.* List of validated PCR cyclers was updated immediately on the website www.generi-biotech.com	
6.	By when should the action be completed?	01.01.2023
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	**Mgr. Jitka Kašparová, Ph.D.**

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.