Recall of Genrui's SARS-CoV-2 Antigen Test Kit (Colloidal Gold) for Self-testing

Dear Customers,

Following reports of false positive events with the **SARS-CoV-2 Antigen Test Kit (Colloidal Gold)** for self-testing, the manufacturer, Genrui Biotech, is recalling two specific lots as follows:

Lots: 20211008, 20211125.

After a thorough investigation, Genrui Biotech isolated the root cause and confirmed that these incidents of false positives are limited to these two specific lots 20211008, 20211125. Genrui Biotech has confirmed that the reliability of negative results is not affected by this issue.

Genrui Biotech has committed to voluntarily remove and replace all affected tests on the market and sincerely apologise for the stress and inconvenience caused by this issue and are continuously committed to offering high-quality products and services.

Genrui Biotech Inc.
Date: 13 Jan, 2022

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Genrui Biotech Inc.

FSN Ref: 20220105-01 FSCA Ref: GR220105-1

Date: January 13, 2022

Urgent Field Safety Notice
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Company Name: Company Add: Contact person: Email: Tel:

Genrui Biotech Inc.

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Urgent Field Safety Notice (FSN)
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The product is an immunochromatographic assay for the detection of SARS-CoV-2 antigen. The test kit is intended for self-testing.
1.	2. Commercial name(s)
	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
1.	3. Unique Device Identifier(s) (UDI-DI)
	/
1.	4. Primary clinical purpose of device(s)*
	The product is for the qualitative detection of SARS-CoV-2 antigen. The test kit is intended for self-testing.
1.	5. Device Model/Catalogue/part number(s)*
	1T/kit, Ref: 52104097
1.	6. Software version
	/
1.	7. Affected serial or lot number range
	20211008, 20211125.
1.	8. Associated devices
	/

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	We noted an increased chance that GENRUI's SARS-CoV-2 Antigen Test Kit (Colloidal Gold) may provide an incorrect positive result.
2.	2. Hazard giving rise to the FSCA*
	Hazard: An incorrect diagnosis or classification of an illness or other problem.
2.	3. Probability of problem arising
	/
2.	4. Predicted risk to patient/users
	If false positive occurs, users' daily life is affected, as they may be required to follow the local medical control and management policy.
2.	5. Further information to help characterise the problem
	/
2.	6. Background on Issue
	Due to the identified sample diluent contamination from specific lots: 20211008, 20211125, GENRUI's SARS-CoV-2 Antigen Test Kit (Colloidal Gold) may have a potential to give an incorrect positive result.
2.	7. Other information relevant to FSCA
	/

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	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 1）Check if their test is from an affected lot (20211008, 20211125) and contact their supplier for replacement. 2）SARS-CoV-2 LFD detection assay and reagents have their limitations, the antigen self-testing product cannot be used as sole basis for the diagnosis of SARS-CoV-2 infection. The test result should be combined with other diagnostic information, such as a PCR Test, to determine whether the user is infected.	
3.	2. By when should the action be completed?	In February, 2022.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes. In February, 2022.
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 1. Notify the distributors of GENRUI's SARS-CoV-2 Antigen Test Kit (Colloidal Gold) in EEA, candidate countries and Switzerland that may have received the affected tests (20211008, 20211125) to quarantine the affected tests, remove the unused affected tests for replacement. 2. Initiate FSCA.	
3	6. By when should the action be completed?	No later than 3 months.
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	/
4.	**3.** For Updated FSN, key new information as follows:	
	/	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	/	
4	6. Anticipated timescale for follow-up FSN	/
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Genrui Biotech Inc.
	b. Address	4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China
	c. Website address	www.genrui-bio.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	Title: General Manager
		Signature: 

	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.