HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Genrui SARS-CoV-2 Antigen Self-Test Kit (Colloidal Gold)

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2022(01) **Issue Date: 18 January 2022**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Genrui Biotech Inc. (manufacturer)	V49837

ISSUE
The Health Products Regulatory Authority (HPRA) is issuing this Safety Notice to raise awareness of a product recall of two batches of the Genrui SARS-CoV-2 Antigen Self-Test Kit (Colloidal Gold) manufactured by Genrui Biotech. On 5 January, following advice from the HPRA, retailers in Ireland removed the Genrui SARS-CoV-2 Rapid Antigen Self-Test from sale on a voluntary basis pending further investigation. This action was taken following the receipt of a high number of medical device user reports by the HPRA, from Irish consumers reporting false positive results when using the Genrui SARS-CoV-2 Rapid Antigen Self-Test. The manufacturer, Genrui Biotech, has now investigated the high number of reports of false positive results and has advised that an issue relating to contamination of the sample diluent has been identified with two specific batches; **20211008 and 20211125**. The manufacturer is now recalling these batches from affected retailers and members of the public. Retailers in Ireland are advised to continue the voluntary suspension from sale of the Genrui self-test while the recall is ongoing.

ACTION OR RECOMMENDATIONS

The HPRA advises users/members of the public:

1. If you have not already returned these self-tests under the voluntary removal from sale, you should immediately identify any Genrui self-tests that you have in your possession with the batch number 20211008 or 20211125. These self-tests should not be used.
2. You can return these self-tests to the retailer you bought them from.
3. If you received a positive result following the use of any rapid antigen self-test, including this test, you should follow the current public health advice on the HSE website.
4. If you have already reported a false positive result for this self-test to the HPRA, you do not need to send an additional report.
5. If you experience a false positive or false negative result associated with this self-test, or any other rapid antigen test, you can report the occurrence via the HPRA's reporting form.

The HPRA advises all suppliers and retail outlets of the Genrui self-test to:

1. Immediately identify and quarantine all stock with batch number 20121008 or 20211125 listed in the accompanying Field Safety Notice (FSN), if you have not already quarantined these self-tests under the voluntary removal from sale by retailers on 5 January.
2. Forward a copy of this safety notice and the accompanying FSN to all those that need to be aware within your organisation and to any suppliers and retail outlets you have supplied these tests to.
3. Ensure that a copy of this safety notice and the accompanying FSN is available to all customers that you may have supplied this test to, including members of the public.
4. Contact your supplier for further instruction on actions for quarantined stock.

TARGET GROUPS

- Members of the public
- All retail outlets
- Retailers
- Pharmacies

BACKGROUND

The HPRA has received a high number of medical device user reports from Irish consumers, reporting false positive results when using the Genrui SARS-CoV-2 Rapid Antigen Self-Test.

The HPRA contacted the manufacturer on 5 January to advise of the significant number of false positive results reported by Irish consumers and to request the manufacturer to investigate the matter.

The HPRA highlighted its concern to suppliers and retailers of the Genrui self-test in Ireland, who took a voluntary action as a precautionary measure and temporarily suspended the sale of these devices pending further investigation on 5 January.

The manufacturer has conducted its investigation and has identified an issue with two specific batches (20211008, 20211125) relating to contamination of the sample diluent. It has advised that no other batches are impacted by this issue and that the reliability of negative results is not affected by this issue.

The HPRA is continuing to liaise with the manufacturer and an assessment of this issue remains ongoing. This safety notice may be updated should further relevant information become available.

The manufacturer will continue to temporarily suspend the sale of Genrui self-tests to Ireland while the recall is ongoing.

The HPRA wish to acknowledge all those who have reported false positive results with this self-test.

The HPRA strongly encourages members of the public and healthcare professionals to report any safety issues that they have experienced with a medical device to us. Issues or concerns about a medical device can be submitted through the HPRA's online reporting system or by downloading and completing our incident report form.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Genrui Biotech Inc.
4-10F, Building 3, Geya Technology Park,
Guangming District, 518106, Shenzhen,
China

Telephone: +86 13632668542
E-mail: service.ireland@genrui-bio.com

Enquiries to the **authorised representative** should be addressed to:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Telephone: +31644168999
E-mail: peter@lotusnl.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie