Urgent Field Safety Notice

Genedrive® MT-RNR1 ID Kit
FSCA-Feb2024-AT/GR
Ref: NCP-359
Device Recall

Date: 06 FEB 2024

Dear Valued Customer,

The purpose of this letter is to advise you that Genedrive Diagnostics Ltd., is conducting a Field Safety Corrective Action (FSCA) for the in-vitro diagnostic devices listed below (Table 1). Our records indicate that you have received purchased units of the affected device(s). Please read the following information carefully.

DETAILS ON AFFECTED DEVICES:

Table 1 List of Devices

Product name	Catalog number	Lot number	Expiration date	UDI (kit)	UDI (carton of 10 kits)
Genedrive® MT-RNR1 ID Kit	ID-RNR1-01	230311	08Dec2024	010506065486000417241208112302221023031 1	01050606548600111724120811230222102303 11

Genedrive® MT-RNR1 ID Kit Intended Purpose:

The Genedrive® MT-RNR1 ID Kit is a qualitative *in vitro* molecular diagnostic test for the detection of the single nucleotide polymorphism (SNP) m1555A>G affecting the mitochondrial gene MT-RNR1 in human buccal cells.

The Genedrive® MT-RNR1 ID Kit used in conjunction with the Genedrive® System provides an automated result of an individual's MT-RNR1 m.1555 variant status to inform the clinician ahead of antibiotic treatment decisions.

The Genedrive® MT-RNR1 ID Kit is intended to be used by healthcare professionals within a near patient setting.

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REASON FOR THE FIELD ACTION

It has been identified that the devices listed in Table 1 suffer a degradation in performance following prolonged storage at ≥40°C. This degradation in performance manifests itself in the production of a 'Test Failed' result, when tests at a low target copy number, are performed.

The storage temperature conditions for the Genedrive® MT-RNR1 ID Kits are 2-30°C. The degradation in performance at ≥40°C, however, could indicate that the labelled shelf life of these kits may be compromised.

DESCRIPTION OF THE ISSUE

The issue is linked to the manufacture of a specific raw material lot used in the impacted Genedrive® MT-RNR1 ID Kit lot. There is no reason to question the performance of other Genedrive® MT-RNR1 ID Kit lots.

RISK TO HEALTH/IMPACT ON PATIENT RESULTS

The devices listed in Table 1 are not currently displaying any degradation in performance when stored and used as defined in device labelling, at 2-30°C. Any degradation in stability would manifest itself in the production of a 'Test Failed' result, requiring a re-test, and as such, the patient's *MT-RNR1* m.1555A>G variant status may not be diagnosed ahead of antibiotic treatment decisions, if time does not permit a repeat test to be performed.

ACTIONS BEING TAKEN BY THE MANUFACTURER

1. Genedrive Diagnostics Ltd., will provide free of charge replacement devices within the scope of this FSCA.
2. We will take the necessary actions to prevent further reoccurrence of this issue.
3. Genedrive Diagnostics Ltd., has informed the appropriate Regulatory Agencies including the MHRA (GB), National Organization for Medicines (GR) and Austrian Federal Office for Safety in Health Care (AT).

ACTIONS TO BE TAKEN BY DISTRIBUTORS

1. Please notify affected customers of this Field Safety Corrective Action using this Field Safety Notice.
2. Please contact Genedrive Diagnostics Ltd. at m.kyriacou@genedrive.com and j.barber@genedrive.com to inform us of your and your customer's stock status of this Genedrive® MT-RNR1 ID Kit **LOT 230311**, within 2 working days of receipt of this field safety notice. We will then arrange the return and replacement of devices, as required.
3. Your customers may continue to use the impacted devices until replacement devices have been received.
4. Please maintain records of all Field Safety Actions. If necessary, such as a request from a Regulatory Agency, we will request copies of these records to be provided to us.

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ACTIONS TO BE TAKEN BY THE USERS

1. Users should inform their in-country distributor (see table 2) of their stock status of Genedrive® MT-RNR1 ID Kit **LOT 230311.**
2. Users may continue to use the impacted devices until replacement devices have been provided. Impacted devices should then be returned to the distributor.

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.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

CONTACT DETAILS OF LOCAL DISTRIBUTORS

Table 2

Country	Distributor Name	Distributor Address	Distributor Contact Details
Austria	Connect Medizintechnik GmbH	Connect Medizintechnik GmbH Gspanngasse 4, A-2130 Mistelbach, Österreich	office@connect-medizintechnik.at +43 (0) 257 232 400
Greece	ΑΝΤΙΣΕΛ	Κτίριο SPECTRA 12ο χλμ. Θεσσαλονίκης – Ν. Μουδανιών, 57001 Θέρμη, Θεσσαλονίκη	support.md@antisel.gr +30 231 0322525

Contact reference person:
The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Colleen Phythian
Director of Quality Assurance and Regulatory Affairs