MT-RNR1 ID Kit

Genedrive®
MT-RNR1 Product Range

World's **first point of care genetic** test used to influence neonatal management in an acute setting and **reduce aminoglycoside induced hearing loss**

An in vitro diagnostic (IVD) molecular assay for use on human buccal cells

- **Reduces** the likelihood of aminoglycoside induced hearing loss
- **Rapid genetic screening** prior to aminoglycoside antibiotics treatment prescription
- **Non-invasive** test, uses buccal swabs to collect samples

Advancing diagnostics to the point of care

genedrive

Background

- The m.1555A>G is a gene variant of known clinical interest
- Individuals with m.1555G gene variant develop profound irreversible hearing loss if exposed to aminoglycoside
- In case of suspected Sepsis, antibiotic treatment must be administered within 1 hour of admission to the unit (NICE Guidelines)[1]
- It is estimated from population-based studies that the prevalence is 1:500 people that have the m.1555G gene variant
- These individuals are highly susceptible to irreversible, bilateral hearing loss, when given gentamicin

- Gentamicin *(aminoglycoside antibiotic)* is the first line of treatment for newborn babies who are suspected to be at risk of sepsis caused by bacteria (NICE guidelines 2021)[1]
- Sepsis is a life-threatening medical emergency, which without timely treatment, can rapidly lead to tissue damage, multiple organ failure, and death
- Aminoglycoside antibiotics are used, because they are a low cost, broad-spectrum antibiotic with fewer resistance strains
- In the UK alone approx. 100,000[2] neonates per year, with suspected sepsis are treated with an aminoglycoside antibiotic

The solution to the clinical need

When the Genedrive® System and the MT-RNR1 ID Kit is utilised, it reduces the likelihood of aminoglycoside induced hearing loss for patients who have been tested for the m.1555A>G gene variant.

- It allows healthcare professionals to perform a genetic test in under 30 minutes
- Within the 'Golden hour' of treatment – 1 hour from admission
- It enables the healthcare professional to select the appropriate antibiotic treatment for their patients in a clinically actionable timeframe[3]
- This approach when widely adopted could significantly reduce the burden of Antibiotic Induced Ototoxicity (AIO)[3]

Current Situation

Baby admitted to NICU

Clinician has 1 hour to administer gentamicin and benzylpenicillin

499 in 500

Administer gentamicin and benzylpenicillin

Patient has no loss of hearing

MT-RNR1 A variant

1 in 500

Administer gentamicin and benzylpenicillin

Patient has severe loss of hearing

MT-RNR1 G variant

The solution...

Baby admitted to NICU

Clinician has 1 hour to administer gentamicin and benzylpenicillin

499 in 500 Not Detected

Administer gentamicin and benzylpenicillin

Patient has no loss of hearing

MT-RNR1 A variant

In under 30 minutes clinician uses Genedrive System with Genedrive MT-RNR1 ID Kit to detect the presence of an MT-RNR1 gene variant

1 in 500 Detected

Administer alternative antibiotic

Patient has no loss of hearing

MT-RNR1 G variant

Genedrive® System

The Genedrive System is an automated system used for qualitative in vitro molecular diagnostic tests. The Genedrive System performs tests, using single-use disposable cartridges, allows viewing of results on the touch screen and the ability to export the results.

Our new Genedrive System uses patented technology to rapidly amplify and detect target nucleic acid sequences without the requirement for nucleic acid isolation.

- Designed to be used as a point of care genetic test
- Delivers accurate and rapid patient diagnosis, in just 26 minutes, making it ideal for use in time critical situations
- Allows trained users to perform tests, using single-use disposable cartridges
- Easy to operate touch screen, with clear visual display of results
- With wireless connectivity and printer options, for fast access to print and export results
- Provides test history tracking and instant result transfer to SFTP
- To be used with the Genedrve MT-RNR1 ID Kit, and the Genedrive MT-RNR1 Control Kit to reduce the aminoglycoside induced hearing loss in neonates

Key Features:

- Reduces the likelihood of aminoglycoside induced hearing loss
- Provides a clear patient benefit, by informing the clinician ahead of antibiotic treatment decisions
- Rapid genetic screening prior to aminoglycoside treatment
- Single use, cost effective test for use by healthcare professionals with minimal training
- Easy adoption into existing neonatal admissions process
- Non-invasive sampling using buccal swabs

Genedrive® MT-RNR1 ID Kit

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.

The test consists of a target DNA amplification step and an end-point melt curve analysis. The data is interpreted by the system software which displays the result clearly on the screen. The average analysis time from sample collection to result is 30 minutes.

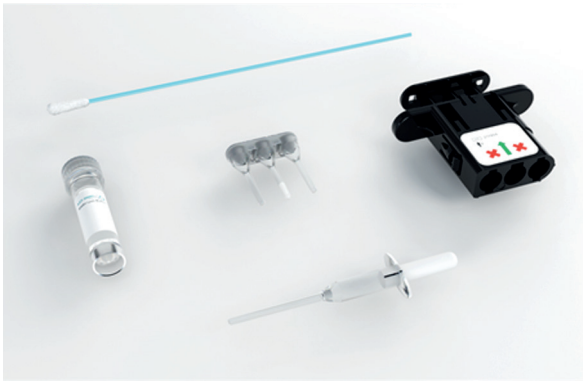
Each individual Genedrive MT-RNR1 ID Kit contains all the reagents and accessories required for the detection of SNP m.1555A>G affecting the mitochondrial gene MT-RNR1 in human buccal cells.

The Genedrive MT-RNR1 ID Kit contains a buccal swab and sample collection tube containing lysis buffer for the collection of buccal cells.

The Genedrive assay cartridge contains all the reagents needed to perform amplification and detection, in a lyophilised format.

The lyophilised reagents are reconstituted with the lysis buffer using the Minivette.

The cartridge is then closed and inserted into the Genedrive System, where the data is inputted via the touchscreen prior to starting the test.



Genedrive® MT-RNR1 Control Kit

The Genedrive MT-RNR1 Control Kit is a qualitative molecular test which enables trained healthcare professionals to perform routine Quality Control testing of the Genedrive System. Genedrive MT-RNR1 Control Kit is used in conjunction with the Genedrive MT-RNR1 ID Kit on the Genedrive System.

It tests the ability of the Genedrive System to detect both the positive (detected) and the negative (not detected) variant for the m.1555A>G single nucleotide polymorphism (SNP) affecting the mitochondrial gene MT-RNR1.

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

Each Genedrive MT-RNR1 Control Kit contains, four foil pouches each containing:

- One tube of lyophilised synthetic positive control (m.1555G)
- One tube of lyophilised synthetic negative control (m.1555A)
- Two dual bulb pastettes (to transfer the reconstitution lysis buffer provided separately in the Genedrive MT-RNR1 ID Kit) to the control tube.

Each foil pouch is single use only and once rehydrated there is enough material to perform eight tests for each control.

Following complete reconstitution, the cartridge is then closed and inserted into the Genedrive System, where data is inputted via the touchscreen prior to starting the test.

To learn more about Genedrive® MT-RNR1 Product Range, please visit our website at **www.genedrive.com**

Ordering Information

Product Code	Product Description	Pack Quantity
GS-002	Genedrive System	1 unit
ID-RNR1-01	Genedrive MT-RNR1 ID Kit	1 box (10 Kits)
RNR1-CTRL-01	Genedrive MT-RNR1 Control Kit	1 box (4 Kits)
GS-002-PTR	Genedrive Star label printer with charging cradle	1
GDS-187	Replacement Printer Labels	20 rolls

References

1. National Institute for Health and Care Excellence, Neonatal infection: antibiotics for prevention and treatment, (2021), NICE.

2. Bliss on hospital admissions to Neonatal Units https://www.bliss.org.uk/research-campaigns/neonatal-care-statistics/statistics-about-neonatal-care

3. McDermott J et all. Rapid Point-of-Care Geontyping to Avoid Aminglycoside-Induced Ototoxicity in Neonatal Intensive Care. JAMA Pediatr.doi.10.1001/jamapediatrics.2022.0187 (2022)

Intellectual Property

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