

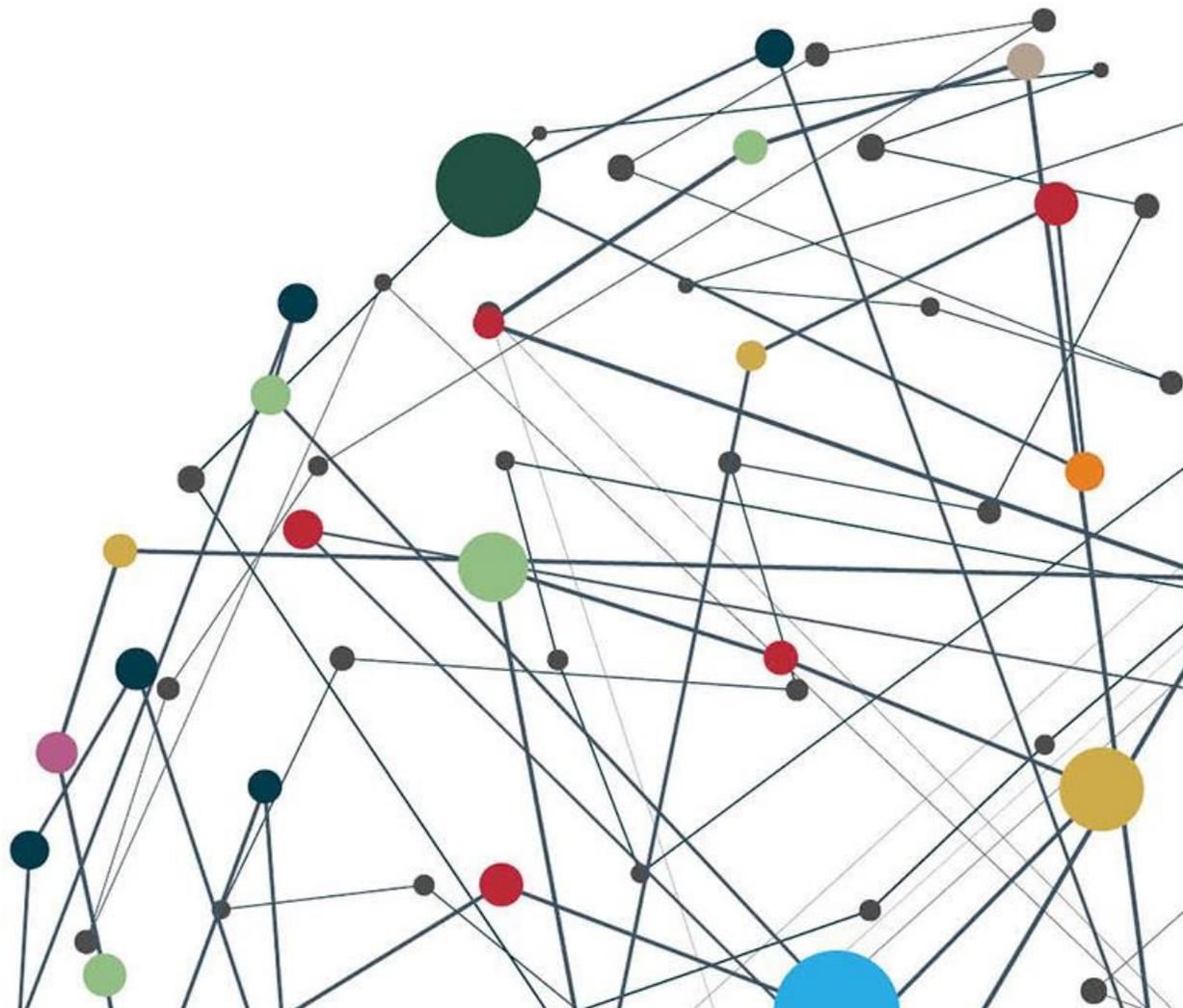
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# ADVANCING MOLECULAR DIAGNOSTICS TO THE POINT-OF-CARE

21 November 2022

Year End Results:  
Jun-22

genedrive



# DOCUMENT INFORMATION

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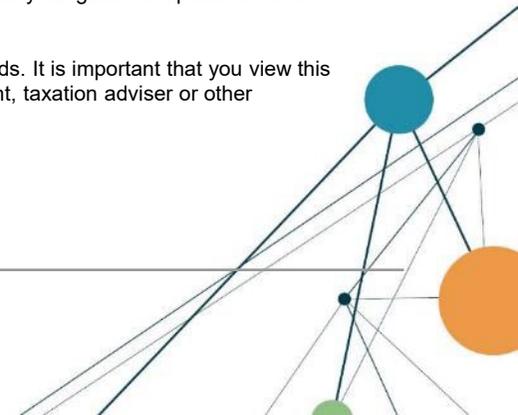
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# CAPABILITIES OVERVIEW



## GENEDRIVE TECHNOLOGY

### ✓ Rapid Point-of-care or Decentralised location testing

- Patented amplification technology.
- Two low-cost platform options - (1) single button menu (& android app) or (2) integrated touchscreen system.
- Total Analysis Time: 7.5 - 90 minutes depending on target and amplification chemistry.

### ✓ Easy of Use by those with no previous molecular diagnostic experience

- Solid-state components, no field repair.
- Single use disposable freeze dried assays – no complex reagent preparation.
- Closed system for specific clinical applications.
- Assay specific software.

### ✓ Versatile Test Menu

- Existing tech developed for HCV, COVID19, MT-RNR1, Military Pathogens.
- Supports a variety of amplification technologies (PCR, RT-PCR, LAMP, RT-LAMP, real-time or end-point detection and discrimination of DNA or RNA targets).

## STRATEGY - GENETIC INFORMATION FOR URGENT TREATMENT CHALLENGES

- genedrive has a solid track record for innovation.
- Increasingly focused on acute medicine / pharmacogenetics where rapid genetic information can help tailor emergency medical care.
- In 2022, genedrive was the first company to deploy a commercial point-of-care genetic test (Genedrive® MT-RNR1 ID Kit) into an emergency care setting.
- In development is our 1-hour Genedrive® CYP2C19 assay that can be used across a broad range of indications.
- Portfolio of other tests, including a direct from plasma confirmation of HCV infection test and a rapid 7.5 min point-of-care test for COVID-19 detection.

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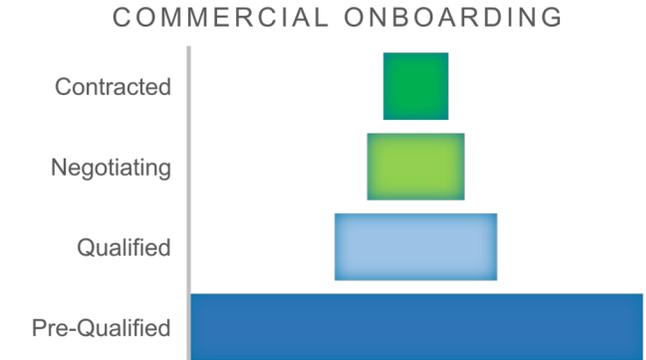


## OPERATIONAL HIGHLIGHTS (FY AND ONWARDS)

- **JAMA Pediatrics'** PALOH (Pharmacogenetics to Avoid Loss of Hearing) paper published.
- Launched **2nd generation Genedrive® system** to support strategy focus of pharmacogenomics into emergency care settings.
- **First sales** for Genedrive MT-RNR1.
- **First deployments** of the Genedrive® System for Antibiotic Induced Hearing Loss at Manchester Royal Infirmary (St Mary's) & subsequent routine clinical use.
- New **CYP2C19 product development** programme initiated for use of Genedrive® Point-of-Care device for ischemic stroke treatment in emergency care settings.
- **NICE accelerated evaluation** of the Genedrive® MT-RNR1 ID test to Q1 2023.
- NICE includes Genedrive® CYP2C19 ID Kit in Diagnostics Assessment Programme.
- Point-of-Care Genedrive® COV19-ID Kit received Coronavirus Test Device Approval ("**CTDA**").
- Filed **US FDA Pre-submission** for the Genedrive® MT-RNR1 ID product range.

# COMMERCIAL HIGHLIGHTS (FY AND ONWARDS)

- New Commercial Sales team recruited since mid-year
  - RNR1 Commercial Sales in UK and Supporting Inspiration Healthcare activities
  - Diligence and Contracting/Onboarding new MT-RNR1 partners internationally, with a primary focus on Europe
  - Pursuing COVID-19 opportunities in selected countries if opportunity presents
- New Commercial Marketing Team established
  - Managing and driving NICE processes
  - Supporting NHS Trust through their business case process to get funding into place, prior to national commissioning and NICE recommendations
  - Engagement of the market to raise awareness on Genedrive MT-RNR1.
  - Over 2 dozen independent publications on Genedrive innovations since January



# CLINICAL MARKET AWARENESS



## UK Study Supports Clinical Adoption of Genedrive Newborn Hearing Loss Test Within NHS

Apr 07, 2022 | [Justin Petrone](#)



NHS Develops World-First Bedside Genetic Test To Prevent Babies Going Deaf



**CLARE JENNINGS**  
NICU Nurse, Wythenshawe Hospital

**Manchester University**  
NHS Foundation Trust

**“**  
I am absolutely thrilled with the success of the study, and that this testing is now going to be used in three of our hospital's neonatal intensive care units - it's actually going to make a real difference so babies are not going to lose their hearing for a preventable reason.”  
**”**

Professor Bill Newman PALoH study lead and Consultant in genomic medicine at MFT



**Manchester University**  
NHS Foundation Trust

**“**  
Such an amazing study to be part of, and to see it being implemented into clinical practice so soon is just fantastic.”  
**”**

Nicola Booth  
Research Nurse Manager, NICU  
Saint Mary's Hospital



**Manchester University**  
NHS Foundation Trust

**“**  
This test is great, and I think all babies should have it.”  
**”**

Mary, mum of Khobi, who took part in the PALoH study at Saint Mary's Hospital, part of MFT

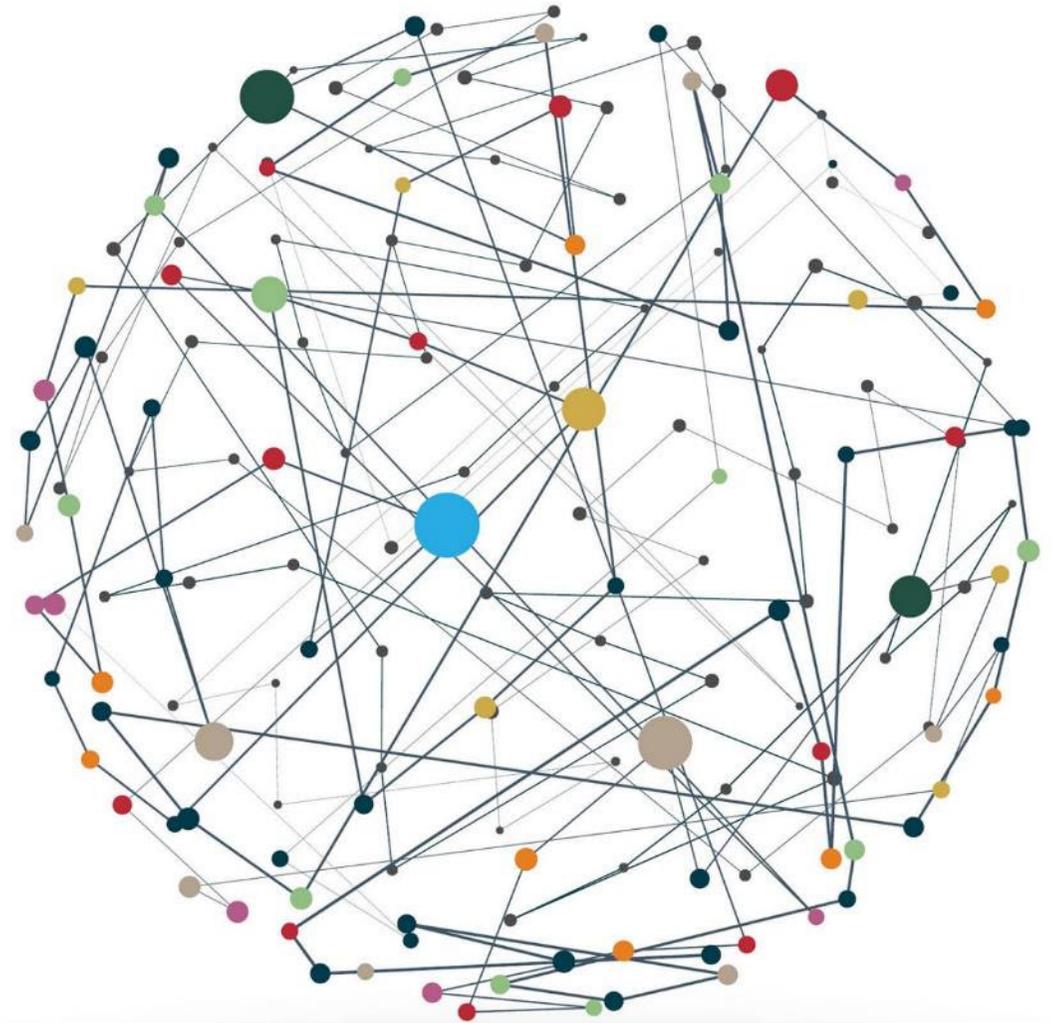


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# Antibiotic Induced Hearing Loss (AIHL)

Genedrive MT-RNR1 ID Kit



## Pioneering PALOH study using Genedrive MT-RNR1 ID Kit

JAMA Pediatrics | [Original Investigation](#)

### Rapid Point-of-Care Genotyping to Avoid Aminoglycoside-Induced Ototoxicity in Neonatal Intensive Care

John H. McDermott, MD, MRes; Ajit Mahaveer, MD; Rachel A. James, PhD; Nicola Booth, RN, PhD;  
Mark Turner, MD, PhD; Karen E. Harvey, RN; Gino Miele, PhD; Glenda M. Beaman, PhD; Duncan C. Stoddard, MSc;  
Karen Tricker, PhD; Rachel J. Corry, MSc; Julia Garlick, MSc; Shaun Ainsworth, PhD; Thomas Beevers, BSc;  
Iain A. Bruce, MD, PhD; Richard Body, MD, PhD; Fiona Ulph, PhD; Rhona MacLeod, PhD; Peter L. Roberts, BA;  
Paul M. Wilson, BA; William G. Newman, MD, PhD; for the PALOH Study Team

- 26-minute test, described as “entering a new era”, and “an important step” in the management of neonatal sepsis
- No disruption to clinical pathway by using test.
- 3 babies identified as having the MT-RNR1 1555A>G variant, and alternative antibiotic given to avoid lifelong hearing loss.

## AIHL – GENEDRIVE MT-RNR1 ID KIT

### Genedrive® MT-RNR1 ID Kit

- Ototoxicity from antibiotics is a widely known issue with specific clinical guidance (CPIC) on genetic mutations
- High unmet need, with an addressable market globally >£100m
- Provides an automated result of an individual's MT RNR1 m.1555 genetic variant status to inform the clinician ahead of antibiotic treatment decisions
- Manchester St Mary's adopted and live, 2\* more expected on stream shortly and 8\* more clusters in the sales funnel. (\*Subject to contracts)
- High enthusiasm for adoption by NHS front line staff
- Inspiration Healthcare appointed as the UK distributor – Spain also now contracted and 3 other countries imminent
- Currently subject to NICE accelerated Early Value Assessment

High unmet need  
100k UK  
1/500

Addressable Market  
>£100m

CE Marked  
Sensitivity 100%  
Specificity 99.2%

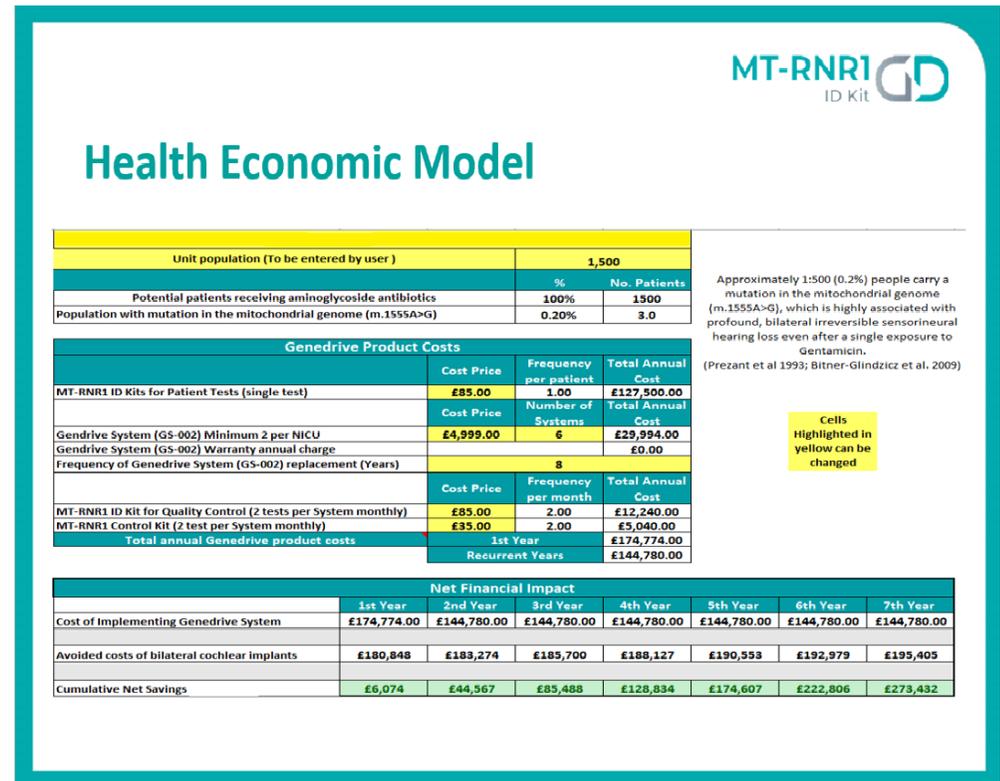
Positive  
Health Economics

NICE  
FDA  
PALOH

# AIHL – GENEDRIVE MT-RNR1 ID KIT

## Health Economics

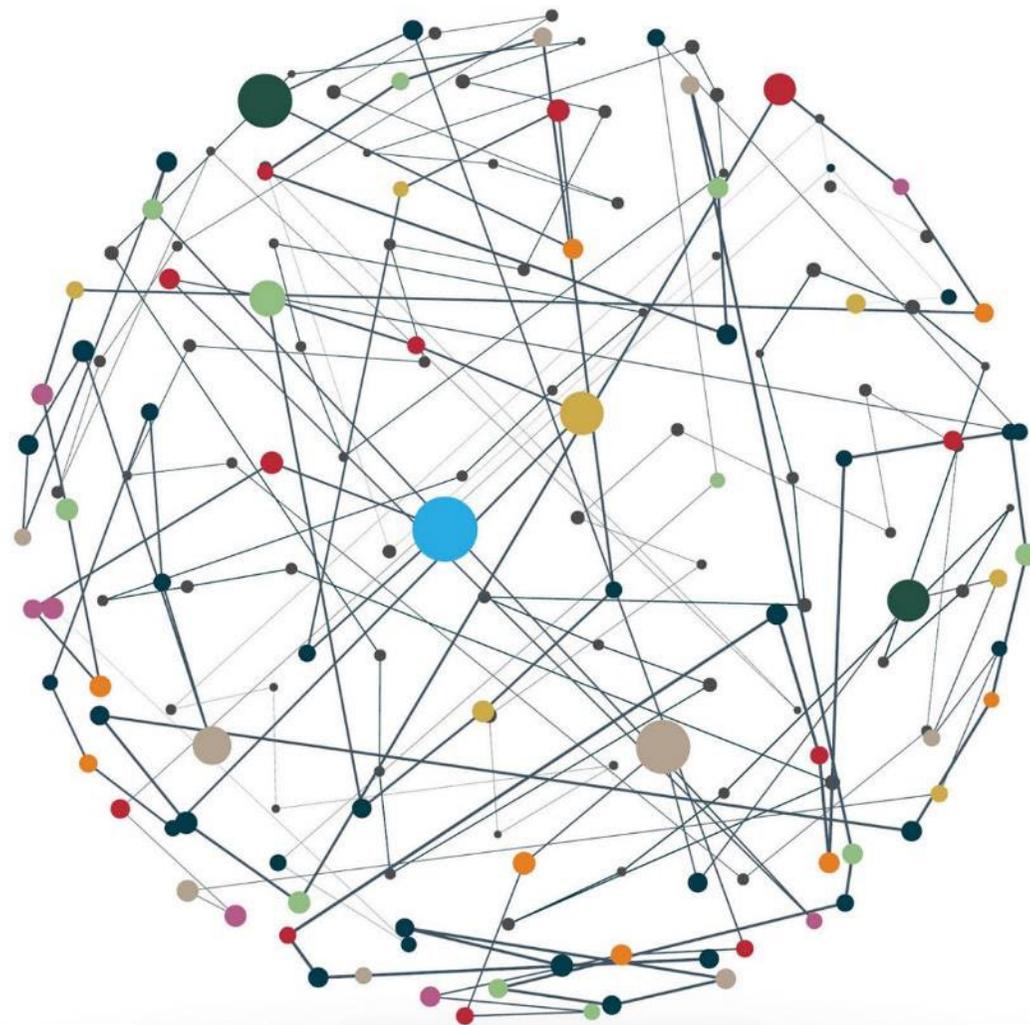
- Significant unmet need globally, with no direct competition currently
- Clinician interest level is encouraging
- National commissioning process
- NICE review/recommendation
- Supporting Individual Trusts with Business Cases through the buying process with Independently validated Health Economic Outcome Model
- Demonstrating the cost benefits of running Genedrive vs avoided costs of Cochlear implants



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Genedrive<sup>®</sup> CYP2C19-ID Kit



- Genedrive's AIHL clearly demonstrates opportunities in the evolving point of need pharmacogenetics market
- Drugs such as Clopidogrel can prevent further strokes or cardiac events can be highly effective, or not effective at all in some individuals depending on their CYP2C19 gene.
- Very large opportunities – for example, over 32 million antiplatelet items were prescribed in 2020/21 at a total cost to the NHS of over £78m.
- USA market has high value and established reimbursement (Medicare CPT Code 81225, circa \$291)
- NICE has now included Genedrive's CYP2C19-ID Kit in new Diagnostics Assessment Programme
- Looking to country specific distribution partners where CYP2C19 clinical guidelines are applicable

## Genedrive®

### CYP2C19 ID Kit\*

A new easy to use molecular point of care test for rapid CYP2C19 genotyping for emergency care settings.

The Genedrive® CYP2C19 ID Kit will provide a rapid, automated result of targeted CYP2C19 genotypes to inform clinicians on metaboliser status ahead of treatment strategies using drugs that are metabolised by Cytochrome P450 2C19 (CYP2C19).

Pharmacogenetic testing assists prescribers to select tailored treatment and doses that are most effective and avoid those which may cause adverse reactions in an individual with a known genetic variant. This facilitates effective prescription in a clinically relevant timeframe, thereby improving patient outcomes.

Clopidogrel is a prodrug, requiring conversion by the enzyme CYP2C19 and is administered for the management of ischaemic strokes.

Relevant genotypes which define CYP2C19 metaboliser status are well described and dosing recommendations have been produced by the Clinical Pharmacogenetics Implementation Consortium (CPIC)<sup>1</sup>.



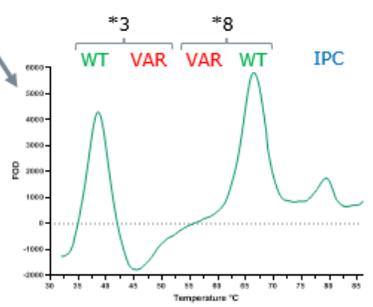
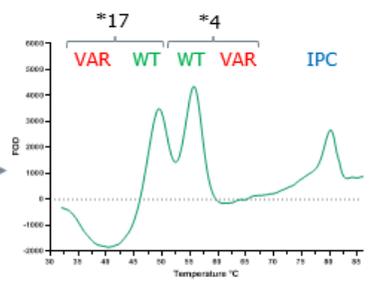
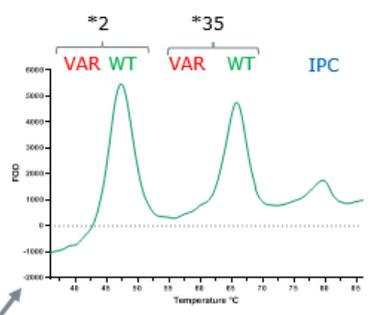
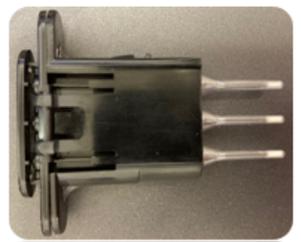


<b>Speed</b>	Rapid results in less than one hour for use in urgent care settings
<b>Simple to use</b>	Point of care test performed by healthcare professionals
<b>Ready to use</b>	Ambient temperature-stable reagents, negating the requirement for cold chain storage, for immediate use
<b>Non-invasive</b>	Test performed using a single buccal swab sample from the inner cheek
<b>Comprehensive</b>	Broad variant coverage identifying clinically relevant alleles of CYP2C19 including *2, *3, *4, *8, *17 and *35

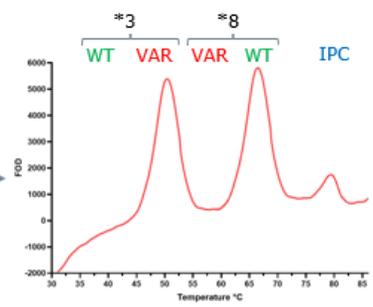
\*New product is currently in development and does not have regulatory approval, with final specifications subject to change - availability 2023  
<sup>1</sup> Lee CR, et al 2022 CPIC Guideline for CYP2C19 Genotype and Clopidogrel Therapy: 2022 Update

# HOW CYP2C19 ASSAY FUNCTIONS

CYP2C19 ID Kit



Normal Metaboliser



Poor Metaboliser

- Product currently entering Verification and Validation phase
- Targeting a UK launch date March/April 2023
- Will be subject to new IVDR regulation for EU
- Commercial Team doing due diligence on commercial partners

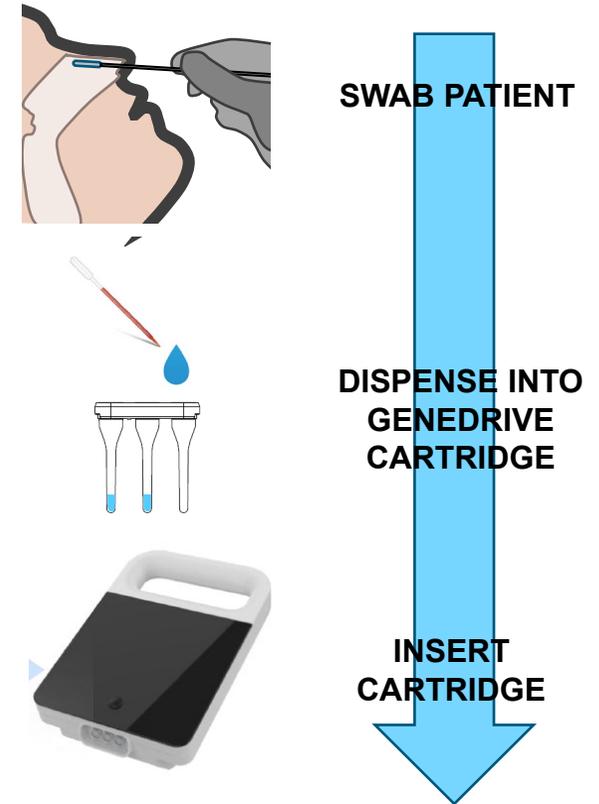


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Genedrive<sup>®</sup> COVID-19-ID kit

# PRODUCT: GENEDRIVE® SARS COV-2 ID KIT

- CE marked in December 2021 and CTDA approval in May-22
- 7.5-17 minute test time = faster than competitive systems
- No viral extraction = avoids complexity
- Simple workflow (similar to lateral flow antigen test procedure)
- Launched after the last meaningful wave of COVID infection
- Testing has not yet returned (actively being discouraged) but we are able address any uptick should market demand change



(+) as little as 7.5 minutes



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## Summary Financials

# SUMMARY FINANCIALS

## Income statement

	FY22	FY21
	£'000	£'000
Revenue	49	687
Operating costs	(5,664)	(6,169)
Operating loss	(5,615)	(5,482)
Finance (costs)/income	(16)	3,630
Loss before tax	(5,631)	(1,852)
Tax	956	1,161
Loss after tax	<b>(4,675)</b>	<b>(691)</b>

## Cashflow

	FY22	FY21
	£'000	£'000
Cashflow from operations	(5,327)	(5,237)
Working capital	(433)	(933)
Taxation	1,166	1,018
Other	(85)	(180)
Net cashflow from operations	(4,679)	(5,332)
Settlement of convertibles	-	(358)
Proceeds from share issue	6,694	46
Net cash flow	2,015	(5,644)
Cash at bank b/f	2,574	8,218
Cash at bank c/f	<b>4,589</b>	<b>2,574</b>

## Underlying monthly burn rate:

	FY22	FY21
	£'000	£'000
Gross	(487)	(529)
Adjusted for taxation	(390)	(444)

## Income statement

- Operating costs reduced by £0.5m due to sales activity and tight cost control
- Settlement of last convertible Loan Notes generated finance income, contributing to £3.6m income in FY21

## Cashflow

- Cash consumption from operations is £5.3m - similar to FY21
- Working capital consumed £0.4m – £0.5m less than FY21 due to reduction in creditors
- £1.2m receipt from HMRC R&D tax credit scheme
- Final convertible loan notes settled - £0.4m outflow in FY21
- Fund raise of £6.6m net in October 2021
- Unaudited cash at 31 October 2022 of £3.0m
- Underlying cash consumption of £487k per month
- Adjusting for R&D tax credit received - monthly rate reduces to £390k

# ANTICIPATED NEWS FLOW

## <6 Months

- Sign up and contracting of additional distribution partners for MT-RNR1
- Additional go-live sites in the UK for Genedrive MT RNR1
- Completion consultation of NICE review for Genedrive MT RNR1
- Promotion and launch of Genedrive MTRNR1 assay in other EU countries
- Launch of CYP2C19 in the UK (UKCA mark)

## >6 Months

- Completion of NICE review for Genedrive CYP2C19
- Launch of CYP2C19 in other territories following IVDR registration
- Begin FDA registration processes pending positive pre-sub process and funding



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Thank you.