genedrive

genedrive plc

David Budd | Chief Executive Officer

Presentation has been modified from original use to remove competitor names

VOX Markets Presentation 12 June 2020

GENEDRIVE – AIM:GDR

Genedrive®: the Point-of-Need, molecular diagnostic gene reader

- We develop highly accurate molecular diagnostic assays for use on our Genedrive® instrument
- PCR is the base chemistry

- **Rapid results** – in as little as 27 minutes
- **Single use**, disposable reagent cartridge revenue model
- **Same instrument** platform is used across a range of applications
- **Low cost** - <£500 unit, <£5-8 tests
- **Customer price/test** £15-£80

GENEDRIVE – COMMERCIAL STAGE COMPANY

Antibiotic Induced Hearing Loss

World's first rapid genetic test for neonatal acute care

Hepatitis C (HCV)

Blood-based, viral testing

World Health Organization

Institut Pasteur

US Military Detection

Sole supplier to US military for handheld bio warfare

Tuberculosis

Sputum based bacterial testing

GLOBAL HEALTH INVESTMENT FUND

SARS-CoV-2

Rapid saliva based* POC in ~30 mins

96 SARS-CoV-2

High Throughput PCR beads

NHS National Institute for Health Research

Genedrive® Development

3rd party

Commercial /CE Marked

genedrive

* Design goal

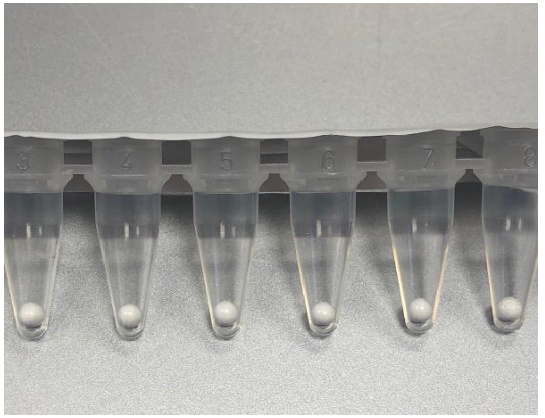
Genedrive® 96 SARS-CoV-2 Kit

GD-96
SARS-CoV-2 Kit

Genedrive® 96 SARS-CoV-2 Kit

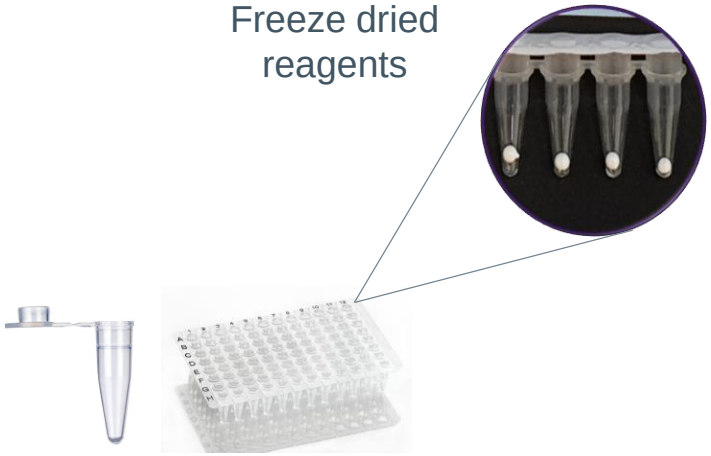
Innovative PCR to meet the need for increased consistency, throughput, and ease of use in COVID-19 PCR

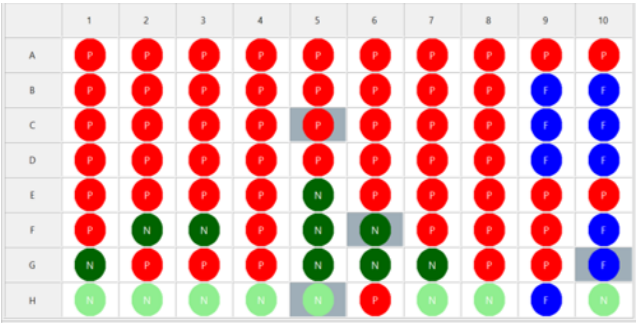
- A Unique, one-step CE-IVD PCR assay designed to detect SARS-CoV-2 infection
- Single PCR solid bead format eliminates the need for time-consuming, error prone reagent preparation
- Streamlines the laboratory workflow and allows for high volume throughput.
- Room temperature stability to access a global market
- £8-£10 / test (x96), circa 60% GM, manufacturing capacity with Cytiva 10,000 test / hour



cytiva
genedrive

Simple ‘1-step’ Test





Load extracted RNA sample directly into the plate, mix and centrifuge

Run on Real-Time PCR machine

Time to result = 100 mins (96 tests)

Load sample

Run test

View results

Performance Characteristics

Performance study data

180 clinical specimens, collected using various swab types (BD, Copan, Sterilab) and extraction kits/methods.

Metric	Result (%)	95% Confidence Interval (%)
Sensitivity	100.0%	97.0 - 100.0
Specificity	98.2%	90.4 - 99.9
Diagnostic Accuracy	99.4%	96.9 - 99.7
PPV	99.2%	95.6 - 100.0
NPV	100.0%	93.4 - 100.0

Limit of Detection = 0.5 copies/µl (10 copies per reaction)

Sample Comparison Workflow Summaries

genedrive

Step 1 – Add sample /controls to the lyophilised plate

Step 2 - Transfer to centrifuge

Step 3 - Centrifuge

Step 4 - Detection

Comp A

Step 1 - Add buffer to lyophilised instrument plate

Step 2 – Add sample /controls to the lyophilised plate

Step 3 - Transfer to centrifuge

Step 4 - Centrifuge

Step 5 - Detection

Comp B

Step 1 - Mix master A + B liquid

Step 2 - Transfer mastermix to plate

Step 3 – Add sample /controls to the lyophilised plate

Step 4 - Transfer to centrifuge

Step 5 - Centrifuge

Step 6 - Detection

Comp C

Step 1 – Re-suspend lyophilised mastermix

Step 2 - Transfer mastermix to plate

Step 3 – Add sample /controls to the lyophilised plate

Step 4 - Transfer to centrifuge

Step 5 - Centrifuge

Step 6 - Detection

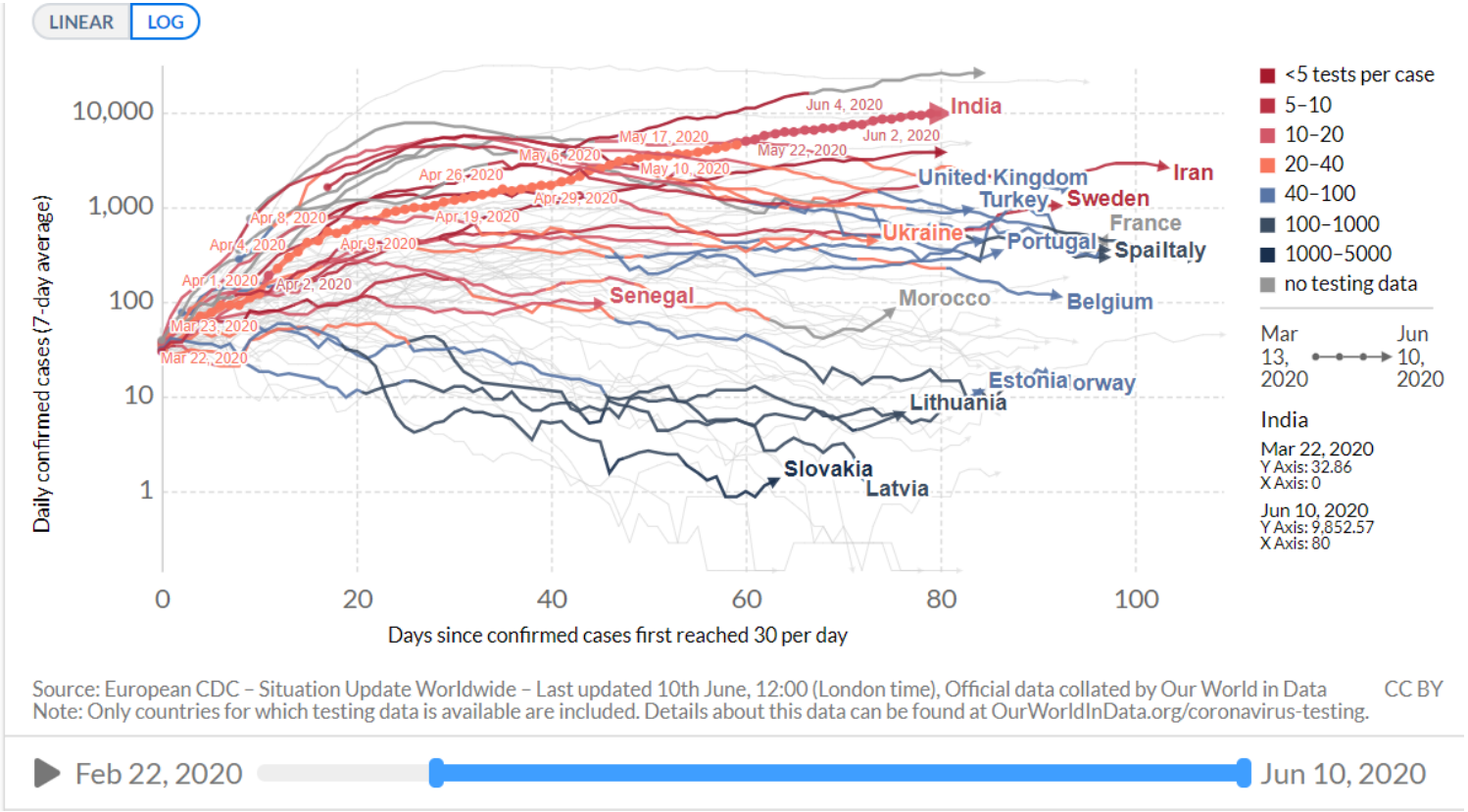
Competitor Comparison

	genedrive	Comp A	Comp C	Comp D	Comp B	Comp E	Comp F
Test Name							
Ambient shipping/storage	Yes	Yes	No	No	No	No	Yes
Multiple Gene Targets	Yes	Yes	No	Yes	Yes	Yes	?
Human RNA control	Yes	No	No	No	No	No	No
Operator interactions	4	6	6	6	6	6	6
Pipetting steps	1	2	3	2	3	3	1

GD-96 SARS-CoV-2 Kit

A Global Market

WHO chief Tedros Adhanom warned on Tuesday against complacency ""*Although the situation in Europe is improving, globally it is worsening*".



https://ourworldindata.org/epi-curve-covid-19

GD-96 SARS-CoV-2 Kit

Current / Distribution Agreements

	Regulatory status
Europe: Austria, Germany, United Kingdom, Switzerland, Turkey, Spain, Portugal, Belgium, The Netherlands, Luxembourg, Poland, Hungary, Czech Republic, Slovakia, Sweden, Norway, Denmark, France, Cyprus **Central East Europe:** Romania, Slovenia, Croatia, Ukraine, Estonia, Lithuania, Latvia, Moldova, Albania, Bulgaria, Serbia, Bosnia and Hercegovina, Montenegro	CE Mark 22 May
Africa: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Congo, Democratic Republic of Congo, Cote d'Ivoire, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Lesotho , Liberia, Libya, Madagascar, Malawi, Mali, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan,	WHO EUA Applied + Country Specific
Sudan, Swaziland, Togo, Tunisia, Uganda, Zambia, Zimbabwe. **Middle East:** Iran, Iraq, Saud Arabia, Yemen, Syria, United Arab Emirates, Israel, Jordan, Palestine, Lebanon, Oman, Kuwait, Qatar, Armenia, Bahrain, Turkey, Azerbaijan, Uzbekistan Tajikistan, Turkmenistan, Kyrgyzstan, Kosovo, Kazakhstan **India**	Country Specific

Desired Distribution Channels -

USA South America Mexico	FDA EUA Applied Country Specific

Genedrive 96 SARS-CoV-2 Summary

Huge market potential and currently limited price sensitivity

- Unique product design with meaningful, valuable benefits to the user
- Top tier clinical performance specifications
- Temperature stable nature facilitates global distribution to global markets
- Competitive pricing with attractive margins
- Commercial scale manufacturing capability with Cytiva
- Distribution routes established and even more being established
- CE Marking achieved, additional registrations in process
- Global pandemic continues to grow, making global distribution capability important
- COVID-19 can only be controlled through constant monitoring (testing), social distancing, and treatment (vaccine)
- Company anticipates recording first sales this month.

MT-RNR1 ID Kit

Antibiotic Induced Hearing Loss

Genedrive® MT-RNR1 ID Kit

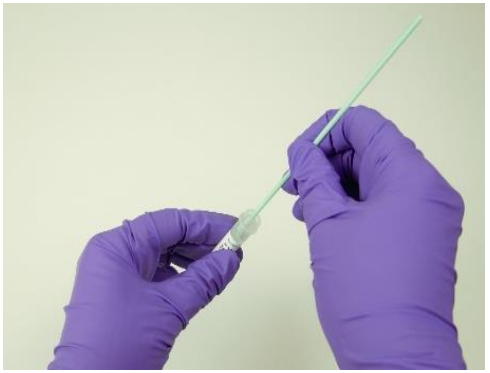
First to Market Global Opportunity

First to market opportunity

- Percentage of children (1/500) will suffer permanent deafness when given the drug gentamycin.
- Given within 1 hour of admission to Neonatal Intensive Care.
- Caused by a genetic mutation called MT-RNR1.
- Use Genedrive test to give a rapid (27 min) genetic result in the NICU ward.
- Give alternative antibiotics which are readily available.
- Genedrive is the first company in the world to develop a genetic test for rapid testing of this sort.

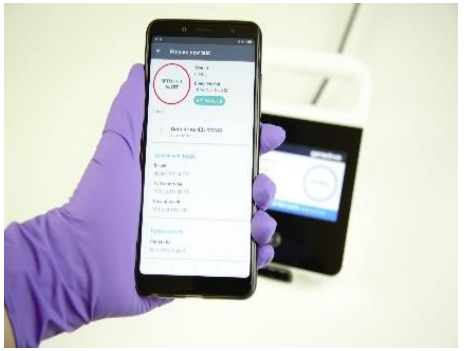
Genedrive Workflow

Baby admitted to NICU With infection



Nurse takes buccal swab

Run the 27 min test on Genedrive



Get a positive result and treat with alternative antibiotics

Clear Benefits in Health and in Cost

UK Example

- The current hospital tests used take 2-5 days for a result, therefore they are unsuitable for emergency care
- The test provides a clear patient benefit by helping to prevent antibiotic related hearing loss in neonates
- In the UK there are approx. 90,000 babies admitted to neonatal intensive care each year
- Therefore our test has the potential to save approx. 180 babies each year in the UK from going deaf
- Health economic case is positive vs. the need for expensive clinical interventions, including bilateral cochlear implants

MT-RNR1 ID Kit

Market Opportunity

- Approx 90,000 babies admitted each year to NICU in the UK
- Assume ‘Western World” market opportunity 1.25M tests / year
- Test economics - <£10 to make, £35 to distributors, £50-£85 direct depending on reimbursement / country
- Approx 1:500 carry the mutation (Preliminary UK Biobank study of 500,000 individuals)
- Based on this mutation frequency approx. 2500-3000 babies could be prevented from going deaf every year in EU/USA
- Global market value estimated at £40-£65M per year depending on route to market.

Clinical Performance

Diagnostic accuracy of Genedrive MT-RNR1 ID Kit

		Reference Test	
Index Test		Detected	Not detected
	Detected	59	0
	Not detected	0	244

- **Sensitivity = 100% (93.9% to 100% CI)**
- **Specificity = 100% (98.5% to 100% CI)**

MT-RNR1 ID Kit

Genedrive AIHL Summary

- World first product design with health economic benefits
- Clinical performance specifications match best in class lab testing
- Temperature stable cartridges contract manufactured by Cytiva
- Competitive pricing with attractive margins
- Launching autumn 2020 with scalable Distributor contracted
- CE Marking achieved


INDEPENDENT

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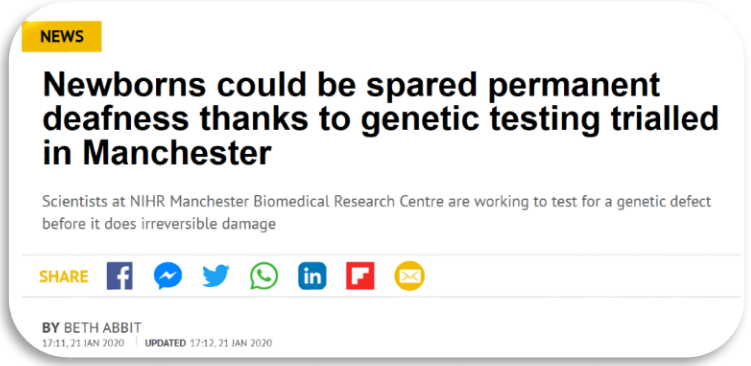
News > Health

World's first emergency genetic test can save newborns from permanent deafness with simple cheek swab

Exclusive: New method undergoing trial in UK could spare more than 180 babies profound hearing loss a year – and save NHS millions

Rachel Pugh | Tuesday 21 January 2020 13:30 |


NEWS

Newborns could be spared permanent deafness thanks to genetic testing trialled in Manchester

Scientists at NIHR Manchester Biomedical Research Centre are working to test for a genetic defect before it does irreversible damage

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BY BETH ABBIT

17:11, 21 JAN 2020 | UPDATED 17:12, 21 JAN 2020

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