

MDx COLLABORATION OPPORTUNITY



Molecular Dx sensitivity & specificity

Suitable for patient self-testing

Integrated sample preparation

Application configurable

Ultra low cost

Rapid and robust

Battery powered

Overcomes the main entry barriers normally associated with clinical MDx

The device incorporates patent protected platform technology developed by UK company, GSG Technology Ltd.

Configurable for various sample types, integration of third-party assays and alternate detection technologies. Expandable to multiplexed assays.

Device cost estimates (volume dependent):

Drive pack < \$30 COGS

Disposable test strip < \$2 COGS (excluding reagents)



DEVELOPMENT BACKGROUND:

Device developer, GSG Technology Ltd, is a UK-based medical engineering consultancy led by Graham Gutsell who has over 35 years experience in the application of technology and the innovation, development and scale-up of medical devices for major multinationals, start-ups and institutions.

The first-generation device from which the current offering has been derived was created in collaboration with UK government.

First generation device:

- simple portable MDx system
- · low cost consumable and device
- · lateral flow detection
- · lacks sample preparation



The present device addresses the needs of the clinical diagnostics market through the integration of sample handling, user convenience and low cost.



- simple and robust portable MDx system
- integrates sample handling, sample preparation & detection
- low cost consumable and driver pack
- · multiplexing capability
- suitable for integration into 3rd party product developments
- configurable for alternatives, for example:
 - sample preparation techniques and chemistries
 - amplification assays
 - detection technologies

PATENT STATUS:

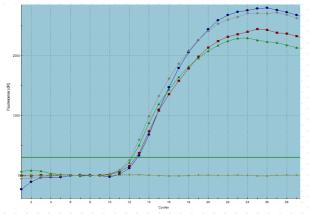
Different aspects of the technology are protected by two key patent families:

US10006867 B2 (plus equivalents in all major territories) – granted June 26 2018 **WO2018127741** (plus equivalents in all major territories) – PCT application, priority date Jan 09 2017



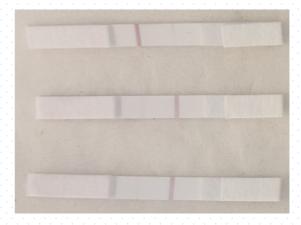
EXAMPLE: Proof of concept testing

Proof of concept testing to extract, amplify (isothermal LAMP) and detect nucleic acid in *Streptococcus* bacterial suspension. The figures below shows comparison of device LFD readout against amplification plots using a standard bench-top analyser.



<u>Figure 1:</u> Amplification plots from extracted DNA amplified with a Strep LAMP assay

Blue: Test device lysed bacteria Red: Test device lysed bacteria Green: Hot block lysed bacteria Grey: Hot block lysed bacteria Yellow: No Template Control



<u>Figure 2:</u> Extracted DNA amplified with a Strep LAMP assay and tested using a LFD.

Bottom – test device extracted DNA Middle - heat block extracted DNA Top - negative control

NEXT STAGE:

GSG Technology is seeking discussion with diagnostic companies interested in any of the following:

- · co-developing the technology into a fully commercialised product
- integration of the technology, or parts thereof, into own or third-party product development
- licensing elements of the technology.

CONTACT:

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