



## **New test delivers positive results in approximately 30 minutes**

**Dublin, Ireland, 20 May 2020** – HiberGene Diagnostics (“HiberGene”) is pleased to announce that it has successfully completed the CE marking of a new fast molecular COVID-19 test, which is now available for sale in Ireland and internationally. This announcement follows the completion of a clinical evaluation study at the Mater Private Hospital, Dublin, Ireland, that has demonstrated the efficacy of the product.

The new COVID-19 test, which expands the company’s product range to 13 tests, employs HiberGene’s proprietary molecular reagent format to accurately detect the virus in nose and throat swabs, utilising HiberGene’s small, portable HG Swift instrument to test four samples concurrently. The new COVID-19 assay utilises an easy to use freeze-dried reagent format.

Using a low-complexity sample preparation protocol, the test has excellent performance for samples with high to moderate viral loads. Positive results are returned within 30 minutes on average, enabling rapid diagnosis of the disease at the early and highly infectious stage of infection. Negative results are returned within 60 minutes. When coupled with a nucleic acid extraction method, the system provides sensitivity equivalent to that of the current PCR systems for samples from individuals at all stages of COVID-19 infection.

Further studies and collaborations to evaluate potential additional uses of the test, such as compatibility with new specimen types and patient cohorts, are planned including clinical evaluations at IRCCS Ospedale Policlinico San Martino in Genoa, Italy; Queens University in Belfast, Northern Ireland; and at laboratories in China, in collaboration with HiberGene’s Chinese distribution partner, Medcaptain Medical Technologies (“Medcaptain”).

The project is supported by a grant of €930,000 from Horizon 2020, the EU programme for research and innovation.

This new test complements HiberGene’s menu of current tests for respiratory disease such as Flu, RSV and Mycoplasma Pneumoniae.

---

**Business Address**

Block 2  
Bracken Business Park  
Sandyford  
Dublin 18  
Ireland, D18 RR24

**Registered in Ireland**

No. 476990

**Registered Address**

21 Palmerston Gardens  
Rathmines  
Dublin 6  
Ireland, D06 V652

**Commenting, Seamus Gorman, CEO of HiberGene, said:**

*“The COVID-19 pandemic is the greatest challenge to humanity in our lifetimes. HiberGene has responded to this global challenge by leveraging our proprietary technology to accelerate the development of an accurate and reliable test for COVID-19. The test is suitable for both decentralised facilities requiring rapid molecular tests for screening and centralised labs requiring additional tests for confirmation or out of hours testing. The support of the EU through the Horizon 2020 programme has been instrumental in delivering this project.”*

**Commenting on the project, Minister for Business, Enterprise and Innovation, Heather Humphreys TD, said:** *“I would like to congratulate HiberGene on their announcement today – an Irish based company which is answering the call and stepping up to the plate in our national and global effort to defeat COVID-19. Their hallmark as a company is innovation and adaptability, and the awarding of the CE mark to their COVID-19 diagnostic device to facilitate rapid testing is testament to that. I would like to commend them on their wonderful achievement and wish them every success as they bring the product to market and help Ireland and indeed the world to deal effectively with COVID-19.”*

**Commenting on Enterprise Ireland backed company HiberGene’s announcement, Julie Sinnamon, CEO of Enterprise Ireland, said:** *“I applaud the many Irish companies that are innovating in response to the COVID-19 pandemic and it is exciting to see HiberGene, who are at the forefront of innovation in the delivery of molecular testing for human infectious diseases, use its technology to develop this diagnostic device, which will help address the urgent global demand for testing with fast results. I wish HiberGene success with the development of this new product and we at Enterprise Ireland look forward to continuing to work with the company and other Irish businesses, as they develop new and innovative solutions in response to the crisis.”*

**Commenting on the project, Mariya Gabriel, Commissioner for Innovation, Research, Culture, Education and Youth, European Commission, said:** *“This is a great example of EU research in action. I am encouraged to see that these researchers have risen to the challenge, developed this new diagnostic system so fast, and delivered on one of the aims of our first emergency call. It’s crucial to diagnose coronavirus more quickly and more accurately, as it reduces the risk of further spread of the virus.”*