



**HIHI Project Report**  
**HiberGene Diagnostics Ltd.**  
**[www.hibergene.com](http://www.hibergene.com)**

<b>Project Title</b>	Independent Accredited Laboratory Evaluation of HiberGene's PCR Adapt COVID-19 Test against other commonly used PCR Kits.
<b>Company</b>	HiberGene Diagnostics Ltd.
<b>Project Hospital</b>	Bon Secours Hospital, Cork (BSHC)
<b>Project Department</b>	Microbiology Laboratory
<b>Clinical Location</b>	David Keane and Theresa Cunningham
<b>Project Champion</b>	
<b>HIHI Project Manager</b>	Niamh Allen HIHI
<b>Project Type</b>	HIHI Pilot of CE approved PCR test.

Report prepared by: Niamh Allen, HSE Clinical Liaison, HIHI Cork  
and Theresa Cunningham, BSHC.

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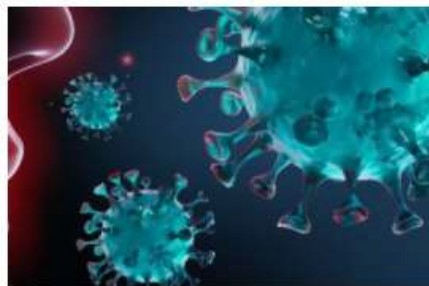
## Project Background

HiberGene Diagnostics is a Dublin-based, private Irish company that develops, manufactures and markets molecular diagnostic tests. To date, it has developed and commercialised a range of near-patient molecular tests in the areas of critical infectious diseases, sexually transmitted infections and hospital acquired infections.

In May 2020, HiberGene successfully completed the CE marking of a new molecular COVID-19 test. HiberGene's PCR Adapt COVID-19 RT-qPCR is a CE marked dual-target SARS-CoV-2 test for nasopharyngeal (NP), oropharyngeal (OP) and anterior nasal swabs. This assay may be performed in either direct (non-extracted) format or in extracted format using a commercial RNA extraction kit.

The new COVID-19 test expands the company's product range to 13 tests. Positive results are returned within a few hours, enabling rapid diagnosis of the disease at the early and highly infectious stage of infection.

HiberGene engaged Health Innovation Hub Ireland to facilitate an independent assessment of the PCR Adapt kit within an accredited, high throughput clinical laboratory.



### **Irish diagnostics manufacturer, HiberGene Diagnostics launches innovative PCR Adapt COVID-19 test**

Dublin, Ireland, 30th November 2021 -  
HiberGene Diagnostics is pleased to  
announce that it has successfully  
developed and CE Marked ...

[Read More](#)

## Objectives:

The Bon Secours Hospital in Cork operates a private SARS-CoV-2 testing facility, with high throughput testing using two alternate test kits- (1) EURORealTime SARS-CoV-2 (Euroimmun, a PerkinElmer Company) and (2) Xpert® Xpress SARS-CoV-2 (Cepheid).

The aim of this validation study was to compare HiberGene's **PCR Adapt COVID-19 RT-qPCR test against two commercially available standard tests currently employed in the Bon Secours Hospital testing facility.**

A comparison study (facilitated by the Bon Secours laboratory Scientists) was performed on 100 positive and 151 negative samples, previously tested using either the EURORealTime or Xpert® Xpress tests, or both. All samples were tested with HiberGene's PCR Adapt test. Samples used were frozen between -18°C and -25°C -18 and extracted using standard methods. The results were assessed by the laboratory scientist and concordance value provided for all samples.



## Project Plan:

Following a number of virtual meetings, the project process was agreed. PCR plate template and cycling protocols were provided by HiberGene to the BSHC.

### The agreed process:

- HiberGene provided 3x192 test kits to allow for test runs and a repeat run if required.
- The validation study was performed in the Microbiology laboratory of BSHC. 251 samples were analysed using the HiberGene kit and compared with results obtained previously using either 1) EURORealTime SARS-CoV-2 (Euroimmun, a PerkinElmer Company) or (2) Xpert® Xpress SARS-CoV-2 (Cepheid), or both.

- The samples used had been stored between -18°C and -25°C. It is noted that this is not optimal storage for RNA viruses however this has been notified to HiberGene in advance.
- Data from the study was prepared by BSHC and provided to the company directly in the report below.
- Complete data report is provided in Appendix.
- As a follow on from this study, HiberGene was introduced by HIHI to the UCC PI for the UniCov COVID study- Dr John McSharry who has agreed to consider including this test and others developed by HiberGene Diagnostics, into the University COVID testing programme.

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## Bon Secours Hospital Microbiology Laboratory Report

### HiberGene PCR Adapt COVID-19 Pilot Study

#### Report

The PCR Adapt COVID-19 test is a real-time PCR-based test which detects two individual target regions in the nucleocapsid (N) gene of the SARS-CoV-2 viral genome. The test also includes an internal control for the RNase P housekeeping gene found in human specimens.

The Microbiology Department of the Bon Secours Hospital Cork agreed to participate in a pilot study to test the performance of the PCR Adapt COVID-19 test. The study was conducted using stored samples which had previously been characterised as 'DETECTED' or 'NOT detected' with the Euroimmun EURORealTime SARS-CoV-2 assay, the Cepheid Xpert® Xpress SARS-CoV-2 assay, or both. The EURORealTime SARS-CoV-2 assay detects two defined sections within the ORF1ab- and N-genes of the SARS-CoV-2 genome. The Xpert® Xpress SARS-CoV-2 assay detects a region in the SARS-CoV-2 nucleocapsid protein gene (N2) and a conserved region in the structural protein envelope gene (E).

## Materials

Material	Lot Number	Expiry
<b>Reagents</b>		
MagMAX Viral/Pathogen II Nucleic Acid Isolation kit		
• Wash Solution	01035276	31/01/2022
• Elution Buffer	01058007	31/03/2022
• Binding Solution	01076767	30/04/2022
• Binding Beads	01045105	28/02/2022
• Proteinase K	01044020	28/02/2022
Ethyl alcohol	K2380S	n/a
Nuclease Free Water	2101426	n/a
PCR Adapt COVID-19 kit	HGPCOV1922101	11/02/2022
<b>Plastic Consumables</b>		
KingFisher Flex Deep Well 96 Plates		
KingFisher Flex Tip Comb for Deep Well Magnets		
KingFisher Flex Tip Comb Holder Plates		
Sigma X-Pierce Film		
Sarstedt PCR Plates 72.1980		
Microseal B PCR Plate Sealing Film MSB1001		
Assorted Pipette Tips		
Sterile 100ml containers		
RNase/DNase-free 2ml tubes		

## Samples

Stored combined nasopharyngeal and throat swabs collected in Biocomma Transport and Preservation Medium or Copan Universal Transport Medium.

- Positive Samples (n = 100)
- Negative Samples (n = 151)

## Method

SARS-CoV-2 RNA was extracted using the Thermo Scientific KingFisher Flex with the MagMAX Viral/Pathogen II Nucleic Acid Isolation kit. Real-time PCR was performed using the HiberGene PCR Adapt COVID-19 assay according to the manufacturer's specifications.

## Result Interpretation

A fluorescence limit of 650 RFU was applied to channels FAM, HEX and Texas Red as instructed in technical bulletin "*HG PCR Adapt Covid – HGPCOV192: Interpretation of Results*". Samples where either N1 or N2 amplified on their own were repeated as per the manufacturer's guidelines. Repeat testing was performed following repeat extraction from the primary sample, not on stored extract from the initial runs. Please see the table below for detailed review of the results.

## Discussion

251 samples were included in this study of which 100 were positive and 151 were negative for SARS-CoV-2. Concordance with the expected result was achieved in 250/251 samples (99.6%). SARS-CoV-2 was not detected in sample F51641 on initial testing or on repeat testing. SARS-CoV-2 was detected in sample X71786 in one target only on initial testing but failed to detect in either target on repeat testing. Factors that may have contributed towards lack of detection in these samples:

- samples were retrieved from sub-optimal storage at -20°C.
- some variation between assays is to be expected with low level target which may be attributed to the differing targets, differing limits of detection and stochastic variation.

## Conclusion

The PCR Adapt COVID-19 assay demonstrated excellent correlation with the EURORealTime SARS-CoV-2 assay and the Xpert® Xpress SARS-CoV-2 assay.

*Testing performed and report prepared by:*

Theresa Cunningham  
Specialist Medical Scientist  
Microbiology Department  
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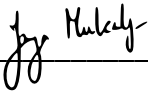
November 23<sup>rd</sup>, 2021.

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Signature Page

**Signed on behalf of Health Innovation Hub Ireland:**



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Dr Tanya Mulcahy

Interim Director,

Health Innovation Hub Ireland.

**Signed on behalf of Microbiology Department Bon Secours Hospital, Cork**



Ms Theresa Cunningham

**Signed on behalf of HiberGene Diagnostics Ltd.**

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Peter Kidney,

HiberGene Diagnostics Ltd.

**Appendix**