

## **GenomEra® 2.0 assay kit for COVID-19 CE marked - introduces second-generation usability and sensitivity to PCR testing**

The Finnish diagnostics company Abacus Diagnostica, part of Uniogen, is launching its second-generation COVID-19 test, the GenomEra® SARS-CoV-2 2.0 Assay Kit in the European market. The assay kit has recently received European CE marking for In Vitro Diagnostic (IVD) medical devices. It is intended for healthcare professionals, and it detects the SARS-CoV-2 virus in respiratory samples in 50 minutes.

- The assay kit provides rapid PCR test results with excellent sensitivity (98.3%) and high specificity (99.8%).
- The sample is collected to an inactivating sample collection media, which means that neither extensive safety measures nor dedicated PCR facilities are required.
- After a short and simple sample preparation, the assay process is fully automated. The results are automatically interpreted after 50 minutes. With one GenomEra® test system, up to four samples can be analysed at the same time. Capacity can be extended to 32 samples by combining up to eight instruments.
- The test performance is not affected by emergence of different COVID-19 variants, as the test simultaneously detects two different targets in the SARS-CoV-2 virus genome – the RdRp and E genes.

Abacus Diagnostica has worked decisively on the development of SARS-CoV-2 diagnostics since the beginning of the COVID-19 outbreak. The first SARS-CoV-2 assay for the GenomEra® CDX™ system received the CE IVD approval for the European market in July 2020.

“After further development, we are now proud to be able to offer this second-generation COVID-19 test. The fast and reliable test takes the usability to a whole new level. Additionally, the test has shown outstanding sensitivity and specificity in performance evaluations. The assay kit combines simplicity of use with the superior sensitivity of the PCR method,” says Erno Sundberg, CEO of Abacus Diagnostica.

The GenomEra® 2.0 development project has received funding from the European Union’s Horizon 2020 research and innovation programme.

“Both the funding and the CE mark prove that our outstanding team has done excellent job in developing the test. Together, we can reach the ambitious goals we have set at Uniogen,” concludes Sundberg.

**For more information, please contact:**

**Erno Sundberg**

CEO, Abacus Diagnostica

+358 40 727 8690

erno.sundberg(at)abacusdiagnostica.com

### **Abacus Diagnostica in brief**

Abacus Diagnostica is a frontrunner in molecular testing and rapid PCR tests, offering systems for diagnosis of infectious diseases such as coronavirus, influenza and intestinal bacteria. The automated test system developed and manufactured by the company consists of test chips, instrument and software interpreting the results. Abacus Diagnostica's customers are typically hospital laboratories. The test system can also be used in any healthcare unit, as it is easy to use and requires virtually no special expertise. The company's products are sold through distributors in more than 25 countries, mainly in Europe and Asia. Abacus Diagnostica has been operating since 2004, and the company is now part of Uniogen Oy.

[www.abacusdiagnostica.com](http://www.abacusdiagnostica.com)

### **Uniogen in brief**

Uniogen is a global pioneer in clinical diagnostics, point-of-care testing and instruments for life sciences. Our goal is to enable the right diagnosis and care at the first patient appointment. With point-of-care testing for infectious diseases and cancer diagnostics, among others, we provide patients and healthcare with faster, easier and more cost-effective diagnosis.

Our GenomEra rapid PCR tests for COVID-19 are currently a significant part of our business. Through contract development and manufacturing, we also provide laboratory instruments and tests for e.g. heart diseases and detection of coronavirus antibodies. Our Upcon system, consisting of brightly luminescent upconverting nanoparticles, instruments and software, brings great benefits to point-of-care testing. We are also developing the first total solution for point-of-care testing on the market that allows both antibody and PCR testing and thereby diagnostics for several diseases to be performed simultaneously with a single, versatile and easy-to-use device – virtually in any healthcare setting and without special expertise.

Uniogen was established when Abacus Diagnostica, a frontrunner in molecular testing and rapid PCR tests, Kaivogen, a specialist in immunoassays and antibody testing, and Labrox, an innovator of high technology laboratory instruments and diagnostic readers, joined forces in the beginning of 2022. The company is headquartered in Turku, Finland and employs close to 100 life science professionals. Uniogen's products are sold in about 100 countries around the world. In 2021, the combined annual net sales of the three companies forming Uniogen was approximately EUR 15 million.  
[www.uniogen.com](http://www.uniogen.com)