Rapid COVID-19 test granted EU approval

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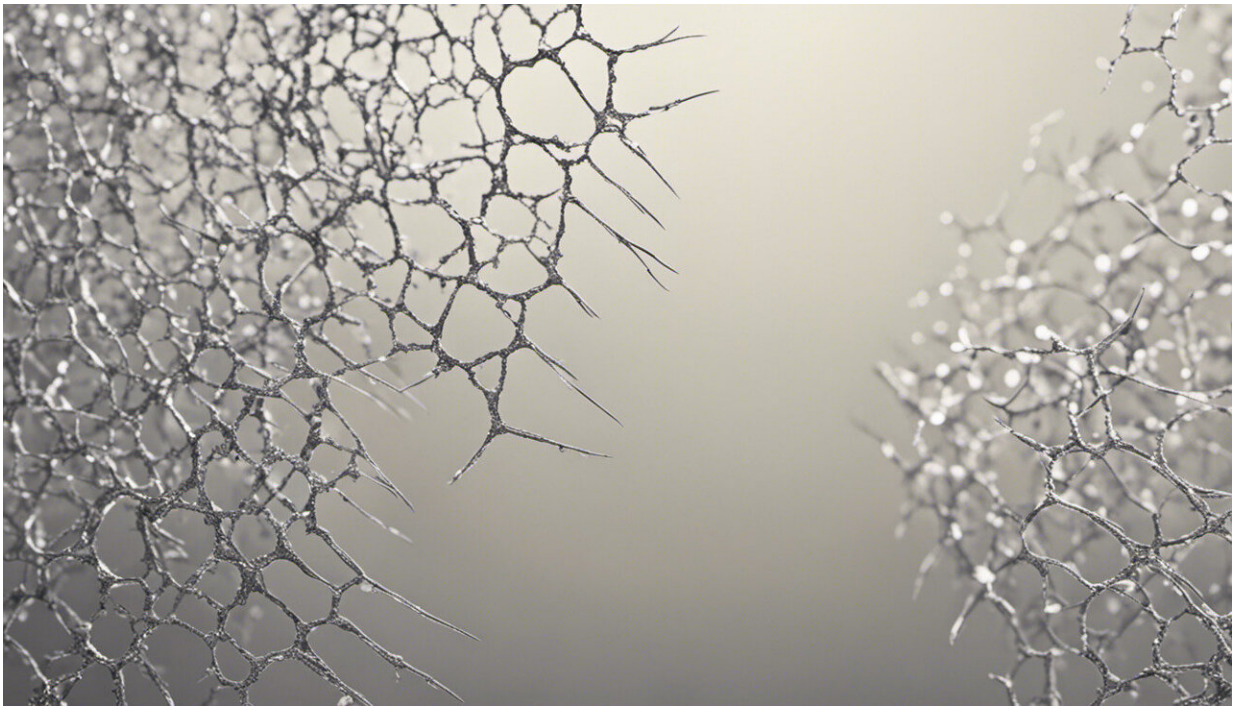

Credit: AI-generated image (disclaimer)

Even as coronavirus testing is ramping up across the world, the issue of speed and accuracy in diagnosis still poses a challenge for public health authorities. A research group supported by the EU-funded HG nCoV19 test project has developed a test enabling rapid diagnosis of COVID-19 at its early and highly infectious stage. It can detect the presence of the virus in 30 minutes, while negative results are delivered within 60 minutes. "When coupled with a nucleic acid extraction method, the

system provides sensitivity equivalent to that of the current PCR [polymerase chain reaction] systems for samples from individuals at all stages of COVID-19 infection," as stated in a press release by project coordinator HiberGene Diagnostics.

The company says,"It has successfully completed the CE marking of a new rapid molecular COVID-19 test, which is now available for sale in Ireland and internationally." It notes: "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." CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It's required for products manufactured anywhere in the world that are then marketed in the EU.

"Using a low-complexity sample preparation protocol, the test has excellent performance for samples with high to moderate viral loads," according to the same press release. "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," it states, adding that these will be held in China, Italy and Northern Ireland.

Remote and lab-based

The test can be deployed in both decentralised facilities requiring rapid molecular tests for screening and centralised labs that are frequently required to run additional tests for confirmation or out-of-hours testing. "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," as stated in the company's news release.

Quoted in the same press release, Mariya Gabriel, EU Commissioner for Innovation, Research, Culture, Education and Youth, comments: "It's crucial to diagnose coronavirus more quickly and more accurately, as it reduces the risk of further spread of the virus." The ongoing HG nCoV19 test (Development and validation of rapid molecular diagnostic test for nCoV19) project is scheduled to end in August 2021.

More information: HG nCoV19 test project: cordis.europa.eu/project/id/101003713

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