

Stilla Technologies presents a novel approach for COVID-19 testing combining group testing with digital PCR and publishes the largest comparative study to date for group testing of SARS-CoV-2

The approach significantly reduces costs and increases testing capacity while offering a diagnostic sensitivity greater than the current standard of individual RT-PCR tests

Paris, June 5, 2020 - Stilla Technologies, a leading French provider of pioneering solutions for high-precision genetic analysis, is offering a new high-throughput and cost-effective testing approach for COVID-19 by combining its digital PCR technology with the group testing method and publishes the largest comparative study to date for group testing of SARS-CoV-2.

“We continue our efforts in the fight against Covid-19 and are proud today to present an innovative approach that greatly increases the testing capacity and meets the highest quality standards. This digital PCR based group testing method has a diagnostic sensitivity superior or equal to the current standard - that is individual RT-PCR testing - for group sizes up to 16 samples. The main benefit of this method is that it reduces the amount of reagent required to test a population by about 80% while reducing costs by as much and increasing test capacities by up to 10 times”, said **Rémi Dangla, Co-founder and CEO of Stilla Technologies.**

Currently, testing for SARS-CoV-2 infections is central to strategies deployed to contain the spread of the virus worldwide. Patients are diagnosed predominantly using virological tests based on a technology called real-time reverse transcription polymerase chain reaction (RT-PCR).

RT-PCR technique is reaching its limits as the demand for SARS-CoV-2 RT-PCR testing is increasing worldwide as more countries are impacted by COVID-19. Firstly, because testing individual samples using RT-PCR is not scalable. Indeed, testing facilities are facing a scarcity of reagents worldwide while the demand reaches millions of tests. In fact, laboratories experienced a severe shortage of reagents at the start of the pandemic and are still under tension today to stock up on supplies. Secondly, because the cost of testing is not scalable to the world population. Group testing or sample pooling has been proposed as a solution to expand testing capabilities.

Test positivity rate for COVID-19 testing after lock-down (and before a pandemic) is usually below 10%, often around 1%, which means that 99 tests out of 100 are expected to yield negative results.

Group tests are optimal in such a configuration of low positivity rate. In a group test, the samples of 8, 16 or 32 individuals are combined into a pooled sample. This pooled sample is then tested. If the test is negative, it means that all the individuals in the group are negative. If it is positive, it means that at least one individual is a carrier of SARS-CoV-2. It is then necessary to test every sample separately again to identify the carrier(s). With a test positivity rate of 1%, only 1 in 10 groups will be positive. The test savings are therefore substantial, around 80%. Additionally, this group testing approach multiplies the number of individuals tested for a given amount of reagents by a factor of 5.

However, a risk associated with group tests is their sensitivity, which is deemed to be lower for large groups ($n > 4$). This reduction in sensitivity means that there is an increased risk of not detecting certain carriers of the virus with pooled tests compared to individual tests. This is where Stilla Technologies' Crystal digital PCR™ technology comes in. Digital PCR is known to be more sensitive than standard RT-



PCR technology. Recent studies have verified it for the detection of SARS-CoV-2. Thus, the association of digital PCR with the group testing method would address the main problem of sensitivity.

This is what the study released today confirms. This study, conducted by the Virology Department of Bichat Hospital (AP-HP) in collaboration with CREST (Ecole Polytechnique) and Stilla Technologies is the largest comparative study carried out to date, systematically comparing group tests of SARS-CoV-2 to individual reference tests. It is also the first study to evaluate group tests combined with digital PCR.

Out of 448 samples tested, 26 and 25 tested positive by digital PCR group test, for group sizes of 8 and 16 samples. Against 25 tested positive with individual reference tests in RT-PCR. Thus, the study demonstrates a similar sensitivity to better for group tests by digital PCR, compared to individual tests by RT-PCR.

In conclusion, this new approach of group testing by digital PCR appears to have a diagnostic sensitivity "similar to better" compared to current tests in individual RT-PCR. However, this method makes it possible to reduce the amount of reagent required by up to 80% while reducing costs as well and increasing the capacity of testing by digital PCR up to 10 times. In conclusion, these are substantial advantages that make this approach a precious weapon to deploy in the fight against the pandemic.

About Stilla's Naica System

The Naica System is a highly sensitive digital PCR solution that runs on the company's next-generation genetic testing and nucleic acid quantification technology, Crystal Digital™ PCR. The Naica System is uniquely capable of characterizing multiple types of nucleic acids with its three-color detection capability. Its ease of use and fastest time to results — in two hours and 30 minutes — set this innovative technology apart in the digital PCR market. The Naica System supports a wide-range of genetic tests and molecular biology assays — including liquid biopsy tests for cancer diagnostics, viral load quantification, pre-natal testing, and GMO detection. Overall, the Naica System's superior performance makes it a preferred technology for precision medicine research and therapeutic monitoring.

About Stilla Technologies

Founded in 2013 at Ecole Polytechnique, Stilla Technologies is a Paris-based European life sciences company that focuses on accelerating the development of next-generation genetic tests by providing a ground-breaking and flexible digital PCR (dPCR) solution: the Naica System. Taking advantage of cutting-edge microfluidic innovations, Stilla aims to make dPCR a lab commodity for all areas of the life sciences. Stilla actively advises and supports its customers worldwide through its dynamic and multidisciplinary R&D team, with expertise spanning from microfluidics to chemistry, including molecular biology and AI. www.stillatechnologies.com

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