

BillionToOne announces groundbreaking new COVID-19 test to unlock 1 million daily tests.?

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Unique Testing Protocol from Precision Diagnostics Company Unlocks 1 Million Tests Per Day

MENLO PARK, CA (April 7, 2020) - The precision diagnostics company [BillionToOne](#) today announced a significant development in the struggle against the COVID-19 pandemic. BillionToOne has developed a highly accurate and cost-effective novel COVID-19 test protocol, unlocking the capacity to perform 1+ million tests per day in the United States alone. Test reagents will be available in 2 weeks, pending the manufacture of the kits and an EUA being awarded by the FDA.

"We've all seen the impact this pandemic has had on every aspect of our daily lives," Dr Oguzhan Atay, the CEO of BillionToOne, said. "From the loss of lives and the damage to the economy to the strain on the healthcare system, this coronavirus has delivered a crippling blow to the country. We're honoured to be on the front line of this fight against the pandemic, and we're certain that this unique technology will help save lives and stop the spread of the virus."

As detailed by leading health professionals, extensive testing – ten times more than the current capacity – is needed to stop the spread of the coronavirus in the United States and other countries. At the present, current quantitative PCR (qPCR) methods do not support the testing volume needed for a rapid COVID-19 response. Additionally, the extreme surge in demand for the same reagents and instruments has caused multiple bottlenecks in the supply chain.

Using the patent-pending qSanger™ spike-in and proprietary machine-learning algorithms, BillionToOne's COVID-19 assay takes advantage of the 30x higher throughput for Sanger sequencing (1536 simultaneous samples using qSanger vs 48 simultaneous samples using qPCR). qSanger™ technology allows each Sanger instrument to perform 3840 tests per day automatically, and hundreds of instruments can be made available by the Human Genome Project alone, unlocking a potential capacity of millions of tests per day.

The BillionToOne COVID-19 test does not use the same instruments and chemicals as the existing COVID-19 tests, enabling labs to unlock this unused capacity. We sequence the virus's genome, which makes the tests extremely sensitive and specific, on par with or better than the other COVID-19 tests available. Additionally, the test is easily adoptable at any labs with Sanger Sequencers, with minimal training.

Test reagents will be available in 2 weeks, pending the manufacture of the kits and an EUA being awarded by the FDA. International laboratories without EUA requirements can start testing immediately by using their own reagents and BillionToOne's bioinformatics pipeline.

"I'm extremely grateful for the hard work and the dedication of the BillionToOne team in getting this vital resource developed so quickly," Oguzhan said. "Our mission here at BillionToOne is to remove the fear of the unknown by making powerful molecular diagnostics available to all. We believe our COVID-19 test can contribute greatly in removing the unknowns from the COVID-19 crisis response."

About BillionToOne

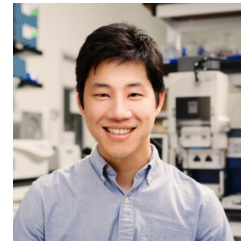
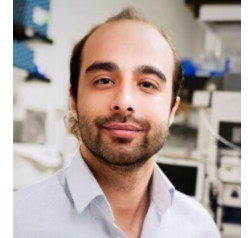
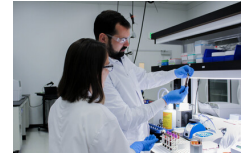
BillionToOne headquartered in Menlo Park, California, is a precision diagnostics company with a mission to make molecular diagnostics more accurate, efficient and accessible for all. The company's patent-pending QCT molecule-counting platform is the only system that can accurately count single DNA molecules. BillionToOne's first product, UNITY, is the first and only non-invasive prenatal screening that tests DNA from foetal cells for cystic fibrosis and spinal muscular atrophy using a single sample of the mother's blood. BillionToOne was co-founded by Oguzhan Atay, PhD, and David Tsao, PhD. For more information, visit www.billiontoone.com.

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