



BillionToOne Announces Groundbreaking New COVID-19 Test Unlocking One Million Daily Tests

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Unique Testing Protocol From Precision Diagnostics Company Unlocks One Million Tests Per Day: The BillionToOne COVID-19 test uses different sets of instruments and chemicals from existing COVID-19 tests, enabling labs to unlock a new set of unused capacity.

MENLO PARK, Calif., April 7, 2020 (NewsWire.com) - 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 more than one million testing capacity per day in the United States alone. Test reagents will be available in two weeks, pending manufacturing of kits and EUA from 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 to the damage to the economy to the strain on the healthcare system, the coronavirus has delivered a crippling blow to the country. We're honored to be on the front lines 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 - over 10 times the current capacity - is needed to stop the spread of the coronavirus in the United States and other countries. At the present moment, current quantitative PCR (qPCR) methods do not support the testing volume needed for rapid COVID-19 response. Additionally, the extreme surge in demand for the same reagents and instruments have 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 Sanger sequencing capacity (1,536 samples on qSanger at a time vs 48 samples on qPCR at a time). qSanger™ technology unlocks each Sanger instrument to automatically perform 3,840 tests per day, and there are hundreds of instruments available from the Human Genome Project alone, unlocking millions of testing capacity per day.

The BillionToOne COVID-19 test uses different sets of instruments and chemicals from existing COVID-19 tests, enabling labs to unlock a new set of unused capacity. BillionToOne sequences the virus' genome - making the test extremely sensitive and specific, on par or better than other COVID-19 tests available. Additionally, the test is easily adoptable at any labs with Sanger Sequencers, with minimum training.

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

"I'm extremely grateful to the hard work and dedication of the BillionToOne team to get 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 molecular counter platform is the only technology platform that can accurately count DNA molecules to the single-count level. BillionToOne's first product, UNITY, is the first and only noninvasive prenatal screening that tests fetal cell-free DNA for cystic fibrosis (CF) and spinal muscular atrophy (SMA) through a single sample of the mother's blood. BillionToOne was co-founded by Oguzhan Atay, Ph.D., and David Tsao, Ph.D. For more information, visit www.billiontoone.com.

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