# New York Blood Center Research Confirms Effectiveness of Rapid Serological Test for COVID-19

## Clungene® SARS-CoV-2 IgG/IgM Rapid Serology Test Showed High Degree of Sensitivity and Specificity for Detecting COVID-19 Antibodies

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NEW YORK, Aug. 26, 2020 /PRNewswire/ -- The New York Blood Center Lindsley F. Kimball Research Institute announced the results of an independent study that showed the Clungene® SARS-CoV-2 Virus (COVID-19) IgG/IgM Rapid Test Cassette possesses a high degree of sensitivity and specificity for detecting COVID-specific antibodies.

The study by the New York Blood Center was done with convalescent blood plasma, following authorization from patients who self-reported COVID-19 infections and had not experienced symptoms for at least 14 days prior to their donation. Clungene® SARS-CoV-2 Virus (COVID-19) IgG/IgM Rapid Test Cassette were used to determine the presence of COVID-specific antibodies. The IgG results are consistent with the manufacturer's 97.4% clinical performance data which showed positive IgG agreement with known positive RT-PCR test. The IgM results are consistent with recently published data which shows that IgM can persist more than 23 days after symptom onset and can be earlier, synchronous or later than IgG.

"Having the ability to accurately identify the presence of antibodies is the first step in understanding individual immune response to COVID-19 and evaluating future risk for exposure," said Larry Luchsinger, Assistant Member, Lindsley F. Kimball Research Institute of the New York Blood Center. "This is critical for creating informed public health policies and charting a path forward for our communities."

The Clungene® SARS-CoV-2 Virus (COVID-19) IgG/IgM Rapid Test Cassette produces rapid results in 15 minutes from a finger prick of whole blood, serum or plasma. The test does not require laboratory equipment, software or specialized training to process readouts. Users do not have to send samples to labs in order to obtain results. The test is manufactured by Hangzhou Clongene Biotech and is distributed in the U.S. by Proven Pharmaceuticals.

The test has been submitted to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) and is awaiting approval. The FDA is currently allowing the test to be made available in the U.S. as the agency reviews its EUA application.

**Use of this product is for in vitro diagnostic use under emergency use authorization only (Submission Number: EUA201121) and should be limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Results should not be used for diagnosis of acute COVID-19. Do not use this product as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status of COVID-19.**

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**ABOUT NEW YORK BLOOD CENTER**

About New York Blood Center: Founded in 1964, New York Blood Center (NYBC) is a nonprofit organization that is one of the largest independent, community-based blood centers in the world. NYBC, along with its operating divisions Community Blood Center of Kansas City, Missouri (CBC), Innovative Blood Resources (IBR), Blood Bank of Delmarva (BBD), and Rhode Island Blood Center (RIBC), collect approximately 4,000 units of blood products each day and serve local communities of more than 75 million people in the Tri-State area (NY, NJ, CT), Mid Atlantic area (PA, DE, MD, VA), Missouri and Kansas, Minnesota, Nebraska, Rhode Island, and Southern New England. NYBC and its operating divisions also provide a wide array of transfusion-related medical services to over 500 hospitals nationally, including Comprehensive Cell Solutions, the National Center for Blood Group Genomics, the National Cord Blood Program, and the Lindsley F. Kimball Research Institute, which — among other milestones — developed a practical screening method for hepatitis B as well as a safe, effective and affordable vaccine, and a patented solvent detergent plasma process innovating blood-purification technology worldwide.

**ABOUT PROVEN PHARMA**

Established in 2012, Proven Pharma is a service provider to the healthcare and life science industries. The company offers a wide range of solutions that include specialty distribution, comparator sourcing for clinical trials, dedicated inside sales teams, marketing support, digital transformation, and technology consulting. Their solutions are informed by more than two decades of extensive experience across many areas of the healthcare landscape.

In an industry full of uncertainty, Proven Pharma provides confidence to its customers. The company delivers on-time, every time - using recognized best practice and process to ensure safety and compliance every step of the way. Prove Pharma is dedicated to constantly improving its customers' experience so those customers can improve the lives of their patients. The company's success results from the honesty, integrity and dependability of its team.

**About Hangzhou Clongene Biotech**

Hangzhou Clongene Biotech is a high-tech, leading manufacturer of biological raw materials and in vitro diagnostic products. The company has a solid reputation for offering diversified services and superior flexibility to professional distributors and partnering affiliates in the global market.

Founded in 2004, Hangzhou Clongene Biotech is equipped with state-of-the-art ISO 13485:2016 accredited China GMP compliant R&D and manufacturing facilities covering 19,000 square meters in Hangzhou, China. Their products have obtained CE certificates, FSC certificates, and US FDA 510(k) Clearances.

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