



## ANSWERS FOR CANCER

### **Genetron Health Announces Its Novel Coronavirus Nucleic Acid Detection Kit Is CE Marked and FDA-EUA Application Accepted, with Three Laboratories Passing NCCL's COVID-19 EQA**

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Genetron Holdings Limited ("Genetron Health"), a China-based precision oncology company that covers full-cycle cancer care, announces that its independently developed Detection Kit for Novel Coronavirus (SARS-CoV-2) RNA (PCR-Fluorescence Probing) has been issued CE marking and had its application accepted by FDA-EUA. Based on the test kit, three of Genetron Health's clinical laboratories have passed the COVID-19 External Quality Assessment (EQA) by China's National Center for Clinical Laboratories (NCCL).

In addition to CE marking and FDA-EUA application acceptance, Genetron Health's nucleic acid detection kit has also performed excellently in a verification project held by the Beijing Center for Disease Prevention and Control. The kit enables comprehensive, accurate, efficient, and safe testing for larger-scale samples. Additionally, Genetron Health's new aerosol particle sampler for lower respiratory tracts has also applied for medical equipment approval and clinical verification, in hopes to help control the SARS-CoV-2 pandemic.

Moreover, the GENETRON S5 (China National Medical Device Registration 20193220820), semiconductor high-throughput sequencer, and supporting instruments have been donated to Wuhan Huoshenshan Hospital. As currently Huoshenshan Hospital's only next-generation sequencing (NGS) platform, it can perform accurate molecular test of clinical samples to yield comprehensive genomic data. Such data is acutely instrumental in current and future clinical and epidemiology research in battling the disease, monitoring mutations of the coronavirus as well as in continuous management and prevention of the COVID-19 outbreak (including formulation of preventive measures, research and development of related diagnostic kits, vaccines and drug treatment).

GENETRON S5 sequencing platform also effectively and efficiently complements the current PCR test, thus enhances reliable testing for weak positive cases using a substantially shorter time. In addition, it can aid diagnosis of any co-infections and support follow-up precision treatment.

#### **About Genetron Health**

Genetron Holdings Limited ("Genetron Health" or the "Company") is a leading and fast-growing precision oncology company in China that aims to provide one-stop genomic profiling solutions for multiple scenarios covering early screening, diagnosis and monitoring, and biopharmaceutical services. The company collaborates with over 400 hospitals and dozens of biopharmaceutical companies and research institutions and has developed a large proprietary genomic database.

Genetron Health has established R&D centers in both the United States and China, two manufacturing facilities with both ISO 13485:2016 certification and ISO 9001:2015 certification in China and five clinical laboratories in Beijing (CLIA accreditation and CAP certification), Shanghai, Hangzhou, Chongqing and Guangzhou. The R&D capacities of Genetron Health are supported by a best-in-class research and development team led by scientists at the forefront of cancer genomics research. The company has published many research papers in highly influential worldwide peer-reviewed scientific journals, such as Nature Genetics, Nature Communications, Cell Research and PNAS.