GENETRON 泛生子

ANSWERS FOR CANCER

Genetron Health Receives FDA Emergency Use Authorization for SARS-CoV-2 RNA Test and Approval for Export by Chinese Authority

June 6, 2020

Beijing, 6 June 2020 – Genetron Holdings Limited ("Genetron Health"), a China-based precision oncology company that covers full-cycle cancer care, announced that its independently developed detection kit for the novel coronavirus (Genetron SARS-CoV-2 RNA Test) received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration. Additionally, the kit received approval for export from the relevant authorities in China.

Genetron Health was whitelisted as an approved COVID-19 reagent manufacturer by the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), which means Genetron Health is granted to export Genetron SARS-CoV-2 RNA Test.

Prior to receiving the FDA EUA and being whitelisted by CCCMHPIE, Genetron SARS-CoV-2 RNA Test had already obtained CE marking (Registration Number: DE/CA20/IVD-Luxuslebenswelt-111/20); registration certification by European representative Luxus Lebenswelt GmbH; and its technical file also passed SGS review. All of these certifications indicate conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

Genetron SARS-CoV-2 RNA Test is an accurate, fast, contamination-free testing solution, which efficiently detects large-scale samples for the novel coronavirus. Features include:

- **Comprehensive and Accurate Testing:** Genetron SARS-CoV-2 RNA Test detects two different and highly specific gene sequences of SARS-CoV-2: ORF1ab and N, which improves both its accuracy and specificity. It also includes an internal reference to prevent possible false negative results. Each test is capable of detecting SARS-CoV-2 RNA as low as 10 copies.
- **Easier to Operate and Less Time-Consuming**: With patented technology, the One-Step Seq Method, the process integrates reverse transcription of viral RNA and quantitative PCR reaction in a single step. The entire process takes less than 2.5 hours, including only 10 minutes of hands-on time.
- **Contamination Free:** The application of contamination resistant dUTP and UDG enzymes allows the system to degrade non-specific and nucleic acid-contaminated PCR products.

Genetron Health has supplied its SARS-CoV-2 RNA Test to some high-risk areas in the world to aid in their large-scale coronavirus testing. Genetron Health is committed to fighting and controlling the COVID-19 pandemic with high-quality testing products and diligent assistance.

For any purchase requirements, please contact: BD-IC@genetronhealth.com

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 500 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. For more information, please visit www.genetronhealth.com.

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