

Introduction to Shanghai BioGerm Medical Biotechnology Co., Ltd

Shanghai BioGerm Medical Biotechnology Co., Ltd (hereinafter referred to as “BioGerm”) was established in March 2017. It is a high-tech company dedicated to the development and application of molecular diagnostic reagents for infectious pathogens, especially multiple fluorescent PCR diagnostic reagents. With the main focus on infectious pathogens, the company provides a complete set of solutions for emergency response of epidemics, screening of the patient in outpatient clinics, detection of patients in the ward, and etiological diagnosis of difficult and critically ill patients based on the development of diagnostic reagents, diagnostic instruments, sequencing services and medical laboratory services, and many other modules, and dedicates to solving the difficulties in the market of the rapid genetic mutation of the pathogens and difficult diagnosis.

The main body of the company is located in Fengxian Fengchuang Valley, Shanghai Juke Biotech Park. On the 13th floor, there is a clean plant with 1,600 square meters that meets the quality requirements for kit production, and it is used for research and development, production and quality control of diagnostic reagents, with the certification in both ISO 91001 and 13485. On the 10th floor, there is a service area with 1,200 square meters for instrument production and sequencing, which is used for production of clinical diagnostic instruments and relevant sequencing services. The company’s wholly-owned medical laboratory is located in Pudong International Medical Park, covering an area of 1,000 square meters, which is already qualified for molecular genetics and microbial testing. It is a registered level 2 biosafety laboratory equipped with ABIQ5, ABI7500, Roche CobasZ480, Bio-Rad CFX9, Slan96 and other fluorescent PCR machines, and Illumina and Ion Torrent second-generation sequencers and other equipment.

The company’s three co-founders all have 15 years of working experience in the field of infectious pathogens, are familiar with the needs of customers in the field of pathogen detection, and understand the difficulties in the market. They are familiar with the application of fluorescent PCR technology in this field for nearly 20 years and participated in the response to the epidemics, such as SARS 2003, H1N1 A 2009, and H7N9 Avian Influenza 2013. The project “high-throughput rapid combined detection technology and field application of respiratory pathogens” co-accomplished by the founder won the first prize of Shanghai Science and Technology Progress.

The company’s several main modules fully cover the complete solution of respiratory pathogen infectious diseases and support each other.

With regard to diagnostic reagents, there are a large number of pathogens that cause respiratory infections. During the "Twelfth Five-Year Plan" period, there were more than 90 kinds of pathogens detected in febrile respiratory syndrome. At present, there are a total of more than 400 nucleic acid detection kits for detection of pathogens in the company’s nucleic acid diagnostic reagent product library, which include the nucleic acid detection reagents not only for detection of the above-mentioned more than 90 pathogens, but also for typing of these pathogens. These detection kits, in combination with a number of independently developed nucleic acid extraction reagents, have been widely used in various Centers for Disease Control and Prevention in China. At present, the company has applied for 23 patents and obtained the NMPA registration certificates and production licenses for three products. The clinical trials of four types of diagnostic kits related to respiratory infection have been completed and are now in the supplementary stage.

With regard to sequencing services, the respiratory pathogens, especially viruses, are highly susceptible to mutation, and sequencing and typing of pathogens using metagenomic sequencing to identify the pathogen species or to discover unknown pathogens have become an important means of epidemiological surveillance. BioGerm has a database of more than 4,200 viruses, bacteria and fungi, which not only covers the genome sequences of all legal infectious diseases in China, but also collects the epidemiology, clinical symptoms and clinical medications and other information corresponding to the pathogens, with the accumulation of rich experience for epidemiological monitoring and diagnosis and treatment. As of now, BioGerm has undertaken monitoring of nearly 60% of influenza samples in China, and has accumulated 11 subtypes of influenza A virus data alone.

In addition, the use of metagenomic sequencing platforms to monitor pathogens has also greatly contributed to the development and optimization of diagnostic reagents. Relying on the sequencing platform, BioGerm is able to identify the subtypes of the pathogens by sequencing of the specimens collected from suspected influenza patients or those with “unknown causes” submitted by the Centers for Disease Control and Prevention or other medical institutions, which are then confirmed by the existing nucleic acid diagnostic reagents. If pathogens could not be detected due to mutations, the nucleic acid detection kits can be immediately optimized or developed based on the sequencing data, thereby ensuring that the nucleic acid detection kits can detect the pathogens in the first time and be quickly used for detection and screening of the actual large number of samples.

BioGerm can quickly respond to this novel coronavirus epidemic in the early stage, which is due to the company’s dedication and long-term accumulation in the field of respiratory virus nucleic acid diagnostic reagents and sequencing services: (I) Before the outbreak, BioGerm’s existing respiratory tract relevant nucleic acid detection reagents assisted the identification of the pathogen in patients with unknown pneumonia as a coronavirus in Wuhan Center for Disease Control

and Prevention. (II) In the early stage of the epidemic, BioGerm took the advantage of emergency R & D and production in the field of respiratory viruses and took the lead in completing the development of the kit and passed the verification of the Chinese Center for Disease Control and Prevention. This ensures that the suspected infection is diagnosed in the early stages of the epidemic. (III) BioGerm's respiratory pathogen nucleic acid detection reagents are of high quality, and the registration approval of the 2019 novel coronavirus (ORF1ab/N genes) nucleic acid detection kit (fluorescent PCR method) was obtained from the National Medical Products Administration, and the overall feedback is very good in the application of epidemic prevention and control.

With the outbreak of COVID-19 globally, including the United States, BioGerm is also actively applying for the Emergency Use Authorization (EUA) of FDA. BioGerm has already tested more than 1.68 million specimens in China with this novel coronavirus nucleic acid detection kit from January 31 to February 27, 2020 in 321 units belonging to CDCs, including 273 hospitals, 26 customs and ports, and 12 medical laboratories all over China. The detection of first case of novel coronavirus was performed using the detection kits produced by BioGerm in 26 provinces and cities nationwide.

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