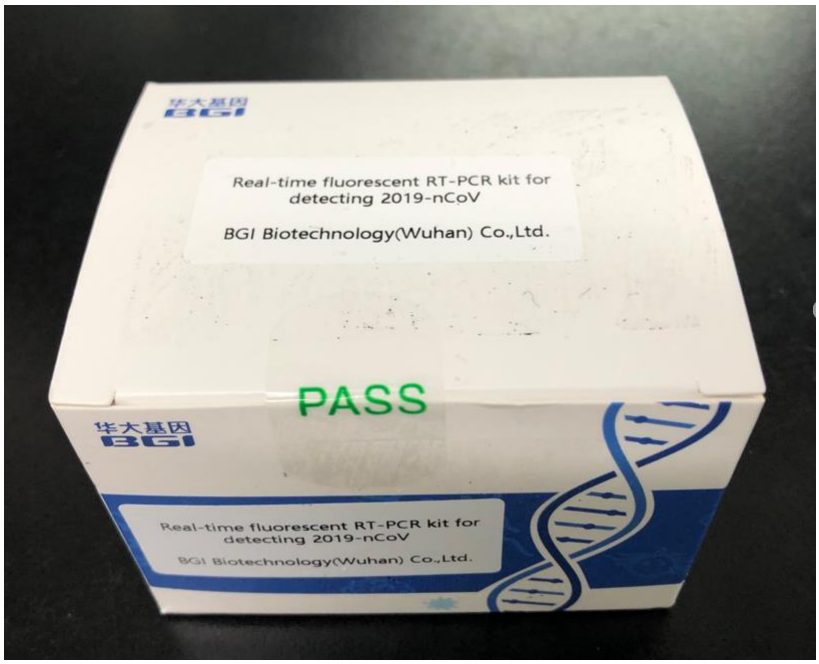
BGI RT-PCR Kit and PMseq® Solution for Detecting 2019-nCoV

Summary: BGI is a world-leading genomics company headquartered in Shenzhen, China, and the third-party collaborator authorized by China's National Health Commission in detecting the 2019-nCoV virus in China. BGI has developed a Fluorescent RT-PCR Kit for Detecting the 2019 Novel Coronavirus, which is ready for international delivery. BGI 2019-nCoV RT-qPCR Kit and PMseq- 2019-nCoV Kit passed the approval of National Medical Products Administration. The combination of RT-PCR and BGI metagenomics solution PMseq® can detection of both known and novel microorganisms in addition to 2019-nCoV.



As widely reported in the media, a new coronavirus has been identified in China, which has been given the name "2019 novel coronavirus" or "2019-nCoV." Building on BGI's expertise and technologies of developing solutions for rapid pathogen detection, BGI has developed a real-time fluorescent RT-PCR kit for detecting the 2019 Novel Coronavirus. The kits have already been issued to many hospitals and disease control centers.

Coronaviruses are a family of viruses, circulating mainly among animals, including camels, cats and bats. Rarely, animal coronaviruses can evolve and infect people and then spread between people such as seen with MERS and SARS. 2019-nCoV is a new strain of virus that has not been previously identified in humans.

In response to this situation, and immediately after the occurrence of unexplained pneumonia in Wuhan on December 31, 2019, BGI successfully developed a Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV, which can issue results in a few hours. It's been proved that the kits can specifically detect 2019-nCov in high sensitivity without cross-reactivity with other strains of Coronavirus. Kits are then produced immediately and delivered to Wuhan and other cities in China for epidemic prevention and control. In addition, a product based on metagenomics were also developed by NMPA for sequencing 2019-nCoV from suspect's specimen.

The combination of RT-PCR and metagenomics detection can cover the 2019-nCoV virus detection faster and more comprehensively and monitor the evolution that may occur during transmission of the new coronavirus. Equipped with a one-stop sequencing workstation MGIFLP, the sequencer manufactured by MGI can be loaded with an automatic detection system for unknown pathogens, enabling real-time sequencing. Using DNBSEQ-T7, 128 samples can be simultaneously screened and sequenced by SE50 within 5 hours, and 128 samples can be simultaneously tested and sequenced by PE100 in 22 hours. The PMseq solution can detect any pathogens in suspect's specimen not limited to 2019-nCoV in a single test, as well as monitor possible mutation and evolution. The use of PMseq® has provided strong technical support for the scientific clinical prevention and control of the epidemic in Wuhan and the formulation of prevention and control strategies for the public health system.

On January 26, 2020, BGI's 2019-nCoV kits and DNBSEQ-T7 sequencing platform passed the emergency approval procedure of the National Medical Products Administration, becoming the first officially approved testing products in China for surveillance, discovery and identification of unknown infection disease.

The approved BGI 2019-nCoV RT-qPCR Kit can achieve rapid detection within 3 hours; The other is a metagenomic sequencing kit named BGI 2019-nCoV PMseq Kit is based on combinatorial Probe Anchor Synthesis（cPAS). It can differentiate and diagnose the infection of new coronaviruses from other coronaviruses or respiratory pathogens, and obtain virus genomic information in the meantime.

国家药品监督管理局
National Medical Products Administration

国家药监局应急审批新型冠状病毒核酸检测试剂 全力服务疫情防控需要

2020年01月26日 发布

近日，国家药品监督管理局应急审批通过4家企业4个新型冠状病毒检测产品，进一步扩大新型冠状病毒核酸检测试剂供给能力，全力服务疫情防控需要。

疫情发生后，国家药监局立即启动医疗器械应急审批程序，按照"统一指挥、早期介入、随到随审、科学审批"的原则和确保产品安全、有效、质量可控的要求，全力加快审评审批速度。目前，已应急批准新型冠状病毒2019-nCoV核酸检测试剂盒（荧光PCR法）和2019新型冠状病毒核酸测序系统等4个产品。同时已要求省级药监部门加强对上述产品生产企业的监督检查,确保产品质量安全。

国家药监局将继续对疫情防控所需的药品医疗器械采取特殊审批程序，争取相关产品尽快上市。

中华人民共和国医疗器械注册证

注册证编号：国械注准20203210062

注册人名称	华大生物科技（武汉）有限公司
注册人住所	武汉市东湖新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋
生产地址	武汉市东湖新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋五楼、B1栋一楼
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒2019-nCoV核酸分析软件
型号、规格	PMseq-2019-nCoV-1；PMseq-2019-nCoV-2
结构及组成	该软件由PMseq-2019-nCoV-1和PMseq-2019-nCoV-2组成，软件发布版本号V1。PMseq-2019-nCoV-1：由输入模块、处理模块和输出模块组成。产品硬件由软件安装移动硬盘组成。PMseq-2019-nCoV-2：由输入模块（样本中心、实验中心）、处理模块（分析中心）、管理模块（系统管理）组成。产品硬件由软件安装移动硬盘组成。产品数据库由病原体序列库组成。病原体序列库版本号：PMDB_V1.0.0。病原体序列库具体包括细菌、真菌、寄生虫、病毒（包含2019新型冠状病毒）四个病原体序列库和内标序列库。
适用范围	该软件与华大生物科技（武汉）有限公司生产的新型冠状病毒2019-nCoV核酸检测试剂盒（联合探针锚定聚合测序法）、测序反应通用试剂盒（联合探针锚定聚合测序法）及基于联合探针锚定聚合测序法的基因测序仪配合使用，适用于新型冠状病毒2019-nCoV核酸检测数据的分析。
附件	产品技术要求
其他内容	/
备注	请注册人在产品上市后继续完成以下工作：1.本产品仅适用于新型冠状病毒2019-nCoV核酸检[illegible]的分析，注册证有效期为一年。2.企业应当在延续时按照医疗器械注册管理办法[illegible]报资料。

审批部门：国家药品监督管理局

批准日期：二〇二〇年一月二十[illegible]日

有效期至：二〇二[illegible]二十五日

中华人民共和国

医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20203400059

注册人名称	华大生物科技（武汉）有限公司
注册人住所	武汉市东湖新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋
生产地址	武汉市东湖新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋五楼、B1栋一楼
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒2019-nCoV核酸检测试剂盒（联合探针锚定聚合测序法）
包装规格	32人份/盒
主要组成成分	包装盒1、包装盒2、包装盒3（具体内容详见说明书）
预期用途	本试剂盒用于体外定性检测新型冠状病毒感染的肺炎疑似病例、疑似聚集性病例患者、其他需要进行新型冠状病毒感染诊断或鉴别诊断者的肺泡灌洗液和咽拭子样本中的新型冠状病毒（2019-nCoV），配套本公司的基因测序系统使用。
附件	产品技术要求、说明书
产品存储条件及有效期	包装盒1及包装盒2置于-18℃以下，包装盒3置于2℃～8℃保存，有效期暂定为6个月。
其他内容	/
备注	[illegible]

审批部门：国家药品监督管理局

批准日期：二〇二〇年一月二十[illegible]日

有效期至：二〇二[illegible]二十五日

中华人民共和国

医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20203400060

注册人名称	华大生物科技（武汉）有限公司
注册人住所	武汉市东湖高新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋
生产地址	武汉市东湖高新技术开发区高新大道666号武汉国家生物产业基地项目B、C、D区研发楼B2栋五楼、B1栋一楼
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒2019-nCoV核酸检测试剂盒（荧光PCR法）
包装规格	50人份/盒
主要组成成分	2019-nCoV反应液、2019-nCoV检测酶液、2019-nCoV阳性对照品、2019-nCoV空白对照品。（具体内容详见产品说明书）
预期用途	本试剂盒用于体外定性检测新型冠状病毒感染的肺炎疑似病例、疑似聚集性病例患者、其他需要进行新型冠状病毒感染诊断或鉴别诊断者的肺泡灌洗液和咽拭子样本中，新型冠状病毒（2019-nCoV）ORF1ab基因。
附件	产品技术要求、说明书
产品存储条件及有效期	避光储存于-18℃以下，有效期暂定6个月。
其他内容	/
备注	[illegible]

审批部门：国家药品监督管理局

批准日期：二〇二〇[illegible]二十[illegible]日

有效期至：二〇二[illegible]二十五日

中华人民共和国医疗器械注册证

注册证编号：国械注准20203220061

注册人名称	武汉华大智造科技有限公司
注册人住所	中国武汉市东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期24栋
生产地址	中国武汉市东湖新技术开发区高新二路388号武汉光谷国际生物医药企业加速器3.1期24栋
代理人名称	/
代理人住所	/
产品名称	基因测序系统
型号、规格	基因测序仪DNBSEQ-T7，全自动样本加载仪MGIDL-T7
结构及组成	包括基因测序仪（DNBSEQ-T7）和全自动样本加载系统（MGIDL-T7）。基因测序仪由主机架构、软件主机（内嵌软件版本号：V1）、光学系统、XYZT-平台、载片平台、气液系统、电子控制系统、试剂存储系统、电源系统、显示系统组成。全自动样本加载系统作为基因测序仪的附件，由主机和控制软件（版本号：V1）组成。
适用范围	该产品采用联合探针锚定聚合测序技术，在临床上用于对来源于人体样本的脱氧核糖核酸（DNA）和核糖核酸（RNA）进行测序，以检测基因序列，这些基因序列可用于辅助诊断疾病或疾病易感性。该仪器在临床上仅限于与国家药品监督管理部门批准的体外诊断试剂以及软件配合使用，不用于人类全基因组的测序或从头测序。
附件	产品技术要求
其他内容	/
备注	请注册人在产品上市后继续完成以下工作：1.请企业完善对新型冠状病毒2019-nCoV序列的[illegible]，注册证有效期为一年。2.企业应当在延续时按照医疗器械注册管理办法[illegible]报资料。

审批部门：国家药品监督管理局

批准日期：二〇二〇年[illegible]二十六日

有效期至：二〇二[illegible]二十五日

BGI has been working with relevant Chinese authorities including the Chinese Center for Disease Control and Prevention, through which the kits have been issued to various hospitals and local disease control centers.

The kits are ready for international delivery to assist the global endeavor in fighting the epidemic, a number of which have already been sent to nearby countries. The kits are equipped with English manuals and BGI is prepared to offer online training. Detection are expected to process within local laboratories and issue results in 3 hours

The development of the 2019-nCoV detection kit builds upon BGI's previous experience developing rapid diagnostic solutions for pathogen detection. For example, in April 2003, BGI successfully sequenced the SARS virus in less than 20 hours, and developed an enzyme immunoassay test kit in 96 hours. In 2011, BGI successfully developed a diagnostic kit for the Enterohaemorrhagic Escherichia Coli (EHEC) epidemic that broke out in Germany. All scientific data and information was made available to the international community, laying an important scientific foundation to control the epidemic.

About BGI

BGI, as one of the world's leading life science and genomics organizations, has been actively building the global laboratory service network. So far, BGI has 16 central laboratories and more than 200 joint medical testing laboratories in China, including more than 20 laboratories with the ability to apply genetic testing for pathogen infection. In addition, BGI has more than 20 overseas central and joint laboratories in 17 countries and regions including the United States, Canada, the United Kingdom, Australia, Denmark, Croatia, Thailand, Russia, Italy, Turkey, Malaysia, Singapore, Hong Kong and etc. The service network covers more than 100 countries and regions in the world, and the high-throughput multi-omics laboratories have been safely operated for more than 1 million hours, providing services to more than 3,000 overseas medical and scientific research institutions. Through years of safety and high-quality laboratory management practices, including ISO15189, CAP, CLIA,

ISO13485, ISO9001, ISO14001, OHSAS18001, ISO/IEC 2700, BGI has already refined GLMS (Genomics Laboratory Management System) and BGI-CSPro (BGI Certified Service Provider Program) certification system to ensure each joint laboratory can be operated in a standardized manner, and every report issued is accurate and reliable.