The People's Republic of China
Medical device registration certificate (in vitro diagnostic reagent)

Registration Certificate No.: Domestic Device Registration Approval：20203400831

Name of registrant	Beijing Jinwofu Bioengineering Technology Co.,Ltd.
Residence of registrant	Room.420,1st Building,No.10 Xinghuo Road,Technology Park of Fengtai District, Beijing, China
Production address	Room 206, 1st Building,No.26 Jinyuan Road,Daxing District, Beijing,China
Name of agent	
Residence of agent	
Product name	NOVEL CORONAVIRUS (2019-nCoV) ANTIGEN RAPID TEST KIT
Package & specification	Strip: 1test/box、5test/box、10test/box、20test/box、25test/box、30test/box、40test/box、50test/box、100test/box、200test/box Card: 1test/box、5test/box、10test/box、20test/box、25test/box、30test/box、40test/box、50test/box、100test/box、200test/box
Main components	Novel coronavirus (2019-nCoV) antigen rapid test kit, Extraction solution, Collection & transportation Kit (Check the instruction manual for detail)
Intended use	Intented use of this product is to detect the novel coronavirus N antigen from the oropharyngeal swabs and the nasopharyngeal swabs that have been sampled from the people who were suspected of being infected by the novel coronavirus pneumonia. The antigen test is generally carried to the sufferers in their acute infection period, that is, the sample test is applied to the suspected crowd with onset symptoms within 7 days. detect the novel coronavirus N antigen from the oropharyngeal swabs and the nasopharyngeal swabs that have been sampled from the people who were suspected of being infected by the novel coronavirus pneumonia.The antigen test is generally carried to the sufferers in their acute infection period, that is, the sample test is carried to the suspected crowd with onset symptoms within 7 days. Antigen test cannot be used solely for the diagnosis of novel coronavirus infection. It should be combined with the other diagnostic information such as nucleic acid test, imaging etc.,and with the medical history, and the contact history to determine the infection status. The positive result of the antigen test can be used for early triage and rapid management of the suspected crowd, however, the positive result only indicates the presence of the novel coronavirus N antigen in the specimen, and it can not be used as the diagnostic basis of the confirmation cases of the novel coronavirus infection. Negative results cannot exclude novel coronavirus infection, nor can it be used solely as the basis for making treatment and disease management decisions.Both positive and negative results of the suspected crowd should undergo further nucleic acid test. This product should not be used for screening purpose in the general population. This product should be used by professionals in the professional laboratories.
Additional documents	Technical requirements of the product, and the Instruction manual
Storage conditions & expiry date	Preservation and protection from sunlight between 4~30℃, Tentative valid period is 6 months
Others	
Note	1. This product is only used as an auxiliary diagnosis and the emergency reserve of the pneumonia caused by the novel coronavirus(2019-nCoV).The registration certificate is valid for one year. 2. For renewing the registration, a summary report of the clinical application data shall be submitted in accordance with the following requirements: The continuous clinical application data of this product shall be collected from more than three clinical institutions(including the centers for disease control and prevention at all levels). The clinical application data should include complete information, the sample volume should meet the statistical requirements, and the signature and seal should meet the requirements. 3. When renewing the registration, the enterprise should complete all registration application materials in accordance with the requirements of the IVD reagent registration management measures.

Examination and approval department:National Medical Products Administration

Approval date: 3rd, Nov. 2020

Expiry date: 2nd, Nov. 2021

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20203400831

注册人名称	北京金沃夫生物工程科技有限公司
注册人住所	北京市丰台区科学城星火路10号1号楼420室
生产地址	北京市大兴区金苑路26号1幢206室
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）抗原检测试剂盒（乳胶法）
包装规格	条型:1人份/盒，5人份/盒，10人份/盒，20人份/盒，25人份/盒，30人份/盒，40人份/盒，50人份/盒，100人份/盒，200人份/盒； 卡型:1人份/盒，5人份/盒，10人份/盒，20人份/盒，25人份/盒，30人份/盒，40人份/盒，50人份/盒，100人份/盒，200人份/盒。
主要组成成分	新型冠状病毒2019-nCoV抗原检测试剂卡、样本抽提液、一次性采样器。（具体内容详见产品说明书）
预期用途	本产品用于新型冠状病毒感染肺炎疑似人群口咽拭子、鼻咽拭子样本中新型冠状病毒N抗原检测。抗原检测一般用于急性感染期，即疑似人群出现症状7天之内的样本检测。 抗原检测不能单独用于新型冠状病毒感染的诊断，应结合核酸检测、影像学等其他诊断信息及病史、接触史判断感染状态。 抗原检测的阳性结果可以用于对疑似人群进行早期分流和快速管理，但阳性结果仅表明样本中存在新型冠状病毒N抗原，不能作为新型冠状病毒感染的确诊依据。阴性结果不能排除新型冠状病毒感染，也不得单独作为作出治疗和疾病管理决定的依据。疑似人群抗原阳性及阴性结果均应进行进一步的核酸检测。 本产品不得用于一般人群的筛查。 本产品应在专业实验室由专业人员使用。
附　　件	产品技术要求、说明书
产品储存条件及有效期	4～30℃避光储存，有效期暂定6个月。
其他内容	/
备　　注	1.本产品仅为新型冠状病毒（2019-nCoV）感染的肺炎的辅助诊断及应急储备，注册证有效期为一年。 2.延续注册时应按照如下要求提交临床应用数据的总结报告：应在三家以上临床机构（包括各级疾病预防控制中心）收集该产品连续临床应用数据，临床应用数据应具有完善的信息，样本量符合统计学要求，签字盖章符合要求。 3.企业应当在延续注册时按照体外诊断试剂注册管理办法的要求完善所有注册申报资料。

审批部门：国家药品监督管理局

批准日期：二〇二〇年十一月三日

有效期至：二〇二五年十一月二日