People's Republic of China Medical Device Registration Certificates

(In Vitro Diagnosis Test)

Registration No.: GuoXieZhuZhun20203400176

Registrant Company	Guangzhou Wondfo Biotech Co., Ltd.
Registrant Address	No. 8 Lizhishan Road, Scientific City, Luogang District, Guangzhou, Guangdong, P.R. China 510663
Manufacturing Address	No. 8 Lizhishan Road, Scientific City, Luogang District, Guangzhou, Guangdong, P.R. China 510663
Agent's Name	/
Agent's Address	/
Product Name	2019-nCoV Antibody Test（Colloidal Gold Method）
Package Specification	1 test cassette in one pouch, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 40 tests/kit, 50 tests/kit.
Main Content	The test kit consists of test cassettes, detection buffer, droppers. (See the instructions for details)
Intended Use	The test is used to qualitatively detect novel coronavirus (2019-ncov) antibodies in human serum, plasma, and venous whole blood samples in vitro.It is only used as a auxiliary indicator for suspected cases which the nucleic acid test result of the new coronavirus is negative or used in conjunction with nucleic acid test for suspected cases. It should not be used as a basis for the diagnosis and exclusion of pneumonia from novel coronavirus infection. Not suitable for screening in the general population. Only for use by medical institutions.
Appendix	Technical requirement and operation instruction.
Storage and Shelf Life	Store at 2-30℃, the shelf life is 6 months.
Other content	/
Remark	1.The test can only be used as an aid or emergency reserve in the diagnosis. The registration certificate is valid for one year 2. A summary report of the clinical data should be submitted as required for continuation of registration 3. The enterprise shall, at the time of continuous registration, complete all registration declaration materials in accordance with the *in vitro* diagnostic reagent registration regulation

Approved by: China Food and Drug Administration

Approval Date: 22th February 2020

Valid Until: 21th February 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20203400176

注册人名称	广州万孚生物技术股份有限公司
注册人住所	广州市萝岗区科学城荔枝山路8号
生产地址	广州市萝岗区科学城荔枝山路8号
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体金法）
包装规格	卡型：1人份/袋、1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。
主要组成成分	测试卡、样本稀释液（滴瓶）、滴管。（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人血清、血浆、静脉全血样本中新型冠状病毒（2019-nCoV）抗体。仅用作对新型冠状病毒核酸检测阳性疑似病例的补充检测指标或疑似病例诊断中与核酸检测协同使用，不能作为新型冠状病毒感染的肺炎确诊和排除的依据，不适用于一般人群的筛查。 仅限医疗机构使用。
附件	产品技术要求、说明书
产品存储条件及有效期	2～30℃保存，有效期暂定6个月。
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：[illegible]医疗机构（包括各级疾病预防控制中心）收集该产品连续临床[illegible]数据，临床应用数据应具有完整的信息，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[illegible]法律要求[illegible]有注册申报资料。

审批部门：国家药品监督管理局

批准日期：〇〇〇年[illegible]二十二日

有效期至：〇〇〇年[illegible]二十一日