ISSN: 2091-2749 (Print)
2091-2757 (Online)

Serological rapid diagnostics test kit "Wondfo" for COVID-19 in Nepal

Divya RSJB Rana*

*Freelancer, MSc Molecular Biology, Lalitpur, Kathmandu, Nepal

Letter to Editor

Dear Editor,

Extensive discussions about the applicability of rapid diagnostics kits/tests for corona virus disease 2019 (COVID-19) detection has taken place in Nepal. A critical, and authentic information about the kit is necessary in order to fight the COVID-19 infection. Online news portal eKantipur 12 April, 2020 reported that "Wondfo" kit made by the Guangzhou Wondfo Biotechnology company was bought by Nepal Government.[1] The National Medical Product Association of China, until 16 March 2020, has given emergency approval to 19 SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona virus-2) detection kits among which 8 are based on immunological assay.[2] The Wondfo kit is a lateral flow-based assay utilizing colloidal gold for visualization as reported in Chinese science news portal ScienceNet.cn on 24 February 2020.[3] This science new portal, a part of China Science Daily Media Group, is claimed to be a Chinese language virtual community of Chinese scientists, co-sponsored by Chinese Academy of Sciences, Chinese Academy of Engineering, National Natural Science Foundation of China and China Association for Science and Technology.[4] It reported that National Medical Product Association gave emergency permission for the use of the kit to diagnose COVID-19 and has mentioned that it was the first kit of its kind to detect COVID-19 infection and to be granted approval for use. The official China medical equipment government validation number of the kit is 20203400176. The news said that the kit doesn't differentiate between IgG or IgM antibodies but detects both, increasing the chance of detection of serological conversion of COVID-19 patients. The news reported that Dr. Zhong Nan Shan, an academician at the Chinese Academy of Engineering,[5] said the kit was able to detect infection on the 7th day of infection and 3rd day of onset of symptoms. Scientifically, this means the kit can't detect infection before 7th day of being infected or before 3rd day of start of symptoms. The news clearly mentions the kit would help “supplement or synergize” i.e. “buchong or xietong” in Chinese (Youdao translation, https://en.wikipedia.org/wiki/Youdao), the results of PCR (polymerase chain reaction) tests.

Correspondence
Divya RSJB Rana
Birgunj, Parsa, Nepal
Email: div_rana@yahoo.com

Peer Reviewers
Prof. Dr. Jay N Shah
Patan Academy of Health Sciences

Asst. Prof. Dr. Ashis Shrestha
Patan Academy of Health Sciences

Submitted
19 Apr 2020

Accepted
25 Apr 2020

How to cite this article
Divya RSJB Rana. Serological rapid diagnostics test kit "Wondfo" for COVID-19 in Nepal. Journal of Patan Academy of Health Sciences. 2020Apr;7(1):4-6.

DOI:
https://doi.org/10.3126/jpahs.v7i1.28842

The news section in the official website of Wanfu biotech, on 6 March 2020, says that the "Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)" had got EU CE label.[6] This is European Union's "European Confirmation" for the kit meeting the high safety, health, and environmental protection requirements for use in the European Union countries. China Daily, an English language newspaper in China, confirms it.[7]

Search for "Wondfo coronavirus" not "wanfu coronavirus" in the Google Scholar resulted in a scientific article uploaded in MedRxiv (pronounced med-archive) website. The MedRxiv is a preprint server which, after screening for non-scientific content and plagiarism, assists authors to posting their articles which are not yet peer-reviewed.[8] The study from Nanjing Medical University, China, used the kit to check the infectivity of 13 patients and 9 showed positive tests. But the tests were carried 15 to 40 days after the onset of symptoms.[9] It was not mentioned if the tests were also carried earlier. This is an important aspect because, testing so late is of no use because the COVID-19 patients can transmit disease if not detected at early stages of the disease.

An another study from Wuhan Institute of Virology, Chinese Academy of Sciences found that on day 0 of testing, 81% (13 out of 16) of COVID-19 patients had detectable antibodies and by 5th day everybody had (either IgG or IgM or both).[10] But the study has not clarified the days when the patients were tested for immunoglobulins or the duration of days from onset of symptoms to hospitalization. The study used another technique called enzyme-linked immunosorbent assay (ELISA) to detect the antibodies which have better limits of detection, hence sensitivity, compared to lateral flow assays in rapid diagnostic kits.[11] Research has shown that the increase in detectable immunoglobulins for SARS-CoV-2 takes place only after more than 1 week of symptom onset.[12] Unlike immunoglobulins, the viral load is highest in the early days of onset and can be detectable by nucleic-acid amplification-based detection methods.[12] Due to paucity of data on the ability of the immunoglobulin-based rapid diagnostic kits to detect infectivity as soon as symptoms arise, it's difficult to conclude if such kits have any benefits to prevent transmission. So, the PCR or nucleic acid amplification-based technique still remains a validated method to detect infection on the day or just within few days of symptom onset.

Conflict of Interest

None

Funding

None

Reference

1. Acharya R. How effective is RDT kit actually? "आरडीटी" किट खासमा कति ठीक ? eKantipur [internet]. 2020 Apr 11; Kantipur News. [Accessed 2020 Apr 13] Weblink
2. National Medical Products Administration. State Food and Drug Administration emergency approval of new coronavirus detection products. (in Chinese, 国家药监局应急审批新型冠状病毒检测产品.) [internet]. 2020. [Accessed 2020 Apr 14] Weblink
3. Sciencenet.cn. Wanfu Bio-New Coronavirus Antibody Rapid Test Reagent is officially approved for listing [internet]. (in Chinese-万孚生物新冠病毒抗体快速检测试剂正式获准上市—新闻—科学网) 2020 Feb 24; News. Weblink
4. Sciencenet.cn. To build a global virtual community for Chinese-speaking scientists [internet]. 2020. [Accessed 2020 Apr 13] Weblink
5. Zhong N. Journal of Thoracic Disease. Jtd.amegroups.com [internet]. 2020. [Accessed 2020 Apr 14]. Weblink
6. Wondfo Biotech. Wanfu Bio's three new crown antibody detection reagents are approved by the EU CE (in Chinese-万孚生物三个新冠抗体检测试剂获欧盟 CE 准入-最新动态 - 广州万孚生物技术股份有限公司). Wondfo Biotech [internet]. 2020 Mar 6. [Accessed Apr 14] Weblink
7. Zhihua L. Chinese testing kit exports soar as COVID-19 spreads. Chinadaily.com.cn

[internet]. 2020 Mar 17; Business. [Accessed 2020 Apr 15] Weblink
8. MedRxiv. Advancing the sharing of research results for the life sciences. 2020. [Accessed 2020 Apr 14] Weblink
9. Song C, Wang Y, Li W, Hu B, Chen G, Xia P, et al. Detection of 2019 novel coronavirus in semen and testicular biopsy specimen of COVID-19 patients. MedRxiv. 2020. [Preprint, not peer reviewed] DOI GoogleScholar PDF
10. Zhang W, Du RH, Li B, Zheng XS, Yang XL, Hu Ben, et al. Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerg Microbes Infect. 2020;9(1):386-9. DOI PubMed GoogleScholar PDF
11. Zherdev AV, Dzantiev BB. Ways to reach lower detection limits of lateral flow immunoassays. In: Rapid test: advances in design, format and diagnostic applications. London: Intech Open; 2018. p 9-43. DOI GoogleScholar PDF
12. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020. [Epub ahead of print] DOI PubMed GoogleScholar PDF