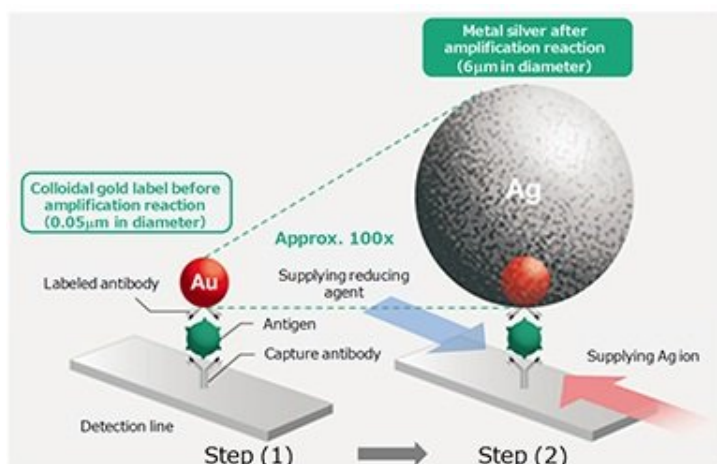


Fujifilm applies for manufacturing and marketing approval for a SARS-CoV-2 antigen test kit

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Uses silver amplification immunochromatography method



Fujifilm Corporation on 17 Dec 2020 announced that it has filed an application with the Pharmaceuticals and Medical Devices Agency to obtain manufacturing and marketing approval for a rapid and simple antigen test kit for detecting SARS-CoV-2, using silver amplification immunochromatography method*, as in-vitro diagnostic medical device. This kit has been developed with the use of highly-sensitive detection technology based on silver halide amplification response used in the photo-developing process.

In a bid to establish a production structure for this test kit, Fujifilm is making a capital investment in Fujifilm Yuwa Medical Products Vietnam Company Limited (Head office in Bình Dã, Hanoi, Vietnam), which manufactures Fujifilm's diagnostics medical products. The investment has been chosen for the third round of a business support program by the Japan External Trade Organization (JETRO) for diversifying overseas supply chains.

Antigen tests can be carried out quickly and produce results on the spot. Despite these advantages, antigen tests have lower sensitivity than PCR tests and there are growing needs for the improvement of their sensitivity. From their advantages, antigen tests are now being considered globally for use not only at hospitals but also at airports, event venues and other premises as economic activities begin to resume. This has created the need for ensuring stable supply of antigen test kits.

From October this year, Fujifilm and the Public University Corporation Yokohama City University (Kanagawa, Japan) jointly develop the rapid and simple antigen test kit for SARS-CoV-2 using silver amplification immunochromatography method, which is Fujifilm's proprietary highly-sensitive detection technology. The test kit is due to be produced at Fujifilm's Ashigara Site in the Kanagawa Factory. However, in anticipation for the product's global deployment in the future, FUJIFILM YUWA in Vietnam will start gradually reinforcing its production facilities next year to ensure supply stability for the test kit.

The Fujifilm Group has contributed to making SARS-CoV-2 testing faster by supplying PCR test reagents and the reagents for use with the fully-automated immunoassay system "TASWako g1,"*** capable of performing simple and rapid PCR testing in full automation. (These SARS-CoV-2 reagents are currently available in Japan only.) By providing a wide range of

products and services that meet the needs of medical frontline, the Fujifilm Group will continue to help improve the efficiency of SARS-CoV-2 testing while contributing to the improvement of the quality of life and medical care.