

Press Release

Medical & Biological Laboratories Co., Ltd. launches real time PCR-based assay kit products for SARS-CoV-2

NAGOYA, Japan – March 23, 2020 – Medical and Biological Laboratories Co., Ltd. (MBL), a JSR Life Sciences company, announced today that its subsidiary company, G&G Science Co., Ltd. has successfully completed the development of a real-time PCR assay kit for “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The kit was evaluated with clinical samples provided by the National Institute of Infectious Diseases (NIID). NIID and the Japan Ministry of Health, Labour and Welfare (MHLW) published today that the results of the kit 100% corresponded to that of the current NIID system on both positive agreement rate and negative agreement rate. Therefore, now on, the kit can be used not only for the emergency test being executed under the Infectious Diseases Control Law of Japan but also for the clinical test with the coverage of public medical insurance.

MBL has begun manufacturing the RUO kits with the name of FLUORORESEARCH Novel Coronavirus (SARS-CoV-2) Detection Kit at a capacity of several tens of thousands of tests per month and will begin accepting orders for customers in Japan on March 23. Shipping is expected to begin on March 27th. MBL expects sales to expand beyond Japan in the coming months.

The kit was developed using a real time PCR assay platform described in the “Pathogen Detection Manual 2019-nCoV” by NIID, and yields comparable assay performance through a considerably simpler procedure. Each kit includes 100 tests. MBL will also launch a complementary SARS-CoV-2 Positive Control kit.

The current NIID system requires two individual assay steps to identify the two gene regions of SARS-CoV-2. The MBL system can simultaneously detect these two regions in one single assay step by multiplex real time PCR. The accuracy of the MBL system is also improved by the addition of internal controls.

More information on the FLUORORESEARCH Novel Coronavirus (SARS-CoV-2) Detection Kit can be found here: <https://www.mblbio.com/bio/g/info/news/2020/SARS-CoV-2.html>

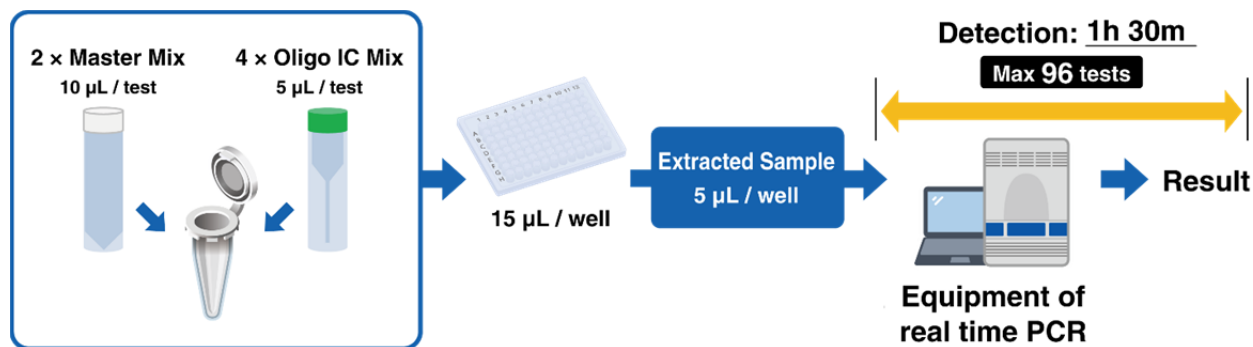
About MBL Medical & Biological Laboratories, Co., LTD.

MBL was founded in 1969 as the first manufacturer of antibodies in Japan. Using technology built on advances in immunology and molecular biology, MBL offers clinical diagnostics and research reagents designed for analysis of proteins and/or genes associated primarily with autoimmune disorders, cancer, gynecological diseases, and infectious diseases. In recent years MBL has also been actively developing biomarker reagents and companion diagnostics, taking advantage of our strength in immunological and gene detection techniques. MBL is a JSR Life Sciences company.

FLUOROSEARCH Novel Coronavirus (SARS-CoV-2) Detection Kit



Test flow:



Contacts:

In Japan & Asia Pacific: kouhou@mbi.co.jp

Rest of World: Missy Bindseil mbindseil@jsrlifesciences.com