MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.
A JSR Life Sciences Company

Press Release

"MEBRIGHT™ SARS-CoV-2 Kit" was approved with marketing authorization in Japan for the detection of novel coronavirus "SARS-CoV-2"

NAGOYA, Japan – May 21, 2020 – Medical and Biological Laboratories Co., Ltd. (MBL), a JSR Life Sciences company, today announced that "MEBRIGHT™ SARS-CoV-2 Kit" to be used for real-time one-step PCR assay was approved with marketing authorization of Pharmaceuticals and Medical Devices Act (PMDA) in Japan for the detection of novel coronavirus "SARS-CoV-2".

In addition, the release date will be 2020/5/25 after it is covered by medical insurance of Japan.

This kit was developed using a one-step real-time PCR assay platform described in the "Manual for the Detection of Pathogen 2019-nCoV" by National Institute of Infectious Diseases (NIID) and yields comparable assay performance through a considerably simpler procedure.

As an improved version of NIID method, which two target genes of novel coronavirus are interpreted in different wells, this kit uses a single-well dual-target assay. Furthermore, internal control is implemented to check if the PCR is working properly. In consequence of these improvements, both operability and performance are enhanced.

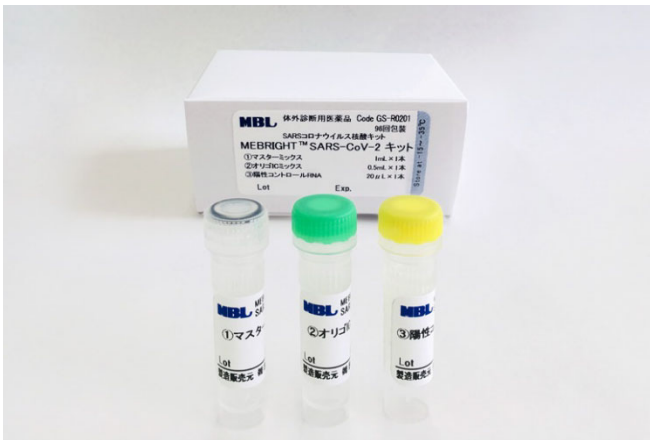
About MBL

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.

MEBRIGHT™ SARS-CoV-2 kit

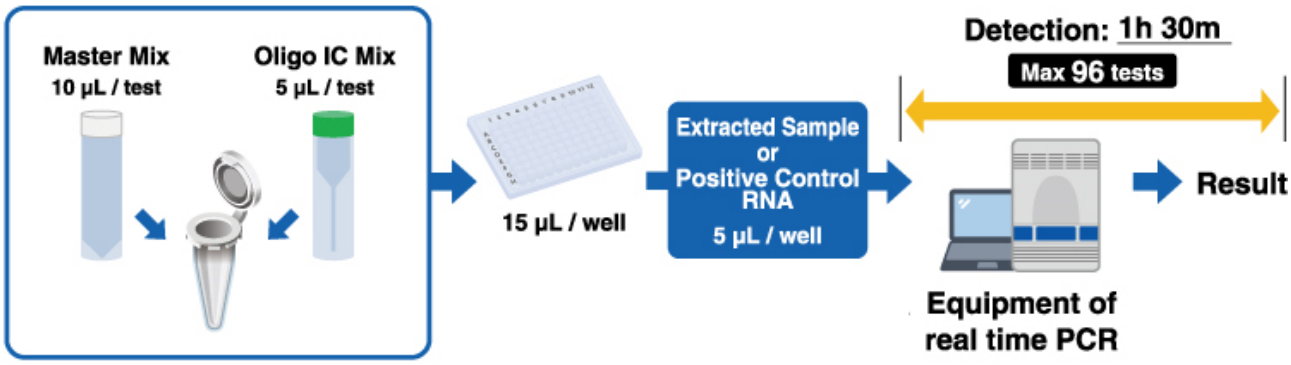
Product name	MEBRIGHT™ SARS-CoV-2 kit
Approval date	2020/5/21
Release date	2020/5/25
Approval number	30200EZX00029000
Intended Use	Detection of SARS-CoV2 RNA in upper respiratory tract samples (nasopharyngeal swab samples) or lower respiratory tract samples (sputum or bronchoalveolar lavage fluid) （to help diagnose SARS-CoV-2 infection）

Kit components:



1. Master mix
2. Oligo IC mix
3. Positive control RNA

Test flow:



Contacts:
In Japan & Asia Pacific: kouhou@mbl.co.jp
Rest of World: Missy Bindseil mbindseil@jsrlifesciences.com