Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

First Approval of Antigen Test for COVID-19

13th May, 2020

On 13th May, 2020, the first antigen test to detect SARS-CoV-2 that causes COVID-19 was approved in Japan with several post-marketing commitments. This product reached marketing approval within three weeks from its regulatory submission and became the world's first COVID-19 antigen test that was approved through the regular review scheme including taking the Expert Discussion. By using this new diagnostic test, quicker virus detection will be enabled, and testing capacity for COVID-19 in Japan will be strengthened and expanded.

Until today, detection of SARS-CoV-2 in Japan has routinely utilized a method called nucleic acid amplification test (NAT), including polymerase chain reaction (PCR) that is mainly used. While this methods is relatively accurate, it takes a couple of hours to obtain test results. On the other hand, the antigen test approved today can provide test results within 30 minutes. In addition, an antigen test does not require a special device like PCR or other NAT method does, allowing the results to be obtained right at the testing site. Therefore, the antigen test is expected to enhance the speed and accessibility in detection of the novel coronavirus. Through these advantages, it is anticipated that more patients can be tested for SARS-CoV-2, providing an additional testing option to the clinical settings that are largely affected by the pandemic.

While an antigen test has these advantages, there are cases where other testing methods may be preferred. With the new type of diagnostic test available, health care professionals can now choose appropriate testing methods to detect SARS-CoV-2 by considering characteristics and performance of each testing method that are suitable to the testing purpose. All types of diagnostics, i.e. PCR, other NAT method and antigen test, can be utilized complementarily to help diagnose the infection by the novel coronavirus.

Protecting the public health during the COVID-19 pandemic is our top priority, and it had been long-awaited to increase testing capacity for COVID-19. As a part of our commitment, the PMDA today provided access to a new testing method for detection of SARS-CoV-2. The PMDA, cooperating with the MHLW, will continue to help health care professionals to fight against this crisis by offering more product options in a timely manner. A list of medical products approved in Japan for COVID-19 including the antigen test is available here.

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