Editorial

DOI: 10.5582/bst.2022.01074

Increasing demand for point-of-care testing and the potential to incorporate the Internet of medical things in an integrated health management system

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SUMMARY As the number of people with COVID-19 increases daily around the world, point-of-care testing (POCT) is gaining attention as a tool that can provide immediate test results and greatly help to deter infection and determine what to do next. POCT has several drawbacks such as a low sensitivity and specificity, but according to studies POCT has increased sensitivity on par with that of polymerase chain reaction testing. The advantage of POCT is that the results can be obtained quickly, regardless of the location. To further enhance its benefits, POCT is being developed and researched in conjunction with the Internet of medical things (IoMT), which allows POCT results to be collected, recorded, and managed over a network. IoMT will be beneficial not only for the use of POCT simply as a testing tool but also for its integration into diagnostic and health management systems. IoMT will enable people to regularly receive their test results in their daily lives and to provide personalized diagnosis and treatment of individual conditions, which will be beneficial in terms of disease prevention and maintenance of health.

Keywords point-of-care testing, Internet of medical things, COVID-19, Japan

Point-of-care testing (POCT) is a concept that has been gaining attention due to the global outbreak of COVID-19. POCT is a simple test that can be performed at the patient's side by a healthcare professional or the patient himself. Information on the results of a test for a suspected disease is essential to making a proper diagnosis or deciding a treatment in a medical setting. With POCT, tests can be performed quickly in the required time, and results obtained in real time eliminate the time lag between diagnosis and care and enable a rapid response. In addition, quick testing and immediate results will improve the quality of medical care provided to patients and their quality of life. POCT is a concept that refers not only to testing equipment and reagents, but to the entire system for quick testing and immediate results (*1,2*). In the past, clinical tests were performed at specialized facilities such as testing centers using large specialized analyzers, but testing methods, kits, and systems are being researched and developed each year in response to the needs of the medical field for quick testing and immediate results.

POCT does not necessarily have to be done in a hospital or other medical facility. If necessary, it can be done at the patient's home or workplace, as long as the test results can be obtained immediately and can be used for testing and diagnosis in a location near the patient. The location-independent advantage of POCT was evident during the global outbreak of COVID-19. In the early stages of COVID-19 testing, PCR testing was the main method used, but PCR testing requires a special machine to be used after specimens are collected, and test results can take more than a day to be obtained (*3*). With the number of infected people increasing every day, the PCR test alone cannot keep up with the required number of tests. Antigen test kits were later introduced as POCT, and results can be obtained in about 30 minutes after specimen collection (*3*). In addition to antigen testing, nucleic acid testing using the Loop-mediated isothermal amplification method and biosensor testing using new sensor detection technologies such as surface plasmon resonance and electrochemical methods are also being studied, but immunochromatography is currently the main method in commercial use because of its stability and cost (*4*). According to a survey by the Tokyo Metropolitan Government, when the number of tests performed peaked in the sixth wave of COVID-19 on

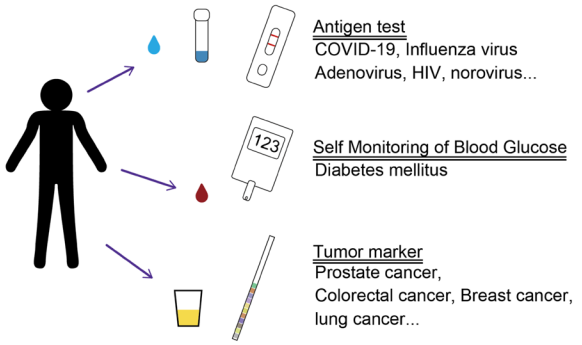

Figure 1. Test methods available for point-of-care testing.

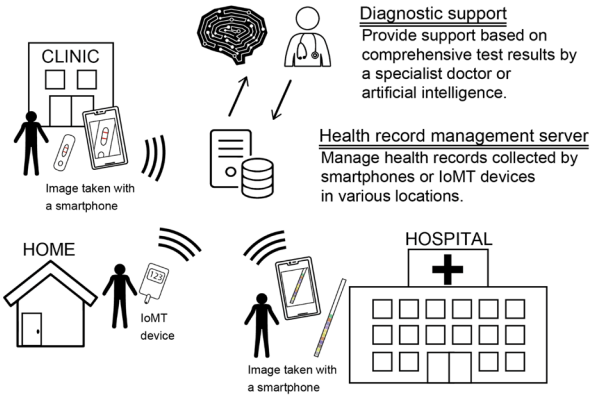

Figure 2. A location-independent health management system with point-of-care testing using the Internet of medical things and immediate support from expert doctors or artificial intelligence.

January 24, 2022, 35,182 people were tested in Tokyo, of which 11,154 underwent antigen testing (*5*). Although there are concerns about the availability of sufficient numbers of antigen test kits and their diagnostic accuracy, POCT, which can provide test results quickly and in the necessary time, will greatly help to decide diagnosis and treatment.

Current status of POCT

The area of POCT has been attracting attention as a test for COVID-19, but POCT itself has been actively developed and researched, and test kits have been developed and used for a variety of subjects. Figure 1 summarizes the testing methods that can be used in POCT and the conditions that can be tested for, including antigen tests and tumor markers (*1,2,6*). Antigen tests are used to test for antigens against various viruses such as SARS-CoV-2, which causes COVID-19, and reagents and test kits have been developed to test for influenza virus antigens, adenovirus antigens, HIV antigens, norovirus antigens, and antigens of many other infectious microorganisms. Immunochromatography is the main method used for antigen testing and POCT for tumor markers. The advantage of immunochromatography is that the results can be confirmed visually on the spot. However, there may be differences in negative and positive results depending on the lot and reagent.

In addition to the development of the tests for various infectious diseases and cancers as described above, the testing methods used in POCT are also being improved. Although POCT enables rapid testing, high accuracy is also required because POCT plays a major role in determining diagnosis and treatments. However, POCT has the disadvantage of having a lower sensitivity and specificity than an enzyme-linked immunosorbent assay or a polymerase chain reaction, which are the test methods commonly used in laboratories. In contrast, immunochromatography, which is often used to test for antigens of infectious microorganisms, is a test method involving the use of a paper test strip; it is low cost and easy to perform but tends to be less accurate. In recent years, research has been conducted to improve assays and enrich samples via preamplification to solve the problem of low sensitivity. Moreover, a low specificity can be increased by assay optimization and the identification and use of highly specific affinity molecules (*7*). Research has progressed to the point where POCT has performance on par with PCR testing.

Future development of POCT

POCT is an area where significant market growth is expected in the future. The global market for POCT reached $24.8 billion in 2021 and is expected to grow to over $43.5 billion by 2026 (*8*). Increasing demand for kits to test for infectious diseases, the incidence of cancer and chronic diseases, and a large elderly population are the major factors driving that market growth. In addition to the increase in the number of people who are candidates for testing, patient needs for quality medical care and convenience in obtaining results remotely and in a familiar place (home, office, or nearby clinic) are also factors that are expected to contribute to the growth of the market worldwide. Medical professionals have needs as well due to the shortage of medical personnel as a result of the aging population, a decrease in the size of the workforce, and the uneven distribution of medical personnel in Japan (*9*). Therefore, tests and systems that can be used remotely or by patients themselves, such as POCT, are expected to be developed.

POCT using the Internet of medical things (IoMT) is being researched in order to allow remote POCT systems to collect, record, and manage test results (*10,11*). Early detection and real-time treatment of infectious diseases is important to reducing the spread of infection, but it is a difficult task for limited medical personnel. As shown in Figure 2, systems that communicate via the IoMT and that collect, manage, and analyze information obtained via POCT, smartphones, and small testing devices will be beneficial. Diagnosis of infectious diseases using machine learning is also becoming a possibility (*12,13*). In addition, smart applications that screen for conditions based on physical information such as blood

glucose levels, blood pressure, and weight are being brought to market (*14*). In the future, POCT could share information *via* the IoMT, applications could analyze that information, and medical facilities could collaborate to create a system that immediately provides people with useful diagnostic information. POCT that can be easily and regularly performed in daily life would allow health to be gauged on a regular basis; this will lead not only to the early detection of lifestyle-related diseases but also to the immediate detection of their signs. Based on those signs, an analysis by an application or a doctor's remarks in real time would provide information on immediate lifestyle modifications. POCT using the IoMT will be beneficial in terms of public health and disease prevention.

Funding: None.

Conflict of Interest: The authors have no conflicts of interest to disclose.

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Received February 2, 2022; Revised February 18, 2022; Accepted February 20, 2022.

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Released online in J-STAGE as advance publication February 22, 2022.