Looking back on Accuracy of SARS-CoV-2 nucleic acid detection tests and Dynamics of Humoral and Cell-Mediated Immunity with vaccine-induced. -Hamamatsu cohort in Japan-

Keita Yamashita*
*Department of Laboratory Medicine, Hamamatsu University School of Medicine

Over three years have passed since the onset of the coronavirus disease-2019 (COVID-19) epidemic, and we are now controlling it. The reason why Japan has reached this phase is probably the establishment of a nucleic acid detection test system using PCR and the spread of vaccines. From 2021, we have resolved research question of clinical laboratory for these two perspectives.

In our hospital, various SARS-CoV-2 nucleic acid detection tests are used. Particularly, the GeneXpert® System and Cepheid Xpert Xpress SARS-CoV-2 assay kit (GX) is used for routine and emergency testing. We identified a cluster of COVID-19 cases within a short period among hospitalized patients and staff members from June to July 2022. Suspecting a nosocomial infection, we used GX to screen many contacts, and some SARS-CoV-2-positive cases were detected among individuals who had not yet developed symptoms. We noticed a characteristic preliminary finding in the GX results—the two Ct values of the N2 region of the nucleocapsid gene (N2) and envelope gene (E) targets were markedly different: the Ct value of N2 was approximately 10 cycles higher than that of E. Mutations in the qRT-PCR primer and probe binding sites have been reported to cause the discrepancy in the Ct values of these two gene targets. therefore, we aimed to determine the base sequence of the GX detection site. We led to the detection of the G29179T mutation of N2 region in the PCR primer and probe binding sites. This discrepancy was useful in analyzing multiple cluster cases that occurred at the same time based on changes in the genotype.

At the beginning of SARS-COV-2 mRNA vaccination (March 2021), it was unclear that the long-term behavior of these induced- humoral and cellular immunity. Therefore, the humoral immunity (Roche anti-RBD total Ig antibodies; Sysmex anti-RBD IgG; Neutralizing antibodies) and cell-mediated immunity (T-SPOT) of each subject were evaluated over one year using the same analytical methods. Our prospective cohort study was conducted by narrowing the subjects to healthcare workers based at one facility with relatively similar behavioral histories in the same area and with tightly controlled vaccine dose intervals. This study highlights the following findings: (1) anti-RBD total Ig was significantly increased by three doses of the BNT162b2 vaccine compared to anti-RBD IgG and NAb; (2) it was suggested that the difference between humoral immunity and cell-mediated immunity with age are complementary to each other, and it was reconfirmed that immunity to COVID-19 cannot be evaluated by antibody titer alone.

Reference; Yamashita, K et al. Differential Dynamics of Humoral and Cell-Mediated Immunity with Three Doses of BNT162b2 SARS-CoV-2 Vaccine in Healthcare Workers in Japan: A Prospective Cohort Study. Vaccines 2022, 10, 1050. https://doi.org/10.3390/vaccines10071050

The lessons learned from the COVID-19 pandemic

~challenges in Japan's genetic testing system~

Yuki Hara
Japanese Red Cross Aichi Medical Center Nagoya Daini Hospital
Japanese Association of Medical Technologist (JAMT)

It has been three years since the pandemic caused by SARS-CoV-2 began, which infected many people around the world and caused numerous deaths in the early stages of the epidemic. The emergence of SARS-CoV-2 was a significant shock to laboratories worldwide, including those in Japan. This article outlines the challenges and future prospects for genetic testing for infectious diseases in Japan. Currently, there are various diagnostic tests available for COVID-19, such as antigen tests and nucleic acid detection tests. However, during the early stages of the pandemic, nucleic acid detection tests were the only diagnostic method available. At that time, genetic testing was limited to specialized facilities such as university hospitals. As a result, facilities capable of diagnosing COVID-19 were very limited, and many people were unable to undergo testing. The Japanese government has provided various forms of support to establish a system for implementing genetic testing, and as a result, the number of facilities capable of conducting genetic testing has significantly increased compared to before the pandemic. While the number of facilities capable of conducting genetic testing has increased, there is still a lack of trained personnel knowledgeable in the methods and quality control of genetic testing. In other words, although the number of facilities capable of conducting genetic testing has increased, the system to respond promptly to pandemics has not yet been established. To establish a testing system that can respond promptly to pandemics, it is important to train experts in genetic testing from a medium- to long-term perspective. Additionally, policies that promote the spread of infectious disease genetic testing are also necessary. I would like to discuss the promotion of infectious disease genetic testing in Japan with the participants by having discussions with people from Korea and Taiwan at the symposium.

Title : Looking back on the activities of Biomedical Laboratory Science(BLS) in the COVID-19

Subtitle : A review of the laboratory's COVID-19 testing system and its future role

Name : Youjung KIM

Department of Laboratory Medicine, Seoul ST. Mary's Hospital,
The Catholic University of Korea, Seoul, Korea

Since the first COVID-19 patient occurred in South Korea in January 2020, The risk of a global pandemic required the development of a rapid test method.
Real-time reverse transcription polymerase chain reaction (rRT-PCR) test method with high discrimination power using known nucleotide sequence information
It was developed, and through the emergency use approval system, private medical institutions can perform tests in a short time.
Because it was developed in a short time, all possible samples from various institutions were used.
The validity test was conducted, and the accuracy of over 95% based on the world's best diagnostic capability
The test was carried out with a diagnostic kit.
In a short period of time, the diagnosis method will be commercialized and spread nationwide.
By quickly and accurately identifying confirmed cases, early detection and self-isolation of contacts
made follow-up possible.
In this laboratory, it was approved as a COVID-19 laboratory on February 5, 2019 after completing training for practitioners and an accuracy test conducted by the state, and it has been 3 years since the first COVID-19 test was performed.
Accordingly, the authors look back on the many experiences they have had while conducting corona tests in this laboratory for the past three years, share their experiences, and think about the role of the progressive laboratory in coping with another pandemic in the future.

A brief summary of the main points to be shared
-Contamination rate improvement in sample collection, nucleic acid extraction, PCR reagent manufacturing stage
-Improving nucleic acid extraction methods
-Differences between COVID-19 gene amplification reagents used
-Changes in retest criteria for undetermined results before and after the explosive outbreak
-Information on computer development for rapid reporting of results
-Inspector's efforts for reduction of inspection time and accuracy of inspection
In addition, I would like to talk about the experiences of promoting effective quarantine policies through a collaborative process with related departments.

Title : Impact on a tertiary care hospital during the COVID-19 pandemic in Korea

Name : Youngeun Cho
Affiliation : Dept. of Laboratory Medicine, Asan Medical Centre, Seoul, Korea

COVID-19 has affected people all over the world. The unprecedented virus has changed not only daily life but also the laboratory practice environment. At the beginning of the pandemic, there was a shortage of personal protective equipment(PPE) such as masks as positive cases were grown. Reinforcing regulation such as physical distance and health condition check daily, frontline workers had more difficulty practicing laboratory work. PPE regulation was reinforced, and also when the positive samples for COVID-19 were ordered, they had to be sealed with a zip bag and marked so that anyone could cause unexpected contagious diseases. Because the virus was highly contagious, if there were symptoms of COVID-19, workers had to be tested to protect other colleagues and prevent the spread of positive cases in the hospital. If a colleague was presented as a positive case for COVID-19, an increased workload was inevitable, and the rest of the employees had to work more. Employees who were confirmed positive must be quarantined for five days from the sample collection date and can resume work on the sixth day. The shortage of workers made the workload more intense, and other left workers had to work harder. This led to mental health issues and made healthcare workers burn out. Medical technologists were involved in various roles not only in limited laboratories but in this article, which focused on introducing performed SARS-CoV-2 and laboratory practice during the COVID-19 pandemic era.

An Infection control team was established for managing SARS-CoV-2 in the hospital. When the employee was confirmed as a positive case of SARS-CoV-2, the infection control team investigated whether any employees or faculty members were exposed to and suspected as positive cases of COVID-19. All commuters had to fill in the form of a medical questionnaire every day including the day off using the application. At least until the 2nd vaccination was mandatory for all workers.

Among various SARS-CoV-2 diagnostic tests, RT-PCR (Reverse transcription polymerase chain reaction) test, RAT (Rapid Antigen Test), and gene X-pert PCR were selected to be used in this hospital. As increased the volume of samples for the SARS-CoV-2 test, a pooling specimens test was proposed for performing NAATs (Nucleic Acid Amplification Tests). It brought reduced time for testing and labor. To prevent the spread of the virus, the laboratory built a more negative pressure isolation system. Then set up a SARS-CoV-2 testing. Testing personnel had to wear PPE including an N94 mask. Once a positive case was confirmed, the designated clinician checked the results were valid. The positive results were sent to the patients' SMS and also sent to the organization which was responsible for public health services.

Continuing Education was affected during the pandemic. As a prohibited gathering, meetings and education conferences were opened through online platform services. Even post-pandemic era, this type of meeting would be able to continue due to being less restricted by location and time. Looking back on the activities of laboratories during the COVID-19 pandemic, it replaced our new normal work circumstances and drove us to build a new regulation for another novel infectious disease.

Looking back on the activities of BLS in the COVID-19

Chao-Wei Liu
Taiwan association of medical technologists(TAMT)
Taipei association of medical technologists(Taipei TAMT)

The 2019 coronavirus epidemic is a global pandemic of severe and specific infectious pneumonia (COVID-19) caused by severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2). As of March 10, 2023, more than 676 million confirmed cases have been reported worldwide, with more than 6.881 million deaths, representing a mortality rate of 2.09%, making it one of the largest pandemics in human history.

In the face of this fierce outbreak, medical teams and public health experts around the world are anxious to identify the cause of the epidemic so that they can effectively and quickly find a solution to combat the epidemic. In Taiwan, on January 30, 2020, we spent three days isolating the first native Taiwanese SARS-CoV-2 from a confirmed case of COVID-19, making Taiwan the fourth country in the world to isolate this virus. In medical research, live viruses are required to analyze the effects of the virus on the human body, to develop drugs and vaccines, and to test the effectiveness of drugs and vaccines. The cultivation of viruses is one of the professional skills of biomedical laboratory scientists, who must cultivate and identify viruses in a very short period of time due to clinical diagnostic needs.

After the outbreak of COVID-19 in 2020, everyone began to pay attention to the work of our biomedical laboratory scientists. In addition to "cultivating viruses", another important job of biomedical laboratory scientists is "testing diseases". The usual work of a biomedical laboratory scientists is to examine a large number of patient samples, such as blood, urine, feces, saliva, etc., to see if there are any abnormalities in them. Under the COVID-19 epidemic, the " COVID-19 REAL-TIME RT-PCR " is also one of the tasks that our biomedical laboratory scientists have to deal with every day.

Biomedical laboratory scientists are health care professionals trained in the art and technology of clinical laboratory medicine. They are employed by hospitals, clinics, pharmaceutical companies and research institutions. Biomedical laboratory scientists are responsible for providing clinical test data to physicians, and they act as the eyes of the physician who must rely on these test reports to make the most accurate diagnosis of a patient.

During the epidemic, these biomedical laboratory scientists were responsible for performing covid-19 virus nucleic acid testing on a daily basis. In the early stages of the epidemic, due to the insufficient number of high-throughput virus nucleic acid testing equipment, the large and rapidly accumulating demand from the public for testing, and the pressure to meet the reporting timelines of relevant government policies on epidemic prevention, coupled with the unknown lethality of the virus, the biomedical laboratory scientists had to wear airtight biosafety protective equipment to work. These hard processes and psychological pressure are unforgettable.

But crisis is also an opportunity, because of the characteristics of biomedical laboratory scientists in the development of education process, many biomedical-related industries are in great demand for people with these abilities and characteristics. The rapid development of laboratory medicine and technology has led to a changing career for biomedical laboratory scientists. The ability of biomedical laboratory scientists to acquire new knowledge and contribute positively to further development is the greatest guarantee that future medical laboratories will be able to adapt to the needs of patients and health services. This requires the education of a sufficient number of biomedical laboratory scientists and the adaptation of educational programs to the future needs of biomedical laboratory science expertise.