

Quick and accurate SARS-CoV-2 detection

The development of ImmunoArrow™ SARS-CoV-2

Antigen test kits are increasingly being used in Japan and overseas as a reliable method for quick and accurate detection of SARS-CoV-2 (which causes COVID-19) and as an aid to preventing the spread of the disease. In June 2021, the Toyobo Group introduced the immunochromatographic ImmunoArrow™ SARS-CoV-2 antigen test kit for medical institutions and testing laboratories. The “arrow” in the name reflects the test’s ability to detect the SARS-CoV-2 antigen as quickly and accurately as an arrow.

We responded to the urgency of the situation and strong social need by vastly accelerating our developmental processes. Below is a dialogue between two of the researchers involved in the project.

We stepped up R&D to meet the urgency of the social situation and successfully created a product

Okamoto The Group has previously developed and delivered the GENECUBE® fully automated gene analysis system and SARS-CoV-2 genetic test reagents. We also

thought that creating an antigen test kit could lessen the burden on medical professionals and help prevent the virus from spreading.

Nishimura Polymerase chain reaction (PCR) testing requires equipment that is generally only available at larger medical institutions. We thought that there was a strong need for an antigen test kit that does not require special equipment so it could be used at smaller medical clinics and be available wider testing.

Okamoto We were already conducting R&D in immunochromatographic testing as one of our base technologies, and when the pandemic broke out we started talking about whether we could develop it for COVID-19. One of our biggest challenges was the fact that this was the first time we were trying to create a product that used the immunochromatographic technique.

Nishimura Honestly, we felt like we were in a huge hurry because we knew that it had to be developed quickly and also because the situation was rapidly changing and other makers had already released immunochromatographic products. But it was a fantastic experience to strongly believe that we could create a better product than what was available and then to bring it to full fruition.



Jun Okamoto

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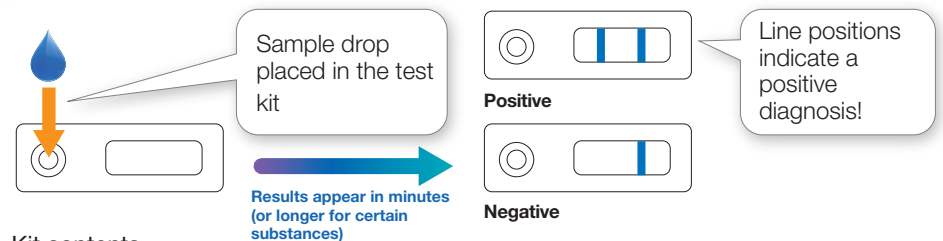
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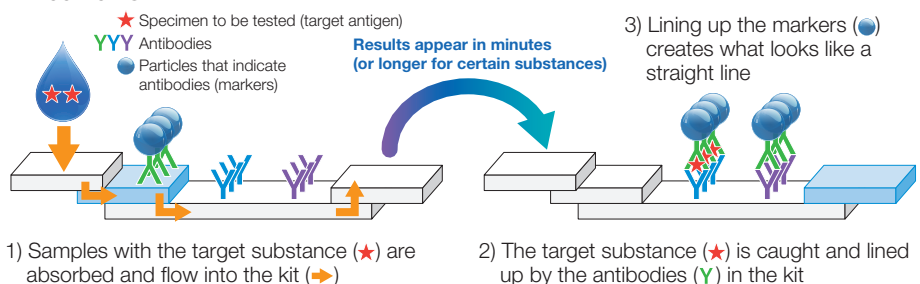
What is immunochromatography?

Immunochromatography is a quick diagnostic method that uses capillary action to measure antigen-antibody reaction, and is used around the world to diagnose influenza and test for pregnancy. The advantages of immunochromatography for SARS-CoV-2 testing and detection are that it is quicker than PCR tests and it does not require special equipment.

Immunochromatography



Kit contents



Technological teamwork with the University of Toyama and others were critical

Nishimura The kit's accuracy requires highly sensitive and specific antibodies and particles to act as markers for visualizing the reaction. The antibodies were developed using the Company's base technologies and through technical cooperation with the University of Toyama. Working together, we conducted multifaceted evaluation testing and in a very short time were able to very efficiently identify promising antibodies from a huge number of candidates.*

Okamoto We selected the particles to use as markers by testing which ones had the highest sensitivity, which led to choosing particles different from those used in conventional immunochromatography methods. A major feature of this product is superior antibodies and particles that it uses.

Nishimura We also enhanced kit performance by adding features like technology to suppress non-specific reactions and to enhance reactivity.

Okamoto That was our first experience with manufacturing, so we did many trial tests and made many improvements to the technology before we released the product.

Nishimura We had to work through many different opinions about how many trials to conduct and how to balance quality with the delivery period, but everyone wanted to put out a product that we all agreed on. We always returned to that as our starting point, and that enabled us to keep working with mutual understanding and respect.

Okamoto We were also hurrying to get it out because we were starting later than other companies and did not yet have a kit on the market. At the same time, everyone on our team felt it was essential to ensure the kit's reliability.

Nishimura I think it was a major point that, through all of the many discussions, everyone on the team had the same mindset. Because of that, a sense of teamwork naturally



ImmunoArrow™ SARS-CoV-2

developed. In the end, I think it worked really well because each person understood their role, and was able to work as a team while thinking independently about who should do what and when. I think the collaboration inside and outside the company is what ultimately made the project successful.

* The antibody used in this product was produced in participation with the Research Program on Emerging and Re-emerging Infectious Diseases (second open recruitment) and Research on the development of immediate clinical testing systems for SARS-CoV-2 of the Japan Agency for Medical Research and Development (AMED) in fiscal 2020.

Immunochromatography will continue to be used for quick action on infectious diseases and mutant viruses

Okamoto When we were creating the immunochromatography method for the kit, we developed our own antibodies, antigens, and other biomaterials in-house. But as we worked, I had the impression that the Company's base materials are fertile ground for creating many more materials. I think there is potential to fuse our non-woven fabrics, membranes, and other base materials with biomaterials to produce new all-Toyobo products with distinctive features.

Nishimura In addition to the PCR test reagents, I would like to build out and serialize the ImmunoArrow™ brand to provide a wide range of solutions for infectious diseases, which is one of our objectives in the life science field. I wonder if, in the future, testing can be easier and be done in more situations, such as before entering a stadium or train station.

We created this kit for COVID-19, but would like to continue improving our antibody acquisition and production technology and our development and production technology related to immunochromatography so we can make test kits more quickly when a highly infectious influenza virus or other type of new virus mutation appears.

I would like us to continue working in this area to become one of the leading companies in the solution business for diagnosing infectious diseases.

Whatever direction we go in, I would like us to continue placing the emphasis on teamwork.

Development team members



Bio-Science & Medical Research Unit,
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Diagnostic System
Department



Biotechnology Research Laboratory