Asia-Pacific
Economic Cooperation

Advancing Free Trade
for Asia-Pacific Prosperity

Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies

APEC Sub-Committee on Standards and Conformance

December 2023

Asia-Pacific
Economic Cooperation

Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies

APEC Sub-Committee on Standards and Conformance

December 2023

APEC Project: SCSC 02 2022A

Produced by

China National Institute of Standardization, China
No.4 Zhi Chun Road, Haidian District, Beijing
Tel: +86 010-58811400
Website: https://en.cnis.ac.cn

For
Asia-Pacific Economic Cooperation Secretariat
35 Heng Mui Keng Terrace
Singapore 119616
Tel: (65) 68919 600
Fax: (65) 68919 690
Email: info@apec.org
Website: www.apec.org

APEC#223-CT-04.11

Table of contents

1. Executive Summary

This report has been developed to support to share best practices and standards for SARS-CoV-2 and help to improve the quality of control and evaluation of the detection of SARS-CoV-2 among APEC economies to better support the APEC PUTRAJAYA VISION 2040 and the Aotearoa Plan of Action. The project included questionnaires and a two-day webinar. The specific objectives of this project include:

- This project aims to provide knowledge about ISO/TS 5798: 2022 for delegates and related organizations of APEC economies;
- to enable application of ISO/TS 5798: 2022, and hence enable effective and efficient detection of SARS-CoV-2 in the APEC region;
- to strengthen the exchange and sharing of scientific research information on the detection of SARS-CoV-2 for supporting global cooperation to address the SARS-CoV-2 challenge.

The two-day webinar was held on 24-25 May 2023. Nearly 100 delegates from Canada; Chile; People's Republic of China; Hong Kong, China; Indonesia; Japan; Malaysia; Mexico; The Republic of the Philippines; Singapore; Thailand; United States and other APEC/SCSC member economies participated in the webinar. The project overseer shared the findings of the questionnaires at the webinar. Four standard development leaders and key drafters from People's Republic of China; United States; and Germany delivered keynote speeches on the content and applications of ISO/TS 5798: 2022. Eight experts from well-known institutions and enterprises in People's Republic of China; Japan and Singapore presented the latest progress in nucleic acid detection research for the SARS-CoV-2.

The pre-webinar questionnaire has to investigate the information on the detection of SARS-CoV-2 in APEC economies from 9 February 2023 to 19 March 2023. The questionnaire's objective is to investigate the situation of detection of SARS-CoV-2 in APEC economies. The target for this questionnaire includes representatives from research institutions, government departments, medical laboratories, reagent manufacturers, certification authorities, and other organizations interested in the standardized research and diagnosis of SARS-CoV-2. A Key Finding Report has summarized and analyzed the questionnaires from each economy and obtained various results.

2. Introduction

Coronaviruses are enveloped RNA viruses that are broadly distributed in the animal kingdom. They have been identified in humans, other mammals, and birds. Until 2019, six coronaviruses have been associated with human diseases:
—severe acute respiratory syndrome-related coronavirus (SARS-CoV),
—Middle East respiratory syndrome coronavirus (MERS-CoV),
—human coronavirus 229E (HCoV-229E),
—human coronavirus OC43 (HCoV-OC43),
—human coronavirus NL63 (HCoV-NL63),and
—human coronavirus HKU1 (HCoV-HKU1).

In 2019, a cluster of patients presenting with respiratory disease were shown by sequencing to be infected with a novel coronavirus. The coronavirus associated with this cluster was subsequently named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses. SARS-CoV-2 is the seventh coronavirus known to infect humans. The disease caused by SARS-CoV-2 was designated coronavirus infectious disease 2019 (COVID-19) by the World Health Organization

Clinical management of COVID-19 and control of infections and spread of SARS-CoV-2 requires effective and efficient in vitro diagnostics. There are several tests and kits for use in the detection of SARS-CoV-2. The number of methods will continue to increase. Acceptable design, development, and establishment of quality SARS-CoV-2 diagnostics based on nucleic acid detection methods is critical to ensure COVID-19 control.

A high level of quality for standardized nucleic acid amplification based on *in vitro* diagnostics for the detection of SARS-CoV-2 is a prerequisite to guarantee optimum patient care, operator safety, and surveillance for the prevention of the spread of SARS-CoV-2. However, false-positive and false-negative results can occur frequently during actual testing. Establishing clear quality assessment requirements for testing reagents was needed, together with guidance to enable accurate, early diagnosis and screening, which are essential to control the spread of the pandemic and treat patients in time.

Clear guidance was needed urgently from the ISO, and that's what led to the development of ISO/TS 5798: 2022. ISO/TS 5798: 2022, published in April 2022, provides recommendations for the design, development, verification, validation, and implementation of analytical tests for detecting SARS-CoV-2

using nucleic acid amplification. It addresses pre-examination, examination, and post-examination process steps for human specimens. Provides recommendations for the design, development, verification, validation, and implementation of analytical tests for detecting SARS-CoV-2 using nucleic acid amplification. It addresses pre-examination, examination, and post-examination process steps for human specimens.

China proposed a project "Sharing standards of detection of SARS-CoV-2 by nucleic acid amplification methods for strengthening the public health system and facilitating trade in APEC economies". This project was submitted to the APEC Project Proposal in June 2022 and lasted from 2022 to 2023. China thanked Hong Kong, China; Japan; Malaysia; Peru; Singapore; and Thailand for co-sponsorship and thanked the participation from APEC economies.

The project is to share related standards for the detection of SARS-CoV-2 by nucleic acid amplification methods. ISO/TS 5798: 2022 provides requirements and recommendations for the design, development, verification, validation, and implementation of analytical tests for detecting SARS-CoV-2 using nucleic acid amplification.

Therefore, this project can help to promote the quality of the detection of SARS-CoV-2, and hence facilitate the mutual recognition of SARS-CoV-2 detection results in the APEC economies facilitate the cross-border movement of people, and promote trade and economic recovery. The importance of the project not only lies in benefiting the controlling of the current COVID-19 outbreak by guiding the quality practice of analytical trials of SARS-CoV-2 but also in sustainably helping APEC economies to strengthen their public health systems to cope with major public health problems that may occur in the future.

The two-day webinar was the main event of the project. The webinar was held on 24-25 May 2023. Four standard development leaders and key drafters from the China; Germany; and United States delivered keynote speeches on the content and applications of ISO/TS 5798:2022. Eight experts from well-known institutions and enterprises in China; Japan; and Singapore presented the latest progress in nucleic acid detection research for the SARS-CoV-2.

3. Summaries of Questionnaire

3.1 Introduction of the questionnaire

This project designed a pre-webinar questionnaire on the detection of SARS-CoV-2 and sent it to all APEC Economies. The questionnaire consisted of 15 questions and will take 5-10 minutes to complete. The questionnaire was originally completed from 9-28 February 2023, but at the request of some economies, the submission period was extended to 19 March 2023.

China summarized and analyzed the questionnaires from each economy and obtained various results.

3.2 Summary of Key Findings

3.2.1 Objectives of the Questionnaire

Chinese project: SCSC 02 2022A — Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies.

The project aims to share best practices and standards for SARS-CoV-2 testing quality control among APEC economies to strengthen their technical exchanges and promote capacity building and economic recovery. A two-day webinar will be scheduled in May 2023, one day to introduce the framework and application of the international standard ISO/TS 5798: 2022, and the other to discuss knowledge and methodologies for the detection of SARS-CoV-2 with the standard.

The project overseer conducted a questionnaire to investigate the information on the detection of SARS-CoV-2 in APEC economies. The objective of the pre-webinar questionnaire is to investigate the situation of detection of SARS-CoV-2 in APEC economies. The questionnaire will be distributed among the APEC economies. The results of this questionnaire will help inform an outcomes document and will be introduced during the webinar.

The target for this questionnaire includes representatives from research institutions, government departments, medical laboratories, reagent manufacturers, certification authorities, and other organizations interested in the standardized research and diagnosis of SARS-CoV-2.

3.2.2 Basic information about the collected questionnaire

A total of 34 questionnaires were collected from 11 economies including Australia; Chile; the People's Republic of China; Hong Kong, China; Indonesia; Japan; Mexico; the Republic of the Philippines; Singapore; Chinese Taipei; and Thailand.

Among 34 questionnaire participants, there are 38% (13/34) female participants and 62% (21/34) male participants.

The population participating in the questionnaire survey covered all types of organizations in the questionnaire, including 4 from public institutions, 10 from the government, 6 from private institutions, 4 from research institutes/universities, 1 from international organizations, and 5 from other organizations.

The key finding from this part is that half of the economies in APEC actively participated in this project. The participants are from the government, private institutions, research institutes/universities, international organizations, and other organizations. The ratio of Female participants and male participants is 38:62.

3.2.3 Knowledge of ISO/TS 5798: 2022 in the APEC economies

Among 34 questionnaire participants, 19 persons work on the detection of SARS-CoV-2 and 7 of them have known or heard about the standard ISO/TS 5798: 2022. 15 Persons don’t work on the detection of SARS-CoV-2, but 6 of them still know or hear about the standard ISO/TS 5798: 2022. On the whole, 13 persons which are about 38% of the questionnaire participants know about this standard, demonstrating a good knowledge of it in the APEC economies.

The job titles of the questionnaire participants who know about this standard include chief operating officer, engagement manager, chief or head of the research-related division of government or public institution, scientific and business relations manager, ISO secretary of the economy, technical advisor, engineer, senior expert, and scientific coordinator. Regarding the question on “percentage of the professionals who have engaged in or are involved in the nucleic acid detection of SARS-CoV-2 in the department”, 12 participants selected <30%, 2 participants selected 30%-50%, 4 participants selected 50%-70%, and 4 participants selected 70%-100% engagement in the nucleic acid detection. The participation of professionals in this field is relatively low.

Nine correspondents understand the specifics of ISO/TS 5798: 2022, and 4 of them have referred to or applied it. The proportion of people who have applied this standard in the total number of participants is 12%, which is relatively low compared to the percentage of participants who know about ISO/TS 5798: 2022. The mentioned parts that helped the participant most include 5 laboratory requirements, verification of patient care, 10 Implementation and use in the laboratory and reporting of results, 11 Quality assurance, Annex A (informative) Nucleic acid amplification techniques.

The key finding from this part is that there is good knowledge of ISO/TS 5798: 2022 in the APEC economies but there is still room for improving the percentage of economies applying it.

3.2.4 Women's participation in the detection of SARS-CoV-2

Regarding the question on "percentage of women who have engaged in or are involved in the nucleic acid detection of SARS-CoV-2 in the department", 6 participants selected <30%, 1 participant selected 30%-50%, 10 participants selected 50%-70%, and 4 participants selected 70%-100% engagement in the nucleic acid detection. The participation of women in this field is relatively high. 13 Participants think it is necessary to improve women's participation. Many measures have been recommended, including updating hiring practices and indicating that women are encouraged to apply to scientific and technical positions in the institute, engaging technical staff in scientific work/activities based on their competencies and skills and not on their gender, providing them with training and enhancing their hands-on skills, providing equal opportunity to employment and promotion and flexible work arrangements, implementing initiatives that place women in life science fields at the center of preparedness, response, and recovery, raising awareness and involving students from related areas in the importance of measurements as preparation for SARS-CoV-2 and future health emergencies, eliminating structural and legal obstacles that hinder all women's participation, being free from bias to have well-rounded participation.

The key finding of this part is that women have participated actively in the detection of SARS-CoV-2, and there are many good measures to further improve women's participation in terms of employment and training.

3.2.5 Nucleic acid testing method used in APEC economies

The selection and implementation of the nucleic acid amplification method will

affect the accuracy of detection results. “ISO/TS 5798: 2022 In vitro diagnostic test systems — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods” specifies the procedures of three nucleic acid amplification methods, namely reverse transcription qPCR (RT-qPCR), reverse transcription digital PCR (RT-dPCR) and isothermal amplification. That is the reason we set the question.

In this questionnaire, 71% (24/34) of participants live in economies that use RT-PCR to test for COVID-19. Only two responses indicated the use of isothermal PCR, and others were not sure.

The key finding of this part is that RT-PCR is currently the main nucleic acid detection method for SARS-CoV-2 in APEC economies.

3.2.6 False-positive results and false negative results during the nucleic acid test for SARS-CoV-2

False positives are usually caused by cross-contamination between specimens during laboratory testing or by contamination of nucleic acids in the laboratory. The main reasons for false negative nucleic acid tests include the initial stage of infection, inaccurate collection sites, delayed specimen testing, problems in the transportation process, or problems with testing instruments and reagents.

In this questionnaire, 35% (12/34) of participants said they had experienced false positives. 32% (11/34) of participants chose NO, and others were unsure. 32% (11/34) of participants said they had experienced false negatives. 29% (10/34) of participants chose NO, and others were unsure.

The key finding of this part is that false positives and false negative results are common in the detection of SARS-CoV-2 in APEC economies. It is necessary to pay attention to false positive and false negative results.

3.2.7 Using standards in APEC economies

As the “gold standard” for pathogen diagnosis and an important basis for the prevention, control, and treatment of COVID-19, nucleic acid testing is characterized by high sensitivity and accuracy. The establishment of quality evaluation requirements for testing reagents and a standardized quality system for nucleic acid testing of COVID-19 is of great significance for APEC economies to ensure test quality, and control the spread of the epidemic.

In this questionnaire, 24% (8/34) of participants live in economies that do not have standards for the detection of SARS-CoV-2. 50% (17/34) of participants said they were unsure. 26% (9/34) of participants live in economies that have relevant standards, such as Australia; Chile; China; Indonesia; Japan; and Thailand. Two of them are using standards developed by ISO or international organizations. And the other species are using their standards.

The key finding of no unified standard of detection of SARS-CoV-2 in the APEC economies. It is necessary to promote the ISO/TS 5798: 2022 application.

3.2.8 The quality of nucleic acid testing for SARS-CoV-2

In this questionnaire, 53% (18/34) of participants said they attach importance to the quality of nucleic acid testing for COVID-19. 29% (10/34) of participants chose NO, and others were not sure

The key finding of this part is that most economies are concerned about the quality of nucleic acid testing for SARS-CoV-2.

3.2.9 Summary

A total of 34 questionnaires were collected, and half of the economies in APEC actively participated in this project. The participants are from the government, private institutions, research institutes/universities, international organizations, and other organizations. The ratio of Female participants and male participants is 38:62.

Women have participated actively in the detection of SARS-CoV-2, and there are many good measures to further improve women's participation in terms of employment and training.

RT-PCR is currently the main nucleic acid detection method for SARS-CoV-2 in APEC economies. False positives and false negative results are common in the detection of SARS-CoV-2 in APEC economies. It is necessary to pay attention to false positive and false negative results. Meanwhile, most economies are concerned about the quality of nucleic acid testing for SARS-CoV-2. However, there is currently a lack of uniform SARS-CoV-2 testing standards in APEC economies.

There is good knowledge of ISO/TS 5798: 2022 in the APEC economies but there is still room for improving the percentage of economies applying it. It is

necessary to promote the ISO/TS 5798: 2022 application

4. Summaries of Webinar

4.1 Introduction of webinar

A two-day webinar was held on 24-25 May 2023. Nearly 100 delegates from Canada; Chile; People's Republic of China; Hong Kong, China; Indonesia; Japan; Malaysia; Mexico; The Republic of the Philippines; Singapore; Thailand; United States and other APEC/SCSC member economies participated in the webinar. The project overseer shared the findings of the questionnaires at the webinar. Four standard development leaders and key drafters from China; Germany; and the United States delivered keynote speeches on the content and applications of ISO/TS 5798:2022. Eight experts from well-known institutions and enterprises in China; Japan; and Singapore presented the latest progress in nucleic acid detection research for the SARS-CoV-2.

4.2 Session 1: Framework and application of International Standard ISO/TS 5798: 2022

Dr. Wu Qi

Dr. Wu Qi, the project overseer, made a presentation named "Summary of Key Findings of Pre-Webinar Questionnaire".

The presentation focused on the key findings of the pre-webinar questionnaire on the information about the detection of SARS-CoV-2, which was distributed among the APEC members before the seminar started. The questionnaire included the basic information of the personnel who filled in the questionnaire, the investigations on the knowledge of the international standard "ISO/TS 5798:2022 In vitro diagnostic test systems — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods", women's participation in the detection of SARS-CoV-2, nucleic acid testing methods used in APEC economies and the use of SARS-CoV-2 detection related standards.

A total of 34 questionnaires were collected, and 11 economies actively participated in this project. The key findings were as follows:

(1) Women have participated actively in the detection of SARS-CoV-2, and

there are many good measures to further improve women's participation in terms of employment and training.

(2) RT-PCR is currently the main nucleic acid detection method for SARS-CoV-2 in APEC economies.

(3) Most economies are concerned about the quality of nucleic acid testing for SARS-CoV-2, and it is necessary to pay attention to false positive and false negative results.

(4) There is currently a lack of uniform SARS-CoV-2 testing standards in APEC economies.

(5) There is good knowledge of ISO/TS 5798:2022 in the APEC economies but there is still room for improving the percentage of economies applying it.

Mr. David E. Sterry

Mr. David E. Sterry made a presentation named "The History of ISO/TS 5798 and an Overview of the ISO Document Development Process".

Mr. David E. Sterry first introduced the development progress of ISO/TS 5798, including scope revision, forming a drafting team, approval of new work item proposal, document development, review and commenting, final WG consultation ballot, final review and commenting, DTS ballot, and publication. Then, Mr. David E. Sterry introduced the contents of ISO/TS 5798, including scope, normative references, terms and definitions, overview, laboratory requirements, design and development, verification for patient care, validation for patient care, design transfer to production, implementation and use in the laboratory and reporting of results and quality assurance. At last, Mr. David E. Sterry introduced the ISO development process for international standards. It started with PWI (Preliminary Work Item), then NWIP (New Work Item Proposal), then Committee Draft (CD), then Draft International Standard (DIS), then Final Draft International Standard (FDIS), at the last publication.

The presentation enabled the participants to learn well about the development history of ISO/TS 5798 and the contents of this international standard and also made the participants know how to develop an ISO document.

Dr. Zhang Zhiying

Dr. Zhang Zhiying made a presentation named "Brief introduction of technical specification ISO/TS 5798 for in vitro diagnostic systems of SARS-CoV-2".

Dr. Zhang Zhiying first introduced the background of developing ISO/TS 5798. Establishing indices for conducting comprehensive quality evaluation of methods and kits both during development and in routine application will ensure the accuracy of the test results and support epidemic prevention and control. Then, Dr. Zhang Zhiying emphasized the scope: This document provides recommendations for the design, development, verification, validation, and implementation of analytical tests for detecting the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) using nucleic acid amplification. It addresses pre-examination, examination, and post-examination process steps for human specimens. This document applies to medical laboratories. It is also intended to be used by in vitro diagnostic developers and manufacturers, as well as by institutions and organizations supporting SARS-CoV-2 research and diagnostics. This document does not apply to environmental samples.

After that, he introduced the contents of ISO/TS 5798 in detail, including an overview, laboratory requirements, design and development, verification for patient care, validation for patient care, design transfer to production, implementation and use in the laboratory, and reporting of results and quality assurance. She then emphasized the important requirements and recommendations in each part, especially focused on design and development, verification for patient care, validation for patient care, quality assurance, and laboratory requirements. The link to this ISO document was given at the end of the presentation.

The presentation made participants fully understand the contents of ISO/TS 5798.

Dr. Shen Ao

Dr. Shen Ao made a presentation named “Requirement and Recommendations in ISO/TS 5798:2022, the Design and Development of Analytical Tests for Detecting SARS-CoV-2”.

The contents of this presentation include five parts, which are (1) background: COVID pandemic, (2) abstract of ISO/TS 5798:2022, (3) framework of document, (4) contents of documents, (5) future perspective. Dr. Shen Ao first introduced the background, that SARS-CoV-2 was now an established and ongoing health issue that no longer constitutes a public health emergency of international concern. Then, he explained the abstract of ISO/TS 5798:2022 in detail, ISO/TS 5798 was the world’s first guideline for nucleic acid testing of SARS-CoV-2. The framework of ISO/TS 5798 included 11 parts, and his

presentation focused on the 6th part, which was "design and development". This part was one of the most important parts, and it detailed the design and development process from start to finish, it included the following 6 subparts: 6.1 customer, patient, and stakeholder needs, 6.2 intended use of analytical test, 6.3 institutional guideline strategy, 6.4 clinical strategy, 6.5 design and development planning, 6.6 optimization of reagents and methods. Dr. Shen Ao interpreted the clauses and statements of these 6 subparts elaborately.

The presentation made participants fully understand the design and development of analytical tests for detecting SARS-CoV-2.

Ms. Jenny Cao

Ms. Jenny Cao made a presentation named "Registration Requirements of SARS-CoV-2 Reagent (PCR) in China".

Ms. Jenny Cao first introduced the overview of the IVD (in vitro diagnostic products) registration process in China, from research & development, product testing, and clinical study to NMPA Review/approval. SARS-CoV-2 reagent was classified as class III IVD in China. Then, Ms. Jenny Cao explained the regulatory requirements of analytical performance study in detail. The non-clinical study, required a raw material study, manufacturing process study, cut-off study, analytical performance study, and reagent stability study. The general requirements of an analytical performance study covered reagent requirements, lots requirements, applicable instruments, sample requirements, and report requirements. She then interpreted the limit of detection (LOD) study, precision study, inclusivity study, analytical specificity study, sample stability study, nucleic acid extraction and purification performance study, reaction system study, and internal reference panel testing. Next, Ms. Jenny Cao introduced the regulatory requirement of the cut-off study. At last, she introduced the regulatory requirements of a clinical study, discussing the subject selection, sample size, statistical analysis, and special situation.

In summary, the registration requirements for SARS-CoV-2 reagents in China included an analytical performance study report, a cut-off study report, a stability study report, a testing report, and another study report.

Dr. Liu Linbo

Dr. Liu Linbo made a presentation named "Development of COVID-19 rapid detection POCT based on microfluidic technology".

Dr. Liu Linbo first introduced the microfluidics. There were many types of microfluidic chips, such as card style, electro-wetting, dish style, electro-chemistry, and paper style microfluidics, and they had the potential for many applications. Then, he introduced the development process of COVID-19 rapid detection point-of-care testing (POCT) based on microfluidic technology. The devices were shown in the presentation and the applications were also introduced.

The presentation made the participants know the newly developed COVID-19 rapid detection POCT based on microfluidic technology.

Dr. Andreas Kummrow

Dr. Andreas Kummrow made a presentation named "ISO/TS 5798: 2022 Application to external quality assurance".

Dr. Andreas Kummrow first introduced external quality control assurance in Germany, showing the CMV and HIV ring trials. Then, he emphasized that the detection method for SARS-CoV-2 was required, and there was a need for quality control material. There were three nucleic acid amplification methods, including quantitative real-time PCR (qPCR), digital PCR (dPCR), and isothermal PCR, involved in ISO/TS 5798: 2022. Digital PCR was chosen as a reference because it showed excellent precision and accuracy. dPCR can determine SARS-CoV-2 virus concentration which was measured in copies per mL, and can provide early support for external quality assurance. Dr. Andreas Kummrow then interpreted relevant ISO/TS 5798: 2022 recommendations for tests and also introduced examples of Digital PCR in expert labs for external quality assessment (EQA).

The presentation made the participants know how ISO/TS 5798: 2022 was applied to external quality assurance.

4.3 Session 2: Knowledge and methodologies for the detection of SARS-CoV-2 in the APEC economies

Dr. Miki Nagao

Dr. Miki Nagao made a presentation named "Overcoming COVID-19 pandemic through collaboration between academia and local government".

As an infection prevention and chief of the laboratory department, Ms. Miki

Nagao focused on the overcoming COVID-19 pandemic through collaboration between academia and local government. She described the establishment of "reliable" diagnostic systems for COVID-19 in clinical laboratories in Kyoto and Osaka and requirements for "good" laboratory testing.

She also described the steps: Step 1, building up a reliable PCR mass testing system in 2020; Step 2, Utilization of PCR mass testing systems for administrative testing from 2020 to now. Step 3, performing a large-scale SARS-Cov-2 whole genome analysis from 2021 to now.

Dr. Zhang Yifan

Dr. Zhang Yifan made a presentation named "SARS-CoV-2 detection techniques and solutions".

Dr. Zhang Yifan shared the SARS-Cov-2 detection techniques and solutions. The presentation described different methods of virus detection and their advantages and disadvantages. She focused on Real time fluorescent RT-PCR and introduced COVID-19 guidelines for laboratory testing in China.

She took Sansure company as an example to describe Nucleic acid diagnostic solutions, antigen screening solutions, and clinical diagnostic solutions.

Dr. Masaaki Kitajima

Dr. Masaaki Kitajima made a presentation named "Wastewater banking: virus detection from archived wastewater reveals community-level infection dynamics".

Wastewater-based epidemiology (WBE) is a mass diagnosis infrastructure for strengthening public health systems and reveals actual prevalence regardless of symptoms, testing capacity, and healthcare-weeking behavior. Virus detection from archives wastewater reveals community-level infection dynamics. The presentation described the development of EPISENS-M, a highly sensitive SARS-Cov-2 RNA detection method from wastewater. Biobanking of wastewater samples+EPISENS-M can serve as an archival record of public health information.

Prof. Hayato Miyachi

Prof. Hayato Miyachi made a presentation named "Lessons from Economy-wide External Quality Assessment of SARS-CoV-2 Nucleic Acid Amplification Tests in Japan".

Prof. Hayato Miyachi talked about standards of the detection of SARS-Cov-2 by nucleic acid amplification methods for strengthening the public health system and facilitating trade in APCE economies. The presentation described a bottleneck of PCR use for SARS-Cov-2 in the very beginning in Japan and solutions and recommendations on urgent strategies, strategies for expansion of tests with quality lab, and economy-wide external quality assessment.

He also described efforts on the development of international standard (ISO/TS 5789: 2022) on quality practice of detection of SARS-Cov-2 using nucleic acid amplification methods.

Dr. Siew Hwa Ong

Dr. Siew Hwa Ong made a presentation named “Effective Testing Strategies During the COVID-19 Pandemic: Ensuring Accuracy and Efficiency”.

The presentation focuses on the accuracy and efficiency of SARS-Cov-2 testing during the COVID-19 pandemic. She described the development and manufacturing of SARS-Cov-2 PCR test kits and introduced Acu-Corona high-throughput COVID-19 RT-PCR kits. She also described the setting up of the SARS-Cov-2 PCR clinical testing laboratory and Acu-Corona workflow for COVID-19 testing. Swab operations in the community, identification and personal data protection, and efficiency and accuracy in the transport of samples were shared.

Dr. Xiwen Jiang

Dr. Xiwen Jiang made a presentation named “Development trend of in vitro diagnosis for pathogenic microorganisms”.

The presentation focuses on the development trend of in vitro diagnosis for pathogenic microorganisms. He mentioned that the instrument foundation and talent reserve established during the COVID-19 pandemic may also contribute to the development of the LDT molecular diagnostic market, and pathogenic microbial detection promotes the development of the IVD industry. He also described the trends in the development of detection reagents and the development direction of IVD industry enterprises.

5. Recommendations

So far, testing for the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has been a great success, and so has the global response to the

pandemic.

ISO/TS 5798 from ISO is the world's first guideline for nucleic acid testing of SARS-CoV-2. The ISO/TS 5798 guidelines fill a gap in the quality control of testing, and apply to medical laboratories, in vitro diagnostic developers and manufacturers, as well as institutions and organizations in support of research and diagnosis of SARS-CoV-2.

But the fight against COVID-19 involves not only nucleic acid testing but also other activities such as infectious disease prevention and control, microbiological testing, and public health emergency response.

In the future, more experiences should be summarized in the fight against the COVID-19 epidemic, and several specifications and standards should be formed to provide experience for dealing with other public health events that may occur in the future. The following aspects are proposed:

(1) It is crucial to support all the APEC economies to develop technologies and standards for detecting, preventing, and controlling infectious microorganisms to avoid cross-infection and effectively manage public health emergencies in the future.

The technologies include nucleic acid, antibody, and antigen detection technologies for infectious microorganisms (such as mycoplasma, adenovirus, syncytial virus, etc.), to achieve accurate and quality-controlled detection results for infectious microorganisms. At the same time, the quality control standards for relevant detection methods are should be developed to break the bottleneck in infectious microbial detection. These standards will ensure that the detection of infectious microorganisms is consistent and effective throughout the APEC region. By promoting and implementing these standards in APEC economies, infectious microorganism detection laboratories will be able to build their capacity and achieve higher consistency and effectiveness in detection.

(2) It is crucial to support all the APEC economies to research on the detection, prevention, and control of major public health emergencies in APEC economies. This will provide guidance for responses to such emergencies and to establish efficient, comprehensive detection and control strategies for major public health crises caused by infectious microorganisms.

To improve epidemic prevention and control effectiveness, emergency public health infrastructure resources have become vital in response to public health

security emergencies. These resources include modular emergency microbial testing laboratories that can be quickly deployed, integrated medical treatment systems, isolation sites, as well as emergency infectious disease patient transport equipment, and so on.

It is recommended to conduct technical research and standard development activities on the public health infrastructure resources as well as emergency infectious disease patient transport equipment. Research could be done on the building standards for inflatable membrane structures with negative pressure clean laboratories. This could help meet the urgent need for medical testing laboratories, in vitro diagnostic reagent production workshops, and precision instrument manufacturing facilities. Similarly, research on medical isolation and transport units with negative pressure functionality, epidemic prevention and control system, and software development standards could help achieve unified evaluation and technical guidance for modular emergency medical treatment and prevention and control integrated systems.

APPENDIX 1 -Questionnaire

Asia-Pacific
Economic Cooperation

QUESTIONNAIRE

Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies

April
2023
Beijing, China

Organizer: *China National Institute of Standardization*

Event held under APEC Project: *Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies* (*SCSC 02 2022A*)
Sponsoring Economy / Project Overseer: *China / Wu Qi (wuqi@cnis.ac.cn)*
Co-sponsoring APEC economies: *Hong Kong, China; Japan; Malaysia; Peru; Singapore; Thailand*
Funded by *Sub-Committee on Standards and Conformance (SCSC)*

Introduction

Chinese project: **SCSC 02 2022A — Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies.**

The project aims to share best practices and standards for SARS-CoV-2 testing quality control among APEC economies to strengthen their technical exchanges and promote capacity building and economic recovery. A two-day webinar will be scheduled in April 2023, one day to introduce the framework and application of the international standard ISO/TS 5798: 2022, and the other to discuss knowledge and methodologies for the detection of SARS-CoV-2 with the standard.

Project overseer are conducting a questionnaire to investigate the information on the detection of SARS-CoV-2 in APEC Economies. The objective of the pre-webinar questionnaire is to investigate the situation of detection of SARS-CoV-2 in APEC Economies. The questionnaire will be distributed among the APEC Economies. The results of this questionnaire will help inform an outcomes document and will be introduced during the webinar.

The questionnaire should take 5-10 minutes to complete. Please respond to the questions based on the experiences of your economy. Please email it to **Wu Qi (wuqi@cnis.ac.cn)** of China National Institute of Standardization with any questions about the questionnaire content or to submit your final responses.

The target for this questionnaire includes representatives from research institutions, government departments, medical laboratories, reagent manufacturers, certification authorities, and other organizations interested in the standardized research and diagnosis of SARS-CoV-2.

Welcoming multiple responses per economy. We kindly request the questionnaire be returned no later than 28 February 2023. For any inquiries, kindly contact the project overseer at **Wu Qi (wuqi@cnis.ac.cn)**.

Kindly answer every applicable question. Thank you for your participation.

1. Contact Details

Name	
Email Address	
Job Title	
Gender	**Please Select One:** ☐ Female ☐ Gender Varian/Not-Conforming ☐ male ☐ Not listed ☐ Prefer not to say ☐
Ministry/Organization	**Please Select One:** ☐ Government ☐ Research institution/University ☐ Public institution ☐ International organization ☐ Private institution ☐ Others
Economy	**Please Select One:** ☐ Australia ☐ Brunei Darussalam ☐ Canada ☐ Chile ☐ the People's Republic of China ☐ Hong Kong, China ☐ Indonesia ☐ Japan ☐ the Republic of Korea ☐ Malaysia ☐ Mexico ☐ New Zealand ☐ Papua New Guinea ☐ Peru ☐ the Republic of the Philippines ☐ the Russian Federation ☐ Singapore ☐ Chinese Taipei ☐ Thailand ☐ the United States ☐ Viet Nam

2. Do you work on the detection of SARS-CoV-2?

☐ Yes

☐ No

☐ Not sure

3. Do you know or hear about the standard ISO/TS 5798: 2022?

☐ Yes

☐ No

☐ Not sure

4. Do you understand the specifics of ISO/TS 5798: 2022?

☐ Yes

☐ No

☐ Not sure

5. Have you ever referred to or applied ISO/TS 5798: 2022?

☐ Yes

☐ No

☐ Not sure

6. If you have referred to or applied ISO/TS 5798: 2022, which part of this standard has helped you most?

Click here to enter text.

7. What is the percentage of the professionals who have engaged in or are involved in the nucleic acid detection of SARS-CoV-2 in your department? Professions include sampling and testing personnel, physician, nurse, clinical technician, quality supervisors, and so on.

☐ <30%
☐ 30%-50%
☐ 50%-70%
☐ 70%-100%
☐ Not sure

8. What is the percentage of women who have engaged in or are involved in the nucleic acid detection of SARS-CoV-2 in your department?

☐ <30%
☐ 30%-50%
☐ 50%-70%
☐ 70%-100%
☐ Not sure

9. Do you think it is necessary to improve women's participation?

☐ Yes
☐ No
☐ Not sure

10. If you think it is necessary to improve women's participation, what measures do you recommend?

Click here to enter text.

11. Which nucleic acid testing method is used in your economy ?

- ☐ RT-qPCR
- ☐ RT-dPCR
- ☐ Isothermal amplification
- ☐ others
- ☐ Not sure

12. Is there a false positive result during the nucleic acid test for SARS-CoV-2?

- ☐ Yes
- ☐ No
- ☐ Not sure

13. Is there a false negative result during the nucleic acid test for SARS-CoV-2?

- ☐ Yes
- ☐ No
- ☐ Not sure

14. Is there a similar standard in your economy?

- ☐ Yes

  Please fill in the standard title.
- ☐ No
- ☐ Not sure

15. Are you concerned about the quality of nucleic acid testing for SARS-CoV-2?

- ☐ Yes
- ☐ No
- ☐ Not sure

APPENDIX 2 – Agenda

Ver 1, 2022

Asia-Pacific
Economic Cooperation

Agenda

Webinar on Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies

24-25 May 2023

Organizer: *China National Institute of Standardization*

Event held under APEC Project: *Sharing Standards of the Detection of SARS-CoV-2 by Nucleic Acid Amplification Methods for Strengthening Public Health System and Facilitating Trade in APEC Economies* (*SCSC 02 2022A*)
Sponsoring Economy / Project Overseer: *China / Wu Qi*
Co-sponsoring APEC economies: *Hong Kong, China; Japan; Malaysia; Peru; Singapore; Thailand*
Funded by *Sub-Committee on Standards and Conformance (SCSC)*

Day 1: 24 May 2023**, 08:00 – 11:30 (Beijing Time)**

Host: Dr. Wu Qi, Associate Professor, China National Institute of Standardization
Platform: MS team; **Meeting ID**: 465 233 470 340; **Passcode**: DfH6GW
Link: https://teams.microsoft.com/l/meetup-join/19%3a1JoCo7viHiZWhJkyjHq-e2sh0ZIdNg740k2aowS7TI41%40thread.tacv2/1684390653953?context=%7b%22Tid%22%3a%22e4906dbd-6037-4d38-b14e-2b6b84d8b4f0%22%2c%22Oid%22%3a%22c6ef12f6-ad83-4acb-b740-14d26f0846d3%22%7d
Topic: Framework and application of International Standard ISO/TS 5798: 2022

Time (Beijing Time)	**Topic**	**Speaker**
08.00 – 08.10 am	Opening Speech	Dr. Wu Qi
08.10 – 08.20 am	Presentation of questionnaire findings	Dr. Wu Qi
08.20 – 08.50 am	The History of ISO/TS 5798 and an Overview of the ISO Document Development Process.	Mr. David E. Sterry
08.50 – 09.20 am	Brief introduction of technical specification ISO/TS 5798 for *in vitro* diagnostic systems of SARS-CoV-2	Dr. Zhang Zhiying
09.20 – 09.50 am	Presentation of content of ISO/TS 5798-part III and Questions	Dr. Shen Ao
09.50 – 10.00 am	Break	
10.00 – 10.30 am	Registration requirements of reagent of SARS-CoV-2 in China	Ms. Jenny Cao
10.30 – 11.00 am	Development of COVID-19 rapid detection POCT based on microfluidic technology	Dr. Liu Linbo
11.00 – 11.30 am	ISO/TS 5798: 2022 - Application to external quality assurance	Dr. Andreas Kummrow

End of Day 1

Day 2: 25 May 2023**, 08:00 – 11:30 (Beijing Time)**

Host: Dr. Wu Qi, Associate Professor, China National Institute of Standardization
Platform: MS team; **Meeting ID**: 451 917 146 968; **Passcode**: eFSpVC
Link: https://teams.microsoft.com/l/meetup-join/19%3a1JoCo7viHiZWhJkyjHq-e2sh0ZIdNg740k2aowS7TI41%40thread.tacv2/1684390699222?context=%7b%22Tid%22%3a%22e4906dbd-6037-4d38-b14e-2b6b84d8b4f0%22%2c%22Oid%22%3a%22c6ef12f6-ad83-4acb-b740-14d26f0846d3%22%7d
Topic: Knowledge and methodologies for the detection of SARS-CoV-2 in the APEC economies

Time (Beijing Time)	**Topic**	**Speaker**
08.00 – 08.30 am	Overcoming COVID-19 pandemic through collaboration between academia and local government	Dr. Miki Nagao
08.30 – 09.00 am	SARS-CoV-2 detection techniques and solutions	Dr. Zhang Yifan
09.00 – 09.30 am	Wastewater banking: virus detection from archived wastewater reveals community-level infection dynamics	Dr. Masaaki Kitajima
09.30 – 09.50 am	Break	
09.50 – 10.20 am	Lessons from economy-wide external quality assessment of SARS-CoV-2 nucleic acid amplification tests in Japan	Prof. Hayato Miyach
10.20 – 10.50 am	Effective Testing Strategies During the COVID-19 Pandemic: Ensuring Accuracy and Efficiency	Dr. Ong Siew Hwa
10.50 – 11.20 am	Development trend of in vitro diagnosis for pathogenic microorganisms	Dr. Jiang Xiwen
11.20 – 11.30 am	Closed Speech	Dr. Wu Qi

End of Day 2

APPENDIX 3 – Speakers

Mr. David E. Sterry

Mr. David E. Sterry received his Bachelor of Science degree in Biology and Biological Chemistry at East Stroudsburg University. He has worked at the Clinical & Laboratory Standards Institute (CLSI) since 2001. He has been the Committee Manager for ISO/TC 212, Clinical laboratory testing, and in vitro diagnostic test systems since 2010, and the project manager for the development of ISO/TS 5798. He has worked for ISO for many years and has rich experience in international standards project management.

Dr. Zhang Zhiying

Dr. Zhang Zhiying holds a Ph.D. degree in biostatistics and epidemiology and has more than 20 years of experience in infection control, including more than 10 years as a senior technical officer in managing the philanthropic program on control of HIV/AIDS, TB, Malaria, and others in China and as project expert on infection control solution in the private manufacturer. He is one of the team leaders of the ISO/TS 5798.

Dr. Zhang Zhiying works as a project expert on infection control in BGI to support the development and distribution of products and solutions to infection diagnosis from a technical perspective, such as for solutions to COVID-19 control, including continuous product development and upgrade, regulatory access (WHO-EUL, FDA-EUA, PDMA, TGA ANVISA and authorities in some specific economies) and technical support to end clients for implementation.

Dr. Shen Ao

Shen Ao is a Senior Technical Manager in the Department of infection control, BGI.

He has nine years of experience in product design and development of molecular diagnostic products for infectious diseases. He has also led and participated in the development and clinical translation of several infection detection products, including the development of metagenomics-based products and nucleic acid-based POCT products.

During the COVID-19 outbreak, he has led his team to successfully register several molecular detection products and has extensive experience in product design and development.

Ms. Jenny Cao

Ms. Jenny Cao, Associate Regulatory Director from Burning Rock. She graduated from Tianjin University, majoring in pharmacy. She has served Roche Diagnostics, Perkin Elmer, and other IVD companies. With 15 years of experience in product registration and research and development in the IVD industry, including product registration, clinical trial, product design, and development, etc. she has led the registration of multiple Class III and Class II IVD products and obtained Chinese National Medical Products Administration approval, including molecular diagnostics, immunoassay, etc.

Dr. Liu Linbo

Dr. Liu Linbo, Ph.D. in Applied Physics jointly trained by the David A. Weitz research group at Harvard University in 2021, and Ph.D. in Mechanical Engineering from the Key Laboratory of Micro and Nano Biomedical Device Design and Manufacturing at Southeast University. Dr. Liu is currently the head and senior project manager of the microfluidic platform at the Research Institute of Guangzhou Daan Gene Co., Ltd., responsible for the development and performance evaluation of microfluidic chips and related nucleic acid self-inspection box series products, wearable device series products, and in vitro diagnostic integrated machine series products. Dr. Liu has led some research projects and completed the development, production transfer, establishment, and certification of production lines of two COVID-19 nucleic acid self-check boxes and a digital PCR all-in-one machine, and participated in the world's largest IVD exhibition (MEDICA exhibition in Germany). He published 13 papers, one of which (Nanotechnology 28, 28 (2017): 285302) was selected as the front cover paper and also featured on the IOP website of the Royal Society of Physics in the UK. 19 patents have been applied for and 6 have been authorized.

Dr. Andreas Kummrow

Dr. Andreas Kummrow was one of the main drafters of the ISO/TS 5798. Dr. Andreas Kummrow studied physics at the Technical University Berlin and received his PhD degree in 1990. Since 2002 he has been with the German National Metrology Institute, the Physikalisch-Technische Bundesanstalt (PTB). He works in the division of medical physics and metrological information technology. Over the past two decades, he worked in the fields of tissue optics, flow cytometry – particularly blood cell counting, and molecular detection of human pathogens. He is interested in developing domestic and

international standards in DIN and ISO, and in promoting reference measurement procedures in international committees like JCTLM.

Dr. Miki Nagao

Dr. Miki Nagao is a professor of Clinical Laboratory Medicine at Kyoto University Graduate School of Medicine. She also serves as a director of the infection control team and clinical laboratory department at Kyoto University Hospital. She is a physician specializing in infectious diseases and clinical microbiology and is responsible for the antimicrobial stewardship program at KUH. She also serves as a chief in the COVID-19 research project organized by Kyoto University and the local government in Kyoto City. The principal areas of her research are infection prevention strategy for nosocomial pathogens, molecular epidemiology of multi-drug resistant pathogens, and development of novel diagnostic tools.

Dr. Zhang Yifan

Zhang Yifan, MD from Shanghai Medical College Fudan University. She is the Medical Affairs Manager at Sansure Biotech Inc., in charge of Respiratory Tract Infection products related medical affairs. She had planned and coordinated 3 clinical trials and collected and forwarded product information for the diagnostic Kit.

Dr. Masaaki Kitajima

Dr. Masaaki Kitajima is an Associate Professor of environmental engineering at Hokkaido University. He earned his Doctor of Engineering degree in the field of urban environmental engineering from the University of Tokyo in 2011. After receiving the doctoral degree, he worked at the University of Arizona in the US as a Post-Doc through the Japan Society for Promotion of Science Postdoctoral Fellowships for Research Abroad from 2011 to 2013. He expanded his research experience by working at the Singapore-MIT Alliance for Research and Technology, a research center of MIT in Singapore, for 2 years from 2014. Since 2016, he has been a faculty member at Hokkaido University in Japan, where he works on environmental virology with a current emphasis on wastewater-based epidemiology of COVID-19. Dr. Kitajima has published 134 peer-reviewed journal papers with 9600+ citations and an h-index of 49. He has been recognized as a Highly Cited Researcher 2022 by Clarivate for the impact of his work demonstrating significant and broad influence reflected in the publication of multiple highly cited papers. His research area covers broad aspects of health-related water microbiology from an environmental engineering perspective, represented by molecular epidemiological analysis of viral pathogens in natural and engineered water systems.

Prof. Hayato Miyach

Dr. Hayato Miyachi holds a degree for Ph.D. (Medicine) from Keio University School of Medicine. He was formerly a Professor of the Department of Laboratory Medicine at the Tokai University of School, Isehara, Japan, for 19 years, and the Director of Clinical Laboratory and Infection Control at the Tokai University Hospital for 20 years. Since April 2022, Dr. Miyachi has been a Professor at the Nitobe Bunka College, Faulty of Clinical Laboratory Sciences, Tokyo, Japan, currently leading the college as a Dean. He is also leading the College of Laboratory Medicine of Japan (CLMJ) as a President.

Dr. Hayato Miyachi is an industrious leader in the quality assurance of molecular-genetic testing through the development of human resources, standards, and schemes, for the realization and promotion of precision medicine, with an ultimate goal of human well-being and a wealthy society.

Dr. Miyachi is currently acting as the Chair of the Committee for Standardization of Molecular-genetic Testing in the Japanese Committee for Clinical Laboratory and Standards (JCCLS). He is also acting as the Chair of the Japanese National Mirror Committee for ISO Technical Committee 212 (Clinical laboratory testing and in vitro diagnostic test systems) and serves in Working Group 1, as a project team member of the established international standard for medical laboratories (ISO 15189: 2022 – Medical Laboratories – Requirements for quality and competence), in the Working Group 4, as a project leader for the development of the international standards for in vitro diagnostic medical devices (ISO 21474-1: 2020 – Multiplex molecular testing for nucleic acids – Terminology and general requirements for nucleic acid quality evaluation, ISO 21474-2: 2022 – Validation and verification, and ISO/CD 21474-3 – Interpretation and reports), as well as in the Joint Working

Group 6, as a co-project leader for the development of the established international standard for in vitro diagnostic test systems for SARS-CoV-2 (ISO/TS 5798: 2022.

With these activities as a background, Dr. Miyachi has been constantly showing innovative leadership in conducting governmental policy research works for regulatory enforcement on the quality assurance of molecular-genetic testing (enforced in the year 2018) and associated studies for the continuous quality improvement in Japan.

Dr. Ong Siew Hwa

Dr. Ong Siew Hwa is a highly accomplished scientist and a well-recognized industry leader in the clinical laboratory testing domain. She was trained in Singapore, the US & Canada, possessing a phenomenal understanding of key biomedical fields (molecular genetics and immunology) and human diseases (cancer, infectious diseases). In November 2019, Dr. Ong sensed that the "mysterious pneumonia" outbreak in Wuhan could be a dangerous condition, with hallmarks akin to the SARS in 2003. She led the Acumen team to develop new PCR diagnostic tests for the new coronavirus, COVID-19 (Acu-Corona), approval from HSA (MOH) and started manufacturing of COVID-19 PCR test kits for local use and export to several ASEAN economies. The journey of saving lives during the pandemic did not stop there; by mid-2020, Dr. Ong led Acumen to set up clinical laboratory testing of COVID-19 for infection control in Singapore. In 2022, Dr. Ong led Acumen into operating a community vaccination center. Dr. Ong and the company have been awarded the Public Service Medal and Certificate of Commendation, respectively, by the Prime Minister's Office for the contribution to the COVID-19 battle.

Dr. Jiang Xiwen

Dr. Jiang Xiwen, who holds a Ph.D. in Microbiology from the University of Hong Kong, is a senior medical devices engineer, who served as Deputy General Manager, Chief Scientist, and R&D Director of Da An Gene Co., Ltd. in Guangzhou.

He is primarily involved in the research and development of In Vitro Diagnostic products, project application, scientific investigation cooperation, strategic planning for technological development direction, and management of daily administrative affairs related to scientific research.

He also is an expert with the title of “High-level Talents in Guangzhou” and “Outstanding Individual in the Fight against COVID-19 in Guangzhou”.

Dr. Jiang has published many high-level papers, including 22 SCI papers, led or participated in 21 projects at or above the municipal level, including 4 domestic key projects, and participated in the formulation of 1 domestic standard, 3 standards of the pharmaceutical industry of the People's Republic of China and 3 group standards.