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Monitoring and evaluation for quality of Thailand SARS-CoV-2 laboratory network: Lessons learnt for policy drive and new guidelines

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ABSTRACT

Background: Due to the COVID-19 outbreak, Department of Medical Sciences, Ministry of Public Health has taken responsibility for SARS-CoV-2 laboratories using Real-Time RT-PCR in network accreditation. Monitoring and evaluation are important to ensure the quality of SARS-CoV-2 laboratory networks after receiving accreditation.

Objectives: This study aims to summarize and provide policy proposals and new laboratory guidelines from on-site-assessment key points to elevate lab quality and support laboratory development to meet the international standard, ISO 15189 accreditation.

Materials and methods: The coaching-type-assessment checklist for SARS-CoV-2 laboratory network was prepared by an expert team and contained 44 requirements in Analytical technique and Biological safety. It was then sent to the laboratory network nationwide for self-assessment. The assessor team used this checklist for on-site assessment from May to September 2020.

Results: On-site assessment of 38 SARS-CoV-2 laboratories showed a total of 156 nonconformities (NCs). The top three NCs in the Analytical technique requirements were 1) accommodation and environment condition (27.6%), (involved performing Pre-PCR activities in the same area as Post-PCR and unidirectional workflow), 2) laboratory equipment, reagents, and consumables (13.5%) and 3) post-examination process (13.5%). In Biological safety requirements, personal protective equipment (PPE) was the most frequently found NC with 8.3%, and involved area constraints with no suitable places to put on or remove PPE.

Conclusion: The monitoring and evaluation for the SARS-CoV-2 laboratory network in Thailand has been developed according to the PCR standards both in terms of management and technical including biological safely for improving and developing the quality of SARS-CoV-2 laboratory network response to an emerging situation. To strengthen the quality of laboratory network in Thailand and preparedness to emerging situation, integrated tools are proposed including laboratory's self-assessment (coaching-type checklist), the proficiency testing (PT) programs, re-accreditation, special assessment from particular request and organizing training to disseminate knowledge to all network laboratories. In addition, this system may apply for other emerging diseases in the future and should encourage laboratories to continue for the ISO 15189 accreditation.

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Introduction

Due to the COVID-19 outbreak, Department of Medical Sciences, Ministry of Public Health has taken responsibility for laboratories implementing SARS-CoV-2 testing. The project named "one laboratory one province" has been launched to develop Laboratories with SARS-CoV-2 testing in every provinces of Thailand serving for diagnosis, treatment, monitoring, disease investigation and surveillance preparedness for peoples of the whole country. The Department of Medical Sciences was the host for work integration between internal and external organizations in establishing the network system for laboratories implementing SARS-CoV-2 testing using Real-Time RT-PCR.[1] The laboratories requesting laboratory network accreditation, need to pass assessment by the Department of Medical Sciences in the capacities of personnel, instrument, equipment, reagents, in a BSL 2 enhanced facility and proficiency testing by giving correct reports for all PT samples provided. Only laboratories in the accredited list of SARS-CoV-2 laboratory networks could join the program of the National Health Security Office (NHSO) for supporting lab analysis and PPE costs. Currently, over 200 laboratories have been accredited leading to rapid diagnosis, infection control and prevention by timely management. However, to ensure the quality of laboratories in the network after receiving accreditation, a monitoring team has been set up to play roles in lab evaluation for re-accreditation and for special assessment on particular request after discordant results from reference labs, and to support laboratories to meet the international standard, ISO 15189 accreditation. During May 2020 to September 2020, there were 4 lab assessments based on particular request, 12 labs with random assessment and 22 labs co- assessed with the National Health Security Office (NHSO). Lab assessment activities brought up the key points that could strengthen the network through development of policy and new guidelines such as reducing test sensitivity by using autolysis in the extraction step, risk of contamination from lab workspace and workflow designs, knowledge and understanding while interpreting test results, management guidelines for the many samples processed during an outbreak, arrangement of examination round, incorrectly opening the sample box outside the BSL2 enhanced room, and putting on and taking off PPE in limited spaces

Objective

1. To summarized assessments and outline the policy proposal and new laboratory guidelines, from key points of on-site assessment, that will strengthen the SARS-CoV-2 laboratory network using real-time RT PCR in Thailand.

2. To support laboratory development to meet the international standard, ISO 15189 accreditation.

Materials and methods

1. The monitoring and evaluation team for the SARS-CoV-2 laboratory network was appointed by dividing into 2 subgroups; 1) expert team (10 members) and 2) assessor team (67 members). The expert team was composed of representatives from the Department of Medical Sciences, specialists from the Faculty of Medicine Siriraj Hospital and representatives from the National Health Security Office (NHSO). Assessor team were assessors from the Department of Medical Sciences, Reginal Medical Sciences Center nationwide, Bamrasnaradura infectious diseases institute, Rajavithi Hospital, and Faculty of Medicine Ramathibodi Hospital.

2. The coaching-type-assessment checklist for the SARS-CoV-2 laboratory network was prepared by the expert team and contained 44 requirements in Analytical technique and Biological safety. Among these, 24 requirements were "The must" representing the critical points with high impact to the correction of analytical results and/or biological safety such as well-trained and knowledgeable personnel, separate designated rooms for Pre-PCR and Post-PCR, and appropriate cleaning for preventing contamination. The laboratories in the network must follow all "The must" requirements. The rest of the requirements can be added in the plan/ directives for improvement with a specific due date in the case of not being able to perform or only partially perform. The outcome of this checklist was of the semi-coaching type with detailed guidelines that laboratories could directly use in practice.

3. The coaching-type- assessment checklists were sent to the laboratory network nationwide for self-assessment, improving and fulfilling the requirements.

4. The assessor team used the coaching-type- assessment checklist for on-site assessment from May 2020 to September 2020. A total of 38 laboratories were assessed by divided into 3 categories; 1) special assessment from particular request according to the order of the Director-General of the Department of Medical Sciences for 4 laboratories, 2) random assessment for 12 laboratories, and 3) co-assessment with the National Health Security Office (NHSO) for 22 laboratories.

5. The expert team analyzed the assessment results and summarized into a policy proposal and new guidelines for the SARS-CoV-2 laboratory network in Thailand.

Results

The assessment checklist

The coaching-type-assessment checklist for the SARS-CoV-2 laboratory network in Thailand waspproposed by the expert team with a total of 44 requirements covered Analytical technique and Biological safety. 24 of the 44 were "the must" requirements. The Analytical technique part was composed of 8 topics arranged in order for the analytical process; 1) personnel, 2) accommodation and environment conditions, 3) laboratory equipment, reagents, and consumables, 4) pre-examination process, 5) examination process, 6) quality control, 7) post-examination process, and 8) interpretation and reporting of results. The Biological safety part consisted of 3 topics; 1) procedure document, 2) personal protective equipment (PPE) and 3) tools and other equipment. An example of a coaching-type-assessment checklist for SARS-CoV-2 laboratory network in Thailand is shown in Table 1 and the Thai version can be downloaded by QR code.

Table 1 Example of the coaching-type-assessment checklist for a SARS-CoV-2 laboratory network in Thailand.

No.	Requirement	Evidence	Recommendations for the assessment
	Analytical technique requirements		
	1. Personnel		
1 The must	A list of personnel who have been assigned to inspect SARS-CoV-2 as a medical technician /medical scientist who have experience in biomolecular examination and biosafety	>Contact list >Education background >Biomolecular experience (… Years) >Biosafety experience	Random inspection of personnel files/ Focused on new personnel/Observe performance/Interview/ In the case of a scientist, it can be performed under supervision of a medical technician or a medical scientist
	2. Accommodation and environment conditions		
2 The must	Semi-Automated PCR Separated areas to prevent cross-contamination by separating into 2 parts: Pre-PCR and Post-PCR reaction as follows: 1. Pre-PCR must provide a working area divided into 2 parts: • Master mix preparation room • Sample preparation and extraction of genetic material room In the case that there is 1 Pre-PCR room, separate activities and must not be performed at the same time as follows: 1) Prepare the master mix solution in a PCR cabinet with UV lamp. 2) Prepare and extract samples of genetic material in a Biosafety cabinet (BSC) Class II by cleaning the area and equipment before and after each operation with the appropriate reagents and methods. For example, 1% sodium hypochlorite for 30 minutes and then wipe off with clean water, 70% ethanol for 10 minutes followed by at least 30 minutes of UV exposure, RNA-destroying liquid, etc. 2. Provide space/area for Post-PCR set up real-time PCR machines for increasing genetic content and analyzing test results. - Organize the workflow chart in one direction from Pre-PCR to Post-PCR - Separate PPE sets, material equipment.	PCR Laboratory layout, instrument layout and direction of wind source/ workflow path	Investigation >Laboratory layout requires separated Pre-PCR and Post-PCR rooms. >Equipment layout / workflow path / practice at every step must ensure that it does not lead to contamination In the case that there is 1 Pre-PCR room, there must be clear procedures using separate times to perform each activity. Avoid preparing Master Mix reagents and preparing samples and extracting genetic material at the same time.
	Biological safety requirements (Additional)		
	2. Personal Protective Equipment (PPE)		
38	>Use a waterproof, disposable lab coat (front fastening type), or a lab coat to be covered with a plastic apron >Appropriate handling methods for lab coats, such as storage and proper disposal. >Provide an appropriate lab coat changing room.	Attach picture	

Opportunity for improvements from the on-site assessment

On-site assessment of 38 SARS-CoV-2-testing laboratories by the assessor team using the 44-requirement checklist found a total of 156 nonconformities (NCs) which enabled the opportunity for improvement. The top 3 NCs in the Analytical technique requirements were 1) accommodation and environment conditions (27.6%) (Table 2, Figure 1), 2) laboratory equipment, reagents, and consumables (13.5%) and 3) post-examination process (13.5%). In Biological safety requirements, personal protective equipment (PPE) was the most frequently found NC with 8.3% (Table 2, Figure 1).

Table 2 Nonconformity from on-site assessment of 38 laboratories using the coaching-type-assessment checklist for SARS-CoV-2 laboratory network in Thailand.

Order	Requirement	Number of NC*	Percentage of NC*
I. Analytical technique requirements			
1.	personnel	17	10.9%
2.	accommodation and environment condition	43	27.6%
3.	laboratory equipment, reagents, and consumables	21	13.5%
4.	pre-examination process	8	5.1%
5.	examination process	15	9.6%
6.	quality control	5	3.2%
7.	post-examination process	21	13.5%
8.	interpretation and reporting results	3	1.9%
II. Biological safety requirements (additional)			
1.	procedure document	5	3.2%
2.	personal protective equipment (PPE)	13	8.3%
3.	tools and other equipment	5	3.2%

**NC = nonconformity*

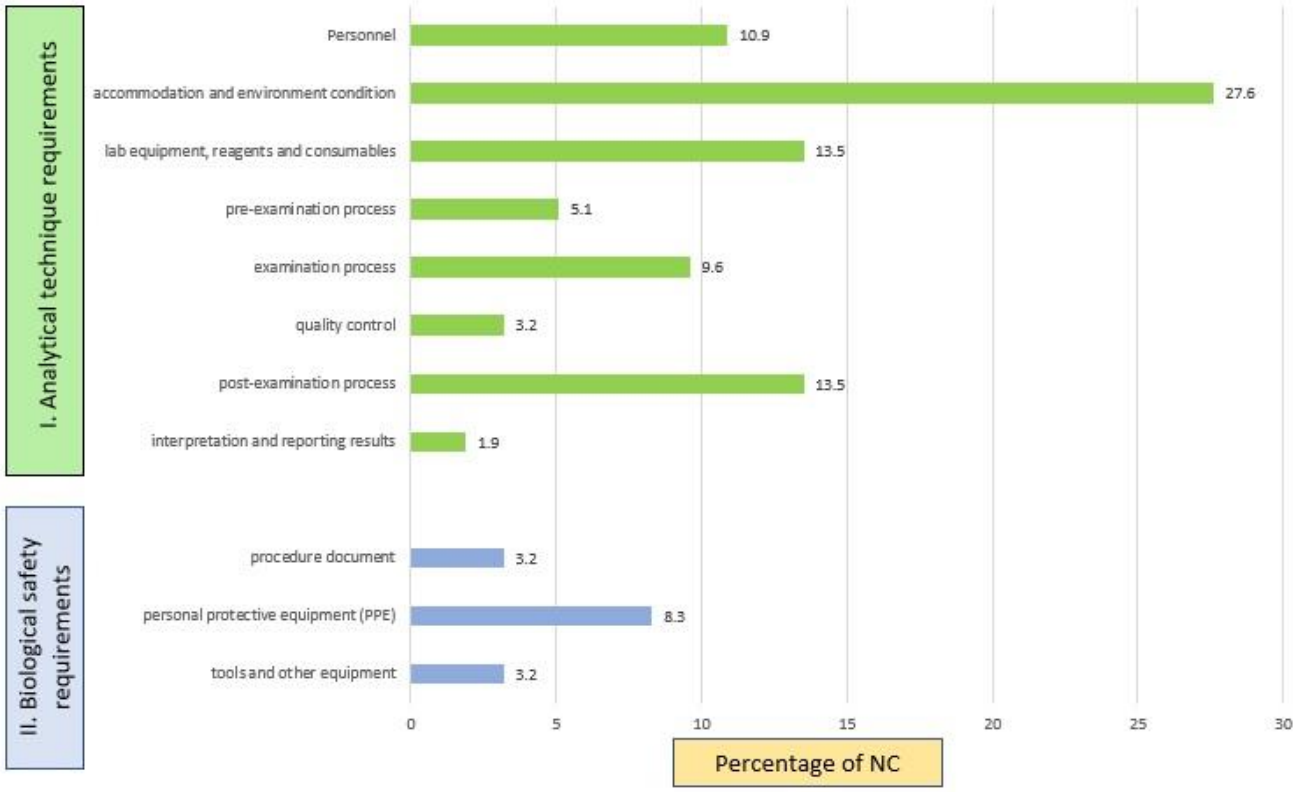

Figure 1. *Percentage of nonconformity from on-site assessment of 38 laboratories using the coaching-type-assessment checklist for SARS-CoV-2 laboratory network in Thailand where it was classified requirements into 2 parts: 1) Analytical technique (green bar) and 2) Biological safety (blue bar).*

Policy proposals and new guidelines

Key points of nonconformity (NC) from on-site assessment of 38 laboratories are listed in Table 3 along with the practical guidelines and suggestions for problem solving and lab improvement. 17 observed key points from both sections, Analytical technique and Biological safety, were analyzed for the causes of problems (Table 3). Three main causes were classified as A) insufficient knowledge (7 key points), B) inappropriate management (4 key points) and C) inappropriate quality of test and control (6 key points). These issues could be guides for developing policy proposals and strengthening the SARS-CoV-2 laboratory network in the future.

Table 3 Key points of nonconformity (NC) from on-site assessment, assessed causes and suggestions for lab improvement.

Observed key point and (cause of problem)	Guideline/Suggestion
Section I: Analytical technique	
Personnel	
1. Practitioners lack knowledge and understanding of the main issues such as result interpretation, and prevention from contamination causing false positive. (A: insufficient knowledge)	1. Provide online training course for the staff of SARS-CoV-2 testing laboratories including the important topics both analytical technique and laboratory safety such as analysis of SARS-CoV-2 by Real Time RT-PCR, sample preparation, extraction of genetic material, reagent preparation, examination process, interpretation and reporting following the guideline of Ministry of Public Health, performing of internal quality control (IQC)/proficiency testing (PT) and solving the problem in the case that the result is out of the acceptable criteria, management and prevention of contamination for PCR, managing/ wearing and removal of PPE, etc. 2. Provide the channel for questions and answers between the laboratory and the expert team by online coaching.
2. During the epidemic period, a large number of samples causing the workload overload of staff. (B: Inappropriate management)	Fatigue from continuous working 24 hours a day during heavy outbreaks may cause an error in the result. The Department of Medical Sciences therefore issues recommendations to organize no more than 3 examination rounds per day in order to allow personnel to have time to rest. It also has time to clean the laboratory and all systems to prevent contamination.
Accommodation and environment conditions	
3. Designing of laboratory area was not suitable; Pre-PCR and Post-PCR were in the same area causing contamination risks such as preparing Master mix reagents and adding a template which was Pre-PCR part in the room where the PCR machine was located as part of Post-PCR includes non-directional workflow from Pre-PCR to Post-PCR. (A: insufficient knowledge)	The PCR room layout depends on the type of equipment used and is divided into 2 types as follows[2]. I. Semi-Automated PCR The laboratory shall use the separated room to prevent Cross-contamination, divide the area into two parts including the Pre-PCR and Post-PCR as following; 1. Pre-PCR, the laboratory shall provide the area divided into two parts; • room for preparing of Master mix reagent • room for sample preparation and extraction But in case of the laboratory have 1 room for Pre-PCR, the laboratory shall separate the following activities and shall not process at the same time. 1.1) Master mix reagent preparation in PCR cabinet which has UV 1.2) sample preparation and extraction in BSC Class II. Clean the room and equipment every time before and after work using suitable disinfectants such as 1% sodium hypochlorite for 30 min, then clean with water or 70% ethanol for 10 min, after that using the UV light at least 30 min or using RNA destructive solution, etc. 2. Post-PCR is the area for the installation of a Real-time PCR analyzer, amplification, and analysis of results.

Table 3 Key points of nonconformity (NC) from on-site assessment, assessed causes and suggestions for lab improvement. (continued)

Observed key point and (cause of problem)	Guideline/ Suggestion
	Separate PPE and equipment for each room. Provide directional workflow from Pre-PCR to Post-PCR. II. Fully Automated PCR The laboratory can prepare the sample in BSC Class II and use Fully Automated PCR to prepare reagent, extraction of RNA, RNA amplification, and analysis in the same analyzer, no need to separate the room. But in case of the analyzer doesn't have the system to prevent the amplicon, the laboratory shall separate the sample preparation room and the PCR room.
4. The doors and walls of the room were blacked out. Can't see the operator inside. (A: insufficient knowledge)	The laboratory shall have the part visible to the operator from the outside. The door can be closed to prevent unauthorized persons and designate the authorized persons who have the right to enter and exit[3,4].
5. The cleaning staff had no knowledge of PCR laboratory cleaning. (A: insufficient knowledge)	Since PCR testing has a chance of contamination from the sample or PCR product that may be left in the room, so cleaning the floor must be careful to not cause diffusion, such as using a dust mop instead of a broom, separate cleaning equipment for each area and cleaning staff must be trained to clean the molecular biology laboratory including prevention of infection.
6. There were no records of those who accessed the laboratory. (B: Inappropriate management)	A laboratory is a place where is a risk of exposure to infection. Therefore, the name, contact address, and the time of being in the laboratory of those who contacted must be recorded. Whether it is an assessor, equipment maintenance technicians, etc. So that the laboratory can follow up in the case of suspected infection in the laboratory.
7. The BSC cabinet was installed in an inappropriate location, causing the air in front of the cabinet to be disturbed by an air conditioner. (A: insufficient knowledge)	To reduce diffusion of samples or PCR products in a BSC cabinet, BSC cabinet placement should be positioned and directed away from doors, windows, corridors, fans, air conditioners, fume hoods and other types of air sources to ensure that the outside wind does not disturb the BSC cabinet air curtain.
Laboratory equipment, reagents, and consumables	
8. Use a wide variety of brands of reagent and extraction kit without verification before use. (C: Inappropriate quality of test and control)	Select reagents and test kits which are registered with the Food and Drug Administration (FDA) and the reagent shall be verified before use with the parameters of analytical sensitivity and specificity. But if there is no such verification result, IQC results and PT results may be used instead, and PT results must be verified as current reagents.
Pre-examination process	
9. Open the sample container outside the BSL-2 Enhanced laboratory. (A: insufficient knowledge & B: Inappropriate management)	Opening of the sample container must be done in a BSC Class II cabinet with the corrected technique in a provided room. Staff must wear the correct and suitable PPE. Use a waterproof, disposable lab coat or use a lab coat cover with a plastic apron, a hair cap, N-95 face-shield, double gloved, closed toe shoes (Practices like BSL3 practice). In case of a large number of samples, other room spaces may be used. There must be a hanging sign to warn those who are not involved in the work area. Also, the sample container must be opened in a BSC Class II cabinet, as well as to wear the correct PPE as required.

Table 3 Key points of nonconformity (NC) from on-site assessment, assessed causes and suggestions for lab improvement. (continued)

Observed key point and (cause of problem)	Guideline/ Suggestion
Examination process	
10. Autolysis was used instead of extraction of genetic material. Making it unsure whether to extract RNA or not. (C: Inappropriate quality of test and control)	Since the evaluation of the test kits and reagents related for the diagnosis of SARS-CoV-2 infection by Real-time RT-PCR method for registration with the Food and Drug Administration (FDA) is covered only the test using extracted RNA sample, Extraction reagent and autolysis step is not included in that evaluation. Therefore, if the manufacturer/ importer refered to Autolysis they must notify the FDA and Department of Medical Sciences to evaluate whether if it covers such procedures. Therefore, if there is no evaluation result, the laboratory shall extract the RNA from the specimen for PCR reaction.
11. There were modifications of the method, which may affect the sensitivity of the test. (C: Inappropriate quality of test and control)	- In some cases, the laboratory may be advised by the staff of the company that is selling reagents to modify test methods to reduce the process and time, but it does not comply with the manufacturer's instruction. Without supported validation, it may decrease sensitivity of the assay, and this may cause a false negative. So the laboratory must strictly follow the protocol specified in the package instructions. - Communication and insisting on an understanding of the staff of the reagent companies are needed in order to provide correct laboratory advice
12. Examination by pooled samples without validation results. (C: Inappropriate quality of test and control)	The pooled sample will cause the sample to be diluted and the genetic material will be reduced. There is a high probability of false-negative effects. Therefore, testing by using a pooled sample must always have the results of the method validation.
Quality control	
13. Using a reagent that had not passed Proficiency Testing with the Department of Medical Sciences (C: Inappropriate quality of test and control)	PT is an important tool in evaluating the laboratory competency. The lab must clearly identify each batch of reagents. If there is a change in the reagent, the laboratory shall inform the Department of Medical Sciences to evaluate the proficiency test (PT) with a new set of reagents before using it.
14. The laboratory used external QC to control the quality of the PCR process. Therefore, the sample quality should also be examined. (C: Inappropriate quality of test and control)	In quality control for Semi-Automated PCR there must be a performed positive control and non-template control for each test. And, where possible, internal control (housekeeping genes) should be performed to examine sample quality. Because the virus multiplies in the cell, the cells also carry housekeeping genes, so when the housekeeping gene is detected, it can indicate that the sample is of quality because the infected cells can be collected[5].
Post-examination process	
15. The laboratory translated results only from the machine, did not neither read the graph nor look at the Ct range for the interpretation of positive control. (A: insufficient knowledge)	Interpretation of results according to "Guidelines for the management of the laboratory testing and reporting system for COVID-19 with a single laboratory system (DMSc_P05)"[6] of the Department of Medical Sciences. Up-to-date version, which set the guidelines as follows

Table 3 Key points of nonconformity (NC) from on-site assessment, assessed causes and suggestions for lab improvement. (continued)

Observed key point and (cause of problem)	Guideline/ Suggestion
	1) Confirm the results of the gene test at least 2 positions 2) Ct value not more than 36, if it exceeds, the lab shall repeat test by starting the process of extraction of new genetic material, if the result is positive, then the report can be released. 3) Interpretation of the result should also consider the curve, which should look like a S-shaped curve or sigmoid curve, as shown in the Figure 2. However, the user should study the instructions given in the test package and follow it strictly.
16. Incomplete reporting information, unspecified reagent name, target gene with Ct value, and summary method, etc. (B: Inappropriate management)	The report shall identify the name of the reagent, target gene with Ct value and the method of summarize of result as set in "Guidelines for the Management of the Laboratory Testing and Reporting System for Covid-19" With a single laboratory system (DMSc_P05)"[6] of the Department of Medical Sciences.
Section II: Biological safety	
17. No appropriate designated area for put on and removal of PPE due to area constraint (B: Inappropriate management)	Lab should provide area for dress up PPE before entry in the working area. In case of space limitation and no outside lab area available, should set up clean corner in the lab for putting on PPE and provide area for taking off PPE and discarding into the infectious waste bin before exiting the lab. However, should provide separate room for PPE removal with hand washing sink in the specimen preparation area followed BSL-2 enhance.

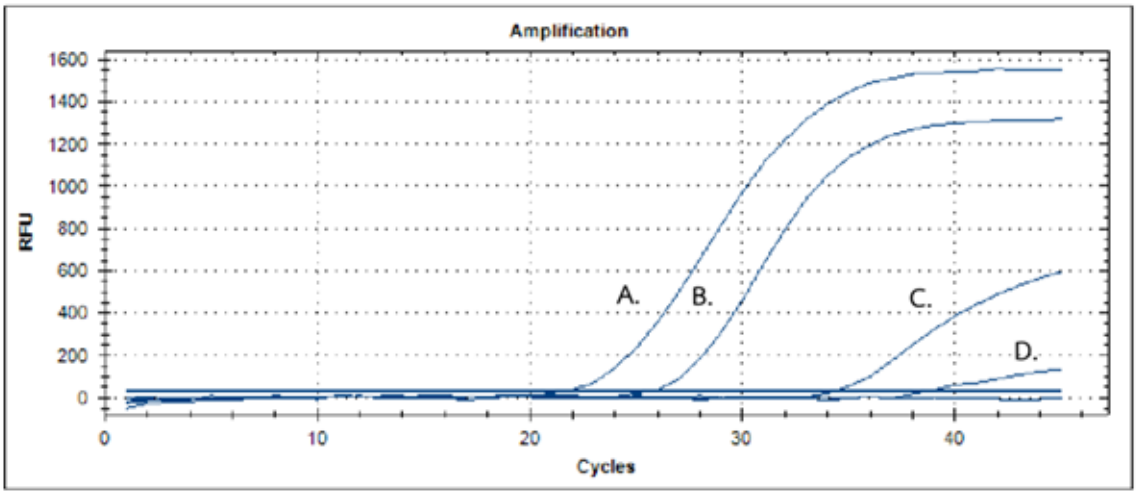

Figure 2. *Curves of SARS-CoV-2 Ct by Real-time RT-PCR method. A: S-curve, Ct 21.41, B: S-curve, Ct 25.50, C: S-curve, Ct 34.23, D: no S-curve format, Ct 38.56.*

Discussion and Conclusion

This coaching-type-assessment checklist for SARS-CoV-2 laboratory network used in Thailand was developed based on the main idea to use this tool for assessment and for practical coaching at the same time. Therefore, each requirement in the checklist also contained the detail of practice guidelines that could be directly applied for use in the laboratories. This advantage could help in rapid lab setup in response to an emergency situation. This checklist, specifically designed to assess capacities of laboratories implementing SARS-CoV-2 testing, was more specific than the WHO questionnaire which focused on overall management at the nation level and competency of lab analysis.[7,8]

The results from on-site assessment in 2020 of 38 laboratories from the total of 237 laboratories with SARS-CoV-2 testing in Thailand showed the main opportunity of improvement (OFIs) for 156 NCs. The most OFI in the Analytical technique part was accommodation and environment conditions 43 NCs (27.6%). The main cause was not the insufficient workspace but from insufficient knowledge and understanding of practitioners such as no separation of Pre- and Post-PCR working areas. The Pre-PCR processes such as master mix preparation and template adding were performed in the room with the PCR machine which counted as Post-PCR area. Also, inappropriate workflow by overlapping between Pre-PCR and Post-PCR activities may lead to cross contamination. In the Biological safety part, the most OFI found was requirements of personal protective equipment (PPE) 13 NCs (8.3%). Most OFIs were related to inappropriate designated area for putting on and taking off PPE. The suggestions for this issue were; 1) should provide area for dress up in PPE before entry to the lab, 2) in case of limitation of space with no outside lab area, should set up clean corner in the lab for putting on PPE and provide area for taking off PPE and then drop into infectious waste before exiting the lab.

Most key points from on-site assessment referred to the main causes of incidents focusing on insufficient knowledge, inappropriate management and inappropriate quality of test and control. Solutions are policy proposals and additional guideline development to improve the quality of the SARS-CoV-2 laboratory network such as a SARS-CoV-2 laboratory guidance document in a Question & Answer format, and online training for nation-wide SARS-CoV-2 laboratories and related stakeholders such as assessors, sale representative, etc. to strengthen the quality of SARS-CoV-2 laboratory network. Many tools were recommended and could be used together. The African Society for Laboratory Medicine recommended use of 3 tools including Quality Control (QC), External Quality Assessment (EQA) and Quality Improvement (QI).[9] WHO proposed the Laboratory Assessment Tool.[8] The nation-wide laboratory network in Taiwan was rapidly established and kept monitoring to achieve reports within 24-hours for infection control efficiency but quality assurance was not clearly mentioned.[10] For Thailand, the committee proposed a policy by using tools that covered all dimensions which were 1) self-assessment checklist, 2) proficiency testing program, 3) on-site assessment for re-accreditation and special assessment on particular request due to the quality of report and 4) training/ coaching program for the entire laboratory network. All integrated tools could be implemented to strengthen the SARS-CoV-2 laboratory network in Thailand and ensure the quality of analytical results to use for diagnosis, surveillance, control and prevention of diseases with efficiency and rapid response. In addition, this molecular detection system may be applied for use for other emerging diseases in the future and should further encourage well-prepared laboratories to apply for international standard ISO 15189.

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