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Piloting an external quality assurance program (QAP) for COVID-19 antigen rapid diagnostic tests (Ag-RDTs): findings and lessons learned from Cambodia

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ABSTRACT

Rapid antigen diagnostic tests (Ag-RDTs) that quickly and accurately identify SARS-CoV-2 are an essential part of the COVID-19 response, but multiple factors can affect the validity of Ag-RDTs results. In Cambodia, several commercial Ag-RDTs have become available since the COVID-19 outbreak, but quality control (QC) and external quality assurance (EQA) of these rapid tests have yet to be fully and systematically implemented. We collaborated with laboratory experts in Australia and piloted an EQA programme of the commonly used COVID-19 Ag-RDTs at the University of Health Sciences' MERIEUX Laboratory (Tier 1 site—responsible for the in-country receipt and distribution of QA material) and four other participating laboratories (Tier 2—healthcare facility based) between November 2021 and November 2022. The preimplementation training including the Khmer-translated documentation was conducted virtually for Tier 1 laboratories and in-person for Tier 2 laboratories. All QC (n=290) and EQA (n=60) specimens were distributed to the laboratories and testing was performed according to the frequency of Ag-RDTs use in each laboratory. All National Reference Laboratory-provided EQA and QC specimens were tested and results were submitted via the EDCNet portal using QR code scanning. The Tier 1 laboratory reported 100% concordance with the EQA reference result, while some of Tier 2 laboratories' results were discordant. While continued capacity building and support with troubleshooting have been key to the successful EQA piloting at the UHS laboratory, the programme experienced delays in the shipping/delivery of EQA and QC panels due to customs and border requirements, which could have hindered implementation and potentially impacted the quality of the QA materials. The pilot EQA programme demonstrated potential scalability and provided data on the reliability of test results at the site. However, to ensure sustainability and practicability of this activity, in-country EQA panel preparation may need to be considered.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Rapid antigen diagnostic tests (Ag-RDTs) that could quickly and accurately identify the SARS-CoV-2 is essential part of the COVID-19 response during the pandemic, but quality control and external quality assurance (EQA) of these rapid tests are yet to be fully and systematically implemented in Cambodia on several commercial Ag-RDTs available in the country.

WHAT THIS STUDY ADDS

⇒ In 2021, a pilot QA programme sponsored by Foundation for Innovative New Diagnostics (FIND) as part of the Accelerator-ACT programme to support the effective testing capacity and efficient uptake of Ag-RDTs had been conducted in Cambodia.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our work showed the importance of QA programme on rapid tests and having an EQA provider with reliable capacity in the country. In order to strengthen and expand this QA programme, key national and international or regional partners relevant to EQA processes should be established, the key quality assurance principles should be regularly reinforced across laboratories providing Ag-RDT services and validation of EQA results using online platform should be considered.

INTRODUCTION

Rapid and accurate detection of SARS-CoV-2 is crucial for the effective isolation of symptomatic cases and the systematic tracing of close contacts, both of which are essential for reducing the community spread of severe COVID-19. Nowadays, reverse-transcriptase PCR is the diagnostic gold standard for COVID-19.[1–3] However, during a pandemic, testing a large number of patients via RT-PCR

assays within a limited time frame is a challenging task. This requires technical expertise, specialised instruments and a significant amount of funding. Rapid antigen diagnostic tests (Ag-RDTs) are particularly suited for point-of-care testing, as they can be easily performed and interpreted without sophisticated equipment, are less expensive and provide efficient turnaround times (within a maximum of 30 min). With results available in a few minutes, rapid tests can meet the need for early diagnosis of SARS-CoV-2 infections. The number of commercially available antigen tests has increased dramatically.[4–9] In Europe, 950 CE-marked antigen tests (560 rapid tests) are currently on the market.[5] With continual increases in available tests, the data from external quality assurance (EQA) programmes, including the end-to-end challenges of implementation and evaluation of these rapid tests, are very important for informing the feasibility and acceptability of these programmes, particularly in regions with limited access to sophisticated molecular technologies, such as RT-PCR.[10 11]

At the end of 2021, the Foundation for Innovative New Diagnostics (FIND) supported several countries in the Indo-Pacific region through the Accelerating the Uptake of COVID-19 Ag-RDTs in the Indo-Pacific Programme to support and inform the effective and efficient uptake of diagnostic technologies for SARS-CoV-2 with a central focus on antigen rapid diagnostic tests. The programme objectives included reviewing and establishing optimal and locally appropriate Ag-RDT testing strategies and ensuring effective procurement of COVID-19 Ag-RDTs. The wider programme objectives also included training healthcare workers to enhance quality and testing capacity, as well as undertaking health system evaluation and implementation research. In Cambodia, one of the proposed outcomes from the programme was the establishment of quality assurance for COVID-19 Ag-RDT testing.

One activity within this broader programme was to implement a quality assurance programme (QAP) for COVID-19 Ag-RDTs. In Cambodia, the Rodolphe MERIEUX Laboratory at the University of Health Sciences was selected as the Tier 1 participating laboratory for this QAP activity. Our paper describes the first implementation of the QAP for SARS-CoV-2 Ag-RDT in Cambodia, involving the Tier 1 and four Tier 2 laboratories, as well as the challenges and lessons learnt from the pilot programme.

Design and contexts of the program

This pilot QAP was initiated by the Kirby Institute, Burnet Institute, Doherty Institute and Clinton Health Access Initiative, in collaboration with health authorities, stakeholders and partners including the National Serology Reference Laboratory in Australia, the University of Health Sciences in Cambodia, the Papua New Guinea Institute of Medical Research and the National Center for Laboratory and Epidemiology in Lao PDR. This programme was conducted from 30 November 2021 to 30 November 2022 to support the effective and efficient uptake of diagnostic technologies for SARS-CoV-2. This project aimed to deliver a pilot QAP for COVID-19 Ag-RDTs and to strengthen COVID-19 responses in a small number of laboratories in PNG, Cambodia and Lao PDR, ensuring that quality assurance was embedded throughout the testing cycle, from planning and implementation through to evaluation.

Goals of the QAP for COVID-19 Ag-RDTs in Cambodia

Quality assurance for COVID-19 antigen rapid testing significantly contributes to reducing the risk of incorrect results, which can have clinical and public health impacts, by ensuring that laboratory test results are accurate, timely and reliable.[1] The goals for modern external quality assessment programmes are to evaluate test operator training and procedures, assess method performance, conduct postmarket surveillance and identify areas for further training, assistance and improvement.

The main objectives of this programme were to support the effective use of SARS-CoV-2 diagnostic techniques, focusing on rapid antigen detection, to enhance testing capacity for an effective and timely COVID-19 response in Cambodia and to guide COVID-19 testing laboratories on quality assurance. This QAP for SARS-CoV-2 Ag-RDTs comprised two components: quality control (QC), which verified the competence of operators undertaking antigen testing and supported operator training, and EQA, which objectively evaluated the performance of diagnostic testing. We achieved this by verifying the competence of operators conducting antigen testing, assisting with the verification of antigen test kits, and troubleshooting unexpected EQA results, all in accordance with best practices.[12] During the implementation of the programme, we also assisted stakeholders involved in COVID-19 testing in establishing, implementing, monitoring and evaluating QAPs for SARS-CoV-2 Ag-RDTs, with the long-term goal of facilitating the implementation of regulatory requirements for point-of-care assays for the rollout of SARS-CoV-2 Ag-RDTs.[13–15]

METHODS

Selection of participating laboratories

The University of Health Sciences, located in Phnom Penh, is a public administrative institution under the Ministry of Health Cambodia, established in 1946. It is an academic institution that provides training for all health science professions including medical doctors, pharmacists, dentists, nurses and laboratory technicians. The Rodolphe MERIEUX Laboratory of University of Health Sciences was selected as the Tier 1 laboratory due to its pre-existing programmes and was responsible for the in-country receipt and distribution of QAP materials.

The pilot QAP supported four other participating laboratories as Tier 2 sites. Four out of approximately 30 laboratories in Cambodia were arbitrarily selected, based on the availability of COVID-19 Ag-RDT services, the average

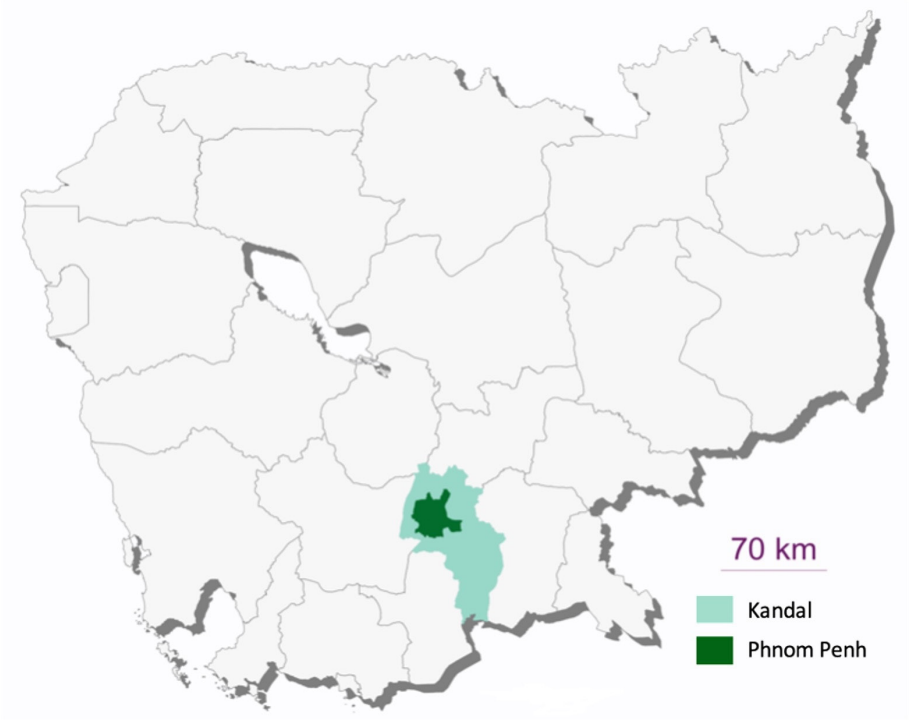

Figure 1 Map of Cambodia, location of the capital Phnom Penh and Kandal province.

number of tests performed per day, and their voluntary participation. We selected two public referral hospitals in Kandal Province and two private clinics in Phnom Penh to serve as Tier 2 participating laboratories (figure 1). The characteristics of each participating laboratory are shown in table 1.

Preparation of relevant forms and standard operating procedures preimplementation

To ensure that our QAP implementation ran smoothly and efficiently, several standard operating procedures and forms related to biosafety, the preanalytical phase, the analytical phase and the postanalytical phase, were developed based on CDC (USA) guidelines for the use of rapid antigen tests for COVID-19. These standard operating procedures were then modified to suit the Cambodian context. All documents were validated by the programme consortium partners and then translated into Cambodian languages to ensure comprehensive understanding and accurate performance of the rapid testing and completion of forms by all participating staff.[14 16 17]

Preimplementation training

The preimplementation training was conducted virtually for the Tier 1 laboratory team by the QAP consortium partners from Australia who were trained to cascade the training to the Tier 2 laboratories. The four Tier 2 laboratories underwent two rounds of training prior to the implementation of the QAP: first, they attended in-person training at the University of Health Sciences,

Table 1 Characteristics of Tier 1 and Tier 2 participating laboratories

	Participating laboratories				
Lab characteristics	**Tier 1**	**Tier 2 #1**	**Tier 2 #2**	**Tier 2 #3**	**Tier 2 #4**
Type of institution	University	Private clinic	Private clinic	Referral hospital	Referral hospital
Average number of tests performed per day in 2022	20–50	10–20	15–20	10–30	20–30
COVID-19 diagnostic tools	PCR/ Ag-RDTs	Ag-RDTs	Ag-RDTs	Ag-RDTs	Ag-RDTs
Distance from Phnom Penh	Located in Phnom Penh	Located in Phnom Penh	Located in Phnom Penh	20 km	38 km
Number of healthcare workers	N/A	80	120	69	51
Number of lab technicians	N/A	06	04	06	01
Number of pharmacists	07	08	06	03	05

Ag-RDTs, rapid antigen diagnostic tests.

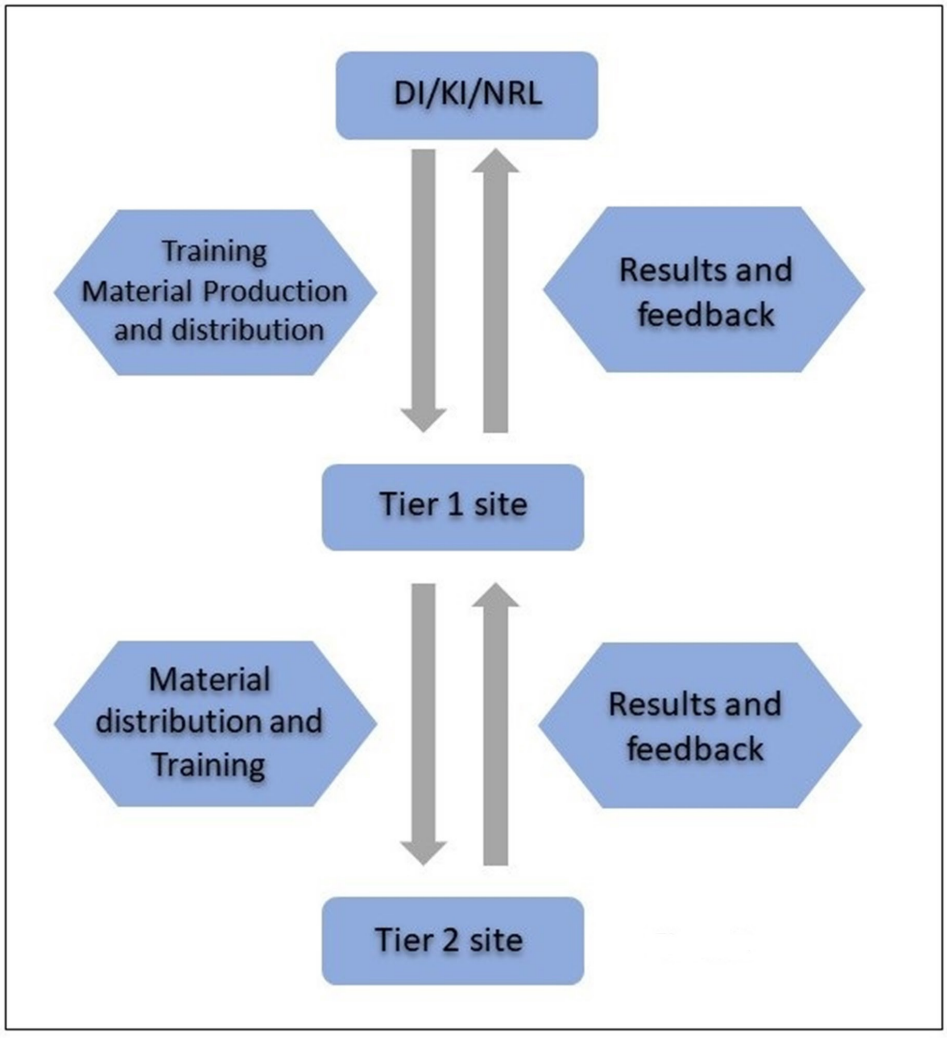

Figure 2 Workflow of preimplementation and panel distribution processes. DI, Doherty Institute; KI, Kirby Institute; NRL, National Reference Laboratory.

followed by a virtual refresher training session before the implementation (figure 2). This training aimed to enhance the testing capabilities across all sites, focusing on the accurate workflow of quality assurance for the SARS CoV-2 Ag-RDTs. This included procedure related to biosafety, personnel training, testing, form completion and result entry into worksheets and the online portal, as well as troubleshooting at each phase.

Preparation of QAP samples and their characteristics

In our programme, QAP materials were prepared and provided by National Reference Laboratory (NRL). The QAP panels consisted of vials containing 50 µL of relevant samples: calibrated concentrations of non-infectious, gamma-irradiated SARS-CoV-2 variants were used as positive samples, while standard Minimum Essential Medium was used as negative samples. The QC panels included a labelled positive and negative sample, allowing operators to immediately compare their results with the expected outcome. The EQA panels contained five samples, the composition of which was unknown to the operators. These EQA panels included a mix of positive samples (different SARS-CoV-2 variants at varying concentrations) and at least one negative sample. Each site received two EQA panels and 29 QC panels, with the Tier 1 site receiving an additional four EQA panels for redundancy. Since the EQA involved running blinded patient-like samples, the results were compared by the EQA provider to retrospectively monitor the accuracy of testing and reporting.[18] The EQA samples were treated as routine patient samples and were processed by personnel who would normally use the Ag-RDT devices at each site.[8 19]

Local distribution and storage of received panels

NRL facilitated development and distribution of the QAP panels to the University of Health Sciences (Tier 1 site), where the panels were stored at −80°C prior to their distribution to the Tier 2 sites. The QAP panels were transported to the Tier 2 laboratories within a temperature range of 2°C–8°C, and were accompanied by all necessary instructions and documentation. On arrival at the Tier 2 sites, the condition of the QAP materials and the temperature of the cold box were checked and recorded using

the provided forms which were completed by the responsible personnel.

Testing frequency

The Tier 1 and Tier 2 laboratories had different testing throughputs; therefore, they tested their QC panels according to the specific requirements of their respective workplaces for example, a QC panel was tested every 2 weeks or whenever a new operator was trained. However, the EQA panels were tested only once during this QAP pilot implementation.

Participants were instructed to handle and test the QC and EQA materials according to the testing protocol, ensuring results were validated by two independent readers. Testing was performed either through 'swab-based testing' (placing a swab into the sample) or 'liquid sample-based testing' (pipetting a specified volume of the sample into an assay buffer) following the manufacturer instructions.[18 20 21] On completion of the QAP testing, participants reported their results ('positive', 'negative' or 'not determined') using a result form and submitted the results into the EDCNet portal via a mobile device by scanning the QR code provided with the panel.

Submission of test results

One of the advantages of this study was the reliability of QAP materials, as the sample materials were provided by the accredited supplier NRL (ISO 17043 and ISO 15189 accredited). Over the duration of the QAP programme, a total of 350 samples were tested by the participating laboratories. Of these, 290 samples were from the QC panels and 60 samples were from the blinded EQA panels. Table 2 shows the distribution of QC and EQA panel testing by each participating laboratory. Each laboratory received 29 QC panels, which were tested at their own determined frequency. The Tier 1 laboratory voluntarily tested four EQA panels, which was double the number tested by each Tier 2 laboratory.

The participants were required to submit the results of the EQA panels within 1 week of receiving the panels, which is a standard turnaround time for most QAPs. For this QAP, qualitative results were recorded and submitted via the EDCNet portal by scanning a QR code with an internet-connected smartphone. The tester entered all the required information related to the testing materials such as the brand of test kit, lot number and expiry date of the test kit, as well as the sample ID, results and any relevant comments. Additionally, a hardcopy of the result report form for recording EQA testing results was available for submission with the option to email the results directly to the EQA provider. The overall performance was determined by comparing the participating laboratory's results with the EQA provider's reference results to evaluate concordance or identify any discrepancies.

RESULTS

Among the 60 blinded EQA samples tested across the participating laboratories, 52 (86.7%) results were confirmed to be concordant with the reference results, while 8 (13.3%) results were identified as aberrant and required further consideration. Three of the participating laboratories (Tier 1, Tier 2#1 and Tier 2 #2) achieved 100% concordance with the reference samples. However, two laboratories (Tier 2 #3 and Tier 2 #4) demonstrated 70% and 50% concordance and 30% and 50% aberrance respectively (table 3).

Regular participation in EQA helps verify that samples are handled properly, results are interpreted correctly and procedures are followed. Our pilot EQA programme provided valuable information for participants by identifying technical errors in their testing processes and methods, and supported ongoing assay evaluations for regulatory approval or postmarket surveillance in Cambodia and the region.

DISCUSSION

Approach for handling unexpected results

In EQA programmes, unexpected results provide information for investigation. These results may indicate concerns with operator competency, testing methods, device functionality or EQA materials. Additionally, unexpected results could arise due to random chance, given that the sensitivity and specificity of Ag-RDTs are not 100%. During the investigation process, key questions included: (1) 'why is something wrong?' (2) 'how can we solve the problem?' and (3) 'how can we prevent the same error?'

In the tiered support model of this programme, the Tier 1 site conducted site visits to the Tier 2 laboratories where aberrant results were observed. These on-site evaluations were useful for obtaining a realistic picture of laboratory practices, providing information for internal process improvement, measuring gaps or deficiencies and understanding 'where we are'. On-site evaluations can be combined with retesting and rechecking schemes to gather more information about

Table 2 Distribution number of QC and EQA panels to each participating laboratory

Panel	Tier 1	Tier 2 #1	Tier 2 #2	Tier 2 #3	Tier 2 #4	Total panels	Total samples
QC	29	29	29	29	29	145	290
EQA	4	2	2	2	2	12	60
Total	33	31	31	31	31	157	350

EQA, external quality assurance; QC, quality control.

Table 3 Summary of the EQA results for each participating laboratory

	Tier 1	Tier 2 #1	Tier 2 #2	Tier 2 #3	Tier 2 #4	Total samples
EQA panels	4	2	2	2	2	12
EQA samples	20	10	10	10	10	60
Concordance Number	20	10	10	7	5	52
Concordance, %	100	100	100	70	50	86.7
Aberrance Nb	0	0	0	3	5	8
Aberrance, %	0	0	0	30	50	13.3

EQA, external quality assurance.

performance to direct support, create an environment of process improvement and ensure the quality of testing for clinical care.[22]

Our cascading support model which allowed local in-country support from teams with in-depth knowledge of the local context was crucial for the success of this pilot programme. It was essential to have a Tier 1 laboratory capable of performing repeat testing and assuring Tier 2 laboratories that the re-examination processes would give dependable results. The Tier 1 laboratory also assisted the Tier 2 laboratories in collecting information for the planning and implementation of training, monitoring and corrective actions.[23] In our programme, troubleshooting unexpected results from Tier 2 sites followed these steps: on-site visits, root cause analysis, refresher training based on the identified root causes and retesting of blinded EQA panels with results reported. Both Tier 2 laboratories that initially reported aberrant results were informed about the objectives of the on-site visit conducted by the Tier 1 laboratory. Potential root causes were identified using a validated checklist prepared by the Tier 1 laboratory. One common problem reported by both Tier 2 laboratories was the delayed panel distribution following the preimplementation training, which could have led to the omission of critical testing steps. Challenges also arose from staff following their habitual testing protocols, and the potential impact of the uncontrollable temperature during transport. The Tier 1 laboratory prepared panels using remnant COVID-19 clinical samples tested at the University of Health Sciences for interlaboratory comparison, with these samples to be retested at the Tier 2 sites following refresher training. Similar to the EQA programme, the Tier 2 laboratories were blinded to the composition of these panels which included two positive samples (of low, medium and high concentrations) and three negative samples per panel.[24] After refresher training on the protocol and band intensity interpretation, both Tier 2 sites tested the panels prepared by the Tier 1 laboratory, and both Tier 2 sites achieved 100% concordant results when checked by the Tier 1 laboratory. This demonstrated the success of the training process provided by the Tier 1 site and supported the transferability of applying these quality assurance principles to other laboratories.

Challenges and lessons learned

In general, external quality assessment has its limitations and is not the only means of evaluating laboratory quality. EQA may not detect all laboratory issues, and a single aberrant result does not necessarily indicate a problem in the laboratory.

Our results from this QAP were influenced by several variables, including language barriers, delays between preimplementation training, panel distribution, and the actual implementation, challenges in internet and digital literacy for online submissions, and other onsite difficulties.

To overcome language barriers, the Tier 1 laboratory played an important role as a coordinator, transferring knowledge and information to Tier 2 laboratories. The Tier 1 laboratory provided preimplementation training, translated necessary documents and facilitated the entire process from preimplementation to postimplementation. This tiered model enabled the Tier 1 laboratory to serve as a training and material distribution site for peripheral laboratories, using a 'train the trainer' approach that created an environment where the importance of laboratory quality was emphasised and communicated widely.

The challenges encountered with panel shipping in this pilot QAP led us to propose establishing a regional or local EQA provider to minimise issues during transportation. The long shipping duration from Australia to Cambodia could cause panel materials to deteriorate and there was a long gap between the preimplementation training and the actual panel testing by the laboratories. In this case, the Tier 1 site provided refresher training to Tier 2 sites after receiving the panels.

Another challenge involved on-site difficulties, including inadequate electricity backup in Tier 2 laboratories, the lack of essential equipment such as centrifuges to spin down small-volume tubes, and the internet connectivity issues for online result submission via QR code. To mitigate errors arising from these problems, the Tier 1 site recommended that Tier 2 laboratories arrange for staff to test the panels immediately on receipt of the panel to avoid prolonged storage. To address the lack of centrifuge, the Tier 1 laboratory suggested transferring all liquid from the tube bottom, tube wall and tube cap into the Ag-RDT

buffer. For issues with online result submissions, Tier 2 laboratories were adviced to manually report results on the provided form and send that form to the Tier 1 site that compiled all data and sent it to the EQA supplier via email.

Conclusions and implications for practice

Based on our observations, there is a high demand in Cambodia for a local EQA provider with the reliable capacity to adhere to ISO/IEC 17043 (requirement for the development, operation and competence of proficiency testing scheme providers). Establishing such a provider would help to reduce the problems caused by overseas shipping, such as cold chain interruptions, potential damage during transportation delays, and of course the costs associated with shipping and importation.

In conclusion, our QAP has successfully trained Tier 1 laboratories on quality assurance processes which were then cascaded to four Tier 2 laboratories. Three main achievements have been obtained from the establishment of this QAP for COVID-19 Ag-RDTs which can be transferable to other infectious disease testing programmes. First, key quality assurance principles were reinforced across five laboratories. Second, a smartphone-based result entry portal using a QR code was validated. Third, national and international networks among key regional partners were strengthened to foster quality assurance processes in the future.

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Contributors CLP conducted the literature search, designed the pilot program in Cambodia, prepared the documents and testing materials, coordinated the testing and result submissions, wrote the manuscript and created the figures. JP, MN and PC conducted the literature search, designed the study and guided the training. SB, KS and KH conducted the literature search. DW, JM, AV, JK and VS conceptualised the study, conducted the literature search and guided the program. All authors provided critical feedback and shaped the final manuscript. All authors have read and agreed to the published version of the manuscript. CLP is the guarantor. DW, JM, AV, JK and VS are joint last authors.

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