A Success Story of EQA Development During the Pandemic

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Background & objectives

Labquality is a Finnish independent EQA provider producing clinically relevant external quality assessment (EQA) for clinical laboratories and point-of-care sites. The first requests for EQA for SARS-CoV-2 detection were presented to Labquality in March 2020. The global acute need for reliable quality control material increased dramatically within a few weeks which made material sourcing challenging. Labquality was rapidly able to respond to the need for EQA both for SARS-CoV-2 nucleic acid detection and antibody (Ab) detection and the pilot scheme samples were distributed already in May 2020. An EQA scheme for antigen (Ag) detection was conducted in November 2020. All pilots were performed free of charge for the participants.

The aim of this study is to show how three successful EQA pilots were conducted rapidly during the acute phase of a pandemic.

Conclusion

Setting up three separate EQA schemes in the early stages of a pandemic was challenging but possible thanks to a good network of virology experts in clinical laboratories as well as industry partners. There was a mutual interest to ensure the quality of the laboratory processes for diagnostics of SARS-CoV-2. All partners involved at the different stages of the EQA development process understood of the importance of having reliable EQA available for clinical laboratories as soon as possible.

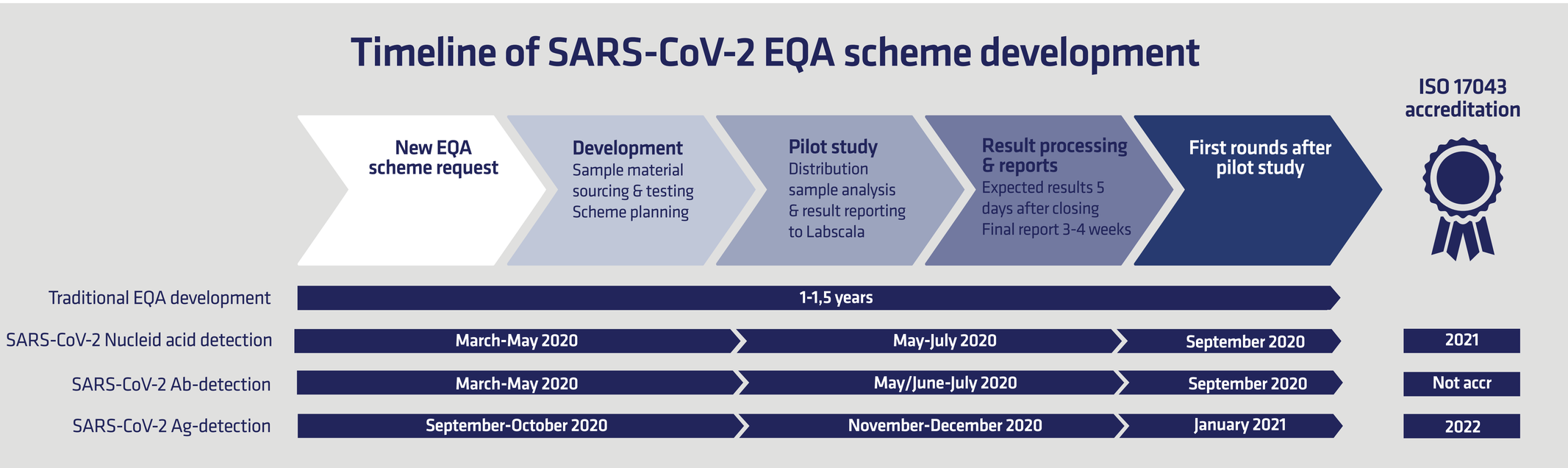

Fig 1. Timeline of SARS-CoV-2 EQA sheme development during the early stage of the pandemic in 2020. The SARS-CoV-2 EQA schemes were performed from planning to final reporting in four months with successful results.

Methods

Sample sourcing and testing: For SARS-CoV-2 nucleic acid detection, the positive sample material used was a SARS-CoV-2 whole genome cDNA swab sample. It was pre-tested in 3 laboratories using 6 different in-house or commercial tests before distributed to the participants. For SARS-CoV-2 Ab detection, two separate pilot studies were performed due to high demand of EQA for antibody detection and the limited amount of available sample material at this early stage of the pandemic. The positive sample materials used were serum from Covid-19 recovered patients tested using a microneutralization test at a clinical research laboratory (pilot 1) and commercial serology antibody detection tests in two clinical laboratories (pilot 2). For the SARS-CoV-2 Ag detection, a synthetic SARS-CoV-2 nucleocapsid protein swab sample was used as positive sample material and it was tested using 3 commercial tests detecting SARS-CoV-2 antigen (table 1).

Pilot preparations: The pilots were announced, participants were registered while preparing eforms and result reports in Labquality's electronic platform LabScala. The planned number of participants was tripled for both nucleic acid detection and antibody detection pilots due to the high demand.

Result reporting: The participants reported their results through LabScala. The expected results were published 5 days after the closing date and the final reports including expert comments were published within 3-4 weeks after closing of the individual rounds.

SARS-CoV-2 Pilot study	Test	Testing site
Nucleic acid detection	In-house (WHO recommended E gene specific RT-PCR/Corman et al, 2020)	Clinical university hospital laboratory
	Cepheid Xpert Xpress SARS-CoV-2 test	Clinical university hospital laboratory
	NeuMoDx SARS-CoV-2 Assay	Clinical university hospital laboratory
	Qiagen QIAstat-Dx SARS-CoV-2	Clinical university hospital laboratory
	Mobidiag Amplidiag COVID-19	Industry partner laboratory
	Mobidiag Novodiag COVID-19	Industry partner laboratory
Antibody detection (1)	Microneutralization assay	Clinical research laboratory
Antibody detection (2)	DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG	Clinical university hospital laboratory
	Abbott ARCHITECT SARS-CoV-2 IgG	Clinical university hospital laboratory
	EUROIMMUN Anti-SARS-CoV-2 ELISA IgG	Clinical university hospital laboratory
	EUROIMMUN Anti-SARS-CoV-2 ELISA IgA	Clinical university hospital laboratory
	Salofa Salocor COVID-19 (SARS-CoV-2) IgG/IgM Rapid Test kit	Clinical university hospital laboratory
	Vircell COVID-19 IgG	Clinical university hospital laboratory
	Vircell COVID-19 IgM+IgA	Clinical university hospital laboratory
Antigen detection	ArcDia mariPOC SARS-CoV-2	Industry partner laboratory
	ArcDia mariPOC Respi+	Industry partner laboratory
	ArcDia mariPOC Quick Flu+	Industry partner laboratory

Table 1. Pretesting methods and testing sites of EQA sample material.

Results

The regular EQA scheme development process was followed, however, the different development stages overlapped each other in order to respond quickly to the needs of the clinical laboratories (figure 1). Material sourcing, testing and evaluation was prioritized. The material for all rounds needed to be safe to use, stable and suitable for a wide variety of tests on the constantly growing market for SARS-CoV-2 detection. The pilot studies for nucleic acid detection and antibody detection were announced in April and the pilot samples were distributed on May 25th and for the second antibody pilot on June 1st, 2020. The rounds were open for three weeks and after evaluating the results, the reports were published to the clients in early July, i.e., in less than four months from the start of the planning of the new rounds. The need for EQA for antigen detection tests was recognized shortly after this and the pilot was conducted in November-December 2020 using the same schedule. The EQA scheme for SARS-CoV-2 nucleic acid detection was ISO 17043 accredited in 2021 and the SARS-CoV-2 antigen detection was included in the accreditation in 2022. A summary of the pilot participants and results is shown in figure 2.

The quickly growing number of participants in the individual EQA schemes demonstrates the acute need for EQA in the time of the pandemic (figure 3). SARS-CoV-2 nucleic acid detection is included in two additional Labquality EQA schemes, these are included in the figure for comparison although they are outside of the scope of this study.

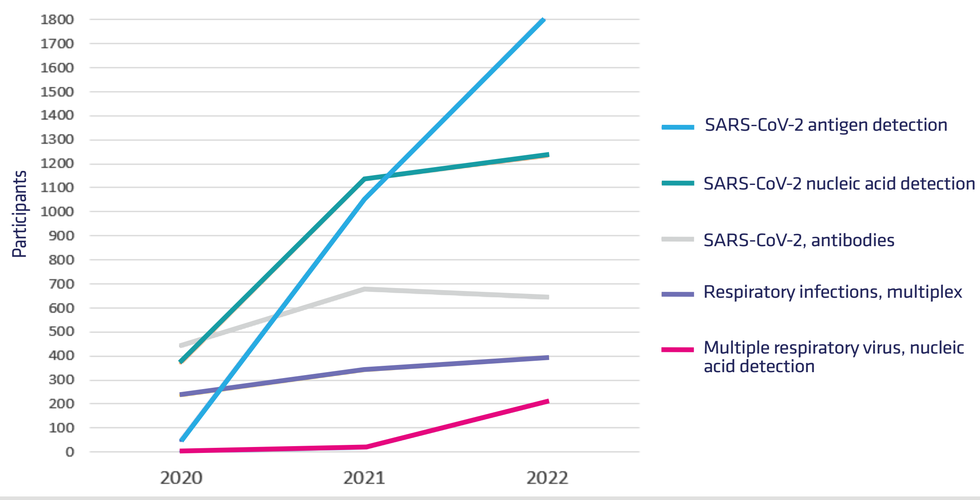

Fig. 3 Development of number of participants in the Labquality SARS-CoV-2 EQA programs in 2020-2022. Included in the figure are two additional EQA schemes where nucleic acid detection of SARS-CoV-2 is included; Multiple respiratory virus introduced as a pilot at the end of 2021 (Influenza virus A and B, RSV, SARS-CoV-2) and Respiratory infections multiplex (Adenovirus, *B. parapertussis*, *B. pertussis*, *C. pneumoniae*, Coronavirus (OC43, 229E, NL63, HKU1), Enterovirus, Influenza virus A/B, Metapneumovirus, *M. pneumoniae*, Parainfluenzavirus 1-4 , Rhinovirus, RSV A/B, SARS-CoV-2, *S. pneumoniae*.

Fig 2. Summary of the results of the pilot studies

SARS-CoV-2 Nucleic acid detection 1, 2020 Pilot

157 Participants
23 Countries
90% Response rate

194 Total number of responses
40 Assays

99% Overall success rate

SARS-CoV-2 Antibody detection 1-2, 2020 Pilots

174 Participants
23 Countries
80% Response rate

385 Total number of responses
60 Assays

98% Overall success rate

SARS-CoV-2 Antigen detection 1, 2020 Pilot

47 Participants
16 Countries
96% Response rate

50 Total number of responses
18 Assays

99% Overall success rate