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Enhancing Accuracy of SARS-CoV-2 Point-of-Care Testing Through Proficiency Testing: Experiences from a Provincial EQA Program in Canada

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Abstract

During the coronavirus disease 2019 (COVID-19) pandemic, the rapid expansion of diagnostic capacity prompted the Canadian Microbiology Proficiency Testing (CMPT) program to establish a new proficiency testing (PT) scheme dedicated to molecular and antigen-based identification of SARS-CoV-2. This initiative specifically targeted point-of-care testing (POCT) locations operating within the eight provincial Health Authorities of British Columbia (BC), Canada, with the primary objective of evaluating and maintaining testing quality. The PT framework involved 6 annual distributions, each comprising 4 samples categorized as either SARS-CoV-2–positive or negative. Program participation commenced with 23 sites in March 2021 and increased to more than 100 participants by December 2021. Evaluation of results from the first two survey rounds indicated that facilities using nucleic acid testing (NAT) consistently demonstrated satisfactory accuracy, whereas sites relying on rapid antigen detection (RAD) methods showed inferior performance, particularly when analyzing weakly positive specimens. Investigation into the causes of poor performance revealed shortcomings in both test execution and result interpretation, most often associated with inexperienced testers newly introduced to diagnostic workflows. Corrective actions included strengthened training and mentorship, comprehensive retraining of staff, revision of specimen handling instructions, and development of an instructional training video for participating sites. Following these interventions, overall accuracy improved, and RAD-based POCT site performance more closely aligned with that of NAT-based testing sites. Collectively, the PT program was highly effective and led to measurable improvements in diagnostic quality across the province. These findings highlight the indispensable contribution of external quality assessment (EQA) providers to patient safety and public health protection, particularly when testing is performed outside accredited laboratory environments.

Keywords: SARS-CoV-2, Proficiency testing, Canada, COVID-19

Introduction

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in China in 2019 and its escalation into a global pandemic in 2020 triggered an unprecedented acceleration in the development, regulatory approval, and deployment of novel in vitro diagnostic (IVD) technologies worldwide [1]. In Canada, this period marked the first occasion on which diagnostic testing for both clinical decision-making and public health surveillance was authorized across multiple commercial platforms, with testing permitted beyond the confines of accredited clinical laboratories [2]. Data generated from these testing efforts were central to informing patient management strategies and public health surveillance and, in many instances, directly shaped public health responses and local policy decisions at all societal levels [3], including throughout Canada.

Nucleic acid tests (NATs) quickly became the reference standard for SARS-CoV-2 detection because of their superior analytical sensitivity and specificity. However,

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widespread adoption of antigen-based testing emerged as a critical component of community-level screening and surveillance during the pandemic. From February 2020 to December 2022, Canada documented 4,440,839 laboratory-confirmed infections and 48,645 COVID-19–related deaths as of December 21, 2022 [4]. In British Columbia (population 5,319,324 as of July 1, 2022) [5], 390,626 confirmed cases and 4,715 associated fatalities were reported. For the first time, diagnostic testing was conducted in a broad range of non-traditional environments, including long-term care facilities, primary schools, airports, and other patient care settings administered by the province's 8 Health Authorities. Most locations were supplied with government-approved rapid antigen detection (RAD) assays or rapid nucleic acid–based testing systems. These assays were designated as "low-complexity," indicating that specialized technical expertise was not required and allowing testing to be performed by non-laboratory personnel. Reported diagnostic performance for RAD assays includes sensitivities of 78.2% and specificities of 99.5%, with higher sensitivity values—up to 92.6%—observed among symptomatic individuals with culture-positive infection [6–8]. The rapid turnaround times of these tests were intended to facilitate the timely identification and isolation of infectious individuals, thereby reducing community transmission.

In June 2020, the Provincial Health Services Authority of British Columbia mandated accreditation for all facilities performing diagnostic testing [9]. In Canada, regulatory oversight of diagnostic testing is governed at the provincial level; in BC, this responsibility falls under the Diagnostic Accreditation Program (DAP) [10]. Participation in an external quality assessment (EQA) program for every diagnostic assay performed, including COVID-19 tests, is a core accreditation requirement.

EQA programs represent a foundational component of resilient laboratory and health systems by providing independent performance evaluation aligned with internationally recognized quality standards [11]. Over the past decade, the applicable international benchmark for medical laboratories has been ISO 15189:2012 [12], revised in 2022, which mandates EQA participation for all assays included in a laboratory's test menu. To meet the urgent need for COVID-19 EQA across BC and Canada, CMPT partnered with the BC Centre for Disease Control (BCCDC) to design and implement a COVID-19 PT program focused on community-based POCT settings, while also allowing enrollment of traditional medical laboratories.

Between January and March 2021, CMPT undertook research and development activities to define suitable challenge materials and engaged in consultations with Health Authorities and DAP to ensure the program's design aligned with regulatory and operational requirements. The program framework was further informed by CMPT's 40 years of experience as an ISO 17043–accredited EQA provider and by expert input from medical laboratory professionals involved in patient care and public health across Canada. Program development, validation, and participant enrollment were completed in early 2021, with the first PT shipments distributed in March 2021. Participation expanded rapidly from 23 sites in March 2021 to more than 100 sites by March 2022, eventually encompassing numerous public and private laboratories and POCT facilities as mandatory testing broadened across BC and Canada. Concurrently, the diversity of testing platforms and technologies increased, prompting CMPT to continually adapt PT materials to reflect evolving testing practices and participant requirements.

In this report, we summarize nearly two years of experience delivering a COVID-19 EQA program and provide recommendations to the medical community, reinforcing the enduring importance of continuous EQA participation as a critical mechanism for ensuring accurate, reliable, high-quality, and safe diagnostic testing.

Materials and Methods

EQA program operating guidelines and implementation policies

Planning, design, and enrollment for the COVID-19 EQA program took place between January and March 2021 and were guided by multiple operational and public health considerations, including testing site geography, site category, and population served, testing throughput, and downstream data use. The program was structured as a continuing initiative aligned with evolving public health demands, consisting of 6 challenge rounds annually, distributed to participating sites at 2-month intervals. CMPT operates as a not-for-profit quality assurance service within the Department of Pathology and Laboratory Medicine at the University of British Columbia. Initial research and development expenses associated with program creation were supported by

CMPT central resources and BCCDC central funding. Ongoing operational costs required for sustained program delivery were recovered through a participant-paid, fee-for-service subscription model. Enrollment in CMPT EQA programs was completed through the CMPT website, after which subscribers were granted access to a secure and confidential online portal for result entry, review of performance letters, and access to final reports. Owing to the rapid uptake of the EQA program and the large number of testing sites enrolling within a short timeframe, CMPT enhanced its data management platform to allow near–real-time data evaluation and reporting. System modifications also enabled accreditation organizations to receive testing outcomes for sites within their jurisdictions within 24 hours. A shared operational policy was adopted whereby, in cases of suboptimal performance—either in a single event or repeatedly—CMPT would provide targeted support, including mentorship, development of online instructional materials, and technical assistance as required. The eight Health Authorities (HAs) in BC additionally contributed by offering training, repeat testing, and activity oversight to improve site performance. The Diagnostic Accreditation Program (DAP) maintained responsibility for follow-up on failed EQA challenges and for requesting root cause analyses from affected sites.

EQA program implementation design

Although the EQA initiative was initially established with POCT sites as its primary audience, the composition of each survey and challenge panel was intentionally designed to be compatible with both nucleic acid testing (NAT) and antigen-based methodologies (see Methods, Section C). Consideration was also given to commonly used respiratory specimen collection approaches, including nasopharyngeal and oropharyngeal sampling. Each of the 6 challenge panels comprised four blinded samples—where sample identity was unknown to the operator—packaged in leak-proof vials. Each vial contained either a SARS-CoV-2–positive or –negative specimen, as outlined in **Table 1**. Inclusion of positive samples spanning a range of viral concentrations reflected the concurrent use of multiple commercial assays across BC and Canada, each characterized by different operating procedures and inherent analytical performance (e.g., sensitivity and specificity). This approach enabled objective assessment of testing performance indicators, such as accuracy and consistency, independent of the assay platform in use.

Table 1. Example of a SARS-CoV-2 EQA survey set.

Sample 1	Sample 2	Sample 3	Sample 4
Positive (medium)	Negative	Positive (strong)	Positive (strong)

Sample identities were randomized and blinded using a unique survey identifier assigned to each distribution. Labels included the prefix “COV” followed by the year and month (e.g., COV2211-1, COV2211-2, COV2211-3, COV2211-4 for a survey distributed in November 2022), and color coding was applied to minimize the risk of sample mix-up during testing. Participants were provided a two-week window to analyze samples and submit results (see Methods, Section C).

Sample preparation and validation

Development of PT challenge materials was performed collaboratively by CMPT and BCCDC under an institutional material transfer agreement, with all primary source materials supplied by the BC Centre for Disease Control. SARS-CoV-2 (Wuhan strain) was propagated in African green monkey kidney epithelial cells using a positive clinical specimen obtained through routine BCCDC surveillance. Virus amplification to high titre was achieved through plaque purification within the BCCDC containment level 3 (CL-3) laboratory in Vancouver, Canada. Viral titre and supernatant purity were assessed by quantitative reverse transcription PCR (qRT-PCR), and material was stored at −80°C under CL-3 conditions before further processing. The undiluted viral stock measured 6.0×10^4 $TCID_{50}$/mL with a CT value of 13.

The stock virus was diluted in Dulbecco’s Modified Eagle’s Medium (DMEM) (Invitrogen, ThermoFisher Scientific) to concentrations of 3.0×10^3 $TCID_{50}$/mL and 1.2×10^3 $TCID_{50}$/mL, designated as strong-positive and medium-positive samples, respectively. Corresponding CT values were 15 for the strong-positive sample and 19 for the medium-positive sample. Following titration, live virus preparations were inactivated using β-propiolactone (BPL) to permit safe transfer to the CMPT laboratory. All subsequent handling of non-infectious material was carried out under CL-2 conditions at CMPT. Because certain nucleic acid assays rely on the Ribonuclease P (RNase P) housekeeping gene as an internal control for RNA integrity, early negative

controls were produced using saliva from healthy donors. To improve consistency and long-term sustainability, these were later replaced with adenocarcinomic human alveolar basal epithelial (A549) cell lysate at 2 million cells/mL, yielding an RNase P CT value of approximately 24. Negative samples were prepared before positive samples to minimize cross-contamination risk. All materials were prepared and stored at −70°C one week prior to distribution.

For shipment, 100 µL aliquots of each sample type **(Table 1)** were dispensed into 2 mL O-ring vials (Axygen, Corning, AZ). From the day of dispatch onward, samples were maintained at ambient temperature to simulate typical transport and storage conditions encountered by most testing sites. Quality control (QC) testing was performed using the Abbott Panbio rapid antigen assay (Abbott Park, Illinois, USA). CMPT PT panels undergo comprehensive stability assessments to confirm acceptable performance for a minimum of 21 days following shipment. Sample stability was evaluated on the shipping day (Day 0), at 7 days post-shipment (Day 7), and on the reporting deadline (Day 14). An additional in-house stability check was conducted on the day the final participant report was received to confirm expected sample behavior.

Participants received detailed written guidance outlining sample handling and result submission procedures. Testing sites were instructed to swab each sample aliquot in the same manner as a patient specimen and to process it as a simulated nasopharyngeal swab. Each vial was handled independently, resulting in four simulated nasopharyngeal swabs per survey. Samples were analyzed in accordance with each site's established protocols. A dedicated helpline was available to address technical questions and troubleshooting needs. Laboratories were encouraged to contact CMPT with any concerns regarding sample processing or data submission, and CMPT provided technical assistance within the defined scope of an EQA provider.

Data entry and analysis

Submission of test results was mandated within 14 days of the shipment date, aligning with provincial policy in British Columbia and supporting near–real-time monitoring of testing quality. All data were submitted through the secure CMPT member online portal [13], which is protected by individualized user authentication and restricted to subscribers of CMPT EQA programs. Participating sites were required to report the following details: date of sample receipt, date of analysis, site and instrument identifiers, name of the reporting individual, testing methodology, and test outcomes. An optional comments field was available for additional notes. CMPT did not collect information regarding the category of testing site (e.g., laboratory-based versus community-based). Upon submission, each participant immediately received an individualized performance report summarizing results and assigned grades; copies of these reports were forwarded to the relevant accreditation body (DAP or other agencies) in accordance with established policy. Participants were informed in advance that their data would be shared with accreditation authorities when applicable. After the close of the 14-day reporting window, aggregated results were analyzed by testing method and compiled into a comprehensive summary report to facilitate interlaboratory comparison; this report was made accessible to all participants via the member portal. While comparative analysis across sites was enabled, individual site identifiers were withheld to preserve anonymity. Sites that failed to submit results by the deadline were assigned an "unacceptable" grade.

Statistical analysis

To address clustering effects arising from repeated measurements—both multiple samples of the same type within a survey and repeated participation of individual sites across surveys—Generalized Estimating Equations (GEE) with logistic regression were applied. The binary outcome variable was categorized as Acceptable or Unacceptable. The model incorporated Test, Sample, and Survey as fixed independent variables and included two-way interaction terms between Test and each of the other variables (Sample and Survey). Testing site identity was incorporated to define clusters, accounting for correlations among observations originating from the same site within and across survey rounds.

Results and Discussion

Number of testing sites

Enrollment in the newly established COVID-19 EQA program expanded markedly during the first year, yielding a representative cross-section of public and private sectors, testing facility types, geographic regions, and populations served **(Figure 1)**. Overall participation increased 3.2-fold within one year. In 2021, six high-throughput laboratory hubs—each located within a different Health Authority (HA) in BC—were enrolled,

along with 91 private-sector POCT sites across Canada between March 2021 and November 2022. Within the public sector, an average of 30 testing sites per survey received PT challenges; these were predominantly long-term care facilities performing routine daily testing and screening. Participant distribution closely mirrored population density and testing priorities within BC, with 57% of enrolled sites located in the metropolitan Vancouver region, 27% from Northern, Interior, and Vancouver Island areas, and 16% from other Canadian provinces.

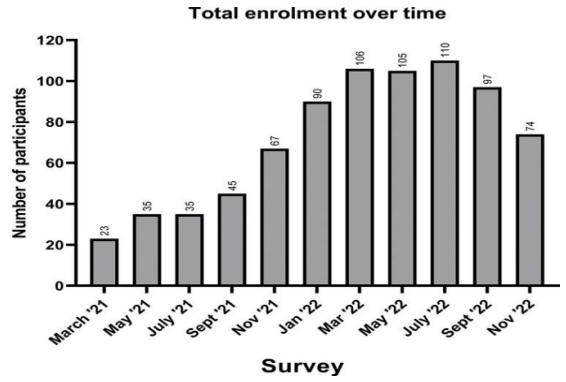


Figure 1. Total number of EQA participants from March 2021 to November 2022.

This figure illustrates participant enrollment and growth from the initial survey conducted in March 2021 through the most recent survey in November 2022, with the highest enrollment observed in July 2022.

Testing site performance

Participating sites employed either rapid antigen detection (RAD) or nucleic acid testing (NAT) methods **(Figure 2)**. Among RAD assays, the Abbott Panbio kit was the most commonly used commercial test **(Figure 3a)**, while the Abbott ID NOW platform was the predominant system utilized for NAT **(Figure 3b)**.

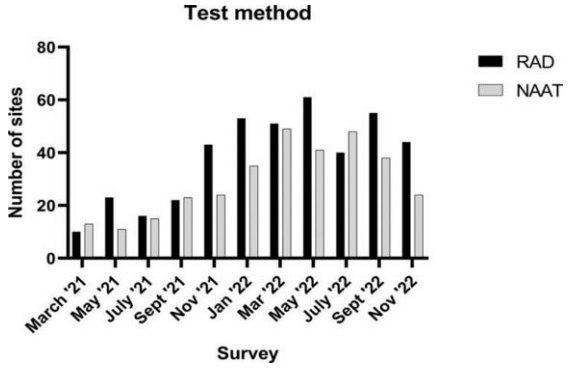
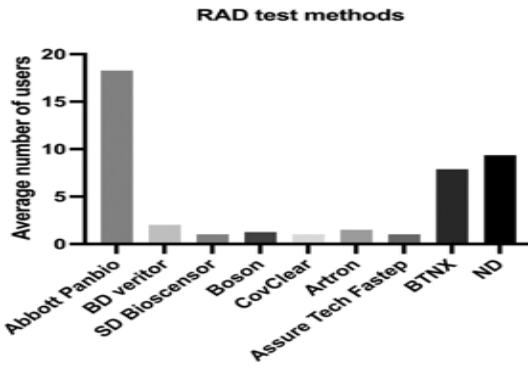
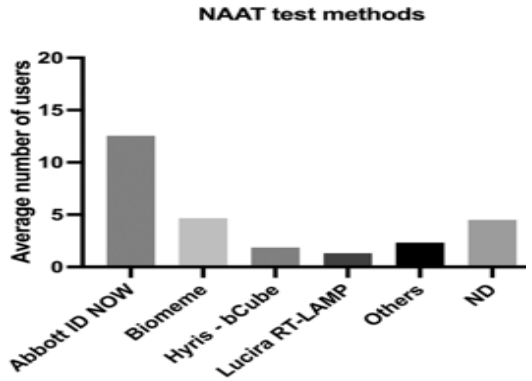


Figure 2. Distribution of site utilization by primary testing method from March 2021 to November 2022.

This figure depicts the increase in participating sites by testing methodology, with the highest enrollment of RAD-based sites occurring in May 2022.



a)



b)

Figure 3. Distribution of RAD and NAT test types used from March 2021 to November 2022.
(a) Total RAD test types employed, with the Abbott Panbio kit representing the most frequently used assay.
(b) Distribution of nucleic acid amplification test (NAAT) platforms, with Abbott ID NOW being the most commonly utilized. The figures display both the cumulative number of uses and the relative frequency of each test type.

Acceptable result rates for sites using RAD methods were low during surveys 1 and 2 (46% and 58%, respectively) but progressively improved, reaching 91% accuracy by January 2022. This level of performance was sustained at greater than 90% accuracy throughout 2022 **(Table 2)**. In contrast, sites using NAT methods consistently achieved

acceptable result rates exceeding 90% across the entire study period.

Table 2. 2021–2022 EQA results—overall performance by survey.

Survey	Total testing sites	Nucleic Acid Tests		Rapid Antigen Test	
		No. of participants	Correct report (%)	No. of participants	Correct report (%)
March 2021	23	13	95	10	46
May 2021	34	11	97	23	58
July 2021	31	15	91	16	98
September 2021	45	23	91	22	83
November 2021	67	24	98	43	67
January 2022	88	35	96	53	91
March 2022	100	49	100	51	99
May 2022	102	41	99	61	98
July 2022	88	48	98	40	98
September 2022	93	38	100	55	98
November 2022	68	24	97	44	95

Negative samples

Across the evaluation period, results generated using either RAD or NAT approaches for negative samples aligned with expected outcomes, and overall site performance remained consistently high **(Tables 3 and 4)**. Use of RAD or NAT methodologies showed a comparable likelihood of yielding a true negative result.

Table 3. Comparison of COVID-19 testing methods for the estimated probability of achieving an acceptable result for negative samples only.

Test	Survey	Estimated probability	*SE
RAD	1	0.923	0.045
NAT	1	0.979	0.021
RAD	2	0.946	0.029
NAT	2	0.976	0.029
RAD	3	1	0
NAT	3	0.934	0.04
RAD	4	0.975	0.013
NAT	4	0.924	0.049
RAD	^6	0.986	0.011
NAT	6	0.969	0.012
RAD	7	0.999	0.001
NAT	7	1	0
RAD	8	0.997	0.004
NAT	8	0.994	0.005
RAD	9	0.998	0.001
NAT	9	0.995	0.005
RAD	10	0.999	0.001

NAT	10	1	0
RAD	11	0.997	0.002
NAT	11	1	0

*SE = Standard error

^ No negative samples were included in the fifth survey

Table 4. Evaluation of COVID-19 testing approaches based on the estimated likelihood of producing an acceptable outcome for negative samples only, including 95% confidence intervals (asymp.LCL, asymp.UCL), reported separately for each survey.

Survey	Estimated probability	asymp.UCL	asymp.LCL	z.ratio	SE	*p.value
1	-0.056	0.084	-0.195	-1.121	0.05	1
2	-0.03	0.085	-0.144	-0.721	0.041	1
3	0.066	0.178	-0.047	1.632	0.04	1
4	0.051	0.193	-0.091	1.011	0.05	1
^6	0.018	0.063	-0.028	1.102	0.016	1
7	-0.001	0.002	-0.004	-1.11	0.001	1
8	0.003	0.021	-0.016	0.384	0.007	1
9	0.004	0.019	-0.012	0.673	0.005	1
10	-0.001	0.002	-0.004	-1.202	0.001	1
11	-0.003	0.003	-0.01	-1.493	0.002	1

* Confidence intervals and p values were adjusted using the Bonferroni correction for 10 comparisons.

^ The 5th survey did not include negative samples.

Medium positive samples

For specimens categorized as medium positive, outcomes generated using NAT platforms closely aligned with expected findings, whereas sites applying RAD methodologies demonstrated inferior accuracy during the initial phase of program implementation, with a substantial proportion of results incorrectly classified as negative **(Tables 5 and 6)**. Over successive survey rounds, performance among RAD-based sites improved markedly **(Figure 4)**. Overall analysis revealed a statistically significant disparity between NAT and RAD methods in the probability of obtaining acceptable results for medium positive samples in surveys 1, 2, 5, and 6 **(Table 6)**.

Table 5. Comparison of COVID-19 testing approaches with respect to the estimated probability (estimate) of achieving an acceptable outcome for medium positive samples.

Test	Survey	*SE	Estimated probability
RAD	1	0.125	0.315
NAT	1	0.025	0.974
RAD	2	0.092	0.402
NAT	2	0.026	0.97
RAD	^4	0.102	0.598
NAT	4	0.06	0.908
RAD	5	0.075	0.59
NAT	5	0.021	0.977
RAD	6	0.071	0.733
NAT	6	0.025	0.962
RAD	7	0.023	0.968
NAT	7	0	1
RAD	^9	0.029	0.958
NAT	9	0.007	0.993

RAD	10	0.023	0.967
NAT	10	0	1
RAD	11	0.039	0.918
NAT	11	0	1

*SE = Standard error
^ Medium positive samples were excluded from surveys 3 and 8.

Table 6. Comparison of COVID-19 testing approaches for medium positive samples only, presenting estimated probabilities of acceptable results with 95% confidence intervals (asymp.LCL, asymp.UCL), stratified by survey.

Survey	Estimated probability	z.ratio	asymp.UCL	asymp.LCL	SE	*p.value
1	-0.66	-5.147	-0.304	-1.015	0.128	<0.00001
2	-0.569	-5.885	-0.301	-0.836	0.097	<0.00001
^4	-0.31	-2.619	0.018	-0.638	0.118	0.07935
5	-0.387	-4.991	-0.172	-0.602	0.078	<0.00001
6	-0.228	-3.017	-0.018	-0.438	0.076	0.02296
7	-0.032	-1.369	0.032	-0.095	0.023	1
^9	-0.036	-1.185	0.048	-0.119	0.03	1
10	-0.033	-1.433	0.031	-0.098	0.023	1
11	-0.082	-2.088	0.027	-0.191	0.039	0.331

^ Medium positive samples were not included in surveys 3 and 8.
* Confidence limits and p values were adjusted using the Bonferroni method for 10 comparisons.

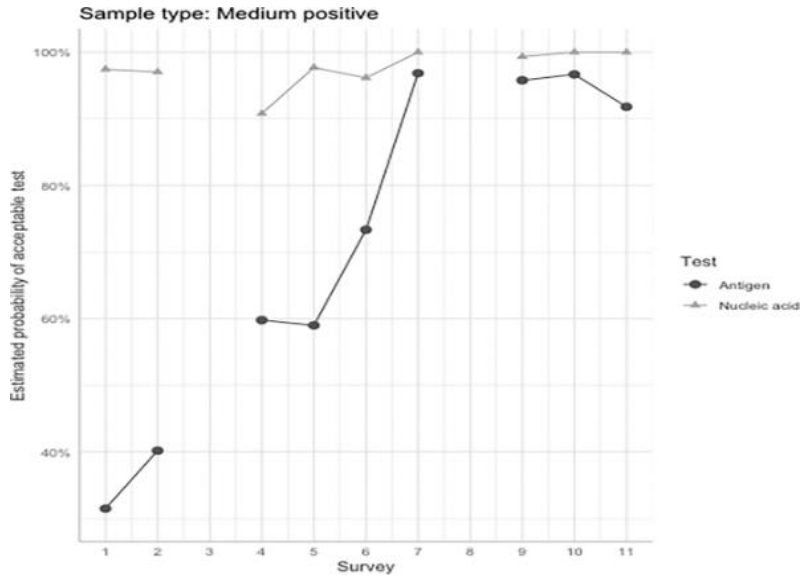


Figure 4. Longitudinal pattern of acceptable result rates across surveys for medium positive samples. This figure demonstrates a progressive increase in acceptable outcomes over time among RAD-based testing sites relative to NAT-based sites.

Strong positive samples

Across all 11 surveys included in the analysis, both RAD and NAT testing strategies yielded results consistent with expected outcomes for strong positive specimens **(Tables 7 and 8)**.

Table 7. Comparison of COVID-19 testing approaches for the estimated probability (estimate) of obtaining an acceptable result for strong positive samples.

Test	Survey	*SE	Estimated probability
RAD	1	0.073	0.862
NAT	1	0.033	0.97
RAD	3	0	1
NAT	3	0.05	0.906
RAD	4	0.025	0.953
NAT	4	0.043	0.892
RAD	5	0.022	0.951
NAT	5	0.034	0.973
RAD	6	0.014	0.974
NAT	6	0.028	0.954
RAD	7	0.002	0.998
NAT	7	0	1
RAD	8	0.006	0.993
NAT	8	0.01	0.991
RAD	9	0.002	0.997
NAT	9	0.009	0.992
RAD	10	0.002	0.997
NAT	10	0	1
RAD	11	0.004	0.993
NAT	11	0	1

*SE = Standard error

Table 8. Comparison of COVID-19 testing approaches for strong positive samples only, showing estimated probabilities of acceptable results with corresponding 95% confidence intervals (asymp.LCL, asymp.UCL) by individual survey.

Survey	Estimated probability	z.ratio	asymp.UCL	asymp.LCL	SE	*p.value
1	-0.108	-1.35	0.116	-0.332	0.08	1
3	0.094	1.874	0.234	-0.047	0.05	0.6096
4	0.061	1.239	0.199	-0.077	0.049	1
5	-0.021	-0.532	0.091	-0.134	0.04	1
6	0.02	0.629	0.107	-0.068	0.031	1
7	-0.002	-1.235	0.003	-0.008	0.002	1
8	0.002	0.176	0.036	-0.032	0.012	1
9	0.005	0.495	0.031	-0.021	0.009	1
10	-0.003	-1.313	0.003	-0.008	0.002	1
11	-0.007	-1.693	0.004	-0.017	0.004	0.9038

* Bonferroni-adjusted confidence levels and p values were applied for 10 comparisons.

Across all survey rounds, no evidence was observed to suggest a difference between testing methodologies in the likelihood of achieving an acceptable outcome for strong positive samples.

Reliable clinical diagnostic testing is a cornerstone of effective patient management and therapeutic decision-making, and test-generated data exerted a profound influence on public health strategies worldwide during the COVID-19 pandemic and the unprecedented expansion of diagnostic screening [14]. To safeguard accuracy, timeliness, and reliability—and to minimize the risk of patient harm—diagnostic testing must be supported by consistent, independent external quality assurance mechanisms. External quality assessment

programs incorporating proficiency testing (PT) [15], therefore, represent essential components of diagnostic quality frameworks and regulatory oversight. Our experience as an ISO 17043–accredited EQA provider during the rapid scale-up of COVID-19 testing in Canada clearly illustrates this value, particularly in contexts involving diverse testing technologies and heterogeneous testing environments. This investigation encompassed nearly two years of data and included 11 discrete survey rounds.

Using GEE-based logistic regression to evaluate acceptable outcomes for RAD and NAT methods across 11 surveys and stratified by sample type, no statistically meaningful differences were detected between methodologies for either negative or strong positive specimens. In contrast, NAT platforms demonstrated a significantly greater probability of producing acceptable results compared with RAD approaches ($p<0.01$) for medium positive samples in surveys 1, 2, 5, and 6 **(Table 6)**. At program initiation, inclusion of sites spanning both public and private sectors—with variation in testing location, testing volume, and populations served—introduced critical contextual variables that enabled effective quality surveillance and timely corrective action. Substantial variability was observed among RAD-based sites when processing medium positive samples; however, false-negative rates declined notably over time **(Table 6 and Figure 4)**, indicating progressive performance improvement.

The exceptionally high accuracy rate observed in July 2021 (98%; survey 3) was most likely attributable to the absence of medium positive specimens in that survey, whereas the decrease in performance noted in November 2021 (survey 5) was likely related to the inclusion of three medium positive samples **(Table 2)**. Throughout the evaluation period, NAAT-based testing consistently maintained acceptable performance levels above 90%. These findings further demonstrate that the high-frequency PT survey schedule (6 distributions annually) enabled early identification of performance gaps and facilitated timely intervention, while also providing valuable longitudinal insight into performance trends across both laboratory-based and community testing sites.

Although CMPT proficiency testing (PT) surveys are typically conducted two to three times annually, the increased survey frequency used in this study (every two months) allowed for faster detection of deficiencies in COVID-19 testing performance and result interpretation shortly after POCT sites initiated testing at high volumes and began releasing results. This higher cadence enabled the collaborative network—comprising reference laboratories, health authorities, and accreditation organizations—to deploy timely, multi-level corrective actions through various quality partners, thereby rapidly addressing and improving the accuracy of results reported by POCT sites.

Experience gained between March 2021 and November 2022 highlighted several limitations and key considerations when diagnostic testing, and consequently PT, is implemented outside conventional clinical laboratory environments. Follow-up investigations and consultations with testing sites revealed that some locations interpreted faint positive bands as “negative,” while others encountered difficulties adhering to sample processing instructions. These sites were identified and provided with targeted assistance to correct procedural and interpretive errors. Such interventions are believed to have contributed to progressive improvements in site performance across surveys 1 to 5, after which a sustained accuracy rate exceeding 90% was observed for the remainder of the study period (surveys 6–11) **(Figure 4)**.

A further challenge identified was limited awareness of the educational value of PT and the benefits of program participation for individual testers. In a CMPT survey conducted in February 2021 [16], approximately one third of respondents reported no prior familiarity with PT and demonstrated even less understanding of EQA processes and requirements. To address this gap, CMPT provided ongoing client support, including guidance on PT execution, interpretation of outcomes, and assistance in achieving and maintaining accreditation. An additional early issue originated from the PT provider perspective: sample processing instructions were initially written for trained laboratory technologists, and early data from non-laboratory sites suggested that these instructions lacked sufficient clarity. After several survey rounds, it became evident that instructions required revision to ensure comprehension by testing personnel unfamiliar with standard laboratory terminology.

This study also identified a third critical consideration in PT program planning for diagnostic testing. EQA results demonstrated strong performance for both RAD and NAT technologies when testing CMPT strong positive samples. However, sites frequently exhibited suboptimal performance when challenged with medium positive samples. The inclusion of samples weaker than the

routine quality control provided in commercial testing kits—particularly for RAD assays—proved highly effective for assessing result interpretation by testers. Marked performance differences were observed between RAD and NAT methods for medium positive samples, with RAD-based sites consistently struggling to achieve accurate results. In July 2021, when medium positive samples were absent, 98% of reports were correct; in contrast, in November 2021, when three of four samples were medium positive, only 67% of results were accurately reported. Focused coaching, training, and mentoring subsequently improved RAD site performance to levels comparable with NAT-based sites by the end of the program's first year.

The rapid expansion and diversification of available testing technologies presented an additional challenge for CMPT as a PT provider, requiring continuous adaptation and development of samples that closely replicated the appearance and behavior of typical respiratory specimens and sampling techniques used in COVID-19 diagnostics. CMPT demonstrated flexibility and innovation in PT sample design to accommodate a wide range of client needs and testing platforms.

Globally, decentralized, low-complexity diagnostic testing conducted in community settings outside traditional laboratories has become increasingly common and, in some circumstances, has significantly enhanced patient care and public health responses during major global health crises, including HIV, tuberculosis, and malaria. For example, rapid identification of newly infected individuals with HIV and immediate initiation of therapy at the community level ("test and start") has unquestionably saved millions of lives and remains a powerful illustration of the benefits of accessible low-complexity diagnostics. Nonetheless, comprehensive post-market surveillance of test performance, combined with oversight of testing sites and robust EQA programs, represents a critical component of governmental quality assurance frameworks—particularly when diagnostic results may directly influence treatment decisions and patient mental health outcomes [17].

Across countries implementing large-scale COVID-19 testing, NAT-based assays for SARS-CoV-2 have consistently demonstrated superior accuracy and reliability compared with RAD methods, a finding supported by data from multiple EQA programs [18–20]. Numerous EQA initiatives focusing on SARS-CoV-2 antigen testing were established alongside national testing expansions and played a key role in monitoring community-based testing quality [21–23]. The development and implementation of a new Canadian EQA program tailored to both NAT and RAD technologies builds upon this international experience [24, 25] and further emphasizes the importance of stakeholder collaboration in diagnostic quality monitoring and public health support. The PT design incorporated a spectrum of viral concentrations (strong positive, medium positive, and negative), enabling evaluation of site performance with weakly positive samples—an ongoing challenge for RAD testing.

Through close collaboration with accreditation agencies and health authorities, sites performing both NAT and RAD testing received targeted mentoring and retraining when indicated. Data from this collaborative EQA effort demonstrate that testing performance can vary substantially depending on site type (e.g., centralized laboratory hubs versus long-term care facilities) and the technologies employed.

This EQA initiative facilitated early assessment of performance characteristics for many newly introduced IVDs and supported prompt identification of false-negative and false-positive trends. Access to near–real-time data empowered quality partners to intervene rapidly through retraining, mentoring, and coaching. Prolonged periods of suboptimal RAD performance suggested that the operational complexity of these assays may have been underestimated and that more intensive pre-implementation training could have been beneficial. In the absence of such training, the true number of falsely negative results remains unknown. Importantly, EQA data also contributed to post-market surveillance of several IVDs newly adopted across Canada. Based on these observations, we strongly recommend that EQA programs incorporate challenge panels spanning a similar range of complexity.

Conclusion

Diagnostic testing, irrespective of testing location, requires external quality assessment and oversight to ensure accuracy and reliability of results. EQA providers play a distinctive and essential role in maintaining diagnostic quality. Through close collaboration with health authorities and key stakeholders, EQA partners can meaningfully support patient care and public health during both routine operations and public health emergencies. EQA programs should be deliberately designed to simulate clinical specimens and to

accommodate diverse testing methodologies. PT challenges should include a range of signal intensities (weak and strong), particularly for rapid diagnostic platforms such as lateral flow assays, where outcomes are often binary ("positive" or "negative"). Comprehensive tester training and sustained supervisory support are essential whenever diagnostic testing is conducted outside accredited medical laboratory settings.

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