First Nations Health Authority
Health through wellness

COMMUNITY-BASED TESTING PROGRAM

Evaluation Report

May 2024

Acknowledgements

The FNHA Evaluation Team would like to sincerely acknowledge everyone who offered their time, knowledge and expertise to support this evaluation, particularly the Health Directors and health leads who shared valuable insight about their experience with the program and made suggestions for its improvement. We would like to thank former and current members of the FNHA executive team, Community-Based Testing Team, and the leadership and staff from both the central and regional offices. Finally, we would like to acknowledge the provincial and federal partners who supported the program and participated in the evaluation.

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Squamish First Nation Territory

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Executive Summary

Tricouni Mountain
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1 Introduction

The Community-Based Testing (CBT) program was developed in 2020 by the First Nations Health Authority (FNHA) and external provincial and federal partners to address the need for improved access and faster turnaround time for COVID-19 testing in rural and remote First Nations communities in BC. Throughout the COVID-19 pandemic, First Nations communities received diagnostic and point-of-care testing devices as well as training and support to administer COVID-19 testing in communities. The program has continued to operate beyond the pandemic with the goal of bringing diagnostic and point-of-care testing closer to home and building the needed infrastructure and quality systems to support it.

The FNHA Evaluation Team evaluated the CBT program to capture the story of the program's implementation and to gather lessons learned and wise practices for its continued growth and continuation.

Key Terminology

BCCDC	BC Centre for Disease Control
DAP	Diagnostic Accreditation Program
GeneXpert	GeneXpert System
ID NOW	Abbot ID NOW Analyzer
ISO	International Organization for Standardization
MHO	Medical Health Officer
NML	National Microbiology Laboratory
NTC	Nuu-Chah-Nulth Tribal Council
OCMO	Office of the Chief Medical Officer
OCNO	Office of the Chief Nursing Officer

2 Evaluation Purpose, Scope, and Approach

2.1 Evaluation Purpose and Scope

The purpose of this evaluation was to:

- Document and understand the activities that took place during the implementation and subsequent operationalization of the CBT program;
- Understand the program outcomes and achievements; and
- Gather evidence and lessons learned to support the program's continuation, improvement and expansion.

The scope of the evaluation covers all work and activities related to the set-up and implementation of the CBT program between April 2020 and January 2023. Program area leadership and staff have provided an addendum of changes made to the program between January 2023 and March 2024, as well as ongoing work to improve the program.

2.2 Evaluation Approach and Methods

The FNHA Evaluation Team conducted the evaluation in-house, and an advisory committee with membership from the CBT Team, FNHA regional teams, and federal and provincial partners provided input on the evaluation scoping and design.

Methods included:

- Engagement with 61 key contributors (including 11 community health leaders) through focus groups, interviews, surveys and written input.
- Document review
- Environmental scan
- Literature review

The FNHA Evaluation Team used NVIVO to code and conduct a thematic analysis of the qualitative data. Findings were synthesized and triangulated across multiple lines of evidence.

> **Limitations**: Due to the inability to access in-community administrative data, this evaluation cannot report on the utilization of the testing devices. Input gathered from key contributors may be subject to confirmation and recall biases. Due to lack of core funding, the program's finances were excluded from the evaluation.

3 The FNHA Community-Based Testing Program

3.1 Rationale

The CBT program was initiated early in the COVID-19 pandemic in response to the need from rural and remote First Nations communities for access to timely and culturally safe COVID-19 testing. In alignment with the 7 Directives, the program aimed to bring testing closer to home and under the decision-making and control of First Nations communities, ultimately helping facilitate timely self-isolation for test-positive individuals, prevent outbreaks, and ensure culturally safe services.

3.2 Program Governance

The CBT program began as a joint initiative between the FNHA and both federal and provincial partners. The program is supported by the Quality Assurance Framework Oversight Committee, which is chaired by the FNHA and includes members from the National Microbiology Laboratory (NML), BC Centre for Disease Control (BCCDC), Provincial Laboratory Medicine Services, and the Ministry of Health Laboratory and Blood Services Branch.

3.3 Program Goals

The CBT program goals are to:

1. Improve the equity of access to testing for First Nations people and communities by bringing COVID-19 testing capability to rural and remote First Nations communities across BC.
2. Leverage additional capacity on devices by considering testing for other communicable diseases as informed by community needs.
3. Focus on resource sustainability to ensure the necessary personnel and infrastructure are in place before and after roll-out.

3.4 Testing Equipment

The following devices were deployed as part of the CBT program.

The **GeneXpert® system** ("GeneXpert"), a real-time reverse transcription polymerase chain reaction device, which received interim use authorization from Health Canada in March 2020 as a diagnostic device for detecting the SARS-CoV-2 virus. Operating the device requires considerable set-up and training; however, it is capable of testing for many other infectious diseases, such as tuberculosis and sexually transmitted and blood-borne infections

The **Abbott ID NOW™ analyzer**, ("ID NOW"), a point-of-care testing – *not diagnostic* – device, which can screen for the SARS-CoV-2 virus via the isothermal amplification method. Operating the device does not require extensive set-up and training; however, its capabilities beyond the SARS-CoV-2 virus are limited.

3.5 Program Implementation

3.5.1 Existing Context (Before April 2020)

In the early stages of the COVID-19 pandemic, access to testing, particularly in rural and remote First Nations communities, was severely limited, leading to delays in receiving test results and impeding effective outbreak control.

Prior to the pandemic, NML had operated a program to advance decentralized infectious disease testing, particularly using GeneXpert devices. In response to the pandemic, NML shipped a small number of GeneXpert devices to the FNHA's central office, following which the FNHA and NML began conversations on how to implement the devices in communities.

3.5.2 Phase I Implementation: Foundational Work and Limited Rollout (April 2020 – December 2020)

To advance program rollout and support device operation, the FNHA formed a governance structure made up of a multi-stakeholder steering committee and an internal operations team. Various workstreams were created within the operations team to drive implementation, including operations and logistics, education and clinical guidelines, public health response, and strategy and communications. Foundational work included developing a quality assurance framework to satisfy regulatory requirements as well as developing standard operating procedures, clinical testing guidelines and reporting pathways.

Early implementation involved deploying GeneXpert devices to three selected First Nations communities and hiring personnel to support testing operations within these communities.

3.5.3 Phase II Implementation: Program Expansion (January 2021 – September 2022)

From January 2021 to September 2022, the CBT program continued to implement Abbott ID NOW and GeneXpert devices in more communities. To determine which communities would receive the testing devices, the program developed a CBT deployment criteria document that considered factors such as distance to higher levels of care, turnaround time for test results, transportation modes and adverse conditions.

The CBT Team engaged extensively with FNHA regional offices and community health leaders to provide information on the technology and its requirements, considering variations in human resources capacity and infrastructure among First Nations communities. Despite capacity constraints, efforts were made to ensure appropriate deployment, prioritizing cultural safety and respecting the pace and needs of communities throughout the engagement and training processes.

3.5.4 Phase III: Program Maintenance and Follow-up

With the arrival of self-administered rapid testing in the summer of 2022, the demand for CBT devices was reduced, especially given that operating and maintaining the devices took time and effort otherwise needed for providing care.

Having completed the foundational work, early workstreams were replaced by a permanent CBT program team, which continued to offer education and support to communities and deploy CBT equipment in new areas.

From program initiation until the time of drafting this report, CBT devices were deployed and used in a total of 30 communities, the majority being in the Northern and Interior regions. Of those communities, 16 have since stopped operating the devices due to limited capacity and/or reduced need. Over time, communities switched from Abbott ID NOW to GeneXpert to take advantage of the latter device's capability of testing for other infectious diseases. In the early winter of 2023, the testing scope of GeneXpert devices was expanded to include influenza A/B and respiratory syncytial virus (RSV).

3.5.5 Note on Program Funding

During its initial years of implementation (2020 – 2022), the CBT program did not have dedicated funding or staff allocation through the FNHA's core funding. During the pandemic, many FNHA staff members were redeployed from their regular roles to respond to the needs raised by the pandemic, including standing up the CBT program. The program's additional costs, such as hiring contractors, travel and incidentals were paid for through emergency COVID-19 funding that the FNHA received from the BC Ministry of Health. The testing devices and cartridges were provided in kind by NML.

Tow Hill
Haida Gwaii First Nation Territory

4. Findings: Outcomes

Outcomes for First Nations Communities: In communities adopting CBT, health teams practiced health sovereignty by offering safe, accurate and timely testing services to their community members, and controlling and managing outbreaks more effectively.

Outcomes for the FNHA: The urgency of the COVID-19 pandemic, and the complexity of the testing initiative, necessitated collaboration among multiple internal and external partners. Apart from demonstrating the FNHA's ability to lead the province in innovation, the CBT program also brought in new knowledge and skills related to laboratory testing and helped the FNHA further strengthen its relationship with First Nations communities.

Outcomes for the Health System: The CBT program showcased that the implementation of a quality-assured decentralized community-based diagnostic and point-of-care testing program is possible and is a model that can be replicated in other jurisdictions. Working closely with the FNHA and listening to its advocacy for First Nations communities, built awareness among federal, provincial and regional partners about their responsibility and accountability towards First Nations communities.

5. Findings: Challenges and Lessons Learned

Operational and Regulatory Challenges: The operational and regulatory challenges that the program faced, especially in early months of rollout, included lack of knowledge among FNHA executives and staff about laboratory services, the need to establish many structures and materials from the ground up, having to advocate to provincial partners to include the needs of rural and remote First Nations communities in discussions about testing, and resistance from some partners about the feasibility of launching such a program.

Health Human Resource Challenges: This program significantly increased the workload of community health nurses, due to its novelty and complexity. Furthermore, it was a challenge to secure enough trained nurses to operate the devices given staff shortages and communities' reliance on agency nurses. Offering online training helped alleviate training challenges to some extent.

Challenges with Infrastructure and Logistics: Lack of space and the need for renovations to house the equipment in some community health clinics, issues with cold-chain maintenance (especially in remote communities) and a lack of integration of electronic health records were among the main infrastructure and logistics challenges that communities faced when operating the CBT program.

6. Addendum (Program Updates Since 2023)

Knowledge gathering for the evaluation of the CBT program ended in 2022. Since then, the program has been through substantial changes and made significant advances to meet the needs of First Nations communities, sustain and improve its quality, and solidify its infrastructure and logistics. A summary of these changes and advancements were provided by the CBT program team and are included below.

6.4 Program Sustainment, Funding, and Scope Expansion

6.4.1 Program Funding and Staffing

The success and potential of the CBT program in bringing testing closer to home made the case for its continuation beyond the pandemic. As such, starting in 2023 the program was renamed to Community-Based Testing and Biomedical Initiatives, and the program received core funding from the FNHA. The program has tripled in size since 2022, and it currently consists of a director, a project manager/informatics specialist, a senior program coordinator, a quality specialist and two medical laboratory technologists.

6.4.2 Expansion of the Program's Scope to Other Testing and Services

Following the expansion of testing to RSV and flu A/B, the CBT program is exploring ways to bring other testing and services closer to home. The program has supported two remote communities to have access to X-rays, allowing community members to receive culturally safe care at home and avoid long travel times outside of their community. The team has placed a GeneXpert device at All Nations Healing House, the newly launched First Nations Primary Care Centre, and will next partner with other FNHA programs such as Sexually Transmitted and Blood-Borne Infections (STBBI), to bring those testing services closer to home.

6.5 Program Improvements

6.5.1 Improvements to Program Quality

The CBT program has revised its training and competency framework to make it more accessible, standardize it and improve its quality. Newly hired medical laboratory technologists provide in-person training sessions that supplement the initial virtual training provided by NML. Device operators must also complete an initial competency assessment and be recertified annually to ensure they are maintaining their competency.

One of the challenges articulated during the evaluation was insufficient health provider capacity in communities to operate the GeneXpert and ID Now devices. By acknowledging this access barrier, the CBT program is lifting up the FNHA 7 Directives and walking alongside communities to create pathways for health systems capacity-building in communities. This capacity-building will involve offering a micro-credential program for community members to become GeneXpert-certified operators. The program is also developing training through

the FNHA's forthcoming simulation lab to build capacity among agency nurses and other health care providers.

Finally, in partnership with BC Children's and Women's hospitals, the CBT program has introduced clinical verification panels – a quality process to assure that the pathway (which includes devices, consumables and operators) is producing true and reliable GeneXpert COVID-19/influenza/RSV results.

6.5.2 Building a Formal Quality System

The Quality Assurance Framework established during early implementation ensured program quality while temporarily meeting regulatory requirements. In reality, the provincial regulatory requirements for diagnostic testing can only be met by full-service diagnostic laboratories in urban areas rather than rural and remote Indigenous communities, which face extreme inequities in accessing testing. To address this challenge, the program is developing a formal quality system for CBT, informed by International Organization for Standardization (ISO) Council standards and the 12 quality system essentials. This system will involve establishing policies, processes, and evidence for over 400 quality standards spanning testing, human resource management, information technology, and occupational health and safety. By implementing this system, the program aims to standardize and ensure safe, reliable and accurate diagnostic testing outside of full-service laboratories, bridging the gap between regulatory requirements and the needs of rural and remote communities.

6.5.3 Improvements to Infrastructure and Logistics

All communities with GeneXpert devices now receive supplies directly from the CBT program (initially supplies were received through regional teams). Flexible shipping pathways have been established to ensure reliable delivery regardless of a community's location and remoteness. Maintaining cold-chain for testing cartridges is no longer required, as validated by NML, except for the clinical verification panels, for which alternate shipping pathways are in place.

The CBT program is building a clinical informatics system to safely collect and store clinical data and share it with partners and users as needed. This system will also allow clinical data to be integrated into provincial databases such as the Ministry of Health's client clinical longitudinal records and the First Nations Client File. The program has received $195,000 from Indigenous Services Canada for this endeavour.

6.6 Addressing Regulatory Challenges

Early in its implementation, the CBT program adopted a Quality Assurance Framework based on the Accreditation Canada Qmentum Global accreditation program, rather than pursuing approval from the Diagnostic Accreditation Program (DAP) of the College of Physician and Surgeons of BC, which would have created unnecessary challenges, given the remote nature of many First Nations communities and the differences between diagnostic devices that are deployed in these communities and formal laboratories in city centres. All diagnostic facilities in BC are legally required to be accredited by the DAP. While the DAP has indicated that FNHA-operated diagnostic services fall outside its jurisdiction, this has not been formally documented. The CBT program is collaborating

with the FNHA's legal department and the vice-president of clinical quality to clarify jurisdictional boundaries.

The clinical verification panels used to maintain GeneXpert testing quality are classified as dangerous goods by Transport Canada, making shipping to remote communities challenging and complex. The CBT Team is working with Indigenous Services Canada and the Public Health Agency of Canada to explore ways to modify these regulatory requirements.

6.7 Research Opportunities

There are opportunities for sharing knowledge and experiences with implementing technologies like the GeneXpert pathway. These stories will have to be told in Indigenous-led ways, informed by Indigenous ways of knowing and being. A national northern remote and Indigenous working group with membership from numerous Indigenous health care organizations across provinces and territories will support this collaborative effort.

7. Conclusion

The Community-Based Testing program has significantly contributed to improving access to culturally safe and timely COVID-19 testing in rural and remote First Nations communities in BC. Through the deployment of diagnostic and point-of-care testing devices, along with comprehensive training and support, the program aimed to empower communities to practice sovereignty in health care decision-making. Despite many operational and regulatory challenges faced early in implementation, the program was successful in bringing testing closer to home in numerous rural and remote communities and to improve access to accurate, timely, and culturally safe COVID-19 testing. The program also showed that it is possible, through close collaboration with federal and provincial partners, to implement a quality-assured decentralized community-based diagnostic and point-of-care testing program.

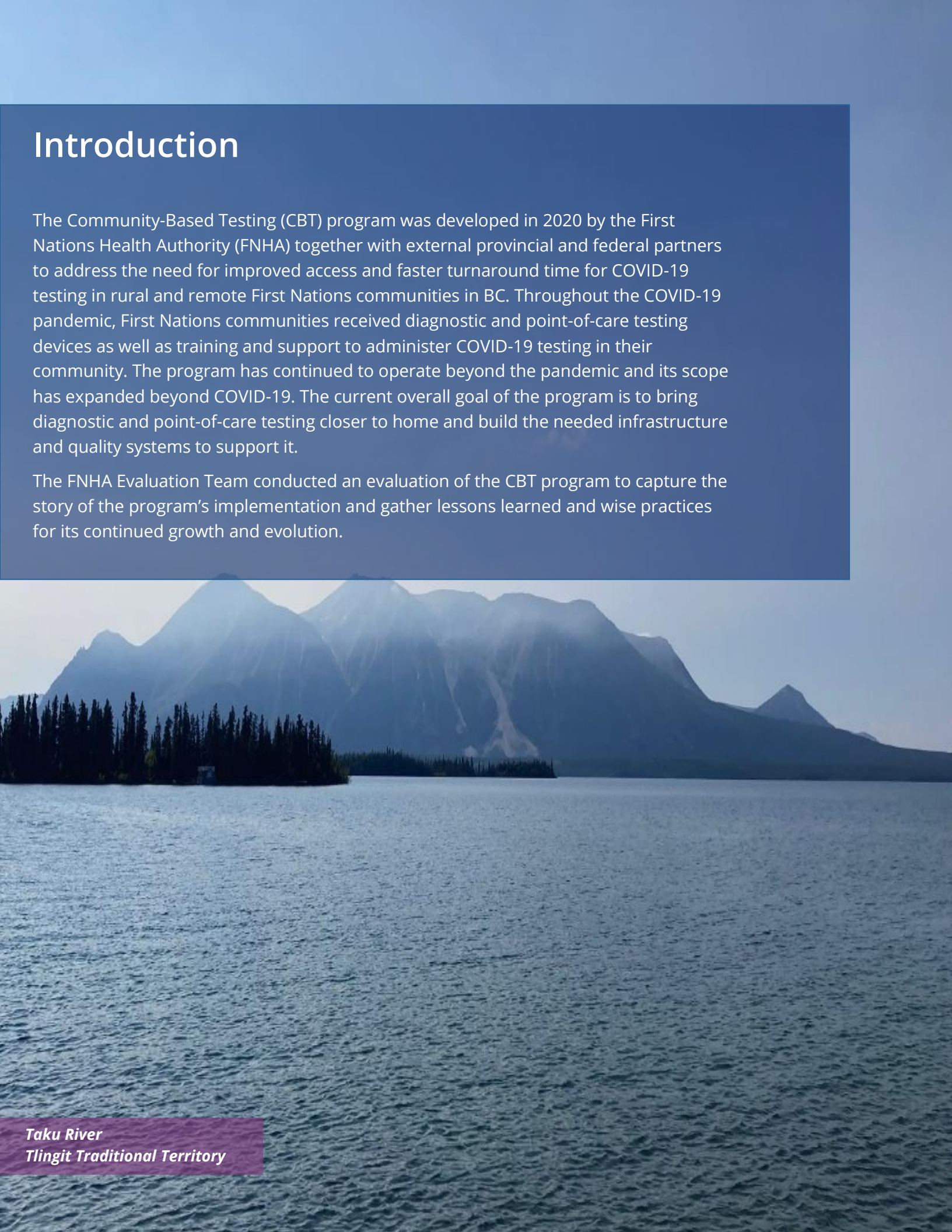
Having gathered knowledge and experience during the pandemic, responding to expressed community need, and in alignment with the 7 Directives, the FNHA sustained and expanded the program with core funding, starting in 2023. The program's focus and improvements in the past year have been aligned with the lessons learned and wise practices gathered through the evaluation. In particular, the program continues to strengthen its quality, build flexible and resilient infrastructure, and broaden its scope to bring more testing pathways closer to home. Taking leadership from First Nations communities, the FNHA also continues to work closely with provincial and federal partners to address infrastructure and regulatory challenges and build an integrated and responsive health system that meets the needs of First Nations.

The CBT program offers a unique opportunity for the FNHA and partners to walk alongside communities and help address inequities that rural and remote First Nations face regarding access to timely, accurate, and culturally safe testing.

Introduction

The Community-Based Testing (CBT) program was developed in 2020 by the First Nations Health Authority (FNHA) together with external provincial and federal partners to address the need for improved access and faster turnaround time for COVID-19 testing in rural and remote First Nations communities in BC. Throughout the COVID-19 pandemic, First Nations communities received diagnostic and point-of-care testing devices as well as training and support to administer COVID-19 testing in their community. The program has continued to operate beyond the pandemic and its scope has expanded beyond COVID-19. The current overall goal of the program is to bring diagnostic and point-of-care testing closer to home and build the needed infrastructure and quality systems to support it.

The FNHA Evaluation Team conducted an evaluation of the CBT program to capture the story of the program's implementation and gather lessons learned and wise practices for its continued growth and evolution.



Taku River
Tlingit Traditional Territory

Evaluation Approach

1. Evaluation Purpose and Scope

The purpose of the evaluation is shown in Figure 1 below.

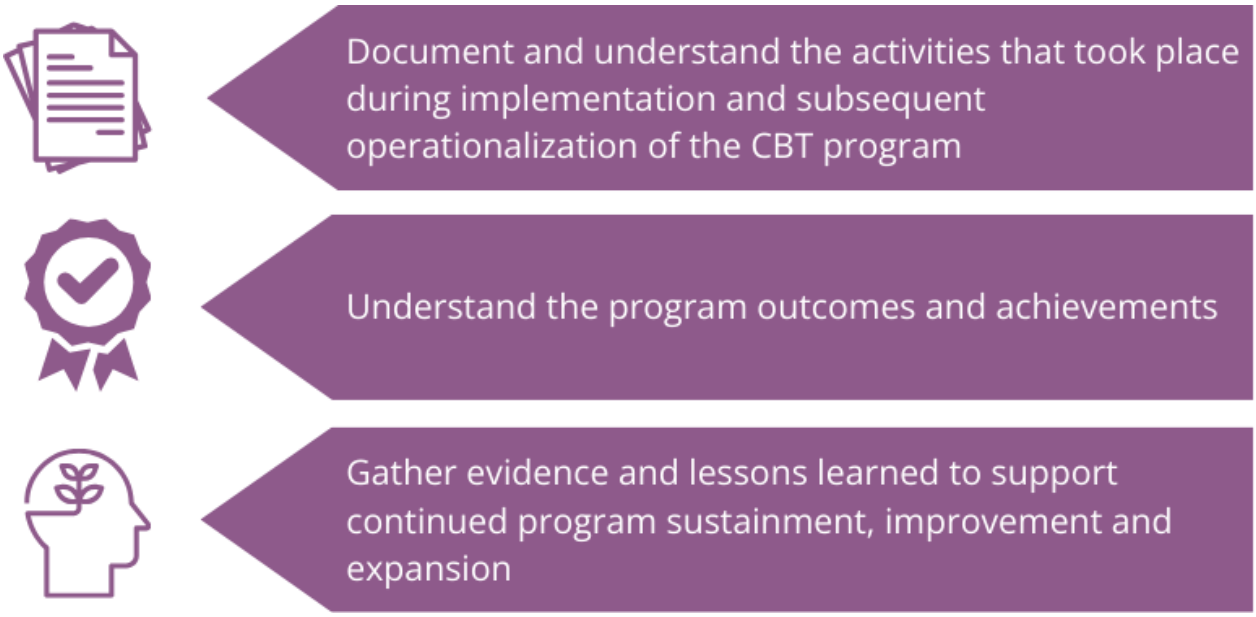


Figure 1. Purpose of the CBT program evaluation

The scope of the evaluation covers all work and activities related to the set-up and implementation of the CBT program between April 2020 and January 2023. An addendum of changes to the program between January 2023 and March 2024, as well ongoing work to improve the program, have been provided by the program area leadership and staff and are included on page 21 of this report.

2. Evaluation Approach and Methodology

The evaluation was conducted with a strengths-based lens, focusing on multiple definitions of success and opportunities for improvement.

The FNHA Evaluation Team conducted the evaluation in-house, and an advisory committee with membership from the CBT Team, FNHA regional teams, and federal and provincial partners provided input on the evaluation scoping and design. Methods included a review of relevant program documents, an environmental scan and literature review, and engagement with 61 key contributors (including 11 community health leaders) through interviews, focus groups, written

input, and online surveys. The methods and sources of knowledge for the evaluation are listed in Figure 2 below.

Figure 2. Summary of evaluation methods and sources of knowledge

The FNHA Evaluation Team used NVIVO to code and conduct a thematic analysis of the qualitative data. Findings were synthesized and triangulated across the multiple lines of evidence.

3. Limitations

Due to the inability to access in-community administrative data, this evaluation cannot report on the utilization of the testing devices. Input gathered from key contributors may be subject to confirmation and recall biases. As explained on page 11, an evaluation of the program's finances was not completed.

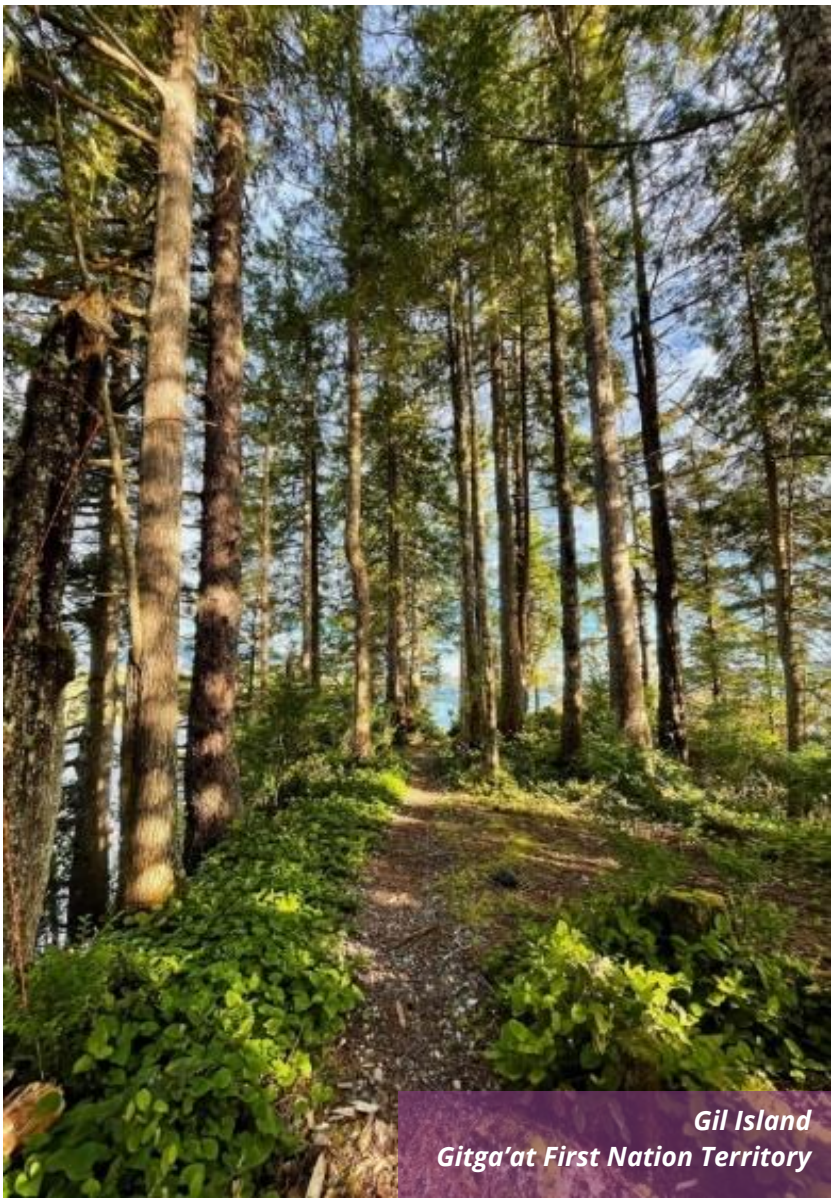
Iskut
Iskut Traditional Territory

The FNHA Community-Based Testing Program

1. Background and Rationale

The CBT program was developed in 2020 by the FNHA and provincial and federal partners in response to a critical need for improved access and faster turnaround times for COVID-19 testing for First Nations in rural and remote communities in BC. At the time, existing provincial testing infrastructure created major accessibility barriers for rural and remote First Nations community members, who often faced long travel times and delays in receiving testing results, which overall resulted in missed and late case identification. These factors contributed to missed opportunities in outbreak control, providing quality care, and timely access to therapeutics preventing onward transmission.

The CBT program was designed to address these barriers by improving equitable access to communicable disease testing, allowing for timely self-isolation of test-positive community members, protecting the community from outbreaks, and allowing for appropriate clinical action. Testing is administered in communities, and the services provided are designed to be culturally safe and support community members in feeling more comfortable during their visit. The CBT program is another step in bringing services closer to home and is line with the FNHA's 7 Directives, which are listed in Table 3 on page 14 of this report.



Gil Island
Gitga'at First Nation Territory

2. Program Governance and Key Stakeholders

The CBT program began as a joint initiative between the FNHA and both federal and provincial partners. The program is supported by the Quality Assurance Framework Oversight Committee, which is chaired by the FNHA and includes members from National Microbiology Laboratory (NML), BC Centre for Disease Control (BCCDC), Provincial Laboratory Medicine Services, and the Ministry of Health Laboratory and Blood Services Branch.

The program's partners are listed in Figure 3 below.

Figure 3. The CBT program's stakeholders during early implementation. *Some stakeholders, including VP Public Health Response, are no longer as closely involved.

3. Program Goals

The goals of the CBT program are to:

1. Improve the equity of access to testing for First Nations people and communities by bringing COVID-19 testing capability to rural and remote First Nations communities across BC.
2. Leverage additional capacity on devices by considering testing for other communicable diseases as informed by community needs.

3. Focus on resource sustainability to ensure the necessary personnel and infrastructure are in place before and after rollout.

4. Testing Equipment

The following devices were deployed as part of the CBT program.

The **GeneXpert® system** ("GeneXpert"), a real-time reverse transcription polymerase chain reaction device, which received interim use authorization from Health Canada in March 2020 as a diagnostic device for detecting the SARS-CoV-2 virus. Operating the device requires considerable set-up and training; however, it is capable of testing for many other infectious diseases, such as tuberculosis and sexually transmitted and blood-borne infections.

The **Abbott ID NOW™ analyzer**, ("ID NOW"), a point-of-care testing – *not diagnostic* – device, which can screen for the SARS-CoV-2 virus via the isothermal amplification method. Operating the device does not require extensive set-up and training; however, its capabilities beyond the SARS-CoV-2 virus are limited.

Figure 4 below shows the GeneXpert and ID NOW devices.

GeneXpert **Abbott ID NOW**

Figure 4. The GeneXpert and Abbott ID NOW testing devices

Table 1 below compares the devices with each other and with self-administered rapid tests. More details can be found in Table 4 in the Appendix.

Table 1. GeneXpert, ID NOW and rapid tests in comparison

	GeneXpert	ID NOW	Rapid Tests
Diagnostic-performance test	Yes	No	No
Positive result confirms infection	Yes	Yes	Yes
Negative result rules out infection*	Yes	No	No
Testing facilities and training required	Yes, considerable	Yes, minimal	No, can be self-administered
Testing duration	~45 minutes	~13 minutes	~15 minutes
Can be used to test for other infections	Able to test for several other communicable diseases	Limited capacity beyond COVID-19	No

** In addition to a test result, additional clinical factors would inform a diagnosis, such as specific symptoms and how long after the development of symptoms the person is being tested.*

5. Program Implementation

5.1 Existing Context (Before April 2020)

In early spring of 2020, at the onset of the COVID-19 pandemic, access to COVID-19 testing was very limited in or near many rural and remote First Nations communities. As the number of infected individuals kept increasing, First Nations communities – particularly those that are rural and remote – were not receiving COVID-19 test results in time for effective outbreak control.

Prior to the pandemic, NML had been operating a proficiency and capacity building program globally for decentralized infectious disease testing, particularly with GeneXpert devices, which had been in use in other parts of the world for many years.

NML shipped a small number of GeneXpert devices to the FNHA's central office; subsequently, the FNHA and NML began conversations on how to implement the devices in communities.

5.2 Phase I Implementation: Foundational Work and Limited Rollout (April 2020 – December 2020)

5.2.1 Formation of a CBT Steering Committee, Operations Team and Workstreams

To advance program roll-out and support device operation, the FNHA formed a governance structure that included a multi-stakeholder steering committee and an internal operations team. The steering committee included members from internal FNHA teams including the Office of the

Chief Nursing Officer (OCNO), Office of the Chief Medical Officer (OCMO), nursing operations, and regional offices, as well as external partners including NML and BCCDC. NML offered expertise and experience in deployment, training, program support, and equipment use. The partnership with BCCDC involved advocating for access and equity aligned with Indigenous frameworks and the needs of remote communities. Communication with partners was also critical to clarify roles and expectations and avoid overlap.

The Operations Team created the following workstreams to advance implementation: operations and logistics, education and clinical guidelines, public health response, and strategy and communications.

5.2.2 Development of the Quality Assurance Framework

The FNHA and its partners developed a Quality Assurance Framework to serve as a proxy for provincial regulatory requirements for testing. The framework was based on the BCCDC's Point of Care HIV Testing Program and Accreditation Canada's Qmentum Global quality assurance program. This path was recommended by the provincial COVID-19 testing sub-committee in lieu of seeking the College of Physician and Surgeons of BC's Diagnostic Accreditation Program (DAP) approval, as the latter would have been more complex and time consuming. A Quality Assurance Framework Oversight Committee was struck and chaired by the FNHA with membership including federal and provincial partners to oversee the development and application of the Quality Assurance Framework. A public-facing Quality Assurance Manual was also developed, which included a synopsis of community-based testing operating procedures (Figure 5). [1]

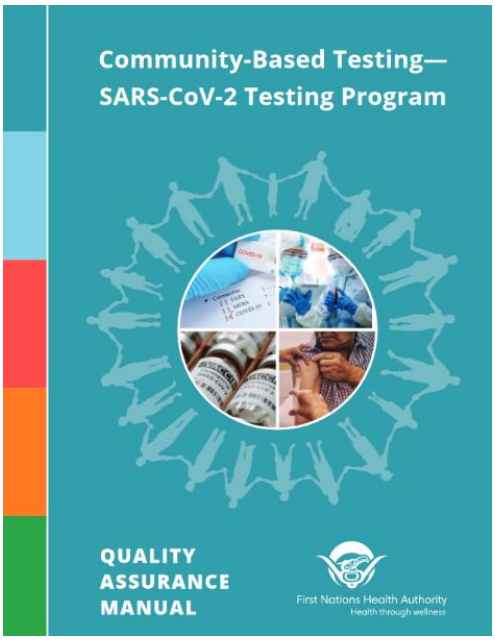


Figure 5. Cover page of the CBT program quality assurance manual.

5.2.3 Other Foundational Work

Through the early months of implementation, the FNHA led extensive foundational work to launch the program. This included:

- Developing standard operating procedures and training materials in partnership with NML;
- Developing clinical testing guidelines for the community health nurses in collaboration with BCCDC and regional health authority Medical Health Officers (MHOs);
- Developing reporting pathways for positive test results in collaboration with regional health authority MHOs; and

[1] Available on the FNHA's website: https://www.fnha.ca/Documents/FNHA-Community-Based-Testing-SARS-CoV-2-Testing-Program.pdf

- Hiring a medical lab technologist to provide training and support to community health nurses tasked with operating the testing devices.

5.2.4 Deployment of Testing Devices in Several First Nations Communities

Initial implementation included deploying three GeneXpert devices in three locations: Nuu-Chah-Nulth Tribal Council (NTC) Tofino office in the Vancouver Island Region, Kwadacha Nation's FNHA nursing station in the Northern Region and Ulkatcho First Nation near Anahim Lake in the Interior Region. These communities were selected as initial recipients of the devices based on their capacity and need.

5.3 Phase II Implementation: Program Expansion (January 2021 – September 2022)

5.3.1 Introduction of Additional Testing Devices and Continued Deployment

In early 2021, Abbott ID NOW testing devices became available for deployment in addition to GeneXpert. Abbott ID NOW offers screening-level rather than diagnostic-level test performance and completely consumes the sample during the test event. However, its installation and operation require less effort and resources than GeneXpert. The lower barrier nature of the Abbott ID NOW devices supported communities' need for access to testing, especially in the subsequent waves of the COVID-19 pandemic.

Figure 6. Sample of the Clean Spot set-up (left), later adopted for handling samples for a GeneXpert device (right of centre).
Image from Hailika'as Heiltsuk Health Centre Society, Bella Bella

To consistently and fairly determine which communities would receive the testing devices, the FNHA developed a CBT Deployment Criteria document. This document had a scoring scale that included factors such as distance to higher levels of care, turnaround time for test results, mode of transportation, and adverse conditions limiting transportation to and from the community.

The document also provided basic information about GeneXpert and Abbott ID NOW devices along with details and requirements for implementing each device.

5.3.2 Community Engagement

In addition to working closely with the FNHA regional offices, the CBT Team conducted extensive engagement to provide community health leaders with sufficient information about the technology and its requirements. FNHA regional teams offered additional insight on the need and capacity of communities, and suggested which communities would be the best candidates for receiving the equipment. Since health human resources capacity and health infrastructure vary considerably between First Nations communities and the devices required substantial resources and training to operate, careful engagement and communication were required to ensure appropriate deployment. Due to capacity constraints, especially in the earlier months of deployment, not all communities who wanted the equipment were able to receive it.

The CBT Team incorporated cultural safety and humility during initial community engagements and training. The team respected the unique needs of each community and did not rush the implementation process, even given the sense of urgency that accompanied the need for testing during the pandemic.

5.4 Phase III: Program Maintenance and Follow-up Support (September 2022 Present)

With the arrival of self-administered rapid testing in the summer of 2022, the demand for CBT devices was reduced, especially given that operating and maintaining the devices took time and effort that could otherwise be allocated to providing care.

With the successful development of training initiatives and other foundational materials, many of the original workstreams were disbanded and replaced by a permanent CBT program team. The CBT Team continued to provide education and quality management support to communities for the ongoing operation of the devices, and to deploy CBT equipment in new communities.

From program initiation until the time of drafting this report, COVID-19 testing devices were deployed and used in a total of 30 communities. Of those communities, 16 have since stopped operating the devices due to limited capacity and/or reduced need. Over time, communities switched from Abbott ID NOW to GeneXpert to take advantage of the latter device's diagnostic abilities and potential to test for other infectious diseases. Early in the winter of 2023, the testing scope of GeneXpert devices was expanded to include influenza (flu) A/B and the respiratory syncytial virus (RSV). At the time of this report's publication, all Abbott ID NOW devices were retired. See Figure 7 below for a timeline of deployment of devices in communities and the expansion to testing for RSV/flu .

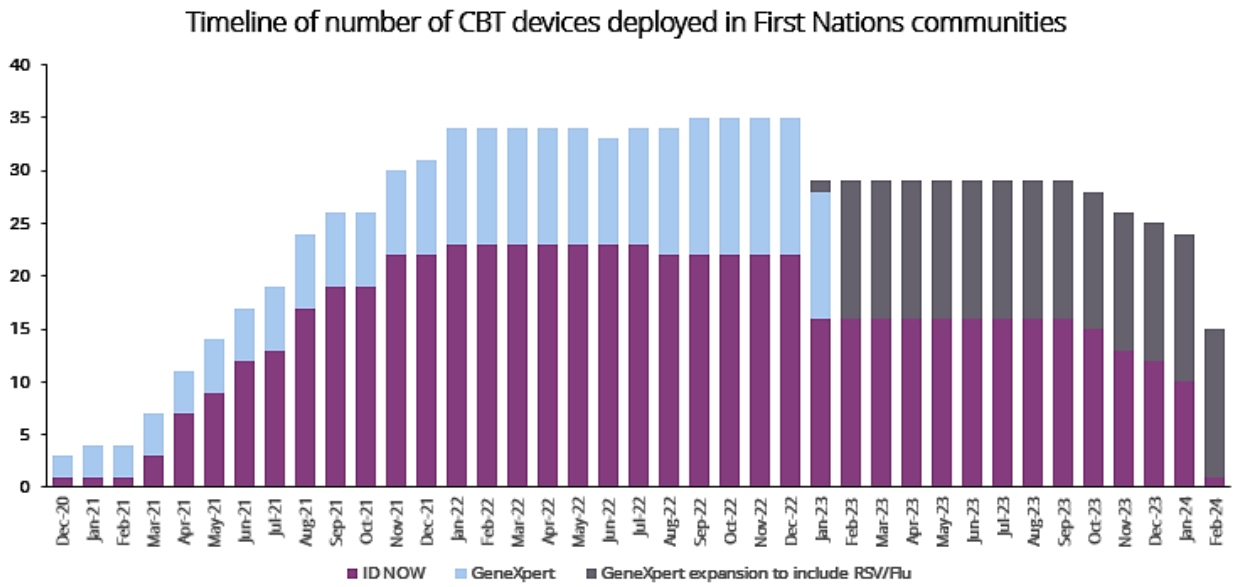


Figure 7. Timeline of deployment of CBT devices in First Nations communities

Regionally disaggregated counts of the number of communities involved in the program and devices deployed are provided in Table 2 below.

Table 2. Regionally disaggregated counts of number of communities and number of devices deployed

	Northern Region	Interior region	Vancouver Coastal Region	Fraser Salish Region	Vancouver Island Region	Total
Number of communities	16	6	4	2	2	**30**
Number of ID NOW devices deployed	15	4	3	1	0	**23**
Number of GeneXpert devices deployed	8	3	2	1	2	**16**
Number of GeneXpert devices expanded to include RSV/flu and currently active	7	3	2	1	1	**14**

The Quality Assurance Framework Oversight Committee continues to meet bimonthly to advance the program's regulatory matters, strengthen its quality, and support its integration into the health care system.

5.5 Collaborative Research Study with BC Children's Hospital (Fall 2022 – Fall 2023)

In collaboration with the FNHA, a research team at BC Children's Hospital conducted a study funded by the Rix Family Foundation to look at factors informing scope expansion of GeneXpert to include influenza A/B and RSV. For this study, health care providers were interviewed to learn about their experiences with CBT during the pandemic. This study assessed the experiences of certified operators in adopting the GeneXpert. Study findings will be used to strengthen the continuation and expansion of the program.

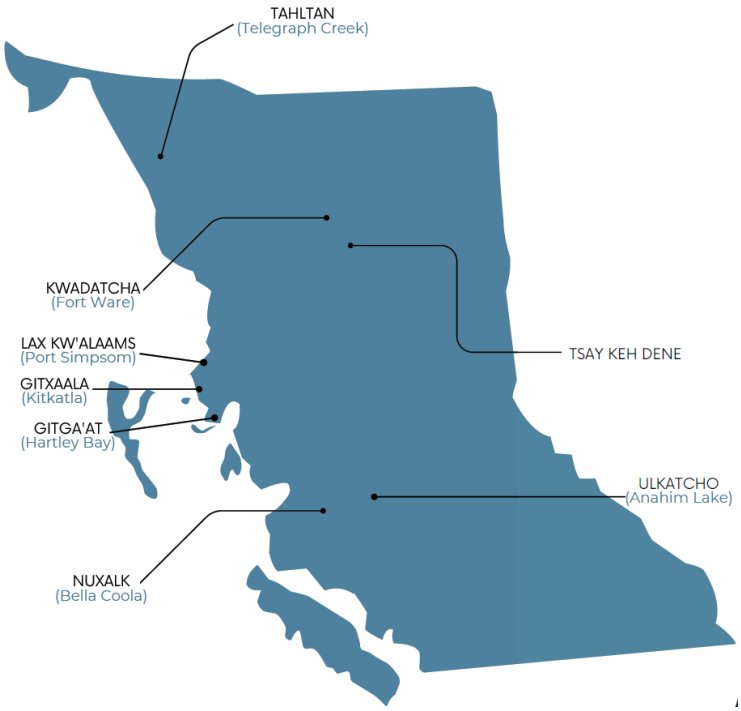


Figure 8. List of communities involved in the Rix Family Foundation-funded research study

6 Note on Program Funding

During its initial years of implementation (2020–2022), the CBT program did not have dedicated funding or staff allocation through the FNHA's core funding. During the pandemic, many FNHA staff members were redeployed from their regular roles to respond to the needs raised by the pandemic, including standing up the CBT program. The program's additional costs, such as hiring contractors, travel and incidentals, were paid for through emergency COVID-19 funding that the FNHA received from the BC Ministry of Health. The testing devices and cartridges were provided in kind by the NML. Due to lack of core funding, the program's finances were excluded from this evaluation.

An update on the current staffing and funding of this program is provided in the evaluation Addendum on page 21.

Findings: Outcomes

1 Outcomes for First Nations Communities

In communities adopting community-based testing, health teams lifted up health sovereignty by offering safe, accurate and timely testing services to their community members, and by more effectively controlling and managing outbreaks.

Partners, including community health leaders and providers, indicated that the program addressed an urgent need at the height of the pandemic in communities where devices were deployed, particularly in remote communities, which were a focus of the program. Without CBT, community members would have had to travel extensive distances to access testing in the nearest urban medical facility or have their sample shipped. In addition, receiving test results through the provincial system could take seven to 10 days. With CBT, members received accurate and reliable COVID-19 test results within a day. This allowed community health teams to quickly isolate infected individuals, control community outbreaks, and offer appropriate culturally safe care in a timely manner.

Communities felt valued and appreciated for having this technology on hand. Improved access to testing helped relieve community member stress. In addition, community members no longer had to wait in isolation for many days for their test results, and could resume their normal activities far more quickly if their test result was negative.

Being able to test here, without having people wait and isolate for several days to get a lab sample out and results back, was so much better for the mental well-being of community members. We are a small community, so having people isolate unnecessarily (if they ended up negative), impacted every department of running the community because people couldn't always work from home. Knowing quickly and having confidence in the results, meant the community did not have to shut down different departments, and people's home life and personal mental well-being was better. It also allowed for nurses to know who was positive, and monitor and support them, in case it became severe. Once treatment became available, it was important to know quickly whether someone was positive or not.

Health Director, community in Northern Region

> ***It's been a very positive thing, especially initially when there were greater repercussions and greater fear of COVID-19; when there was no vaccine and no treatment it was really important to identify and isolate early. We were often staying up very late at night doing testing that we knew was accurate, and then, being able to implement our isolation program early and immediately. Because we're an isolated community, it could end up being seven to 10 days before we get our results. It gave us the ability to ship people out that we were worried about, to wait out their symptoms in the south.***
>
> **Nurse Manager, community in Northern Region**

The expansion of community testing to RSV and flu was also welcomed by health partners, as the strengthened community capacity reduced their costs and workload.

> ***I know our community is very grateful for being able to test for COVID19, RSV and flu…Our local hospital is also appreciative that we can run the tests as they do not always have staff trained to use their device so it costs them $200 to $500 to send the swabs to Vancouver to get results.***
>
> **Nurse Manager, Community in Vancouver Coastal Region**

2 Outcomes for the FNHA

The urgency of the COVID-19 pandemic, and the complexity of the CBT program, required strong collaborative relationships with multiple internal and external partners. Apart from demonstrating the FNHA's ability to lead the province in innovation, the FNHA and its CBT program also brought in new knowledge and skills regarding laboratory testing and helped the FNHA further strengthen its relationship with First Nations communities.

Working in close collaboration across multiple internal departments and with provincial and federal partners, the FNHA was able to quickly launch a complex and novel program. Several departments within the FNHA, including FNHA Regions, Procurement and Contracting, Legal, Facilities, Occupational Health and Safety, and Human Resources, collaborated with the core provincial team to implement the CBT program. Partnerships with federal and provincial organization such as NML and BCCDC were key, as these partners brought in knowledge and expertise related to laboratory testing quality and infrastructure. The partners worked closely together and were able to strategize, problem-solve, and pivot when needed.

Special gratitude continues to be expressed to NML for generously providing devices, materials, training, and other support.

As described in Table 3 below, the CBT program was closely aligned with the 7 Directives.

Table 3. Alignment of the CBT program with the 7 Directives

7 Directives	Alignment
#1: Community-driven, Nation-Based	The program was launched in response to the needs of First Nations communities. Close engagements took place to support communities in decision-making, as well as the deployment and operation of the testing devices.
#2: Increase First Nations Decision-Making and Control	By bringing COVID-19 testing to communities, the program empowered communities to make their own decisions on pandemic response, outbreak control and the health and wellness of their members.
#3: Improve Services	Access to culturally safe COVID-19 testing in partnering communities was improved as a result of the program.
#4: Foster Meaningful Collaboration and Partnership	The FNHA built meaningful partnerships with provincial and federal partners. During deployment, training and maintenance of the program, the FNHA strengthened its relationship with partnering communities.
#5: Develop Human and Economic Capacity	Community health nurses received additional training to administer testing and operate the testing devices.
#6: Be without Prejudice to First Nations Interests	No impact on existing titles and agreements.
#7: Function at a High Operational Standard	In response to the pandemic, the FNHA quickly launched a novel and complex program. The program was evaluated to support its sustainability and quality improvement.

Wahleach Lake
Stolo Nation Territory

We walked with humility in this program. We walked very gently. We were very patient with communities. I will call them delays. We probably could've put a GeneXpert in about 100 more communities if we wanted to, but communities weren't ready for this so we had to really pause and slow down, and teach them what this was about. In those conversations, we enacted what we were taught with cultural safety and humility, and it served us really well. I think it is foundational in health care now for us to have that in anything that anybody does in health care

FNHA Executive

The FNHA really took the leadership role with regard to developing the CBT program. We brag about the FNHA, because they did such a spectacular job, and really took a lot work off our team's plate. Whereas in other jurisdictions, work was very relationship-based between NML and Indigenous communities. I think really the strong point of the relationship that we had with FNHA was they took the ground game.

Federal Partner

3 Outcomes for the Health System

The CBT program demonstrated that implementing a quality-assured decentralized community-based diagnostic and point-of-care testing program is possible and that this model that can be replicated in other jurisdictions.

Working closely with the FNHA and listening to its advocacy for First Nations communities built awareness among federal, provincial and regional partners about their responsibilities and accountability towards First Nations communities.

Through this program, the provincial and regional partners became more aware of the technological, infrastructure and regulatory challenges that limit the access of rural and remote residents, particularly First Nations, to timely laboratory testing and health services in general. This collaboration also shone a light on the responsibility and accountability of regional partners towards First Nations in rural and remote communities. At the same time, the program proved that by working together closely and applying innovative solutions, the health system can overcome these challenges and positive change can happen quickly.

This initiative can serve as an inspiration for other jurisdictions looking to implement their own community-based testing programs in rural and remote regions. The FNHA and its federal partners such as NML can champion lateral knowledge exchange and share their experience across jurisdictions.

By taking on this work, the FNHA has shown BC that they can, from an Indigenous-led perspective, support communities in a way that they've never been supported up until the pandemic. And that it really has transformed the way regional health authorities expected to consider the FNHA's unique setting and needs, and acknowledge their inherent accountability to be serving the Indigenous communities in their regions.

FNHA Program Director

The success of the program has demonstrated that it can be done. That creates space for thinking more carefully about how some of the system barriers are in place, like issues around how laboratory systems are set up and on barriers to do this innovative work or what is really needed at the community level.

Provincial Partner

This is a significant shift from centralized testing in Vancouver to being able to do advanced molecular testing in a northern community. The program has demonstrated that communities can take the leadership on protecting their citizens; they found their own pandemic response.

Federal Partner

At the beginning of the pandemic, there were a lot of people who said it's just not possible. The gold standard is the laboratory. Everything has to be done in the lab to properly connect the tests, for high-quality testing and for reliability. I think the CBT has shown that that's not true, that you can have this if you have the proper processes in place.

Federal Partner

Stave Lake, Mission
Semiahmoo First Nation Territory

Findings: Challenges and Lessons Learned

Although the CBT program had many positive outcomes and was well received and used by First Nations and the health system, its implementation and operation included numerous challenges. This chapter discusses these challenges to share learning and contribute to the continuous improvement of the program.

1 Operational and Regulatory Challenges

The operational and regulatory challenges that the program faced, especially in early months of rollout, included lack of knowledge among FNHA executives and staff about laboratory services, the need to establish many structures and materials from the ground up, having to advocate to provincial partners to include the needs of rural and remote First Nations communities in discussions about testing, and resistance from some partners about the feasibility of launching such a program.

The FNHA did not have the prior experience and expertise for running a laboratory testing program. Particularly, the organization did not have sufficient awareness of the extent and complexity of the regulatory and logistical requirements of this operation, which led to some confusion and frustrations early in rollout.

The workstreams worked very hard internally – and with regional, provincial, and federal partners – to develop the required operational structures and materials and acquire the regulatory certifications. The amount of work required to create the new structures turned out to be significantly more than initially anticipated and contributed to fatigue and burnout, especially since this work was taking place during the early months of pandemic response.

In the initial weeks of the pandemic, the provincial conversations about COVID-19 testing mostly focused on urban centres, particularly those located in the Lower Mainland. The FNHA advocated that the needs of remote Indigenous communities are different and that the current guidelines would not be relevant to them. The FNHA faced resistance from some provincial bodies about the feasibility of setting up community-based testing, but with continued advocacy and support of champions was able to advance dialogue through the Quality Assurance Framework to acquire the necessary regulatory guidance.

We didn't know what the requirements were – that we would need a fume hood. We needed a space to put one of those in and we needed a machine in that space. We needed people who were trained. We needed access to the cartridges. We needed to set up the validation processes so that we knew the machine works, for starters, and people running the machine knew what they were doing and that they could do it. There were significant trust factors, especially from the provincial lab systems who basically wanted to lead everything and wanted to do everything, but of course, that was not acceptable to the communities.

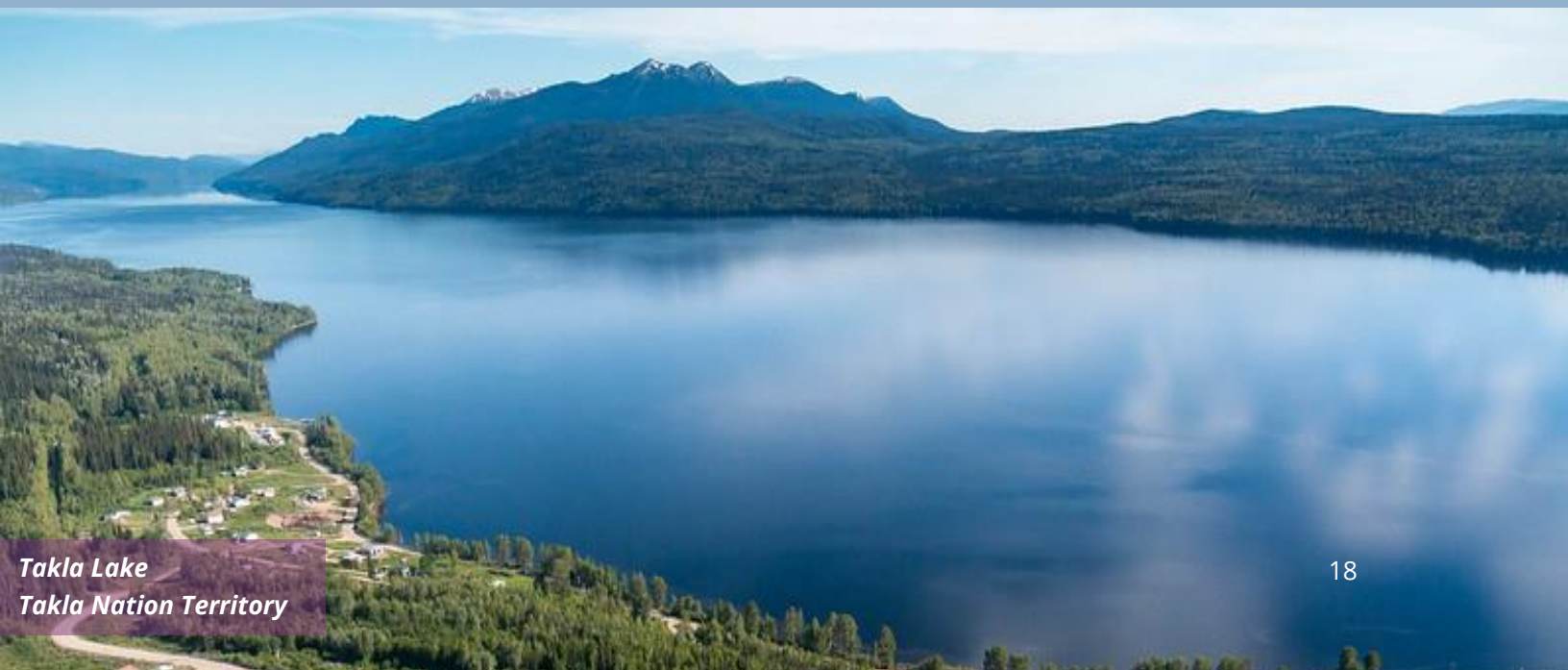
FNHA Executive

Recognizing that the provincial structures weren't working, and creating a separate space and time for those more focused discussions, was really needed. At the same time, one of my challenges as the co-chair of the testing committee was making sure that there was space at the table for the FNHA, and making sure the rural or Indigenous issues were at the forefront because you know, that wasn't the dominant voice through those provincial committees.

Provincial Partner

It became quite clear that testing guidelines were relevant and applicable to the general population but not really applicable to rural, remote, Indigenous communities. There was a significant concern around the timing of getting the guidelines together so we struck a sub-working group to develop guidelines for specifically supporting the needs of those communities with the tests that are available.

Provincial Partner



Takla Lake
Takla Nation Territory

2 Health Human Resource Challenges

This program significantly increased the workload of community health nurses, due to its novelty and complexity. Furthermore, it was a challenge to have trained nurses for operating the devices due to staff shortages and the reliance of communities on agency nurses. To some extent, offering online training helped alleviate training challenges.

Across the board, stakeholders mentioned that the rollout of the CBT program brought significant additional workload to community health nurses. This included, but was not limited to, learning to operate the devices; acquiring the necessary certifications; performing regular quality control activities; collecting, processing, analyzing, and reporting test results to clients and public health; and handling and managing supplies. This additional workload and responsibility was handed to nurses at the time when the community health teams were already under the heavy strain of pandemic response.

Training was another challenge related to human resources. Amid the nursing shortage, many communities rely on agency nurses to staff their clinics. These nurses were often not trained to operate the testing devices, which created challenges in keeping testing running. These challenges were to a certain extent overcome by offering training online, rather than in-person, later in program rollout. Community health leaders expressed gratitude for the FNHA's efforts to provide training and support, but indicated that challenges with training and nurses' workload may remain an issue depending on how health human resources in community are staffed.

…the impact of workload on nurses and capacity. Staffing at the best of the time was challenging, then to add this additional requirement or expectation was difficult. We had to really work through that as well, especially at the peak of COVID. Even for the training aspect, sign-off and certifications and all those kinds of things. It wasn't just learning the unit. It's understanding the whole public health system, response system, our reporting system, trying to engage and that, and have the nurses involved in doing that was pretty significant.

FNHA Program Director

I think the other challenge is training because of the nursing shortage. I had different nurses frequently who were not part of the original training, so we had to go into plan B and C sometimes as to how to accommodate for training. Then it was decided that training could be done online. We did have some challenges, definitely, and we still deal with the nursing shortages. That will continue to be ongoing issue that we need to work through.

Nurse Manager, Community in the Northern Region

3 Challenges with Infrastructure and Logistics

Lack of space and the need for renovations to house the equipment in some community health clinics, issues with cold chain maintenance (especially in remote communities) and the lack of integration of electronic health records were among the main infrastructure and logistics challenges that communities faced when operating the CBT program.

Many First Nations communities did not have the needed space or infrastructure in their clinics to house and operate the equipment. For example, diagnostic standards required samples to be handled in biological safety cabinets for the GeneXpert devices. Installing these cabinets required renovating community clinics, which was a challenge, especially in remote communities. Lack of space was a critical limiting factor for rolling out devices in more communities. The steady supply of materials and maintenance of cold-chain was another logistics challenge for remote communities.

Recording and reporting test results was another challenge faced by communities, especially because COVID-19 was a reportable disease as per the Public Health Officer order, meaning that it was mandatory to report positive results. Reporting difficulties stemmed in part due to lack of appropriate clinical informatics infrastructure or unstable internet access in some communities, and the lack of interoperability between the regional health authority health information systems and those of the First Nations communities. Paper-based forms needed to be developed for some communities, which also were used for downtime reporting.

Iskut Band Health Centre

Addendum (Program Updates since January 2023)

Knowledge gathering for the evaluation of the CBT program ended in January 2023. Since then, the program has been through substantial changes and made significant advances to meet the needs of First Nations communities, sustain and improve its quality, and solidify its infrastructure and logistics. A summary of these changes and advancements were provided by the CBT program team and are included below.

1 Program Sustainment, Funding, and Scope Expansion

1.1 Program Funding and Staffing

The success of the program in bringing testing closer to home made the case for its potential and continuation beyond the pandemic. As a result, the CBT program evolved from a pandemic response program – supported by COVID-19 emergency funding – to a permanently sustained program in the OCNO department. The program is now named Community-Based Testing and Biomedical Initiatives and has been assigned dedicated funding since 2023.

The Community-Based Testing program has tripled in size since 2023 with the hiring of four new team members. As of April 2024, the Community-Based Testing and Biomedical Initiatives Team consists of five permanent full-time positions and one casual position.

1.2 Expansion of the Program's Scope to Other Testing and Services

The FNHA has heard from many First Nations communities about inequities they face accessing culturally safe and responsive screening and diagnostic services. The CBT program is seeking to further improve reach and accessibility by implementing GeneXpert devices in any FNHA operational site, and First Nation Health Service Organization experiencing diagnostic service access inequities. To date, a device has been established at the All Nations Healing House, the new First Nations-led Primary Care Centre in Williams Lake.

The GeneXpert technology offers a long menu of possible testing services and the CBT Team has already broadened the scope of testing for respiratory infections to include RSV and flu A/B. The team is next partnering with other FNHA programs, such as Sexually Transmitted and Blood-Borne Infections, to bring those testing services closer to home.

The CBT program is also walking alongside First Nations communities by introducing other diagnostic services. For instance, X-ray is now being offered in two of BC's most remote First Nations communities and has transformed health outcomes for many of their community members.

Other services that could potentially be brought to communities include blood collection, screening for diabetes and other chronic diseases, and ultrasound.

2 Program Improvements

2.1 Improvements to Program Quality

2.1.1 Revising the Training and Competency Assessment Protocols to Improve Access and Quality and Ensure Standardization

The CBT program has standardized and improved the quality of its GeneXpert training component. In particular, to address training access barriers and support high quality testing outcomes, the training now includes an in-person training session, supported by two newly resourced medical laboratory technologists.

Following a virtual training session provided by NML and in-person training provided by the medical laboratory technologists, trainees undergo a practical competency assessment, where they run challenge samples on the GeneXpert device. Device operators also participate in a newly developed mandatory annual theoretical and practical recertification program to demonstrate their continued competency. Together, the initial assessment and the annual recertification will ensure that device operators' work is standardized and at high quality.

Insufficient capacity among community health nurses and a reliance on agency nurses – who are not always certified to operate the devices – was one of the challenges raised during the evaluation. To help address this challenge, the CBT program is developing a micro-credential program for community members who do not have formal health education to receive the training and gain the skills needed to operate the device. The program is also developing training through the FNHA's forthcoming simulation lab to build capacity among agency nurses and other health care providers.

2.1.2 Ensuring Quality of Testing Performance

As mentioned on page 9 (Phase III: Program Maintenance and Follow-up), in early 2023, testing was expanded beyond COVID-19 to include RSV and influenza A/B. To support this expansion, partners at BC Children and BC Women's hospitals developed clinical verification panels, which are clinically derived blinded samples, to establish the performance of the GeneXpert pathway whenever a new test is introduced. In 2023, the CBT Team traveled to all 14 GeneXpert communities as part of the influenza/RSV test additions.

2.1.3 Building a Formal Quality System

Early in implementation, the program and its partners established a Quality Assurance Framework, including a Quality Assurance Manual, standard operating procedures, an oversight committee and other components to be able to quickly launch the program while ensuring quality and temporarily satisfying regulatory requirements.

As explained below on page 24 (3.1 Clarifying Provincial Regulatory Jurisdiction over the CBT Program), the province's regulatory structure for diagnostic testing is highly restrictive and only

reasonably met by full-service diagnostic facilities located in urban and suburban centres, not rural and remote Indigenous communities, which face extreme inequities in accessing testing.

To bring testing closer to home while maintaining the high standards needed for accurate and reliable diagnostic testing, the program is building a formal quality management system for community-based testing. This quality system will be informed by the International Organization for Standardization's (ISO) requirements for quality and competence in medical laboratories (ISO 15189:2022[2]) and the Clinical and Laboratory Standards Institute 12 Quality System Essentials,[3] both which are globally agreed upon standards.

Building this quality management system will require establishing quality policies, processes and procedures and adjacent evidence for more than 400 explicit quality standards intersecting across the dimensions of testing quality, human resource management, information technology quality, occupational health and safety, facilities management, and others. The resulting quality manual will consist of critical program policies and references to standardized procedures to ensure safe, consistent diagnostic care across all communities with GeneXpert and other diagnostic pathways. In this way, the quality system will bring standardized, safe, reliable, and accurate diagnostic testing formally within reach of rural and remote communities.

Figure 9. GeneXpert device set-up at Tsay Keh Dene Nursing Station

2.2 Infrastructure and Logistics

2.2.1 Direct Shipping of Testing Materials to Communities

Once the FNHA's pandemic emergency funding was discontinued, it was unfortunately no longer possible to ship testing materials from the FNHA's Prince George office. Instead, the CBT Team worked hard to establish direct shipping routes. As of March 2024, all communities with a GeneXpert device receive their supplies directly from the CBT program.

Each time a new community adopts the GeneXpert pathway, the CBT program will identify an appropriate and reliable shipping pathway to meet their needs, regardless of how remote the community is. These shipping pathways need to be flexible, as key individuals and capacity within

[2] https://www.iso.org/standard/76677.html
[3] https://clsi.org/standards-development/quality-system-essentials/

each community change over time. Therefore, the CBT Team has established reliable communication pathways to be aware of any changes and modify the shipping pathway as needed.

Maintaining cold-chain was one of the main challenges for shipping testing cartridges to remote communities. To reduce shipping complexity, NML validated that the testing cartridges can be stored and shipped at ambient temperature and maintaining cold-chain is no longer required. However, shipping the GeneXpert clinical verification panels still needs to adhere to cold-chain protocols. For these materials, alternate shipping pathways have been established.

2.2.2 Improving and Integrating Clinical Data Storage and Reporting Systems

Inefficient data storage mechanisms and lack of data integration and accessibility were raised as a challenge in the evaluation. Clinical data created during the diagnostic procedures need to be recorded and reported in accordance with quality standards. To meet this critical need, the CBT program is building an informatics system to appropriately collect and store clinical data, communicate this data to health partners (such as regional health authorities) as needed, and also to users so they can safely access their own data. Once this system has been created, diagnostic procedures performed in communities can be integrated into provincially held databases such as the FNHA's internal electronic medical records system, the Ministry of Health's client clinical longitudinal records, and ultimately the First Nations Client File. The CBT program was recently awarded $195,000 in funding from Indigenous Services Canada to lay the foundation for this work, including finding suitable informatics products.

3 Addressing Regulatory Challenges

3.1 Clarifying Provincial Regulatory Jurisdiction over the CBT Program

As mentioned on page 7, to quickly set up the program and respond to the need for testing in First Nations communities, the CBT program and its partners established the Quality Assurance Framework, following Accreditation Canada's Qmentum Global quality assurance program in lieu of seeking College of Physician and Surgeons of BC's Diagnostic Accreditation Program (DAP) approval and accreditation. The DAP is a provincial accreditation body that exists to assure patient safety when undergoing diagnostic procedures. DAP assessment standards require meeting hundreds to thousands of criteria (similar to the global ISO 15189 diagnostic standards) before receiving accreditation, without which a BC diagnostic facility is not legally allowed to operate. The decision to build an alternative quality framework to that offered by DAP was due to the extensive infrastructure and resource requirements to meet DAP standards that are misaligned with infrastructure and resources available in remote communities hosting the GeneXpert pathway.

Despite establishing the Quality Assurance Framework and ongoing work to strengthen quality, the CBT program experiences jurisdictional uncertainty relating to the boundaries of regulatory oversight by the DAP. The DAP has previously asserted that the FNHA's operation of diagnostic services is outside their jurisdiction; however, this assertion has yet to be formally articulated in a written record. The CBT program is working closely with FNHA Legal and the Vice-President, Clinical Quality to draft a formal document confirming jurisdictional boundaries for FNHA diagnostic pathways offered to First Nations communities.

3.2 Working with Partners to Address Challenges with Transport Canada Regulations

During shipping to remote locations, packages are often passed among multiple couriers. This poses a risk when shipping temperature-sensitive biological materials, such as the custom-made clinical verification panels, which also require cold-chain maintenance. The CBT Team members therefore prefer to carry these samples to communities themselves. However, the panels are classified by Transport Canada as Category B Infectious Substances (i.e., Dangerous Goods), making it challenging to ship or carry them, especially for air transport. The CBT Team has elevated this issue to partners within Indigenous Services Canada and the Public Health Agency of Canada to explore pathways to modify or seek exemption from Transport Canada's regulatory requirements.

4 Knowledge Exchange Opportunities

The GeneXpert pathway has been in use for diagnostic testing in rural and remote jurisdictions across the world for many years. During the pandemic, other jurisdictions and Indigenous organizations (such as the Sioux Lookout First Nations Health Authority), implemented CBT in rural and remote communities. There are opportunities for the FNHA and other organizations across the country to share experience and knowledge and imagine how diagnostic testing can be brought closer to home. As such, a national working group has been formed to facilitate lateral knowledge exchange and share and leverage stories about implementing the GeneXpert pathway and other important diagnostic technologies in remote Indigenous communities.

Haida Gwaii First Nation Territory

Conclusion

The Community-Based Testing program has significantly contributed to improving access to culturally safe and timely COVID-19 testing in rural and remote First Nations communities in BC. Through the deployment of diagnostic and point-of-care testing devices, along with comprehensive training and support, the program aimed to empower communities to practice sovereignty in health care decision-making. Despite many operational and regulatory challenges faced early in implementation, the program was successful in bringing testing closer to home in numerous rural and remote communities and to improve access to accurate, timely, and culturally safe COVID-19 testing. The program also showed that it is possible, through close collaboration with federal and provincial partners, to implement a quality-assured decentralized community-based diagnostic and point-of-care testing program.

Having gathered knowledge and experience during the pandemic, responding to expressed community need, and in alignment with the 7 Directives, the FNHA sustained and expanded the program with core funding, starting in 2023. The program's focus and improvements in the past year have been aligned with the lessons learned and wise practices gathered through the evaluation. In particular, the program continues to strengthen its quality, build flexible and resilient infrastructure, and broaden its scope to bring more testing pathways closer to home. Taking leadership from First Nations communities, the FNHA also continues to work closely with provincial and federal partners to address infrastructure and regulatory challenges and build an integrated and responsive health system that meets the needs of First Nations.

The CBT program offers a unique opportunity for the FNHA and partners to walk alongside communities and help address inequities that rural and remote First Nations face regarding access to timely, accurate, and culturally safe testing.

Tofino, BC
Tla-o-qui-aht First Nation Territory

Knowledge Gathering Methods and Sources

1 Document Review

Documents and data reviewed as part of this evaluation included:

- Program internal communications, such as briefing notes, decision sheets, correspondences, and PowerPoint presentations.
- Quality Oversight Committee and Evaluation Steering Committee Terms of References, presentations, and meeting summary notes
- Program operational files, such as clinical testing guidelines, deployment criteria, and tracking guideline, and the quality assurance manual
- Program data, such as device deployment information
- Relevant FNHA internal reports, such as the COVID-19 After Action Review
- Correspondences, proposals, presentations, and meeting minutes relevant to the research project being led in partnership with the BC Children's hospital

2 Primary Knowledge Gathering

The following groups were engaged in the evaluation, through interviews, focus groups, surveys, and written input:

- FNHA Executive Leadership
- FNHA Provincial CBT Team
- FNHA Regional Teams
- Federal and Provincial Partners
- Community Health Leadership and staff
- Program Leads in other jurisdictions

Lax Kw'alaams
Lax Kw'alaams Traditional Territory

Appendix – Testing Devices and Technical Information

Table 4. Testing devices and technical information

	Cepheid GeneXpert®	Abbott ID NOW™ Analyzer	Lucira™ *Check It* COVID-19 Test Kit	Rapid Tests (Abbott Panbio and others)
Components	PCR machine, single or multiplex cartridges, computer	Machine and cartridges	Small device and small test tubes	Individual test strips
Sensitivity (for detecting COVID-19 infection)	98.8%, equivalent to lab-based testing	85.5% Sensitivity highest during first 5 days of infection in symptomatic individuals.	91.7% Sensitivity highest during first 5 days of infection in symptomatic individuals.	Varies, overall between 35-61% Sensitivity highest during first 5 days of infection in symptomatic individuals.
Positive result rules in infection	Yes	Yes	Yes	Yes
Negative result rules out infection	Yes (diagnostic test)	No	No	No
Type of molecular test	Real-Time PCR (Polymerase Chain Reaction) of viral RNA	Loop-mediated Isothermal amplification , LAMP) of viral RNA	Loop-mediated Isothermal amplification , LAMP) of viral RNA	Sars-CoV-2 Antigen detection
Sample collection	Nasopharyngeal, nasal swab, or saline gargle collected by a	Requires nasopharyngeal swab, throat or nasal swab	Requires nasal swab specimens.	Requires nasopharyngeal or bilateral nasal swab specimens collected

	Cepheid GeneXpert®	Abbott ID NOW™ Analyzer	Lucira™ *Check It* COVID-19 Test Kit	Rapid Tests (Abbott Panbio and others)
	trained professional	specimens collected by trained HCP Saline gargle specimens are not suitable	Authorized for self-collection for individuals aged 14+ and adult collection for children aged 2-13yrs	by trained professional. Saline gargle specimens are not suitable
Sample processing time	Results in 45min after loading of cartridge	13min	11 min for positive result and 30min for negative result	Result within 15 min.
Training	Requires extensive training. Quality oversight and recalibration required	Required training. Quality oversight and recalibration required	Considered self-test	Considered self-test
Reporting	Follows BCCDC reporting pathway.	Follows BCCDC pathway for reporting	No reporting required.	No reporting required.
Space	Special requirements for testing space to minimize cross-contamination and to protect staff	Some special requirements for testing space to minimize cross contamination and protect staff	None	None
Other applications	Currently, Multiplex cartridge detects SARS-CoV-2 /Flu A & B /RSV 2. Many other tests cartridges	Other cartridges for specific communicable diseases are available for use on this instrument e.g.	None	None

	Cepheid GeneXpert®	Abbott ID NOW™ Analyzer	Lucira™ *Check It* COVID-19 Test Kit	Rapid Tests (Abbott Panbio and others)
	available for communicable diseases including TB, STBBIs, etc.	Flu A,B, RSV & Strep A2.		
Cost (cartridge or strip)	~$55 CAN (Single use SARS- CoV-2) ~$75 (Multiplex: Flu A,B RSV & SARS-CoV-2)	~$15 CAN	~$64 CAN	~$6 CAN