Community-Based Testing—SARS-CoV-2 Testing Program

QUALITY ASSURANCE MANUAL

First Nations Health Authority
Health through wellness
# Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
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<tbody>
<tr>
<td>0.1</td>
<td>2020-09-24</td>
<td>PPQ</td>
<td>Initial draft</td>
</tr>
<tr>
<td>0.2</td>
<td>2020-10-01</td>
<td>PPQ</td>
<td>Revised draft per comments from Executive/Oversight Committees</td>
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<td>Revised draft per comments from Steering Committee, including Updated COVID-19 GENEXPERT: SPECIMEN HANDLING, PREPARATION, AND TESTING section with SOP version October 20, 2020.</td>
</tr>
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<td>2020-10-27</td>
<td>PPQ</td>
<td>Included Reporting Pathway text and diagram</td>
</tr>
<tr>
<td>0.5</td>
<td>2020-11-25</td>
<td>PPQ</td>
<td>Revised draft per comments from Oversight Committee</td>
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INTRODUCTION

Contact Information for the FNHA SARS-CoV-2 community-based testing program

<table>
<thead>
<tr>
<th>Phone:</th>
<th>1 (604) 693 6562</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax:</td>
<td>1 (604) 913 2081</td>
</tr>
<tr>
<td>E-mail:</td>
<td><a href="mailto:jeanne.harper@fnha.ca">jeanne.harper@fnha.ca</a></td>
</tr>
<tr>
<td>Website:</td>
<td><a href="http://www.fnha.ca">www.fnha.ca</a></td>
</tr>
</tbody>
</table>

Purpose:

The purpose of this manual is to provide high-level guidance regarding the clinical use and operational considerations of First Nations Health Authority (FNHA) owned or leased SARS-CoV-2 community-based testing equipment in BC at approved BC First Nation test sites.

This manual is not intended to house all Standard Operating Procedures (SOP); where appropriate, the manual directs the reader to seek further guidance on operations from any relevant SOPs.

The manual is presented as separate topics to enable readers to quickly access information.

Background:

Effective and timely SARS-CoV-2 testing is critical to support the public health response to the COVID-19 pandemic in the province, including BC First Nations communities. A quality assurance framework for community-based SARS-CoV-2 testing tailored for FNHA direct service operational sites (i.e., health centres and nursing stations), transferred direct service sites (i.e., health centres or nursing stations), or regional health authority operated sites is needed to ensure access to effective and timely COVID-19 testing in First Nations communities.

The FNHA intends to implement community-based SARS-CoV-2 testing in First Nations communities using the GeneXpert® system and Xpert ® Xpress SARS-CoV-2 assay (collectively “GeneXpert”). The BC First Nations Community-Based COVID-19 Testing Quality Assurance Program (QAP) is being created, with intended full implementation in FY 2020-21 and to be evaluated as deemed necessary by the QAP Oversight Committee.

GeneXpert has received Interim Use Authorization (March 2020) from Health Canada as a diagnostic device for the qualitative detection of COVID-19 for both laboratory use and
community-based use. The approval for community-based use states that the testing unit may be used by those outside a clinical laboratory and by those who demonstrate proficiency using the testing unit as long as the sample itself (i.e., nasal pharyngeal swab and saline gargle rinse) is collected by a health care professional. Note: The National Microbiology Lab (NML) signs off and certifies users at the end of their training.

The FNHA SARS-CoV-2 community-based testing program is a joint initiative between the FNHA and federal and provincial partners, and it is led by an oversight committee including representatives from the FNHA, NML, Provincial Health Services Authority (PHSA) and regional health authorities.

The FNHA’s community-based SARS-CoV-2 testing program aligns to the BC Centre for Disease Control (BCCDC) guidelines regarding eligibility for testing.

Guiding Principles

Alignment with FNHA 7 Directives:

Directive #1: Community-Driven, Nation-Based

• The Community-Driven, Nation-Based principle is overarching and foundational to the entire health governance arrangement.
• Program, service and policy development must be informed and driven by the grassroots level.
• First Nations community health agreements and programs must be protected and enhanced.
• The autonomy and authority of First Nations will not be compromised.

Directive #2: Increase First Nations Decision-Making and Control

• Increase First Nations influence in health program and service philosophy, design and delivery at the local, regional, provincial, national and international levels.
• Develop a wellness approach to health that prioritizes health promotion and disease and injury prevention.
• Implement greater local control over community-level health services.
• Involve First Nations in federal and provincial decision-making about health services for First Nations at the highest levels.
• Increase community-level flexibility in spending decisions so communities can meet their own needs and priorities.
• Implement the OCAP (ownership, control, access and possession) principle regarding First Nations health data, including leading First Nations health reporting.
• Recognize the authority of individual BC First Nations in their governance of health services in their communities and devolve the delivery of programs to local and regional levels as much as possible and when appropriate and feasible.

Directive #3: Improve Services

• Protect, incorporate and promote First Nations knowledge, beliefs, values, practices, medicines and models of health and healing into all health programs and services that serve BC First Nations.
• Improve and revitalize the Non-Insured Benefits program.
• Increase access to primary care, physicians, nurses, dental care and other allied health care by First Nations communities.
• Through the creation of a First Nations Health Authority and supporting a First Nations population health approach, First Nations will work collectively to improve all health services accessed by First Nations.
• Support health and wellness planning and the development of health program and service delivery models at local and regional levels.

Directive #4: Foster Meaningful Collaboration and Partnership

• Collaborate with other First Nations and non-First Nations organizations and governments to address social and environmental determinants of First Nations health (e.g., poverty, water quality, housing, etc.).
• Partnerships are critical to our collective success. First Nations will create opportunities by working collaboratively with federal, provincial, and regional partners.
• Foster collaboration in research and reporting at all levels.
• Support community engagement hubs.
• Enable relationship-building between First Nations and the regional health authorities and the FNHA with the goal of aligning health care with First Nations priorities and community health plans where applicable.

Directive #5: Develop Human and Economic Capacity

• Develop current and future health professionals at all levels through a variety of education and training methods and opportunities.
• Pursue opportunities to leverage additional funding and investment and services from federal and provincial sources for First Nations in BC.
• Pursue economic opportunities to generate additional resources for First Nations health programs.

**Directive #6: Be Without Prejudice to First Nations Interests**

• No impact on Aboriginal Title and Rights or the treaty rights of First Nations, and be without prejudice to any self-government agreements or court proceedings.
• No impact on the fiduciary duty of the Crown.
• No impact on existing federal funding agreement with individual First Nations, unless First Nations want the agreements to change.

**Directive #7: Function at a High Operational Standard**

• Be accountable, including through clear, regular and transparent reporting.
• Make best and prudent use of available resources.
• Implement appropriate competencies for key roles and responsibilities at all levels.
• Operate with clear governance documents, policies and procedures, including for conflict of interest and dispute resolution.

**Alignment with FNHA Shared Values:**

**Respect**

We believe that maintaining respectful relationships is fundamental to the achievement of our shared vision. Respectful relationships are built upon the recognition that we all have something to contribute as individuals and as participants in the First Nations health governance structure. We therefore commit to treating each other with dignity and generosity, being responsive to one another, and acknowledging that each entity has their own respective processes and practices. We are also committed to respectful interactions with First Nations, tripartite partners and other collaborators.

**Discipline**

We have the historic opportunity to achieve transformative change in First Nations health and wellness, and an obligation to make the most of this opportunity. This will require discipline amongst us, including through loyalty to one another and our shared vision; upholding and supporting our roles, responsibilities, decisions, and processes; maintaining
and nurturing unity and a united front; demonstrating integrity and reliability in fulfilling our commitments; being accountable to one another for these commitments and contributions; and encouraging solutions-oriented and active participation.

**Relationships**

We believe that effective working relationships with First Nations, tripartite partners and one another are the foundation for achieving our vision and implementing our health plans and agreements. We commit to fostering effective working relationships and camaraderie underpinned by trust, honesty, understanding, teamwork and mutual support. We also acknowledge that humour and laughter are both good medicine, and a good way to build relationships.

**Culture**

We are here because of those that came before us, and to work on behalf of First Nations. We draw upon the diverse and unique cultures, ceremonies, customs and teachings of First Nations for strength, wisdom and guidance. We uphold traditional and holistic approaches to health and self-care and strive to achieve a balance in our mental, spiritual, emotional and physical wellness.

**Excellence**

We are humbled and honoured to have been asked by First Nations to work on their behalf to improve health and wellness, and we have a moral and personal responsibility to strive for excellence. Excellence means that our outcomes are sustainable, that our processes are professional and transparent, and that we commit to learn continuously – through capacity development opportunities, from each other and from new, different and innovative models worldwide.

**Fairness**

We work to improve the health and wellness of all First Nations in BC. Our decision-making reflects the best interests of all First Nations and leads to just and equitable treatment amongst all First Nations communities, First Nations organizations and across all regions of British Columbia. We are committed to making room for everyone and are inclusive in our communications, information-sharing and discussions.
**DEFINITIONS AND ACRONYMS**

**Definitions:**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>SARS-CoV-2</td>
<td>Severe Acute Respiratory Syndrome Coronavirus 2, the virus responsible for the disease COVID-19.</td>
</tr>
<tr>
<td>COVID-19</td>
<td>Coronavirus disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).</td>
</tr>
<tr>
<td>Community-based test</td>
<td>Similar to Point of Care Testing (POCT), community-based testing is defined as medical diagnostic testing performed outside the clinical laboratory in close proximity to where the patient is receiving care. However, with Community-Based Testing, specimens will be shipped over considerable distances to the test sites.</td>
</tr>
<tr>
<td>GeneXpert DX</td>
<td>The GeneXpert System is a cartridge-based nucleic acid amplification test and is a widely accepted diagnostic test for SARS-CoV-2. The GeneXpert instrument has specific test cartridges able to detect many communicable diseases. The “Expert Express” test cartridge has been developed specifically to detect SARS-CoV-2 and is authorized for use in Canada. The “DX” designation applies to the type of software used to run the instrument.</td>
</tr>
<tr>
<td>False positive result</td>
<td>A false positive result is reported when the result for confirmatory testing is not indicative of SARS-CoV-2 infection, but the community-based result was reactive.</td>
</tr>
<tr>
<td>False negative result</td>
<td>A false negative result is reported when the community-based test fails to detect a SARS-CoV-2 infection.</td>
</tr>
<tr>
<td>FNHA Nursing Station</td>
<td>FNHA Nursing Stations are led by Community Health Nurses (CHNs) who work in an expanded scope of practice to provide primary care, public health, health promotion and emergency care for First Nations individuals, families and communities, including after hours on-call care. CHNs in FNHA Nursing stations are able to obtain a designated Remote Certification, RN(c) through the BC College of Nurses and Midwives (BCCNM). The FNHA currently has eight Nursing Stations staffed by two to four CHNs in locations ranging from coastal to northern communities. Nursing stations are made up of full-time, part-time and casual positions.</td>
</tr>
<tr>
<td>FNHA Health Centre</td>
<td>An FNHA Health Centre is led by CHNs who provide a comprehensive range of nursing services to First Nation</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>FNHA facility</td>
<td>A facility that is owned and operated by FNHA, governed by FNHA rules and regulations when it comes to health care delivery.</td>
</tr>
<tr>
<td>Non-FNHA facility</td>
<td>A facility that is not owned or operated by FNHA, and therefore is not governed by FNHA rules and regulations when it comes to health care delivery.</td>
</tr>
<tr>
<td>Equipment License Agreement</td>
<td>Legal agreement with non-FNHA entities to share use of the FNHA's COVID-19 community-based testing equipment to conduct COVID-19 tests for eligible First Nations patients on the terms and conditions laid out in the agreement. Non-FNHA facilities using FNHA owned or leased COVID-19 testing equipment require an Equipment License Agreement.</td>
</tr>
<tr>
<td>Proficiency Test (PT)</td>
<td>A high-level Quality Assurance activity that involves a group of test locations performing the same test on the same unknown samples(s). Results are analyzed for all results and the resultant report compares the test location performance to the group.</td>
</tr>
<tr>
<td>Quality Assurance (QA)</td>
<td>All planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil the requirements for quality.</td>
</tr>
<tr>
<td>Quality Control (QC)</td>
<td>The activities undertaken to verify the accuracy of a test result or the operational techniques and activities used to fulfil requirements for quality. Quality control materials are tested to ensure each lot of SARS-CoV-2 community-based test kits is reacting and performing as expected, and to assess that a test provider can see the colour reaction of a weak positive, under the test environment lighting levels.</td>
</tr>
<tr>
<td>Test provider</td>
<td>An individual who performs SARS-CoV-2 community-based tests. This person is aligned with a SARS-CoV-2 community-based test location, and meets test location, health authority and provincial program training and competence requirements.</td>
</tr>
<tr>
<td>QASI-COVID-19</td>
<td>QASI is a Proficiency Testing program developed by the National Microbiology Lab Scientists for GeneXpert SARS-CoV-2 testing. “Blinded” samples are sent on a regular basis (three to four times per year) to test the performance of staff and</td>
</tr>
</tbody>
</table>

Communities. Their practice is grounded in health promotion and disease prevention and aims to build the capacity of individual, family and community wellness. Health centre CHNs work in partnership with community to develop and implement relevant, culturally centered interventions providing services in clinic, home and community settings. CHNs in this setting are not on call and they do not provide emergency services.
accuracy of results of the testing operation in comparison to other facilities' test results. All results are assessed by NML.

Standard Operating Procedures

Established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations.

Competency

The knowledge, skill, ability and judgment required for safe and ethical practice.

Sample/Specimen

Used interchangeably in this document, refers to a person's tissue, fluid or other material derived from the person used for analysis to detect SARS-CoV-2.

Hailcista

The Hailcista quality reporting system is an FNHA web-based tool used to report, document follow-up and learn from incidents and near misses at FNHA Nursing Stations, replacing paper documentation.

Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Term</th>
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<tbody>
<tr>
<td>BC</td>
<td>British Columbia</td>
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<tr>
<td>BCCDC</td>
<td>British Columbia Centre for Disease Control</td>
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<tr>
<td>BCCNM</td>
<td>British Columbia College of Nurses and Midwives</td>
</tr>
<tr>
<td>CHR</td>
<td>Community Health Representative</td>
</tr>
<tr>
<td>HA</td>
<td>Health Authority</td>
</tr>
<tr>
<td>MHO</td>
<td>Medical Health Officer</td>
</tr>
<tr>
<td>NML</td>
<td>National Microbiology Lab</td>
</tr>
<tr>
<td>RN/RPN/LPN</td>
<td>Registered Nurse/Registered Psychiatric Nurse/Licensed Practical Nurse</td>
</tr>
<tr>
<td>MLT</td>
<td>Medical Laboratory Technologist</td>
</tr>
<tr>
<td>NRACP</td>
<td>Non-Regulated Allied Health Care Provider</td>
</tr>
<tr>
<td>PCC</td>
<td>Probe Check Control</td>
</tr>
<tr>
<td>PHL</td>
<td>Public Health Laboratory</td>
</tr>
<tr>
<td>PHSA</td>
<td>Provincial Health Services Authority</td>
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<tr>
<td>PLM EOC</td>
<td>Provincial Laboratory Medicine Emergency Operations Centre</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
</tr>
<tr>
<td>PT</td>
<td>Proficiency Test</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QAP</td>
<td>Quality Assurance Program</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>SPC</td>
<td>Sample Processing Control</td>
</tr>
<tr>
<td>TDG</td>
<td>Transportation of Dangerous Goods</td>
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Reporting Test Kit Concerns

Reporting Concerns Regarding the Quality of COVID-19 GeneXpert DX Tests

Test providers may be the first to suspect issues with the quality of COVID-19 GeneXpert Express tests and/or controls.

Potential indications that GeneXpert tests may not be performing as expected include:

- Increase in the number of clients with invalid or false positive results
- Incorrect GeneXpert test results with the use of QC samples
- Incorrect GeneXpert test results for Proficiency Test samples
- Problems with packaging/shipping/receiving
- Problems with the specimen collection (of viral swabs or saline gargle)

Any concerns of this nature can be reported (and should include the master lot number of the implicated GeneXpert Express test kit or QC test) to:

- GeneXpert Test location Supervisor and/or
- Provincial COVID Testing Program and/or
- BCCDC

Follow up with Technical@Inter-Medico.com for troubleshooting error codes during testing.

Refer to the Inventory Management section below.
# New Site Approval Requirements

The GeneXpert Instrument System consists of an instrument, computer and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the reagents to test for SARS-CoV-2 nucleic acid.

Requirements need to be met to install and operate GeneXpert DX SARS-CoV-2 testing units in community. Requirements also need to be met to transport testing cartridges from a nearby community to a community where a testing unit is located.

New sites may be required to perform WorkSafeBC safety audits.

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategic Location</strong></td>
<td>• Phase one: Ideal placement would be in a community that requires more than six to eight hours for a patient transfer to the nearest higher level of care provincial hospital</td>
</tr>
<tr>
<td></td>
<td>• Phase one: Ideal placement would be in a community that does not have access to daily SARS-CoV-2 testing with a 24-hour turnaround time to receive results</td>
</tr>
<tr>
<td></td>
<td>• Written agreement between FNHA and non-FNHA facility if placed outside of an FNHA-operated facility</td>
</tr>
<tr>
<td><strong>Telecommunication Infrastructure</strong></td>
<td>• Selected communities should have a minimum bandwidth of 10 Mbps and connectivity via fibre. Satellite-only service is not recommended</td>
</tr>
<tr>
<td><strong>Testing Unit Physical Space</strong></td>
<td>• A well-ventilated room that is temperature controlled (15°C-28°C), and includes proper air flow, air circulation and exhaust systems. Subject to inspection</td>
</tr>
<tr>
<td></td>
<td>• A stable surface (such as a table) that is minimum 240-cm (~8 feet) wide in size away from an air conditioning vent or a window and away from direct sunlight to place equipment on, with 5-10 cm of clearance surrounding the equipment from walls or other objects</td>
</tr>
<tr>
<td></td>
<td>• Required equipment includes a laptop; uninterruptable power supply (&lt;30-cm wide), GeneXpert Unit (28-cm wide) wide, a scanner (&lt;340-cm wide) and printer (&lt;60-cm wide)</td>
</tr>
<tr>
<td></td>
<td>• Power source (maximum three required; 1 when connecting through an uninterruptable power supply)</td>
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<tr>
<td></td>
<td>• Floor space for biological safety cabinet that is a minimum 130 cm (L) x 157 cm (H) x 80 cm (W) in size</td>
</tr>
</tbody>
</table>
| Storage of Consumables | • Storage environment for cartridges between 2°C-28°C (such as in a fridge or 24/7 temperature-controlled room/space) and in an environment that keeps them dry and away from moisture/water  
• Back-up power or generator installed for fridges  
• Temperature-controlled fridge at 4°C for storage of reagents |
| --- | --- |
| Transportation of Specimens from Neighboring Community to Testing Unit | • Staff with a Transportation of Dangerous Goods (TDG) training certificate when handling, offering for transport and transporting specimens (patient swabs, saline gargle)  
• Type P650 packaging or Type P620 packaging for handling, offering for transport and transporting of patient swabs  
• Transportation environment between 2°C-28°C  
• Ability to meet a seven-hour timeframe between taking the swab specimen and analyzing it. This timeframe extends up to seven days if swabs are refrigerated. The timeframe does not apply to the saline gargle. |
| Human Resource and Training | • Staff with time/capacity and willingness to undergo approximately two hours of self-directed online education and approximately four hours of an in-person training/competency validation session  
• Staff with TDG training  
• Staff with workload capacity to obtain, prepare, handle and test specimens and report results (approximately 2-3 hours/case)  
• Staff with workload capacity to conduct regularly scheduled QC and maintenance requirements |
**Roles and Responsibilities**

**Roles and Responsibilities of FNHA:**

- Conduct a site assessment at the site and, within FNHA’s discretion, make reasonable improvements to the site where the equipment will be located.
- Collaborate with the site to transport and set up the equipment according to established standards and procedures.
- Arrange for and provide ongoing supply orders and transport those supplies to the site.
- Partner with the site to provide training and clinical guidance on the use of the equipment.
• Validate operator competency and confirm NML certification prior to operating/testing.
• Answer general inquiries related to clinical requirements and information management and technology setup of the equipment.
• Define the reporting requirements for the site’s utilization reports.
• Partner with the Ministry of Health, the BCCDC and others as required to develop a GeneXpert Quality Framework to oversee QA over the equipment and its uses by the site’s users.
• At the FNHA’s discretion, conduct an audit or review of the site’s use of the equipment, the utility of the equipment and the site’s responsibilities.
• Advise the site of any changes to established standards and procedures and mandatory compliance requirement.

Roles and Responsibilities of the site location:

• Hire and/or contract nurse practitioners, registered nurses, medical laboratory technicians and/or medical laboratory technologists to act as authorized users that will use the equipment at the facility.
• Be responsible for managing and processing COVID-19 sample tests.
• Ensure that the equipment and sample results have interface compatibility with the GeneXpert DX system so that all sample results are uploaded, used and disclosed according to established clinical procedures.
• Be responsible for safeguarding and protecting all patient records and data management of the test results and any records created.
• Report, document and action completed COVID-19 tests in accordance with established requirements.
• Ensure that all users:
  o complete the required training to use the equipment and adhere to the clinical and SOPs;
  o are either licensed nurses that are in good standing with the BCCNM or Medical Laboratory Technologists registered with the Canadian Society for Laboratory Technologists or Cross Trained Medical Laboratory that have credentials from a provincially approved institution;
  o adhere to their professional requirements and best practices defined by regulatory bodies, all health and safety protocols that are required prior to
using or operating the equipment, Provincial Health Officer and other health authority orders and other legal requirements;
  o operate all instruments and equipment in a reasonable and safe manner in accordance with the established operating procedures; and
  o have all of the competencies that are required by this license validated by the FNHA and NML.
• Support information sharing with the FNHA where required.
• Ship, maintain and repair the equipment, including conducting and documenting routine and annual maintenance according to the manufacturer and regulatory requirements.
• Enroll in the QASI-COVID-19 proficiency testing program with the Public Health Agency of Canada or an equivalent testing program.
• Communicate collaboratively with the FNHA at regular intervals about the use of the equipment.
• Decontaminate the equipment according to the manufacturer’s instruction documents, prior to maintenance or repair.
• Dispose of all waste and store and maintain the equipment at the facility according to the established standards and the users’ professional and legal requirements.
• Comply with any changes to established or new standards.
• Retain overall responsibility and liability for the actions of its employees, agents and/or contractors that act on the site’s behalf, and the safe use of the equipment by all of its users.
COMPETENCIES AND TRAINING

Competencies are inclusive of “knowledge, skill and decision-making” capabilities for safe care and practice. Health professionals who can be trained to operate this testing unit include Registered Nurses, Nurse Practitioners, Medical Lab Technologists, Medical Lab Technicians and Physicians. Testing of the specimen (swab or saline gargle specimen) will be done by professional practitioners, trained by the FNHA and certified by the NML.

To ensure quality testing and results, competencies and relevant training have been determined for steps along the full spectrum from specimen collection to testing, including QC practices. A comprehensive education plan for learners has been developed and includes all practice elements from specimen collection (nasopharyngeal swabs and saline gargle), quality maintenance and control, specimen testing using the GeneXpert and results reporting. The learning strategies are a combination of learner-directed/self-directed activities (reading of policies, viewing of videos, knowledge competency tests) and on-site, in-person demo/return demonstration and competency validation by a medical lab technologist.

The education pathway for the GeneXpert DX System has been developed to help support new test operators with the necessary training to operate the device. The following topics are included in the learning:

• Scope of practice: RN/LPN/RPN
• Clinical procedure: nasopharyngeal swab procedure
• Specimen reporting
• Lab design and workflow overview
• Installation, setup and data management
• Maintenance of GeneXpert
• Waste and spills management
• Preparing, handling specimens, testing and documentation: Quality Control (QC)
• Specimen handling, preparation and testing
• Specimen reporting pathway

The Lesson Plans are designed to guide learners through learning objectives, learning activities and skill development. Within each learning activity are various modes of learning, including procedure documents, PowerPoints and videos. The total package takes approximately four hours to complete. After working through the learning materials, learners complete an online knowledge competency quiz.
Further competency development will occur through on-site, in-person instruction with a Medical Lab Technologist (MLT). The MLT will validate the learner's competence and sign off the “competency checklist.”

Final certification is granted by NML upon receipt of two testing control reports (Accuplex) for each user.

Records of training and certification are maintained by:

- the FHNA Office of the Chief Nursing Officer Clinical Education
- the NML

Sites are responsible for ensuring that designated operators are trained and certified.

Scheduled re-validation of competency and certification will be supported by FNHA Clinical Education as identified by operators and/or site supervisors, and in accordance with the NML requirements for certification/recertification.

**COMPETENCY VALIDATION CHECKLIST:**

<table>
<thead>
<tr>
<th>Scope of practice</th>
<th>Completed</th>
<th>Date Y/M/D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical procedure: nasopharyngeal swab procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab design and workflow overview</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Installation, setup and data management</td>
<td></td>
<td></td>
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<tr>
<td>Maintenance of GeneXpert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste and spills management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparing, handling specimens/testing and documentation: Quality Control (QC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen handling, preparation and testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Scope of Practice
Demonstrates swab testing within their designate scope in a safe, ethical and competent way that takes into consideration cultural safety and humility

Clinical procedure: Nasopharyngeal swab procedure
Performs procedure to obtain nasopharyngeal specimen suitable for accurate testing

Specimen Reporting
Will demonstrate communication of results to client and/or family in a way that is respectful of where the client is and adheres to components of cultural safety

Lab design and workflow overview
Demonstrates required work flow practices to avoid/decrease risk of infection/exposure to:
- Client
- Self and other staff/ personnel

Demonstrates required infection prevention control practices to decrease risk of specimen contamination/cross-contamination

Installation, setup and data management
Knowledgeable in setup of SARS-CoV-2 testing device, GeneXpert
Safe operation in order to provide accurate and meaningful results for patients

Maintenance of GeneXpert
Validates equipment connectivity/troubleshooting
System login requirements/credentials
| Data management, backup and archiving |  |
| Daily, weekly, quarterly and annual maintenance requirements |  |
| Documentation of maintenance actions in a maintenance log sheet |  |

**Waste and spills management**

- Demonstrates safe lab practices with spills and waste management response inclusive of *spill containment*
- Demonstrates safe lab practices with spills and waste management response inclusive of *spill removal*
- Demonstrates safe lab practices with spills and waste management response inclusive of *spill disposal*
- Demonstrates safe lab practices with spills and waste management response inclusive of *spill reporting*

**Specimen handling, preparation and testing**

- Specimen and cartridge handling precautions
- Working within biosafety cabinet, including cleaning before and after each specimen preparation
- Specimen preparation (agitator/inverting)
- Transferring of specimen to cartridge
- Transporting of cartridge from biosafety cabinet to GeneXpert machine

Safe, quality practice and efficient operation of the GeneXpert testing unit is directed and guided by clinical and operating procedures. Procedures are housed on a SharePoint platform to ensure current version control. Approved clinical procedures for specimen collection and reporting of test results, and standard operating procedures for operation and maintenance of the GeneXpert testing unit include:

- Clinical Procedure: Nasopharyngeal Swab Testing
- Clinical Procedure: Saline Gargle Testing
- Clinical Procedure: Informing and Reporting Test Results for GeneXpert DX (in development)
- GeneXpert DX: Installation, Setup and Data Management
- GeneXpert DX: Calibration, Validation and Regular Quality Control
- GeneXpert DX: Maintenance of GeneXpert DX
- GeneXpert DX: Specimen Handling, Preparation and Testing for GeneXpert DX
- GeneXpert DX: Test Cartridge Materials Management (under final version review)
- GeneXpert DX: Specimen Receiving, Acceptability, Accessioning, Storage, Retrieval & Disposal (under final version review)
- GeneXpert DX: Test Cartridge Inventory Management (under final version review)
- Waste Management for Supply/Equipment Disposal and Spill Management

All procedures are approved and signed by the Medical Director Laboratory Testing.

The availability of staff who have the time to participate in training and who can master these new competencies is a precondition to placing the unit in community. If there is a plan to move a unit between communities, it’s recommended that consistent, trained personnel move with the unit. It is acknowledged that the ability to train and validate competency when the unit is being moved takes time. While group/cohort training may be possible, access to equipment for timely hands-on one-on-one practice, competency development and validation is required.
QUALITY ASSURANCE

Quality Assurance Framework

For quality assurance of testing in community settings, the Provincial COVID Testing Sub-Committee recommended that the FNHA pursue a Quality Assurance Framework (QAF) approach. This QAF for First Nations community-based SARS-CoV-2 testing includes:

1. Quality Oversight Committee, including MHO, NML, Provincial Lab Medicine, Nursing and First Nations Health Directors

2. Quality Manual, to provide guidance regarding the clinical use and operational considerations of FNHA owned or leased SARS-CoV-2 POC testing equipment

3. Quality Systems essentials, based on the Accreditation Canada POCT ‘Qmentum’ Accreditation Program

Elements

All personnel performing SARS-CoV-2 testing using the GeneXpert DX unit should be knowledgeable in its setup and safe operation in order to provide accurate and meaningful results for patients.

1. MATERIALS REQUIRED
   - Two QC samples: a positive and a negative. The AccuPlex™ reference material is a non-infectious recombinant Sindbis virus that contains SARS-CoV-2 target sequences in the positive control, and human RNaseP target sequences in the negative control.
   - AccuPlex™ SARS-CoV-2 reference material.
   - Biological Safety Cabinet with biohazardous waste container, absorbent pad and disinfectant inside.
   - USB flash drive for data storage, which should be encrypted.

2. PROCEDURE

2.1 Quality Control (QC) Assay

   - Assay 2 QC samples, a positive and negative AccuPlex™ SARS-CoV-2 reference material before testing any clinical samples.
   - Set up and run two test cartridges, one with positive control and one with negative control. Expiry date will be populated on the test report automatically.
• Store cartridges upright between 2°C and 28°C.
• Bring cartridges and reference material stored at 4°C to room temperature before running the assay (about 30 minutes).
• Do not use a cartridge that has been damaged or leaked, dropped or shaken (as evidenced by crystallization on lid).
• Do not touch the reaction tube. Always handle the cartridge by its body.
• View results and generate a Test Report.
• If both QC tests come up with the expected result, you have successfully verified the instrument and the equipment can be used.
• If one or both of the tests returns an incorrect result, corrective action will need to be taken to determine the root cause of the failure and repeat testing will be required to meet certification requirements.
• Send the initial test report (in a .pdf document) to NML, who will verify the setup of the system.

2.2 Ongoing Quality Control (QC)

The necessity for ongoing QC depends heavily on testing volume and cartridge supply. Recommendations for QC are provided below, but ultimately are at the discretion of an internal/external qualified professional.

3. DOCUMENTATION

When performing QC, it is important to keep a record or log of which modules were used for QC in the previous week and ensure that different modules are used for QC in the following week.
REPORTING PATHWAY AND NURSE DOCUMENTATION WITH LABORATORY CONFIRMATION

1. REPORTING TEST RESULTS

Reporting to the regional health authority (RHA) Medical Health Officer (MHO)/communicable disease (CD) Team:

Call the RHA MHO/CD Team with positive and negative GeneXpert results using the contact number provided in the documents linked to below:


2. INFORMING THE CLIENT

The CHN and RHA MHO/CD Team should discuss who will be informing the client of the results.

If it is confirmed with the RHA that the CHN is to inform the client/family of a result, the CHN must ensure that if the client wants someone with them when learning the results that the individual is present.

1. For a Negative Test Result:
   • Notify the client to continue to self-isolate if symptomatic.
   • Inform the client that the MHO may request retesting at a later date if the client continues to be symptomatic.
   • Review public health measures to decrease risks of future COVID-19 exposure with the client, including the need for appropriate physical distancing (2 m), staying home when sick, avoiding touching the face and frequent hand washing.

2. For a Positive Test Result:
• Arrange for a time to call the client with the results or if a face-to-face meeting is requested, meet in the client’s home (not a Health Centre).
• Provide reassurance of support from the CHN and the RHA CD team.
• Explain that the RHA CD team have reviewed their tests results.
  • Depending on discussion with the Regional MHO/Regional CD team, either begin a case interview per BCCDC CD Manual COVID-19 case interview, or if the Regional CD team will be doing the case interview, inform the client that they will be contacted by the RHA CD team and/or nurse in community to support contact tracing (p.8).
• Review public health isolation measures and the guide for household members of someone with COVID-19.

3. DOCUMENTATION

• Document as per existing CD charting practice (electronic or paper).

• Document test date, health care provider, location, test result, GeneXpert specific information and action taken to report results to RHA CD team (how, when and to whom the test was reported).

• Confirm with the RHA CD team who will notify client, plan for follow-up monitoring and contact tracing, and plan for how documentation will be done between the CHN and the RHA CD team.
INVENTORY MANAGEMENT

Purchasing

Test kits may be obtained through either the NML or the provincial program through the PHSA via the Provincial Laboratory Medicine Emergency Operations Centre (PLM EOC) which arranges for the supply of COVID-19 GeneXpert Express test kits for participating locations in BC.

Note: Due to the acute shortage of GeneXpert COVID-19 testing cartridges from the distributor/manufacturer (Inter-Medico/Cepheid), the supply to test sites is on an allocation basis determined by both the NML and the PLM EOC.

Costs for COVID-19 GeneXpert Express test kits are paid from the FNHA COVID-19 program budget; kit orders are placed on a weekly basis, but contingency stock is available through national partners, NML, and provincial partners, PHSA, if a location needs kits between order periods due to COVID-19 outbreaks.

Test sites that require more COVID-19 GeneXpert Express test kits than the weekly allocation will be required to escalate their request through the FNHA to the agencies listed above. All questions regarding ordering COVID-19 GeneXpert Express test kits can be directed to the FNHA Testing Program.

Inventory Control

COVID-19 GeneXpert Express test kits are shipped to participating test locations.

It is the responsibility of each test location to reconcile the number of test kits received against the number of tests performed.

This is usually monitored with the Monthly Report.

Missing kits or reports are recorded as waste, and are flagged as an error.

When test kits and QC samples are received, it is recommended that each test location notes/records the following:

- number of test kits or QC samples received
- lot number and expiry dates of test kits and QC samples
- status of supplies (any damage)
**Master Lot # and expiry**

Problems with test kits and QC materials are referred back to the MASTER LOT NUMBER.

**Returning Unsuitable Supplies**

Unsuitable supplies include those that are expired, improperly stored or damaged.

Contact the FNHA Testing Program to request the pick-up, return or disposal of unsuitable supplies.

It is dangerous to keep expired kits at the test location as there is a high probability that someone will use them for a client test by mistake.

Determine the supply destination according to the table below.

<table>
<thead>
<tr>
<th>If the supply involves:</th>
<th>Action:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expired COVID-19 GeneXpert Test Kits</td>
<td>• <strong>Do not use</strong> for client tests – Quarantine from in-date stock</td>
</tr>
<tr>
<td></td>
<td>• Notify the FNHA Testing Program with number and consult to prevent recurrence</td>
</tr>
<tr>
<td></td>
<td>• <strong>Do not keep</strong> expired kits on site as they may inadvertently be used</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Monthly report kits expiry dates are monitored so that near-expiry kits can be replaced and transferred to a high-use location before expiry.</td>
</tr>
<tr>
<td>Expired quality control or proficiency test samples</td>
<td>• Discard as biohazardous waste</td>
</tr>
<tr>
<td>Improperly stored COVID-19 GeneXpert test kits or Quality Control samples</td>
<td>• <strong>Stop</strong> client tests until an investigation is performed</td>
</tr>
<tr>
<td></td>
<td>• Quarantine the materials at the correct storage temperature while an investigation is performed</td>
</tr>
<tr>
<td></td>
<td>• Report incident to testing site supervisor</td>
</tr>
<tr>
<td></td>
<td>• Consider this event as an opportunity to determine why this occurred and to prevent a recurrence</td>
</tr>
<tr>
<td></td>
<td>• Complete an incident report (online Hailcista incident management program if an FNHA site; for all other sites, complete a paper-based document)</td>
</tr>
<tr>
<td>Scenario</td>
<td>Action</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Improperly shipped/received or damaged materials</td>
<td>• Do not use for client tests until an investigation has been completed</td>
</tr>
<tr>
<td></td>
<td>• Report incident to testing site supervisor</td>
</tr>
<tr>
<td></td>
<td>• Contact the FNHA Testing Program for instructions on how to proceed</td>
</tr>
<tr>
<td>Defective materials in kits or quality control samples</td>
<td>• Stop client tests until you know if this is random error or something broader</td>
</tr>
<tr>
<td></td>
<td>• Report incident to the site supervisor and the FNHA Testing Program</td>
</tr>
<tr>
<td></td>
<td>• Save the original materials in the event that they need to be sent for further testing</td>
</tr>
<tr>
<td></td>
<td>• Report on logs so that the kit is recorded as waste for the monthly report</td>
</tr>
<tr>
<td>Recalled GeneXpert test kits or Quality Control samples</td>
<td>• Remove affected supplies and place in quarantine so they cannot be used for any testing</td>
</tr>
<tr>
<td></td>
<td>• Report incident to site supervisor and the FNHA Testing Program</td>
</tr>
<tr>
<td></td>
<td>• Complete recall form and send to the FNHA Testing Program</td>
</tr>
<tr>
<td></td>
<td>• Follow FNHA Testing Program instructions for return or disposal</td>
</tr>
</tbody>
</table>
TEMPERATURE

Temperature monitoring is required to ensure that the SARS-CoV-2 GeneXpert (Express) test kits are stored between 2°C to 28°C.

A temperature monitoring log should be maintained (a sample temperature monitoring log is available as shown in the SOP).

If the temperature monitor indicates that the ambient temperature has increased or decreased outside of the specified range, test kits should be moved to an alternate location for storage and the test location supervisor should be notified.

If test kits have been kept outside of the recommended temperature range (2°C –28°C) overnight or for extended periods in unmonitored locations/spaces, it is recommended that kits be quarantined, moved to a temperature-monitored area, QC samples used and the incident reported to the test location supervisor.

After using the QC and receiving valid results, the kits may be used for client testing.

Kits are vulnerable when they are transported to off-site test locations or events.

Please keep kits with the test providers – do not transport or store in the trunks of cars.

Event preparations should include how to safely transport and store the kits, and perhaps whether or not the temperature monitor and QC materials are included with event supplies.
QUALITY CONTROL

Costs for QC samples and related supplies are paid from the COVID-19 program budget and ordered through the FNHA.

Other testing supplies such as QC materials can also be ordered through FNHA.

- QC samples are distributed as a set of two bottles (known COVID-19 negative and known COVID-19 positive).
- QC samples are stored in the refrigerator until they expire (one-year post-production).
- QC samples may be frozen, but once thawed, they are refrigerated until expiry.
- DO NOT freeze/thaw/refreeze the samples as it may weaken the reactivity.
- QC sample remains OK for up to eight days at room temperature.
- QC samples should be at room temperature before testing.
- QC samples are handled and disposed as biohazard waste.

Internal Controls

Each COVID-19 test cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

Sample Processing Control (SPC)

- Ensures that the sample was processed correctly.
- The SPC verifies that sample processing is adequate.
- Additionally, this control detects sample-associated inhibition of the real-time polymerase chain reaction (PCR) assay, ensures that the PCR conditions (temperature and time) are appropriate for the amplification reaction and ensures that the PCR reagents are functional.
- The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

Probe Check Control (PCC) – Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity and dye stability. The PCC passes if it meets the validated acceptance criteria.

External Controls
See the section titled Calibration, Validation and Regular Quality Control (External Quality) below.
**PROFICIENCY TESTING**

Participation in a proficiency testing program is an expectation for each test location participating in the COVID-19 GeneXpert Testing Program. Proficiency testing is a quality indicator (assessment) of location performance for the FNHA Testing Program, and should be done for the testing location.

Proficiency testing is a higher-level QA activity conducted two to three times per year when an external provider sends unknown test samples to all test locations with a subscription. Proficiency testing may be included as a competence check if different test providers do the testing for each test event.

Health Canada's NML have introduced a new external QA program for SARS-CoV-2 testing. This new program, QASI®-COVID-19, has been developed to serve community-based testing sites, specifically those using the GeneXpert instrument.

The proficiency testing panel will consist of blinded specimens to be handled and tested in the same manner as patient specimens.

Results will be submitted online to the QASI®-COVID-19 website for confidential group analysis.

The QASI®-COVID-19 team will provide feedback in the form of individual performance reports for each community-based testing site and carry out any necessary corrective and preventative actions with participants to maintain the highest quality of testing.

A yearly proficiency test is conducted under the auspices of NML, which operates the program.

Subscriptions are paid per test location from the FNHA COVID-19 program FNHA subscribes to. The NML 'QUASI' program entails:

- The testing of two unknown samples sent to all participants for the test event.
- Two to three test events per year.

Proficiency test samples should be refrigerated upon receipt, warmed to room temperature for testing, and then stored in the fridge or freezer until the performance report is received.

Once the results are deemed acceptable by NML, the samples should be discarded as biohazard waste.

The following is a description of the biosafety and testing procedures for running an Xpert® Xpress SARS-CoV-2 assay on the GeneXpert® system using clinical specimens suspected to contain SARS-CoV-2. All personnel performing SARS-CoV-2 testing by the GeneXpert instrument should be knowledgeable in these procedures in order to provide accurate and meaningful results for patients.

1. **Materials Required**
   - One specimen containing 3 ml transport medium (i.e., sealed tube)
   - Absorbent paper with impermeable backing (e.g., Whatman® Benchkote® surface protector)
   - Tray or waste container with 70% ethanol
   - Spray bottle with 70% ethanol (Isopropyl)
   - Disinfectant 1:10 of the bleach (5.25% concentration) solution wipes (e.g., Clorox Healthcare® Bleach germicidal wipes)
   - Lint-free tissues (e.g., Kimtech Kimwipes™)
   - Xpert® Xpress SARS-CoV-2 cartridge/s
   - Single-use transfer pipettes provided with kit
   - Alcohol-resistant marker for labelling cartridge
   - GeneXpert cartridge rack
   - Autoclave bag
   - Biohazardous waste container

Personal Protective Equipment (PPE)

- Nitrile gloves
- Eye protection
- Single use isolation gown
- Respiratory protection (e.g., medical mask)
- Footwear protection

Technical Equipment

- GeneXpert System (instrument, uninterrupted power supply, laptop, scanner and printer)
- Biological Safety Cabinet
2. **PROCEDURE**

2.1 **Personal Protective Equipment** (PPE) should be worn at all times when working with suspect SARS-CoV-2 specimens. See Section 1. Materials Required (above).

2.2 Place a sign on the lab testing room door saying “Testing in progress - do not enter or disturb”. Another sign must be on the door stating “authorized personnel only” (e.g., nurse or lab technician).

2.3 Handling Incoming Specimens and Specimen logging: See SOP, GeneXpert Specimen receiving, acceptability, accessioning, storage, retrieval & disposal.

2.4 **Cartridge Handling Precautions**
   - Store cartridges upright in a fridge between 2°C and 8°C.
   - Bring cartridges and test specimens to room temperature for at least 30 minutes before running the assay.
   - Handle and prepare only one cartridge at a time. Do not use a cartridge that has leaked or been damaged, dropped or shaken (as evidenced by crystallization on lid). Do not use the cartridge if it appears wet, has been used or has expired, or if the lid seal has been broken or damaged. Do not attempt to open or reuse a previously used cartridge. Cartridges are single-use.
   - Do not reuse pipettes.
   - Do not touch the reaction tube. Always handle the cartridge by its body.
   - Open specimen tube carefully; be aware that the swab might be attached to the lid.
   - Open a cartridge only when ready to add a specimen.
   - Set up one test at a time. A loaded cartridge must be processed on the GeneXpert within 30 minutes.
   - Discard used cartridges in an appropriate biohazard container immediately after the run has completed. Avoid excessive handling of cartridges after the run is completed.

2.5 **Preparing the GeneXpert**
   1. Turn on the GeneXpert using the switch located at the back of the instrument.
   2. Next, turn on the laptop and launch the GeneXpert DX software using the desktop icon.
3. Enter your personal login credentials. The GeneXpert software may launch automatically or may require double-clicking on the GeneXpert DX shortcut icon on the Windows® desktop.

4. Confirm that all modules are detected by the software and ready for testing.

2.6 Preparing and working within a Biosafety Cabinet (BSC)

1. Close any windows and turn off cooling fans when the BSC is in use to minimize disruptions to air movement.

2. Only one person at a time should work in a BSC.

3. There should be no more than two people in a room during test setup.

4. Remove all jewelry and put on PPE as noted above in Section 1. Materials Required. Ensure that you put two nitrile gloves on each hand (double gloving).

5. Keep a bottle of 70% ethanol and lint-free tissues within the BSC while work is being performed. This will reduce the need to remove your hands from the BSC.

6. Disinfect all surfaces of the BSC and its contents before and after use with 70% ethanol. After cleaning, ensure your work surfaces have air-dried.

7. Press and hold the ON key until the blowers start, status indicators illuminate and an audible tone sounds to turn the unit on.

8. Move the window to the work position (8- or 10-inch opening).

9. Wait until the green LED “airflow is steady” illuminates. The BSC is now ready to use.

10. Move the front window to the maximum opening position. This automatically switches the blowers to full speed. Set up a clean BSC and work from clean to dirty and in one direction. First, place the absorbent pad with impermeable backing on a level working surface, ensuring that it does not block the grille. Then place the BSC materials on the absorbent pad.

11. Segregate “clean” items from “dirty” items.

12. Ensure that only the minimal equipment needed is placed on the workspace as additional equipment can impede airflow of the BSC.

13. Avoid blocking the front air intake grille.

14. Avoid resting elbows and arms on the grille or work surface.

15. Work toward the rear of the work area in a BSC.

16. Use slow arm or hand movements inside the BSC and slow body movements in front of the work opening to avoid air turbulence. Arms should enter and exit the BSC slowly and perpendicular to the front opening.
17. Open and prepare patient specimens (swab in viral transfer medium and/or aspirate) for testing only in the BSC.

18. Store specimens and samples away from the kit to avoid contamination. A properly obtained specimen is critical for obtaining accurate results with GeneXpert. Refer to the FNHA clinical procedures on nasopharyngeal swab testing and gargle testing.

19. Before turning off the BSC, close or cover all containers and decontaminate all items with 70% ethanol before removing them from the BSC.

20. Where possible, discard materials in a waste container that is located toward the side of the BSC work space. For disposal of larger items such as the absorbent pad, ensure that a biohazard waste container is immediately beside the BSC.

2.7 Loading the Cartridge
1. Work in a prepared BSC.
2. Check that the specimen transport tube is closed.
3. Label a cartridge on the side near the base with the Sample ID using an alcohol-resistant marker or barcode label. Do not write on the lid or obscure the digital matrix code on the front of the cartridge.
4. Open the cartridge. Once the cartridge is opened, the sample must be loaded and placed into the GeneXpert within 30 minutes.
5. Thoroughly mix the test specimen by inverting the tube 5 times by hand (DO NOT shake rapidly or vortex).
6. Open lid carefully to avoid touching droplets on the inner lid. Ensure that the swab remains in the tube and does not come out.
7. Place lid upright (inner side up) to avoid droplets falling on the work surface.
8. Start the test within 30 minutes of adding the sample to the cartridge.
9. Use the provided single-use transfer pipette to load 300μl of the test specimen into the loading chamber.
   a. Squeeze the upper bulb firmly to ensure pipette aspirates the full volume.
   b. Submerge the pipette tip in the sample liquid completely.
   c. Release the bulb gradually to fully aspirate sample.
   d. Some samples should go into the Overflow Chamber.
   e. Keep tip fully submerged until completely full to avoid air bubbles entering the tip.
   f. **Do not** use the pipette to mix the sample.
   g. Retrieving liquid in the overflow chamber is not possible.
h. Dispense the sample along the side of the loading chamber to avoid creating bubbles in the chamber.

i. DO NOT MIX THE SAMPLE IN THE LOADING CHAMBER.

j. Place the used tips and/or transfer pipettes in 70% ethanol for at least 30 minutes prior to disposal in a biohazard waste bag. Where possible, discard waste in a biohazard waste bag inside the BSC.

10. Secure cap of the patient sample tube and place in rack; save for storage.

11. Firmly snap closed the lid to seal the cartridge. Once the cartridge is closed after adding the specimen, the cartridge lid should never be opened. Always keep the cartridge upright after the specimen has been added to it. Do not shake, tilt or invert the cartridge – this will result in the test failing.

12. Use a lint-free tissue soaked with 70% ethanol or a single-use disinfectant wipe to carefully wipe down and disinfect your gloves, the outer surface of the cartridge (avoiding the reaction tube), the specimen tube destined for storage, and the entire surface before removing from BSC.

13. Remove the outer layer of gloves on each hand and dispose of these in a biohazard waste container immediately beside the BSC. You should now have a clean pair of gloves on your hands.

14. Transfer loaded cartridge to the GeneXpert while wearing the clean gloves.

15. Use a GeneXpert cartridge tray to safely transport cartridges.

16. Remain in full PPE until the cartridge is securely transferred and loaded onto the GeneXpert.

2.8 Creating a test run

1. While still wearing the clean gloves, place the cartridge tray on top of the device.

2. Click on the Create Test icon at top left of screen of the GeneXpert laptop.
   a. Follow a pop-up window prompting you to scan the cartridge barcode (located on the front of the cartridge with the barcode scanner). If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan, then repeat the test with a new cartridge.

3. Select Assay will be automatically populated with the correct assay name for the cartridge in use, e.g., Xpert Xpress SARS-CoV-2.

4. Enter the Patient ID (e.g., PHN) and Sample ID
   a. Fields can have the same ID.
   b. Fields can be entered using a scannable barcode (see Operator Manual for full details).
   c. If the Sample ID is left blank, it will be automatically populated with a GeneXpert-generated number.
5. Check the **Select Module** field to ensure the correct module you want to use is shown. Use the drop-down list to change the module if necessary.

6. Open the instrument module door and load the cartridge ensuring it sits level.

7. Select **Start Test**. A green light will flash above the module that was selected on the GeneXpert instrument.

8. Close the module door firmly; it will latch closed. The test will begin automatically as indicated by the green light and a series of beeps. The test will take approximately 50 minutes to complete. When complete, the module door automatically unlatches and the green light turns off.

9. Remove the cartridge and dispose in biohazardous waste container. Cartridges are one-time use only.

10. Do not turn off or unplug the instruments while a test is in progress. Turning off or unplugging the GeneXpert instrument or computer will stop the test.

### 2.9 Viewing results

1. Select the **View Results** icon from the top menu bar. Results can be observed in real time during a test run.

2. Click **View Test** at the bottom of the screen, and select the test of interest in the pop-up window to view a different test. The selected test result will be displayed under the **Test Result** tab.

3. Select the **Analyte Result** tab to view cycle threshold (Ct) values for the two gene targets (E and N2) and for the internal quality control, SPC (sample processing control). Error messages will be displayed under the **Errors** tab if applicable.


4. Follow up with the NML for troubleshooting error codes during testing: (Sandra Kiazyk: Sandra.kiazyk@canada.ca /Tracy Taylor: Tracy.Taylor@canada.ca)

### 2.10 Generating a Test Report

The default setting is for a test report to print automatically at the end of a test.
run and/or a .pdf test report can be generated for one or more selected patient samples.

a. Click the Report button at the bottom of the screen.
b. Leave the default Analyte Result settings as is, unless previously determined otherwise.
   i. Error Details should be the only checked box.
c. Check the box adjacent to the Patient ID of interest.
   i. Use the Shift or Ctrl keys to select more than one test.
d. Click Generate Report File and save .pdf in desired location.
e. Repeat an INVALID test with a new swab sample in a new cartridge.
f. Repeat an ERROR test using the same swab sample in a new cartridge.
g. A PRESUMPTIVE POSITIVE can be due to another coronavirus strain and can be repeated, and/or sent to a provincial lab for confirmatory testing.

3. DOCUMENTATION
Document in Panorama Case (as available) and Contact Workflow for Indigenous Communities:


Document on chart: test result date, location, health care provider, who was informed, where test was reported, education provided to client and family/household members, plan for follow-up monitoring.
CALIBRATION, VALIDATION AND REGULAR QUALITY CONTROL (EXTERNAL QUALITY)

All personnel performing SARS-CoV-2 testing by the GeneXpert instrument should be knowledgeable in its setup and safe operation in order to provide accurate and meaningful results for patients.

1. MATERIALS REQUIRED

- Two QC samples: a positive and a negative. The SeraCare AccuPlex reference material is a non-infectious recombinant Sindbis virus that contains SARS-CoV-2 target sequences in the positive control, and human RNaseP target sequences in the negative control.
- SeraCare AccuPlex™ SARS-CoV-2 reference material.
- COVID-19 Proficiency Testing Program (QASi®) – materials and instructions provided by NML.
- Biological Safety Cabinet with biohazardous waste container, absorbent pad and disinfectant inside.
- Encrypted USB flash drive for data storage.

2. PROCEDURE

2.1 Quality Control (QC) Assay

- Assay two QC samples, a positive and negative AccuPlex™ SARS-CoV-2 reference material before testing any clinical samples.
- Set up and run two test cartridges, one with positive control and one with negative control. Expiry date will be automatically populated on the test report.
- Store cartridges upright between 2°C and 28°C.
- Bring cartridges and reference material stored at 4°C to room temperature before running the assay (about 30 minutes).
- Do not use a cartridge that has been damaged or leaked, dropped or shaken (as evidenced by crystallization on lid).
- Do not touch the reaction tube. Always handle the cartridge by its body.
- View results and generate a Test Report.
- If both QC tests come up with the expected result, you have successfully verified the instrument and the equipment can be used.
- If one or both of the tests returns an incorrect result, corrective action will need to be taken to determine the root cause of the failure and repeat
testing will be required to meet certification requirements.

- Send the initial QC test results (in a .pdf document) to the NML Quality Assurance Team at QASI covid19@canada.ca for certification; they will verify the setup of the system.

### 2.2 Ongoing Quality Control (QC)

The necessity for ongoing QC depends heavily on testing volume and cartridge supply.

Recommendations for QC are provided below, but ultimately are at the discretion of the Provincial Laboratory Medical Director.

<table>
<thead>
<tr>
<th>Clinical Testing Volume</th>
<th>QC recommendation (2 AccuPlex samples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Monthly</td>
</tr>
<tr>
<td>Low to moderate (samples tested weekly, not daily)</td>
<td>Weekly</td>
</tr>
<tr>
<td>High (samples tested daily)</td>
<td>Daily</td>
</tr>
</tbody>
</table>

### 3. DOCUMENTATION

When performing QC, it is important to keep a record or log of which modules were used for QC in the previous week and ensure that different modules are used for QC in the following week.
Errors and Incidence

Incident reporting for FNHA operation sites (i.e., Hailcista) should be done in accordance with the facility's incident reporting procedure. For non-FNHA sites, use paper-based incident reporting documents.

FNHA site Biosafety Oversight

Safetymatters@fnha.ca

OHN.clinic@fnha.ca

Non-FNHA site Biosafety Oversight

Please refer to the relevant Community Occupational Health Program (i.e. the organization that provides this for the health care workers in the community).