Abbott ID NOW – Training Procedure for Symptomatic Testing

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1.0 Training Goals

- To teach point of care test (POCT) users to be able to collect clinical samples and run tests using the Abbott ID NOW system safely, reliably, and efficiently.
- Using this written document, in conjunction with training videos and hands-on demonstrations, guide the certification process for POCT users.
- Identify and provide comprehensive training to site identified Super Users for ongoing training and support of POCT users.

2.0 Steps to Certification

POCT users must be certified in the use of the Abbott ID NOW system prior to the use of the machine or the collection of any clinical specimens.

Each approved site will identify one staff member as their site Abbott ID Now Super User. The site Super User will be the initial staff trained at each site and complete additional training requirements. The Super User will then provide training and ongoing support to POCT Users.

Certification for POCT users includes:

1. Abbott ID NOW – Symptomatic testing program, an introduction for providers presentation
2. Completion of following training video from NML or Abbott
    - Module 2 – Running QC – 7 minutes
    - Module 3 – Running a Patient Test from a Direct Swab – 9:30 minutes
    - Module 7 – Maintenance and Troubleshooting – 3:20 minutes
    - Module 8 – Clinical Sample Collection – 4:40 minutes
3. Review of Abbott ID NOW Pre- and Post- Test Information for Clients Document
4. Review Abbott ID NOW COVID-19 POCT Assessment Form for COVID-19- Symptomatic testing document
5. PPE training
6. Specimen handling and collection training
7. Preform a Quality Control Test and/or patient test on self/coworker with Super User Supervision
8. Completion of training checklists and quiz as directed by Super User

Additional Super User Training include:

1. Review of Abbott ID NOW COVID-19 Test Clinical Procedure For Symptomatic Testing document
2. Review of Abbott ID NOW Training Procedure for Symptomatic Testing document
3. Review of all Abbott Training video modules

3.0 Training Videos

The video series produced by NML is intended to help POCT users familiarize themselves with the Abbott ID NOW™ machine setup, maintenance, settings, and functionality. The videos accompany

the user guides provided with the Abbott ID NOW system as well as Yukon's Abbott: ID NOW COVID-19 Test - Clinical Procedure(s). If any differences between a training video and Yukon's Abbott: ID NOW COVID-19 Test - Clinical Procedure are noted, Yukon specific direction supersedes.

NML's video series may be viewed here.

Those who are unable to access the NML training video series may view Abbott Laboratories' training video series.

4.0 Yukon Clinical Procedure

The Yukon Clinical Procedures accompany the training video series as well as Abbott Laboratories user guides. The purpose of these procedures is to familiarize the POCT user with the application of the Abbott ID NOW system to special populations within the Territory, especially as it relates to the dynamic context of COVID-19 in Yukon. **Please note** there are specific procedures for both symptomatic testing programs and asymptomatic screening programs.

5.0 Personal Protective Equipment (PPE)

POCT users must have completed appropriate training related to the donning and doffing of PPE **prior** to any clinical sample collection.

POCT users should review the documents and guidelines below as part of the training and certification process. **Recommendations for best practice** also include a) POCT users first *observing* a certified user or Super-User/Manager donning **AND** doffing PPE, and b) POCT users *demonstrating* appropriate donning **AND** doffing PPE with a certified user or Super-User/Manager.

- Recommended practices and personal protective equipment for allied health facilities, interim guidance
- Putting on (donning) Personal Protective Equipment (PPE)
- Taking off (doffing) Personal Protective Equipment (PPE)

6.0 Specimen Collection and Handling

POCT users must have completed appropriate training related to the collection and handling of clinical specimens prior to actual sample collection. See recommended practice in Yukon's Abbott: ID NOW COVID-19 Test - Clinical Procedures.

POCT users should review the documents and guidelines below as part of the training and certification process. Recommendations for best practice also include a) POCT users first observing a certified user or Super-User/Manager collecting **AND** handling a clinical specimen, and b) POCT users demonstrating appropriate collection **AND** handling a clinical specimen with a certified user or Super-User/Manager.

7.0 Hands-on Demonstrations

New users should preform a hands-on demonstration with their Super-User/Manager prior to actual patient testing. This may be done by preforming quality control tests, as described in section 10.1. Practicing in a controlled environment is intended to increase user confidence and efficiency, as well as reduce the risk of invalid results due to user error.

8.0 Checklists, Quizzes and Certification

Super Users will work with the POCT user to ensure:

1. The above requirements have been reviewed and completed,
2. All training checklists and quizzes have been completed and marked as satisfactory,
3. The above checklists and quizzes have been provided to the POCT users immediate supervisor and filed appropriately.
4. Proof of certification is filed by the Super User according to the approved sites protocols. Completed certifications should be provided to YCDC for further filing.
5. Continuing competency and accreditation is maintained by the POCT user.

9.0 Machine Set-up

Before using the machine for the first time, access the 'Setup' menu after logging in using the admin user ID and password on the front of the machine. You must be logged in to the admin account to change the machine settings.

9.1 Date and Time

1. Select the 'Date' and 'Time' options and set the correct local date and time

9.2 Assay Preferences

1. Select 'Assay Preferences'
2. Select 'Influenza A/B' and disable
3. Select 'Strep A' and disable
4. Select 'RSV' and disable
5. Ensure 'COVID-19' is the only option that is enabled

9.3 Patient Details

1. Select 'Patient Details'
2. Enable 'Always Prompt'
3. Enable 'Display Patient Info'
    a. Enable 'On Screen'
    b. Enable 'On Printout'

9.4 Quality Control (QC) Lockout

1. Select 'QC Lockout'
2. Select 'COVID-19'
    a. Enable 'Warn'
    b. Set the interval to 7 days

9.5 Auto Print

1. Select 'Auto Print'
2. Enable this option

9.6 Adding a New User

1. Select 'Users'
2. Create a user ID using your YNET username
    a. Passwords are not required
    b. Each user **must** have their own ID
    c. Do not run tests under the 'Admin' login

10.0 Quality Control and Clinical Validation

10.1 Quality Control

Once steps 8.1 to 8.6 have been completed, the machine is now ready to be quality controlled (QC) for the first time. See Section 7 Quality control in Abbott ID NOW, COVID-19 Test – Clinical Procedure for Symptomatic Testing.

A positive and a negative control should be run to ensure the machine is operating/functioning:

- When first setting up the machine,
- After the machine is moved,
- When training new users,
- With a new cartridge LOT#,
- Every 7 days, otherwise.

Ensure QCs are logged in the machine binder.

10.2 Clinical Validation

Clinical validation of these machines are also required in addition to the QC described in **10.1** This is routine for many non-lab based tests and is a critical step in confirming accuracy of results.

At this time, as the Abbott ID NOW is not intended to replace traditional, 'gold standard' PCR testing. This is a new program within YT and Canada, as such, additional clinical validation is required. As more evidence for such symptomatic testing grows, these requirements will be adapted. However, at present this includes:

Validation of new machines:
The first 10 specimens collected for nasal specimens per ID NOW instrument also need a PCR test, collected at the same visit, for validation of the Abbott ID clinical result. The site may either be nasopharyngeal or saline gargle.

Ongoing clinical validation:
Every subsequent 10th test run per ID NOW instrument will also need a PCR test collected at the same visit, for validation of the Abbott ID clinical result. The site may either be nasopharyngeal or saline gargle.

11.0 ID NOW Performance Best Practices – Quick Reference Guide

Adapted from ID NOW Performance Best Practices with permission from Abbott Laboratories.

Successful testing on ID NOW™ system requires the user adhere to guidelines and recommendations provided within the user manual, assay package inserts, instrument on-screen instructions, and documents contained within assay-specific training folders. To achieve maximum performance of an ID NOW™ assay, this technical memorandum serves to highlight key aspects of the testing process, with particular focus on 11.5 transfer and dispense.

Failure to follow specified directions or best practices may result in invalid tests and results or workplace contamination.

11.1 Lab safety and Disinfection

a) Wear clean gloves and goggles for patient sampling and handling
b) Clean instrument and surrounding bench area **DAILY** with 70% ethyl alcohol or 70% ethanol wipes.
c) **DO NOT** use any form of bleach, hydrogen peroxide preparation, Virox, Accel, Lysol, or any other commercial cleaning solution to clean the ID NOW instrument.

11.2 Proper Sample Collection

a) Due to the sensitive nature of molecular technology, the amount of sample required to perform testing is less than that of rapid antigen detection tests. Excessive or aggressive sample collection may compromise test results.
b) Strictly adhere to guidelines for respective sample collection tech tips documents. See Nasal Swab Collection section 12 Abbott ID NOW, COVID-19 Test – Clinical Procedure for Symptomatic Testing.
c) It is acceptable to return the swab to its original packaging (this will allow excessive amounts

of mucous, saliva, and or other sample matrix material to remain in the wrapper to help minimize risk of inaccurate results).

11.3 Correct Patient Identification

a) Confirm that the patient's name and DOB are correct on the assessment form
b) Ensure that the client is within the first 7 days of symptom onset
c) When entering the patient ID before running the test, use LASTNAME, FIRSTNAME

11.4 Proper Test Procedure

a) Gently mix the swab in the liquid for 10 seconds. Excessive mixing may create bubbles, prevent adequate sample transfer, and may invalidate results. Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab.

11.5 Transfer and Dispense

1. Sample dispense errors

a) Visually inspect the orange indicator of the white Transfer Cartridge to verify that it fully descended. If the orange indicator is still visible at the top of the white Transfer Cartridge, the specimen was not transferred into the reaction tubes of the orange Test Base.
b) Visually inspect the orange Test Base reaction tubes to confirm the liquid levels in both tubes are equal and that all dry (lyophilized) reagents dissolved properly. If the orange indicator was fully descended and the reaction tubes are dry, the sample was never pipetted from the blue Sampler Receiver.

2. Procedural errors

a) Confirm test kits are stored at proper temperatures per package insert
b) Do not remove the foil seal on blue Sample Receiver until prompted by the instrument
c) Timing is important; follow procedural steps as displayed on the screen
d) Press OK when prompted
e) If any test pieces are accidently dropped, do not use any of the pieces for testing

3. Interfering substances – Listed in the package insert

11.6 Invalid Result – Repeating Test

The blue Sample Receiver has enough liquid to preform 2 tests. If the first test is invalid, follow the steps below to conduct a second test using the same blue Sample Receiver without collecting a second patient sample.

1. The used, connected, orange Test Baser and white Transfer Cartridge are considered **biohazards** and **MUST** be attached to a blue Sample Receiver prior to disposal.
    a. Open a new Sample Receiver/Transfer Cartridge from package #2.
    b. Remove the blue Sample Receiver from the package and open by removing the foil seal
    c. Remove the used, connected, orange Test Base and white Transfer Cartridge from the ID NOW instrument
    d. Connect the used pieces to the new, **UNUSED**, blue Sample Receiver and dispose.
2. Retain the used, blue Sample Receiver for repeat testing. **DO NOT re-swab the patient.**
    a. Remove the used, blue Sample Receiver carefully from the instrument
    b. Keep upright to avoid spilling the liquid contents
3. Repeat Test.
    a. Close the instrument lid, select new test from home screen
    b. Use a new orange Test Base and white Transfer Cartridge
    c. Follow the screen prompts; however, when asked to insert the blue Sample Receiver, **resuse the existing blue sample receiver from the first test**
    d. DO NOT re-elute the swab or add additional sample.

If the second result is invalid, **DO NOT retest the sample again.** Additional testing should be done using the traditional PCR nasopharyngeal swab.