Abbott ID NOW 2019-nCoV Symptomatic Testing Program

An Introduction for Providers in Yukon (August 2021)

Fig 1

Important Note

This presentation is not intended to replace the training or certification process for the ID NOW system, and does not provide a comprehensive overview of the system, its implementation, or its use in Yukon.

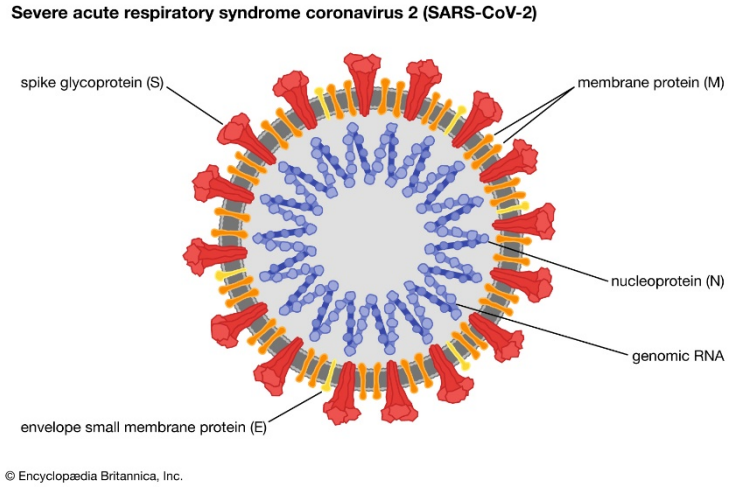
For the Presentation

- Open your Abbott ID NOW box
- Have the machine, cartridges and swabs with you
- Get a feel for the machine and its components!

Backgrounder

- Rapid diagnostic molecular test (<15 min)
- Detects 2019-nCoV viral RNA from a nares/NP/throat swab
  - Isothermal NAAT (RT-LAMP), target genes: E and N2.
- Approved by Health Canada in October 2020
  - ‘Open ended’ direction to Provinces & Territories
- Single use cartridges and small footprint

Fig 2



Backgrounder

- Intended for use in the first 7 days of symptom onset
  - Coincides with viral shedding
  - Also has applications for asymptomatic screening

- Results *approach* that of a PCR with Ct (cycle threshold) values <30
  - PCR is still 'gold standard'
  - PCR will detect early and late infections better

- Abbott data indicates ~95% sensitivity, 98% specificity
  - Data is early & variable, highly dependent on Ct values
  - Overall, literature suggests 77-80% sensitivity

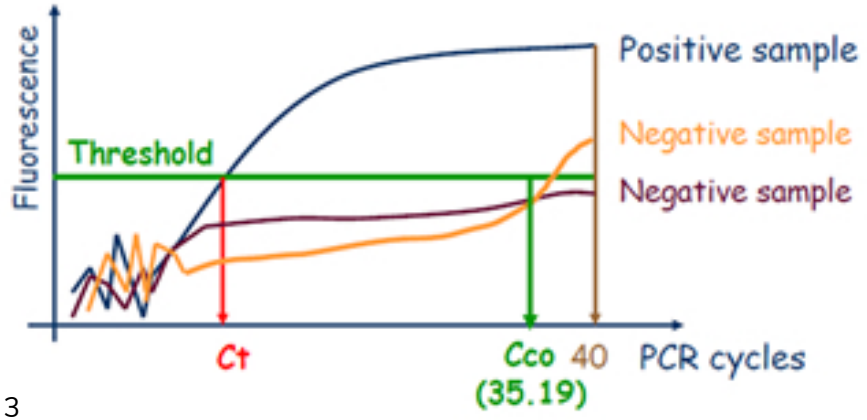


Fig 3

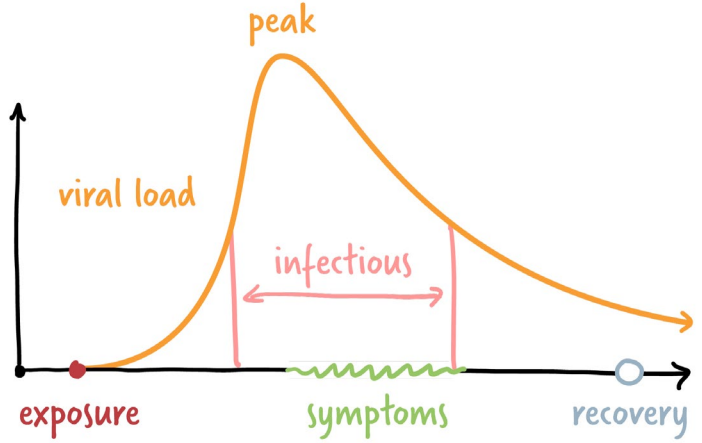


Fig 4

Sensitivity vs. Other Considerations

- Fast turnaround time
- Relatively low cost per test
- Increased testing frequency
- Multiple test settings
- Additional layer, ‘bridging the gap’

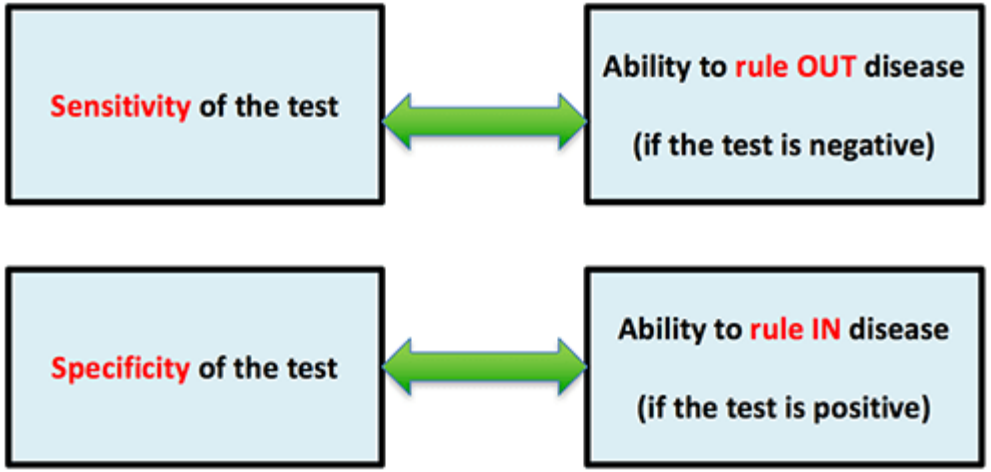


Fig 5

What's in the Box?

*Not pictured:
-Positive Quality Control Swab (silver packet)

-Barcode scanner

Fig 6

ID NOW Cartridges

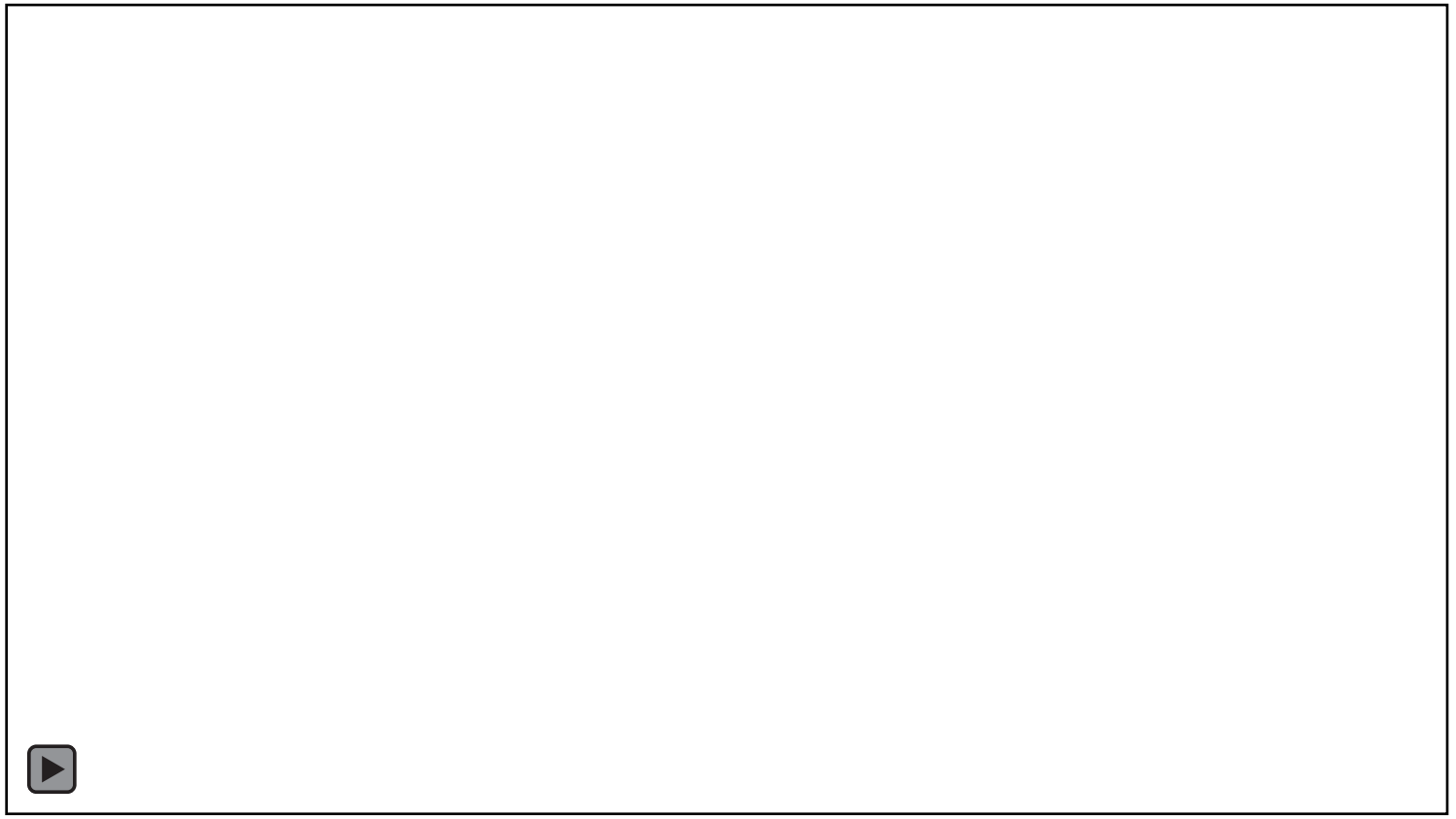
Fig 7

- Test Bases: Orange plastic components containing two reaction tubes of freeze-dried reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.

- Sample Receivers: Blue plastic components containing 2.5 mL of elution solvent.

- Transfer Cartridges: White plastic components used to transfer 2 x 100 µL (microliters) of sample extract from the Sample Receiver to the Test Base

How to Test



Testing Considerations

- Swabs must not be placed in transport media
  - 'Dry' swab should be eluted directly in to sample receiver
- If part of symptomatic testing, clients should be within 7 days of symptom onset
  - Otherwise follow routine processes
- Timing 'post contact' consideration
  - Strong likelihood of negative 1-3 days after exposure (~99%)
  - Slight improvement on day 4 (~67%)

Testing Considerations, Cont.

- Results are considered preliminary
  - Confirmatory testing requirement in some cases

- Reduce interfering substances
  - If client has lots of mucous, blow nose before test

Result Interpretation

Positive:

- Considered ‘preliminary’ and must be confirmed via PCR
- Initiate isolation per routine process as the client is managed clinically as a positive case

Negative:

- Interpret within clinical context and pre-test probability
- Confirm with PCR if strong clinical suspicion of COVID-19
- Continue to isolate if symptomatic or advised to for public health reasons
    - Retest in 2-3 days if symptoms persist

Invalid:

- May repeat the test once using ID NOW **or** use a PCR
- x2 invalid results must be confirmed via PCR

Fig 8

Applications and Considerations

- Useful in settings where rapid turnaround is critical
- Rural or remote settings with long transit times
- Can be used to *support* decision making and public health response in the interim

Applications – Congregate Settings

- Entry upon entry/admission
- Serial testing
- Screening Programs

Applications - Outbreaks

- Testing symptomatic individuals and contacts may allow for early identification
- Expedited case identification and contact tracing
  - Timing ‘post contact’ needs to be a consideration
- Reduced attrition or cases lost to follow-up

Getting Started – New Sites

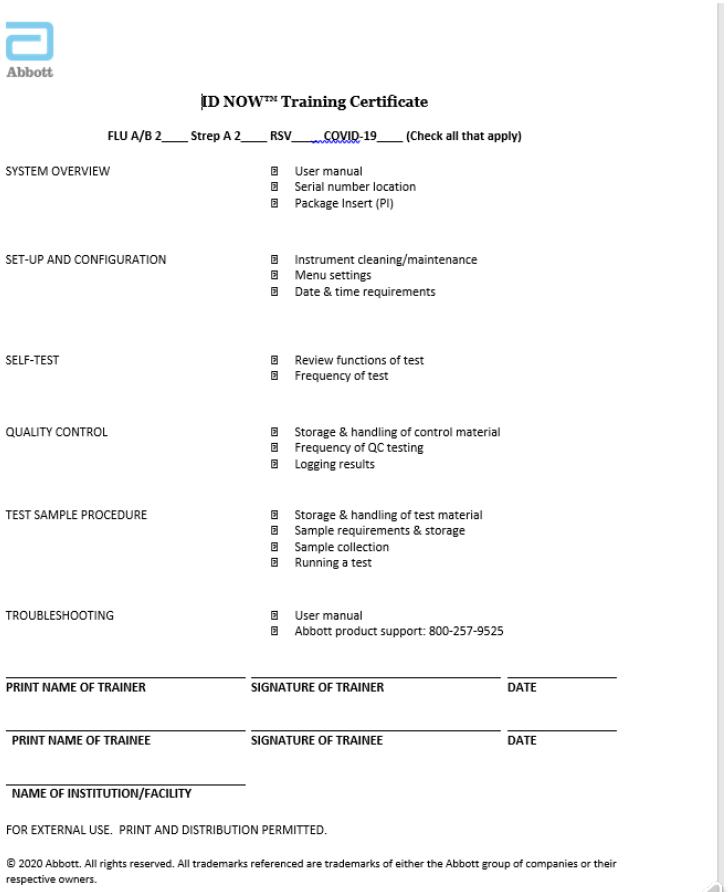
- Training new users & Certification
- Important Documents
- Clinic setup
- Instrument setup & standards
- Clinical Validation
- Quality Control
- Result reporting

Training New Users & Certification

- Outlined process and steps to become certified
  - Detailed in training document

- Training session
- Training videos (NML, Abbott)
- Important documents
- Hands-on practice (quality control)

- Training quizzes and certificate
- Certification provided to YCDC and your supervisor



Abbott

ID NOW™ Training Certificate

FLU A/B 2____ Strep A 2____ RSV____ COVID-19____ (Check all that apply)

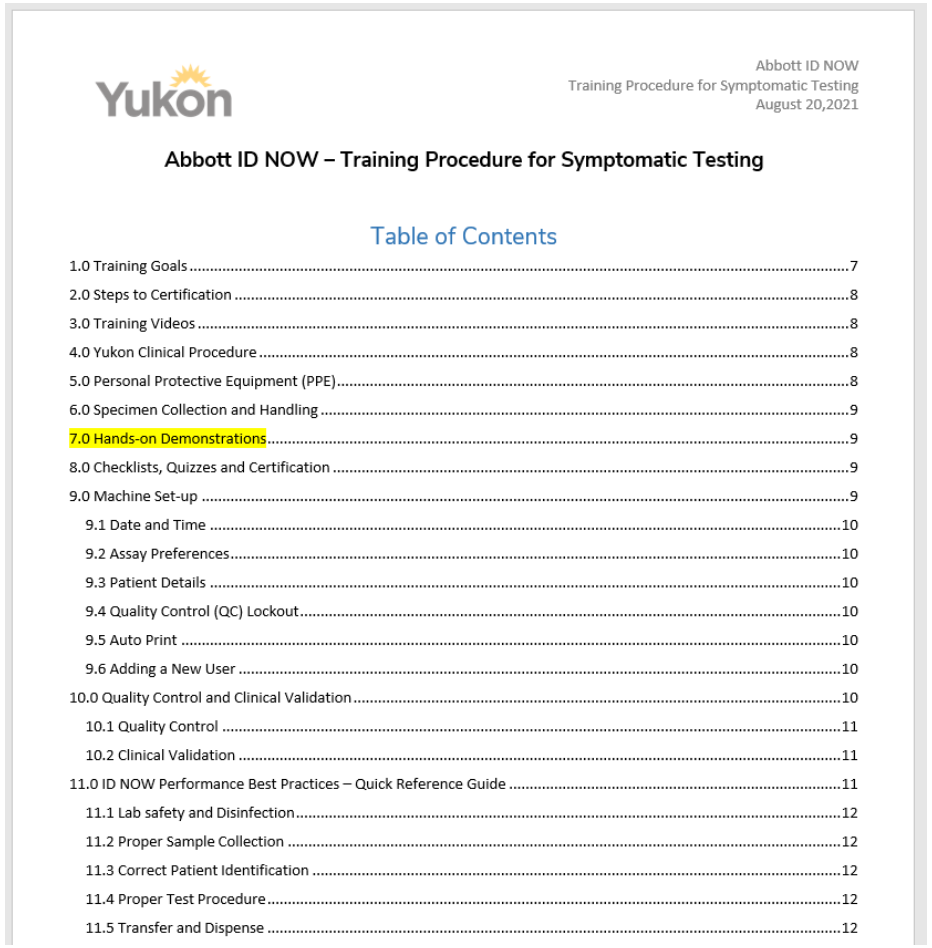
SYSTEM OVERVIEW	☐ User manual ☐ Serial number location ☐ Package Insert (PI)
SET-UP AND CONFIGURATION	☐ Instrument cleaning/maintenance ☐ Menu settings ☐ Date & time requirements
SELF-TEST	☐ Review functions of test ☐ Frequency of test
QUALITY CONTROL	☐ Storage & handling of control material ☐ Frequency of QC testing ☐ Logging results
TEST SAMPLE PROCEDURE	☐ Storage & handling of test material ☐ Sample requirements & storage ☐ Sample collection ☐ Running a test
TROUBLESHOOTING	☐ User manual ☐ Abbott product support: 800-257-9525

PRINT NAME OF TRAINER	SIGNATURE OF TRAINER	DATE
PRINT NAME OF TRAINEE	SIGNATURE OF TRAINEE	DATE

NAME OF INSTITUTION/FACILITY

FOR EXTERNAL USE. PRINT AND DISTRIBUTION PERMITTED.

Training and Best Practices



Yukon

Abbott ID NOW
Training Procedure for Symptomatic Testing
August 20,2021

Abbott ID NOW – Training Procedure for Symptomatic Testing

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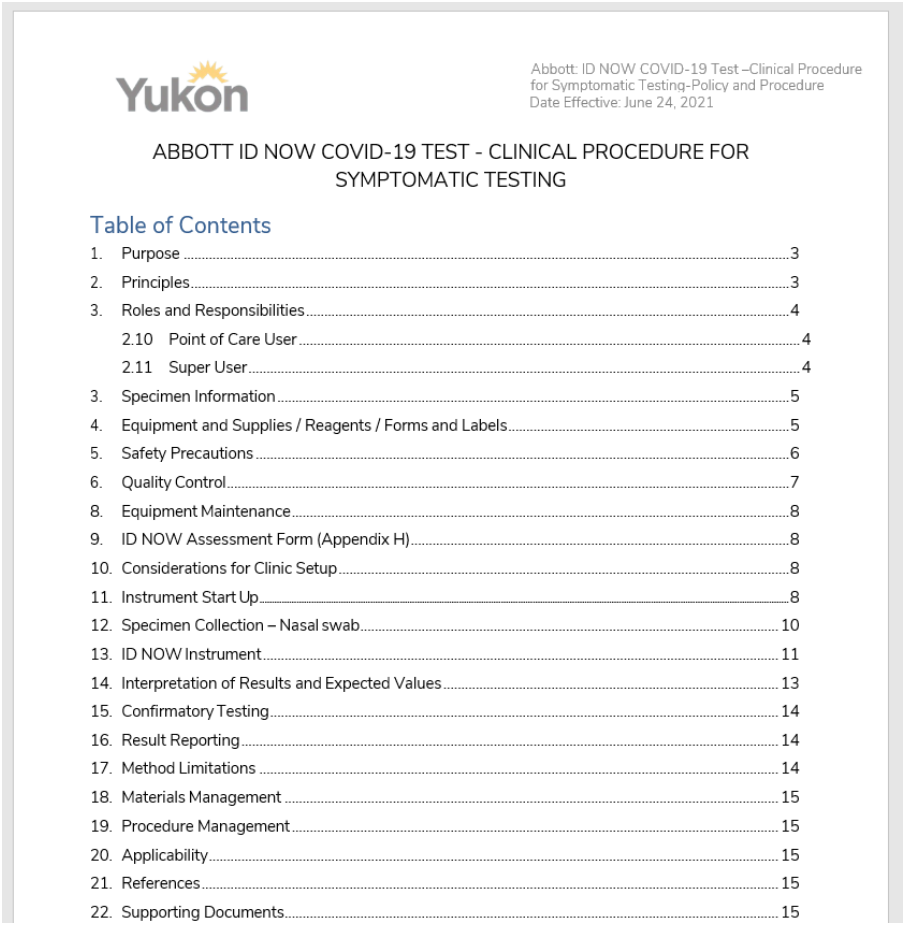
- Outlines training steps and certification process
- Setting up a new machine
- Best practices quick reference guide

Clinical Procedure



Yukon

Abbott: ID NOW COVID-19 Test –Clinical Procedure for Symptomatic Testing-Policy and Procedure
Date Effective: June 24, 2021

ABBOTT ID NOW COVID-19 TEST - CLINICAL PROCEDURE FOR SYMPTOMATIC TESTING

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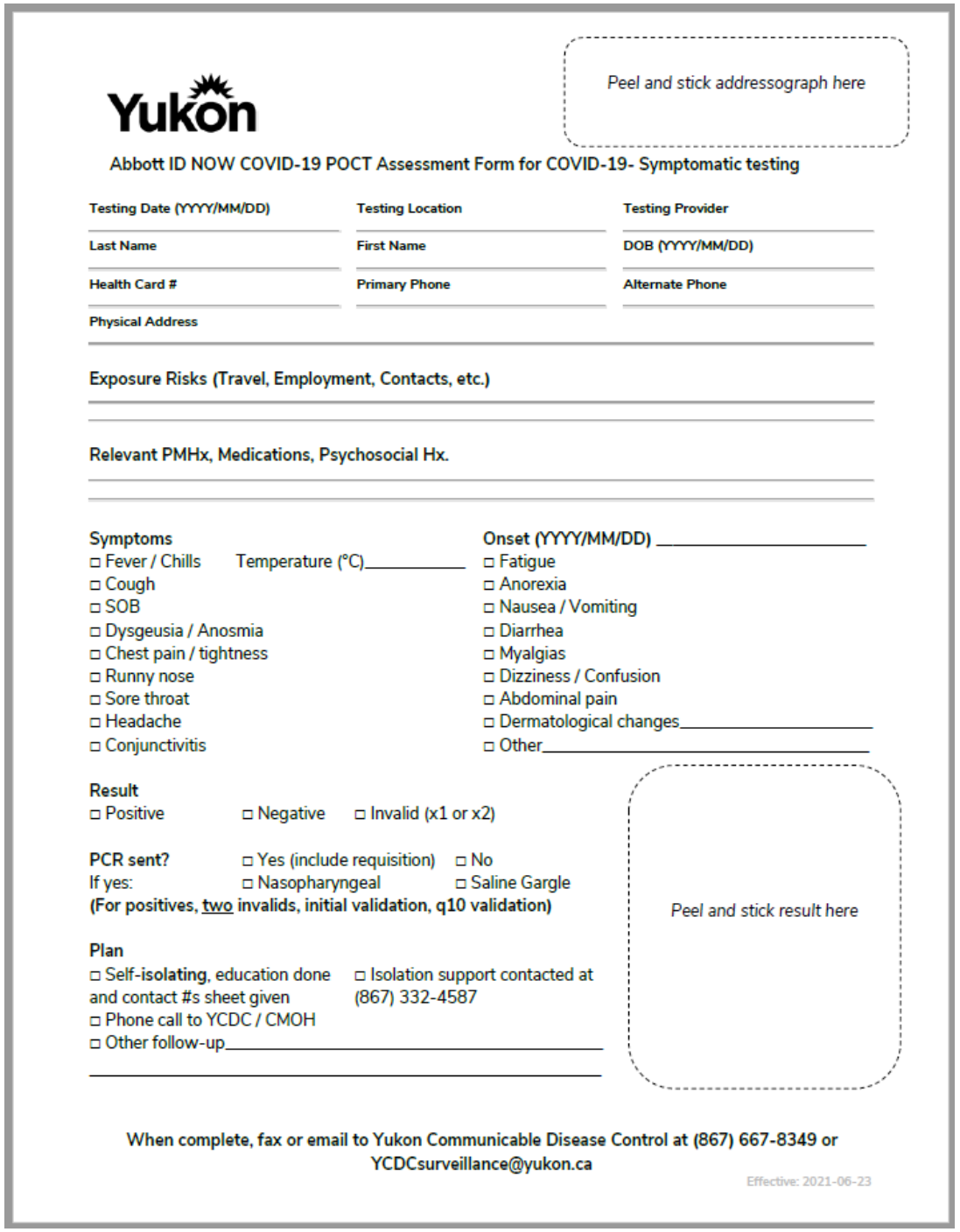
- Detailed background information on Abbott ID NOW in YT
- Procedural information
- Materials management and ordering
- Support information
- Instrument forms



Yukon

Peel and stick addressograph here

Abbott ID NOW COVID-19 POCT Assessment Form for COVID-19- Symptomatic testing

Testing Date (YYYY/MM/DD)	Testing Location	Testing Provider
Last Name	First Name	DOB (YYYY/MM/DD)
Health Card #	Primary Phone	Alternate Phone
Physical Address		

Exposure Risks (Travel, Employment, Contacts, etc.)

Relevant PMHx, Medications, Psychosocial Hx.

Symptoms
- ☐ Fever / Chills Temperature (°C)_____
- ☐ Cough
- ☐ SOB
- ☐ Dysgeusia / Anosmia
- ☐ Chest pain / tightness
- ☐ Runny nose
- ☐ Sore throat
- ☐ Headache
- ☐ Conjunctivitis

Onset (YYYY/MM/DD) _____
- ☐ Fatigue
- ☐ Anorexia
- ☐ Nausea / Vomiting
- ☐ Diarrhea
- ☐ Myalgias
- ☐ Dizziness / Confusion
- ☐ Abdominal pain
- ☐ Dermatological changes_____
- ☐ Other_____

Result
☐ Positive ☐ Negative ☐ Invalid (x1 or x2)

PCR sent? ☐ Yes (include requisition) ☐ No
If yes: ☐ Nasopharyngeal ☐ Saline Gargle
(For positives, two invalids, initial validation, q10 validation)

Peel and stick result here

Plan
- ☐ Self-isolating, education done and contact #s sheet given
- ☐ Isolation support contacted at (867) 332-4587
- ☐ Phone call to YCDC / CMOH
- ☐ Other follow-up_____

When complete, fax or email to Yukon Communicable Disease Control at (867) 667-8349 or YCDCsurveillance@yukon.ca

Effective: 2021-06-23

Assessment Form

- Demographics section
- Risk and history section
- Symptom section
- Result section
  - Confirmatory section
- Plan section

Instrument Setup and Standards

- All machines have an ‘admin’ login
  - Used to change settings and add users
- Follow the YG guide for machine setup/preferences to ensure consistency among test sites
- Each used must have a unique login (use YNET username)

Clinical Validation

- Essential to verify the instrument across different settings and populations
- First 10 tests per machine will be validated with PCR testing
- Every 10th test will be validated with PCR testing
- NP or Saline Gargle

Quality Control

- Machines must be QCd (+ & -):
  - With new user training
  - New cartridge LOT#
  - When the instrument is moved
  - Weekly, otherwise

- Must be logged in machine binder

Results Reporting Standards

- Positives should be emailed/faxed ASAP to YCDC
- Negatives can be batched and sent at the end of the day
- Ensure patient and provider information is entered in the ID NOW **and** on the paper copy
- Fill out forms completely, store according to unit policy

Supply Reporting

- Funding for the machines and cartridges is provided Federally
- Yukon is accountable for the tracking and use of supplies and cartridges
- Log your cartridges weekly for reporting purposes!

Have Questions?

- Questions related to the *application/use in the Yukon*
  - Call YCDC at (867) 667-8323
  - Email ycdcsurveillance@yukon.ca

- Technical questions:
  - Call Abbott Technical Support at 1-800-818-8335
  - Email canproductsupport@abbott.com

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Images used

- Fig 1: https://www.selectscience.net/images/products/7468_ID-NOW-RSV.jpg.ashx?width=250&height=250&bgcolor=white
- Fig 2: https://cdn.britannica.com/47/215947-050-66A6BF8B/Severe-acute-respiratory-syndrome-Coronavirus-SARS-CoV-2-COVID-19.jpg
- Fog 3 https://www.eppo.int/media/uploaded_images/MEETINGS/Meetings_2013/graphic.jpg
- Fig 4: https://static01.nyt.com/images/2020/10/02/us/charting-a-coronavirus-infection-promo-1601682548787/charting-a-coronavirus-infection-promo-1601682548787-superJumbo-v2.png
- Fig 5: https://i1.wp.com/emcrit.org/wp-content/uploads/2017/06/11image.png?resize=500%2C244
- Fig 6: https://www.rapidmicrobiology.com/rmbdata/userfiles/suppliers/abbott_laboratories/news/2019_ID_NOW.jpg
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