ID Now Comparison

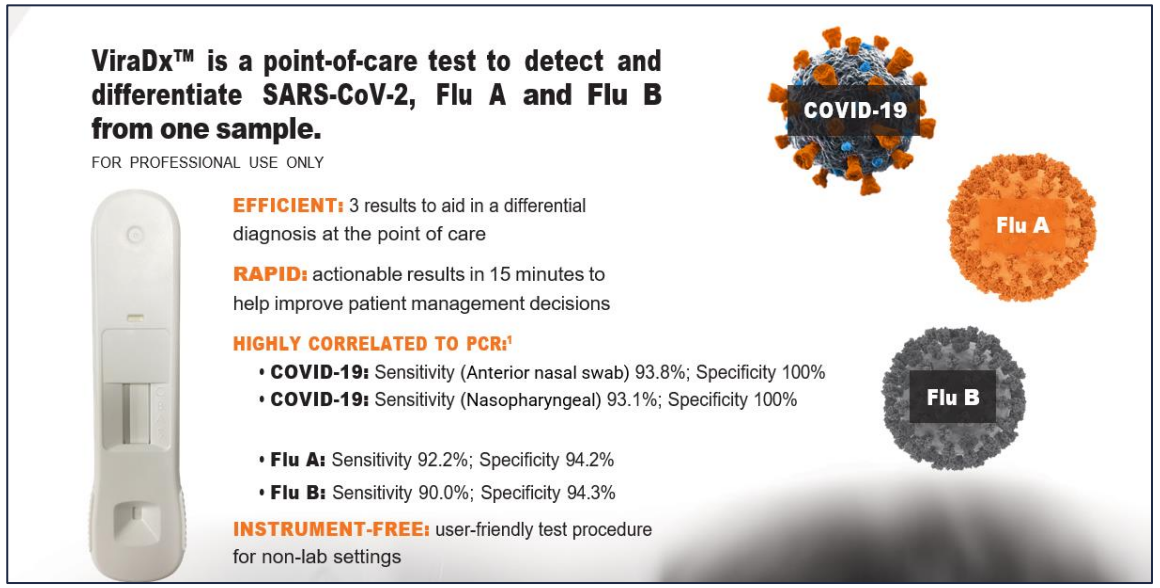
Product Offering Comparison

- ViraDx
  - 1 sample, 3 results
  - No instrumentation
- ID Now
  - Instrument 1: COVID-19 test
  - Flu A&B test
  - Additional test ***and*** instrument required for simultaneous testing (*Instrument 2)*

ID NOW™

ID NOW™ COVID-19 2.0

ID NOW™ INFLUENZA A & B 2

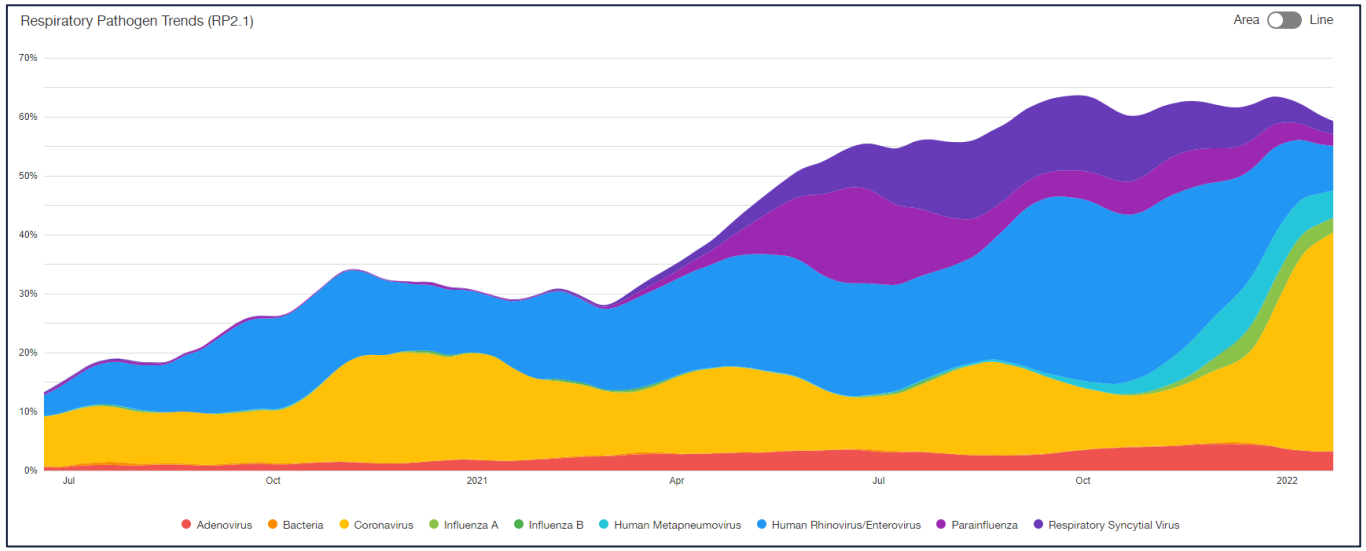


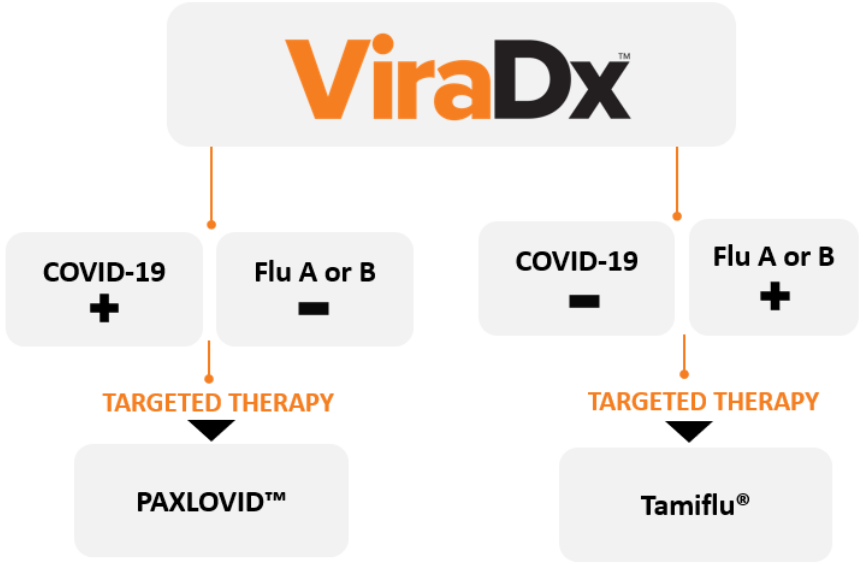
Differential Diagnosis

A differential diagnosis supports treatment decisions

- Flu and COVID-19 need to be managed differently and treatment can be time-sensitive
- A differential diagnosis at the POC will help improve patient management decisions and enable initiation of targeted therapy

Syndromic Trends data as of January 18, 2022





ID NOW Instrument

- Specifications
  - Per instrument
- Accessories
  - Is a printer required?
  - Is a barcode scanner required?
  - Is a USB Drive required?
- Ordering Information
  - How many instruments are required to meet your patient testing objectives?
    - For COVID-19?
    - For Flu A&B?
- Additional instrument considerations:
  - SW License, Maintenance, Service & Support, Training, Security

1.3 Instrument Specifications

1.3.1 Instrument	
Color Touch Screen	3.5”
Communications	10/100 Mbps Ethernet Port for Data Transfer 3 x USB Ports for data export, barcode reader and printer
	999 patient test results

11 ACCESSORIES

Accessories for use with ID NOW Instrument are available separately:

- Universal Printer
- Barcode Scanner
- ID NOW USB Drive

11.1 Universal Printer

Order Number: 55115

Replacement Sticker Roll: 26333

Data Cable: EQ005002

Refer to Universal Printer User Manual for more information. Abbott recommends using the Universal Printer with the ID NOW Instrument.

11.2 Barcode Scanner

Order Number: OPR2001ZWU1-201 or L-22X

Refer to the Barcode Scanner User Manual for more information. Only use the Barcode Scanner provided by Abbott with the ID NOW Instrument.

11.3 ID NOW™ USB Drive

Order Number: EQ004001

Abbott recommends using the ID NOW USB Drive with the ID NOW Instrument.

ID NOW Test Procedure Steps 1-3

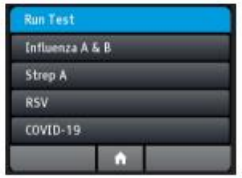
Step 1
Turn on the ID NOW Instrument - press the power button on the side of the instrument.

Note: If the unit is unattended for one hour, the instrument will go to a black screen power save mode. Touch the screen to return the unit to active display operation.

Enter User ID
Press '✓' after entry.

Touch 'Run Test'
This will begin the test process.

Touch 'COVID-19 Test'
This starts a COVID-19 test.



Enter Patient ID using on screen keyboard or barcode scanner.

Touch '✓'.

Verify that the ID was entered correctly, then touch '✓' to confirm entry.

Step 2

Open the Lid and Gently Insert Orange Test Base into Orange Test Base holder

Confirm that the correct test is displayed on the screen.

Touch 'OK' to proceed.

Caution: Once the Test Base has been placed in the holder, the user will have 3 minutes to confirm the test. If the test is not confirmed within 3 minutes, the instrument will time out and the Test Base must be removed and discarded.

If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a self-test before proceeding to the Home screen. Press Run Test and restart the test using the correct Test Base.

Step 3

Gently Insert Blue Sample Receiver into the Blue Sample Receiver holder.

Caution: Once the Sample Receiver has been placed in the holder, the user will have 8 minutes to start the test (Steps 3 through 5). If the test is not started within 8 minutes, the instrument will time out and all test pieces (Test Base and Sample Receiver) must be removed and discarded. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.

ID NOW Test Procedure Steps 4-6

Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once Warm Up begins.

Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT. DO NOT close the lid or insert the sample until prompted by the instrument.

Step 4

Direct Nasal or Nasopharyngeal Swab Test Procedure

When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.

Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.

Immerse the swab head completely in the Sample Receiver buffer and with a strong swirling motion, mix the swab in the liquid for 10 seconds. This helps remove the sample from the swab. Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid. Once the swab is removed, touch 'OK' to proceed.

Discard the swab into a biohazard waste container.

Step 5a

Press the White Transfer Cartridge into the Blue Sample Receiver. With both hands, press down firmly on the top of the White Transfer Cartridge.

Listen for a click.

When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing on to the Sample Receiver until it does.

Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.

Step 5b

Lift and then connect the White Transfer Cartridge to the Test Base. With both hands, press down firmly on the top of the White Transfer Cartridge. Closely observe the orange indicator located in the center of the White Transfer Cartridge.

When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing on to the Test Base until it does.

Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.

Step 6

Close the Lid.
DO NOT OPEN THE LID until the **Test Complete** message appears on the screen.

Note: The test will be cancelled if the lid is opened. A test result will not be reported or saved in Instrument memory.

Caution: This screen will be displayed for 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument will proceed to the Home screen. Collect a new sample from the patient. Press Run Test and restart the test using a new Test Base and Sample Receiver.

When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.

Caution: The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.

ID NOW Test Procedure Steps 7-8

Step 7
The **Test Results** screen displays either a Negative or Positive result for a successfully completed test. If a test error occurs, the display will read 'Invalid'. Refer to the Result Interpretation Section for Interpretation of Results.

Press New Test or Home to complete testing with this patient sample. Press Actions to print or send test results.

Step 8
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.

Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and clicking it into the Sample Receiver, by pressing into the Sample Receiver.

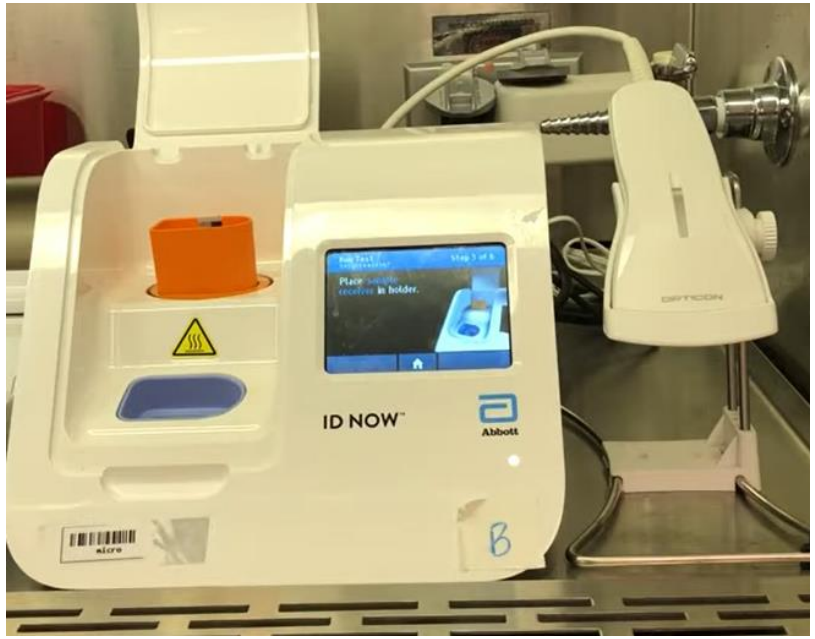
Caution: Do not try to remove the Sample Receiver by any other method as there is a risk of spilling the patient sample.

All test pieces will be connected and can now be removed from the instrument and disposed of according to federal, state and local regulations.

Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.

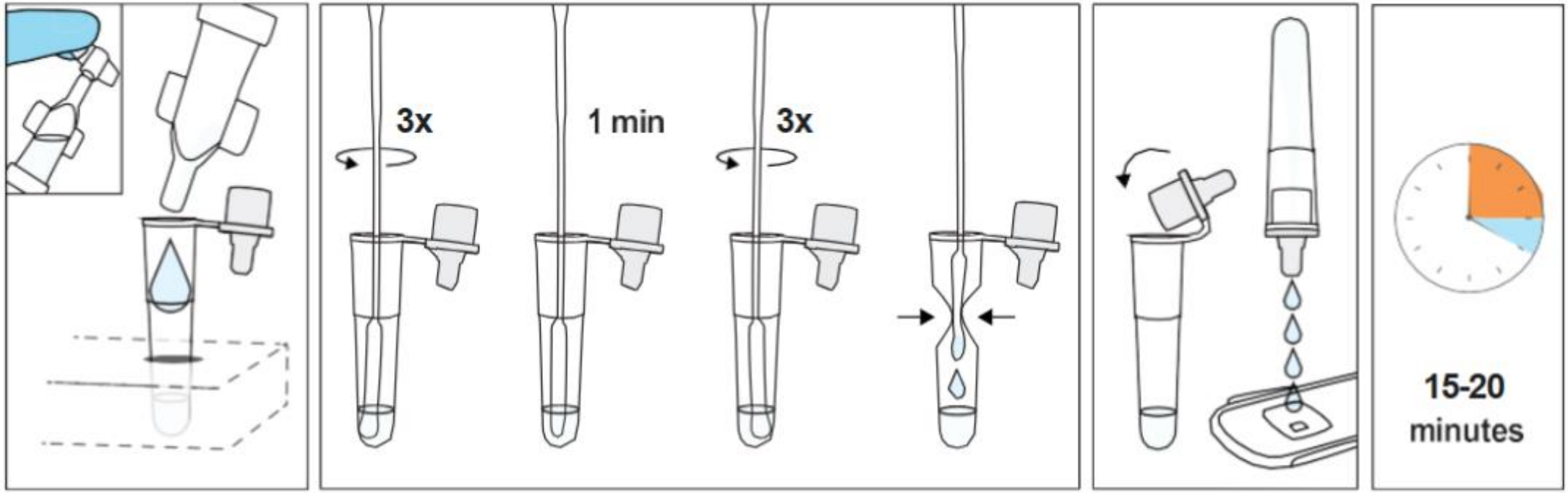
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.



- *See ID NOW video*
  https://www.youtube.com/watch?v=YdMQWCC7UWA

ViraDx Test Procedure



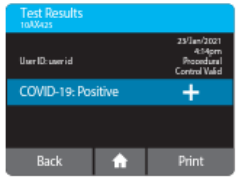
- ViraDx is a much simpler solution

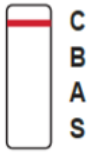
Results Interpretation Comparison

- ViraDx provides 3 easy-to-interpret-results from 1 sample
- No instrumentation required

RESULT INTERPRETATION – ID NOW™ COVID-19 2.0

When the test is complete, the results are clearly displayed on the instrument screen.

Instrument Display	Interpretation of Results and Follow-up Actions
	**COVID-19 Positive** Positive results do not rule out bacterial infection or co-infection with other viruses.
	**COVID-19 Negative** Negative results do not preclude SARS-CoV-2 infection.

A reddish purple S, A and/or B line(s) with C line is POSITIVE.	C line only **NEGATIVE (-)**	No C line **INVALID**
 **A line:** Influenza type A  **B line:** Influenza type B  **S line:** COVID-19		 
 **A & S lines:** Influenza type A & COVID-19*  **B & S lines:** Influenza type B & COVID-19*  **A & B lines:** Influenza type A & B*  **A, B & S lines:** Influenza type A, B & COVID-19*	**Negative results are presumptive and may need to be confirmed with a molecular assay.**	**Repeat with new sample and device.**

Why ViraDx?

- ViraDx is easy to use
  - No instrumentation required
  - No throughput issues
- ViraDx provides 3 results from 1 sample
  - ID Now requires 2 tests to provide the same results
    - Significant cost, time, and workflow burden to healthcare provider *and* patient
  - ID NOW will require additional instrument(s) to meet testing throughput objectives
- ViraDx matches Urgent Care workflows
  - Visual read, lateral flow technologies familiar to Urgent Care providers
  - Isothermal nucleic acid amplification technology (NAAT) and instrumentation less familiar, requiring more training
- ViraDx offers great value to Urgent Care facilities considering ID NOW for COVID-19 testing, and even more value when Flu A&B testing is included in the clinical patient assessment

ViraDx – ID NOW Comparison

Test	Abbott ID NOW COVID-19 2.0	LUMOS DIAGNOSTICS ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test	Abbott ID NOW Influenza A & B
Regulatory status	510k (K221925) , CLIA-Waived	EUA, CLIA-Waived	510k (K232775) , CLIA-Waived
Analytes detected	SARS-CoV-2	SARS-CoV-2, Flu A, Flu B	Flu A, Flu B
Instrument required	Yes – ID NOW	No – visually read	Yes – ID NOW
Technology	Isothermal nucleic acid amplification technology (NAAT)	Lateral flow, immuno-chromatographic assay	Isothermal nucleic acid amplification technology (NAAT)
Sample type	Nasal and NP swabs	Nasal and NP swabs	Nasal and NP swabs
Intended use population	Individuals suspected of COVID-19 within first 7 days of symptoms	Individuals suspected of COVID-19 within first 5 days of symptoms	Individuals with signs and symptoms of respiratory infection
Time to detection	Negative result: 13 minutes Positive result: ≤13 minutes (as early as early 6 minutes)	15 minutes	Negative result: 13 minutes Positive result: ≤13 minutes (as early as early 5 minutes)
External controls	Included (*and available separately*)	Included	Included (*and available separately*)
Tests/kit	24	25	24
Performance	COVID-19 Sensitivity (Nasal): 92.5% COVID-19 Sensitivity (NP swab): 94.0% COVID-19 Specificity (both): 98.5%	COVID-19 Sensitivity (Nasal): 93.9% COVID-19 Sensitivity (NP swab): 93.1% COVID-19 Specificity (both): 100% Flu A Sensitivity: 92.2% Flu A Specificity: 94.2% Flu B Sensitivity: 90.0% Flu B Specificity: 94.3%	Flu A Sensitivity (Nasal): 96.3% Flu A Specificity (Nasal): 97.4% Flu B Sensitivity (Nasal): 100% Flu B Specificity (Nasal): 97.1% Flu A Sensitivity (VTM): 92.8% Flu A Specificity (VTM): 98.5% Flu B Sensitivity (VTM): 100% Flu B Specificity (VTM): 97.7%