Current Status: *Active*		**PolicyStat ID:** *8775708*
	Origination:	*4/7/2020*
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	Final Approved:	*10/30/2020*
	Last Revised:	*10/30/2020*
Valley Laboratories	**Next Review:**	*10/30/2022*
	Owner:	*Lindsey Westerbeck: Dir, Lab*
	Policy Area:	*Lab - Microbiology*
	References:	
	Applicability:	*Valley Laboratories*

Performing an ID NOW COVID-19 Assay

PURPOSE

ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid (13 minutes or less) molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2RNA is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

POLICY

- Order Code: **COVI19** (*SARS-CoV-2 RNA, Qualitative NAA)*
- Testing is to be performed upon receipt by trained CLS and/or MLT staff across all shifts.
- As defined, positive results are to be called to the caregiver of the patient.
- Positive results are electronically reported to local, state and government agencies as required.
- Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high, moderate, or waived complexity tests.
  - The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

EQUIPMENT, REAGENTS AND SUPPLIES

- ID NOW Analyzer
- **ID NOW COVID-19 Test Kit** - Store kit at 2-30°C and use until expiration date marked on the outer packaging and containers
  - Test Bases
  - Sample Receivers
  - Transfer Cartridges
  - Patient Swabs
  - Positive and Negative Control Swab
- PPE - To include mask, eye protection, lab coat and gloves
- One of the following acceptable cleaning agents:
  - 70% ethanol - available in commercial wipes or on a damp, lint free cloth
  - 70% isopropanol - available in commercial wipes or on a damp, lint free cloth
  - 10% bleach - on a damp, lint free cloth only

SPECIMEN REQUIREMENTS

- Direct swabs (using swab provided in kit) should be used for testing and tested as soon as possible after collection.
  - Use freshly collected direct **nasal swab specimens** for optimal test performance. Freshly collected NP or throat swab collected specimens are also acceptable if received for testing.
- If immediate testing is not possible, and to maintain best performance, it is highly recommended that the swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30°C) for up to **1 hour** prior to testing.
  - If the swab is to be returned to its package for transport, carefully return to allow the swab head to **only** come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab.
- If greater than 1 hour delay occurs, a new sample **must** be collected for testing.
- **NOTE**: Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

- Swabs submitted in transport media are **NOT** suitable for use with the Abbott ID NOW COVID-19 assay.
  - Verify order and suggest testing by alternative method (i.e. send out to Shared Lab) if recollection is not possible.
  - Recollect using the direct swab provided in kit if recollection is possible and expedited turnaround time is necessary.

Specimen Type	Acceptable Swab Type
Nasal **NOTE**: Using same swab, perform sample collection from **both** nostrils.	For optimal test performance, use the swabs provided in the test kit • **Acceptable alternative swab types**: Rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs • **NOT acceptable swab types**: Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs
Nasopharyngeal	Sterile rayon, foam, polyester or flocked flexible-shaft NP swabs
Throat	For optimal test performance, use the swabs provided in the test kit. • **Acceptable alternative swab types**: Foam, polyester, HydraFlock® and nylon flocked throat swabs • **NOT acceptable swab types**: Rayon swabs

QUALITY CONTROL - EXTERNAL

- Positive Control Swab and Sterile Swab (Negative Control), which are included in the ID NOW COVID-19 kit, should be tested once with **each** new lot/shipment to ensure that test reagents are working and that the test is correctly performed.
  - External QC will be rotated on ID-NOW instruments with each lot/shipment
- Control swabs should also be tested once for each untrained operator.
- The QC test is run in the same manner as outlined in the "***TEST PROCEDURE***".
  - Refer to subsection in procedure listed above for step by step instructions to process control swab for testing.
  - To program QC testing to run, refer to instructions below.

Step	Action
1	Touch 'Run QC Test' on home screen.
2	Touch 'COVID-19'
3	Select the QC Test to be Run
4	Confirm Test • Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.
5	The ID NOW Instrument will report QC results as **Pass** or **Fail** once testing is complete.
6	If QC passes, lot/shipment is acceptable to use for patient testing.
7	If QC fails, **do not** perform patient tests or report patient results. • Contact Technical Support (855-731-2288) during normal business hours before testing patient specimens on instrument. • If Technical Support is not available, repeat QC using control swabs from a different kit from same lot/shipment. ◦ If QC passes upon testing with new control swabs, quarantine kit that did not pass and do not use for patient testing. ◦ If QC fails again, do not use any kits from shipment until contacting technical support for further troubleshooting. • Notify supervisor immediately of any QC failures and actions taken.
8	Document all external QC results and actions taken on *Form A: ID NOW COVID-19 External QC* log

QUALITY CONTROL - INTERNAL

- ID NOW COVID-19 has built-in procedural controls run with each test performed.
  - Contains an internal control that has been designed to control for sample inhibition and assay reagent function.
  - In positive samples where target amplification is strong, the internal control is ignored and the target amplification serves as the '**control'** to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust.
    - At a very low frequency, clinical samples can contain inhibitors that may generate invalid results.

- The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result.
    - This can be reviewed later by selecting Review Memory on the instrument.

PRECAUTIONS

- For in vitro diagnostic use.
- For use under an Emergency Use Authorization Only.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
- To be used in conjunction with the ID NOW™ Instrument.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test pieces sealed in their foil pouches until just before use.
- Do not tamper with test pieces prior to or after use.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots or from other ID NOW™ assays.
- Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.
- Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
- If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
- All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. Pieces must not be separated once they are assembled.
- All test pieces are single use items. Do not use with multiple specimens.
- Once reacted, the Test Base contains large amounts of amplified target (Amplicon). **Do not disassemble the Test Base and Transfer Cartridge.** In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW™ COVID-19 false positive test results.
- At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
- Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

TEST PROCEDURE

Please refer to the ID NOW™ Instrument User Manual for full instructions.

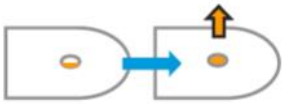
- Before testing with ID NOW™ COVID-19:
    - Allow all samples to reach room temperature.
    - Allow all test pieces to reach room temperature.
    - Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument.
        - Do **not** use the Test Base if a pellet is not visible at the bottom of each reaction tube.

IMPORTANT: Work surfaces should be cleaned and decontaminated before and after processing samples to prevent cross-contamination.

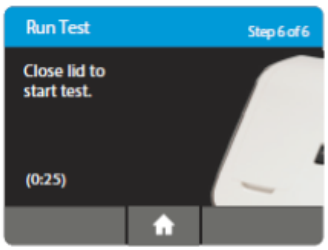
- Use Enhanced Precautions when handling samples and used test pieces, as they are capable of transmitting infectious agents, including wearing a mask and eye protection in addition to lab coat and gloves.
- Change gloves between samples.
- Change or remove gloves before using computer.

Step	Action
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.
2	Enter User ID Press '✔' after entry.
3	Touch 'Run Test' • This will begin the test process.
4	Touch 'COVID-19 Test' • This starts a COVID-19 test.
5	Select Sample Type
6	Scan Sunquest barcode label affixed to patient sample for COVI19 test at "Enter Patient ID" prompt using barcode scanner. • Touch '✔'. • Verify that the ID was entered correctly, then touch '✔' to confirm entry.
7	Open the Lid and insert Orange Test Base into Orange Test Base holder. • **CAUTION**: Do not apply excessive force. Excessive force could damage the instrument.
8	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 **10 minutes** to confirm the test. If the test is not confirmed within 10 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.
9	Insert Blue Sample Receiver into the Blue Sample Receiver holder. • **CAUTION**: Do not apply excessive force. Excessive force could damage the instrument. • **CAUTION**: Once the Sample Receiver has been placed in the holder, the user will have **10 minutes** to start the test. If the test is not started within 10 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.
10	Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once the 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
11	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.
12	Vigorously mix the swab in the liquid for 10 seconds. • Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab. • Once the swab is removed, touch 'OK' to proceed
13	Discard the swab.
14	Press the White Transfer Cartridge into the Blue Sample Receiver • 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 onto 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.

	
15	Lift and then connect the Transfer Cartridge to the Test Base • 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 onto 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 negative results. 
16	Proceed to Test Run and Completion Procedure.

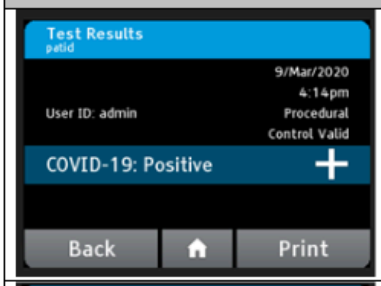
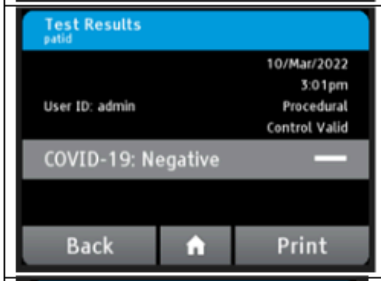
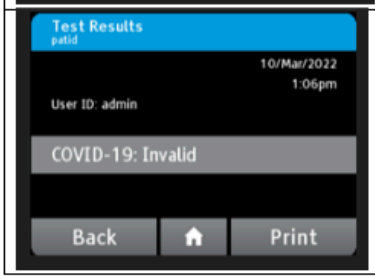
TEST RUN AND COMPLETION PROCEDURE

Step	Action
1	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 all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. ◦ A test result will not be reported or saved in the instrument memory.
2	**IMPORTANT**: This screen will be displayed for up to 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.  • If it times out, the instrument will proceed to the Home screen a new specimen will be required. Press Run Test and restart the test using a new Test Base and Sample Receiver.
3	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.
4	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.
5	Press Print to print test results if they do not print automatically. • Press New Test to run another test. • Press Home to return to the Home screen.
6	After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.
7	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.
8	All test pieces will be connected and can now be removed from the instrument and disposed of in the biohazard waste.

	• **CAUTION**: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.
9	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

RESULT INTERPRETATION

Step	Action
1	When the test is complete, the results are clearly displayed on the instrument screen as well as printed (if universal printer is connected).

Instrument Display	Interpretation of Results and Follow-up Actions
	**COVID-19 Positive**
	**COVID-19 Negative** **This result does not rule out co-infections with other pathogens.**
	**The presence or absence of COVID-19 Viral RNAs cannot be determined.** Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

2	If an Invalid result is received, one additional test may be run using the same Sample Receiver. The instructions below should be followed: • Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. ◦ The connected Test Base and Transfer Cartridge MUST be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package may be used for this. • Remove the blue Sample Receiver separately and carefully from the instrument. ◦ The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents. • From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and **DO NOT** reuse/re-elute the swab.
3	If instrument is not interfaced or interface is down, *Form B: ID NOW Test Result Log* can be used for result documentation and manually reporting of results.

REPORTING RESULTS

If Result Is	Then Report
COVID-19: Negative	• **NOTDET** (*Not Detected*)

	• The following ETCs will auto-append to result: ◦ **COVNGR**: *Negative results do not exclude the possibility of infection. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay.* ◦ **ASYMOL:** *Performance of this test has not been evaluated for asymptomatic individuals and may be associated with false negative results.* ◦ **COVEU2:** *COVID-19 lab tests are currently reviewed by the FDA under Emergency Use Authorization (EUA).* ◦ **COVABT:** *This test was performed by Abbott ID Now methodology* ◦ **COVFTA:** *A Patient Fact sheet is available here: https://www.fda.gov/media/136524/download*
COVID-19: Positive	• **DET1** (*Detected*) • The following ETCs will auto-append to result: ◦ **MOLPOS:** *Positive results should be interpreted in conjunction with clinical evidence, since this assay does NOT distinguish between infectious and non-infectious (e.g. latent, treated) organisms.* ◦ **COVEU2:** *COVID-19 lab tests are currently reviewed by the FDA under Emergency Use Authorization (EUA).* ◦ **COVABT:** *This test was performed by Abbott ID Now methodology* ◦ **COVFTA:** *A Patient Fact sheet is available here: https://www.fda.gov/media/136524/download*
COVID-19: Invalid *(after repeat testing)*	• **INDET2** *(Indeterminate)* • The following ETCs will auto-append to the result: ◦ **MOLIND**: *Indeterminate due to possible inhibiting or interfering substances. Recollect if clinically indicated.* ◦ **COVEU2:** *COVID-19 lab tests are currently reviwed by the FDA under Emergency Use Authorization (EUA).* **COVABT:** *This test was performed by Abbott ID Now methodology* ◦ **COVFTA:** *A Patient Fact sheet is available here: https://www.fda.gov/media/136524/download* • Indeterminate COVID-19 results are called to the caregiver of the patient to notify of the need to recollect if clinically indicated.

TECHNICAL LIMITATIONS

- The performance of the ID NOW COVID-19 test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen.
- As with any molecular test, if the virus mutates in the target region, COVID-19 may not be detected or may be detected less predictably.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.
- ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.
- Swab samples eluted in VTM are not appropriate for use in this test.

REFERENCES

- ID NOW™ COVID-19 Product Insert, IN190000 Rev 6.4 2020/09/21.
- ID NOW™ COVID-19 Technical Brief, *September 2020 ID NOW COVID-19 Labeling Update*, 120007361-01 09/20.

All revision dates: 10/30/2020, 5/11/2020, 4/7/2020

Attachments

Form A: ID NOW COVID-19 External QC
Form B: ID NOW Test Result Log

Approval Signatures

Step Description	Approver	Date
Lab Directors/Managers	Pamela Hill: Dir, Laboratory	10/30/2020
Lab Directors/Managers	Steven Stern: Mgr, Laboratory	10/30/2020
Lab Directors/Managers	Michelle Nordaas: Mgr, Lab	10/30/2020
Lab Directors/Managers	Stephen Medland: Mgr, Clinical Lab	10/28/2020
Lab Directors/Managers	Lise Bashe: Mgr, Ambulatory Lab	10/28/2020
Lab Directors/Managers	Lindsey Westerbeck: Dir, Lab	10/28/2020
Lab Directors/Managers	Mary Cabral: Mgr, Laboratory	10/28/2020
Lab Medical Directors	Jamie Cassity: MD	10/28/2020
Lab Medical Directors	Andrea Ong: MD	10/26/2020
Lab Medical Directors	Marian Butcher: MD	10/26/2020
Lab Medical Directors	Hannah Wong: MD	10/26/2020
Lab Medical Directors	Rowberry Ron: MD	10/26/2020
Lab Medical Directors	Mary Keohane: MD	10/23/2020
Lab Medical Directors	Kristen Vandewalker: MD	10/23/2020
	Lindsey Westerbeck: Dir, Lab	10/22/2020