Title: ID NOW (Influenza A/B & Strep A2) Document No. POC 43 113 Rev. No. 1.2

POC 43 113 ID NOW (Influenza A/B & Strep A2)

Copy of version 1.2 (past periodic review date (1/28/2023))

Last Approval or Periodic Review Completed	1/28/2021	**Controlled Copy**	ID 419216
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Next Periodic Review Needed On or Before	1/28/2023	**Organization**	VA Memphis
Effective Date	1/31/2022		

Comments for version 1.0 (last major revision)
Initial versionPOC 43 113 NOT POC 41 113Updated recertification date. minor formatting issues.
concurReviewed by A. Hankerson

Comments for version 1.2 (this revision)
qc reviewqc revisionreviewedConcurconcurREVIEWED BY A. HANKERSON

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/28/2021	1.0	Eugene Pearlman	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.2	Past Periodic Review Date (1/28/2023)	Minor revision	11/3/2021	1/31/2022	Indefinite
1.1	Retired	Minor revision	2/26/2021	5/12/2021	1/31/2022
1.0	Retired	Initial version	12/12/2020	1/28/2021	5/12/2021

1/31/2022

ID NOW

POC 41 113

Memphis VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine Service

Signatory Authority:
Chief, Pathology and Laboratory Medicine Service

Effective Date:
December 25, 2020

Responsible Owner:
Kimberly Ballard
Ancillary Testing Coordinator

Recertification Date:
December 31, 2025

1. PURPOSE AND AUTHORITY

a. The **ID NOW™ Influenza A & B 2** assay is a CLIA Waived rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection.

b. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

c. The **ID NOW™ Strep A 2 is** a CLIA Waived rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

2. ASSIGNMENT AND RESPONSIBILITY

a. **Chief of P&LMS.** Overall responsible for ensuring the laboratory has an effective communication system.

b. **Ancillary Testing Coordinator.** Responsible for implementing a comprehensive procedure for performing testing on this instrument, conducting operator assessments, and providing any training.

c. **Ancillary Testing Specialist.** Aiding operators, performing training, required troubleshooting of instruments and other duties as needed by Ancillary Testing Coordinator.

d. **All Staff members.** Responsible understanding and adhering to the policies and protocols outlined in this SOP.

3. DEFINITIONS

a. **PPE** Personal Protective Equipment i.e. gloves, face shield, goggles, lab coat, etc.

b. **QC** Quality Controls, to be performed monthly and or every new lot of test kits.

c. **Waived Test** Complexity of the test whereas the interpretation, performance and sampling of the test is of low risk.

4. SPECIMEN INFORMATION

a. **Specimen Collection** Table 1. Specimen Collection and Handling

	Strep A 2	Influenza A & B 2
Specimen:	Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.	Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.
Specimen Collection & Handling Specimen Collection & Handling continued	For optimal performance, use the swabs provided in the test kit. Alternatively, foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples. The BBL™ CultureSwab™ Liquid Amies transport media system has been tested and is also acceptable. Rayon swabs and the BBL™ CultureSwab™ Liquid Stuart transport media system are not suitable for use in this assay. Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[3]	**Nasal Swab:** For optimal test performance, use the swabs provided in the test kit. Alternatively, rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples. Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use in this assay. To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril.

		Nasopharyngeal Swab: Use sterile rayon, foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal sample. To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Pass the swab directly backwards without tipping the swab head up or down. The nasal passage runs parallel to the floor, not parallel to the bridge of the nose. Using gentle rotation, insert the swab into the anterior nare parallel to the palate advancing the swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn. To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. **DO NOT USE FORCE** while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.
Specimen Transport & Storage	Swab specimens should be tested as soon as possible after collection. If immediate testing is not possible, the throat swab can be held in its original package or a clean, dry plastic tube or sleeve at room temperature (approximately 22°C) or refrigerated at 2-8°C for up to seventy-two (72) hours prior to testing. The collection swab is to be tested following the step-by-step instructions shown on the instrument screen. If immediate testing is not possible, the transport media system can be held at room temperature (approximately 22°C) or refrigerated at 2-8°C for up to six (6) hours prior to testing.	Direct nasal or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal or nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct nasal or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection. If the transport of nasal or nasopharyngeal swab samples is required, the transport medias listed below were tested and are acceptable for use in ID NOW™ Influenza A & B 2. Elute the swab

		into 0.5 to 3.0 mL of saline or viral transport media by rotating the swab in the liquid for 10 seconds, within 1 hour of sample collection. Remove the swab and discard. If immediate testing is not possible, eluted swab samples can be held at room temperature (15-30°C) for up to eight (8) hours prior to testing. If the eluted swab sample will be held longer than eight (8) hours, it must be refrigerated at 2-8°C and tested within 72 hours from the time of sample collection. If needed, transport the sample at 2-8°C in a leak-proof container. Swirl eluted swab samples in transport media gently to mix before testing. ***Note:*** *Minimal dilution of the sample is recommended as dilution may result in decreased test sensitivity.* **Transport Media** Amie's Media Dulbecco's Modified Eagles' Medium (D-MEM) Hank's Balanced Salt Solution M4 Media M4-RT Media M5 Media M6 Media Phosphate Buffered Saline Saline Stuart's Media Universal Transport Media Starplex Multitrans
Specimen Transport & Storage continued		It has been determined that Tryptose Phosphate Broth, Brain Heart Infusion Broth, Veal Infusion Broth, and Wako's E-MEM transport media are **NOT** suitable for use with this test.

5. SPECIAL SAFETY PRECAUTIONS

a. Operating Environment: 15-30℃

b. Once reacted, the Test Base contains large amounts of amplified sample (Amplicon). Do not disassemble the Test Base and Transfer Cartridge which could lead to amplicon leakage.

c. Follow proper infection control guidelines for handling all specimens and related items.

6. EQUIPMENT/ FORMS

a. ID Now Instrument

b. Universal Printer

c. Barcode Scanner

d. Power Supply and Adapter

e. ID NOW Patient Worksheet/ Log Sheet

7. REAGENTS

a. **Supplies**

(1) Throat or Nasal Swab (appropriate for test being performed, refer to Table1.)

(2) Orange Test Base

(3) Blue Sample Receiver

(4) White Transfer Cartridge

(5) Control Swabs (Positive and Negative, if performing quality controls)

b. **Kit Handling and Storage**

(1) Handle all specimens with standard universal precautions.

(2) Store kits at 2-30℃. Do not freeze. Kits must be at Room Temperature before use.

(3) Kits are stable until expiration dates marked on the outer packaging and container.

(4) Kits are only to be used with ID NOW instrument and should not be opened until ready to be used on the instrument.

8. QUALITY CONTROLS

a. Required to be performed once a month, once every new lot is received, or new user is trained.

b. Internal quality controls are built-in procedural controls. The result of the procedural controls is displayed on the screen and automatically stored in the

instrument with each test result. This can be reviewed later by selecting ‘Review Memory’ on the instrument

c. Patient testing is prohibited on failed or invalid internal procedural control. Repeat testing is required.

d. External positive and negative control swabs are included in every kit.

e. Quality controls are indicated by either “PASS” or “FAIL”. Instruments where quality controls have “PASSED” are satisfactory for patient use.

f. Instruments or kits where quality controls have “FAILED” should be repeated using a new test strip/ cartridge and control solutions. Failed results could be an indicator of sampling air bubbles, expired reagents/ supplies, or underfilling test strips/ cartridges.

g. Cease patient testing if failed quality controls persist by the third trial. Contact ATC for further troubleshooting instructions, to gain a replacement meter, or other testing supplies.

h. If ATC is unavailable, cease patient testing, remove meter & kit from service (attach a ‘Do Not Use” label or give to charge nurse on duty to arrange return to ATC) collect appropriate patient sample for analysis by the main lab.

(1) For QC testing, select ‘Run QC’ Test on the Home screen.

(2) Select Influenza A & B or Strep A 2, then Positive or Negative.

(3) Press ’Edit QC Sample’ to enter the lot number of the control swab being tested then hit √, confirm test, then press ‘OK’.

(4) Follow same instructions below starting at Step 7 under. Procedure.

9. EQUIPMEMT CALIBRATION AND MAINTENANCE

a. The ID NOW Instrument is factory calibrated and does not require any further calibration.

b. A correlation can be performed at least once a year with samples from Microbiology department.

c. The ID NOW is maintenance free and has no serviceable parts. In the case of instrument failure or damage, contact Ancillary Testing for further troubleshooting assistance or Abbott Technical Support at 855-731-2288 or ts.scr@abbott.com

d. Do not disassemble the instrument.

e. Daily cleaning of the exterior surfaces and surfaces visible under the lid is recommended by the manufacturer. Clean the surrounding bench area between each patient to decrease sample contamination.

f. Acceptable cleaning agents include only 70% ethanol, 70% isopropanol, 10% bleach on a damp, lint free cloth.

10. PROCEDURES

a. **General Procedure.**

(1) Don appropriate personal protective equipment to retrieve sample from patient based on test to be performed.

(2) Turn on the ID NOW instrument by pressing the power button on the rightside panel or touching the screen if it has been in power save mode.

(3) Open both white Package 1 (base) and Package 2 (receivers). Pull tab up without removing the foil seal on the Blue Sample Receiver and set all 3 pieces aside.

(4) Enter the User ID by barcode entry or touchscreen keyboard- Press √ after entry.

(5) Touch 'Run Test'- This will begin test process.

(6) Touch appropriate test (Influenza A & B 2 or Strep A 2) from the menu- This starts the selected test to process.

(7) Enter patient ID using the barcode scanner or touch screen keyboard. Touch √. Verify that the ID was entered correctly, then touch √ again to confirm entry.

(8) Open the lid and gently insert the Orange Test Base into the orange Test Base Holder.

(9) Confirm that the correct test is displayed on the screen within 10 minutes. Touch 'OK' to proceed. The instrument will time out after 10 minutes and the Test base must be removed and discarded if not confirmed.

(10) Insert Blue Sample Receiver gently into the Blue Sample Receiver holder.

(11) When prompted, remove the foil seal by placing two fingers along the outer edge of the Blue Sample Receiver to hold it in place.

(12) Vigorously mix the sample swab into the Blue Sample Receiver 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. Press 'OK' to proceed after the swab is removed.

(13) Discard the swab. Press the White Transfer Cartridge onto the Blue Sample Receiver. Listen for a click.

(14) When the Transfer Cartridge is properly attached to the blue 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 with slight force.

(15) Lift the white Transfer Cartridge onto the orange Test Base. When the white Transfer Cartridge is properly attached to the orange Test Base, the orange indicator on the Transfer Cartridge will lower. If the orange indicator does not lower, continue pushing onto the Test Base until it does.

(16) If the orange indicator does not fully lower, not enough sample will be dispensed into the orange Test Base. This may result in invalid or false negative results. Follow prompts to close lid. DO NOT OPEN UNITIL 'Test Complete" message appears on the screen. The test will be cancelled if the lid is opened.

(17) The Test Results screen will display a Negative or Positive result for a successfully completed test. If a test error occurs, 'Invalid' will be displayed on the screen.

(18) Press 'Print' to print test results if auto print has not been previously saved under settings. Press New Test to run another patient sample or Home to return to the home screen.

(19) The instrument will now prompt to open lid and discard all used test pieces.

(20) Remove test pieces by lifting the attached white Transfer Cartridge with orange Test Base and pressing onto the blue Sample Receiver until a click is heard.

(21) All test pieces will be connected and can now be removed from the instrument and disposed. Do not disassemble any of the testing pieces and do not discard before attaching for disposal.

b. **Limitations.**

(1) Influenza A & B 2

(a) The performance of the ID NOW Influenza A & B was evaluated using procedures provided in the package insert only. Modifications to these procedures may alter the performance of the test.

(b) The ID NOW can only be cleaned using 70% ethanol, 70% isopropanol, or 10% bleach solution with a lint free cloth. Do not spray or pour cleaning solution directly onto the instrument as it may cause damage to the instrument.

(c) Performance of ID NOW Influenza A&B has not been established for monitoring antiviral treatment of influenza.

(d) False negative results may occur if a specimen is improperly collected, transported, handled. They may also occur if inadequate levels of the virus are present in the specimen.

(e) Potential interference effects from FluMist, et. al. have not been evaluated. Individuals who have received nasally administered influenza vaccine may test positive in commercially available influenza rapid diagnostic tests for up to three days after vaccination

(f) Negative results do not preclude infection with influenza virus and should not be the sole basis of a patient treatment decision.

(g) This test has not been evaluated for immunocompromised individuals.

(h) Positive and negative predicative values are highly dependent on prevalence and may vary depending on prevalence and population tested.

(2) Strep A 2

(a) ID NOW Strep A 2 will not differentiate asymptomatic carriers of Group A Strep from those exhibiting streptococcal infection.

(b) ID NOW Strep A 2 will not distinguish between viable and nonviable organisms.

(c) Analytical studies have demonstrated that rayon swabs and BBL CultureSwab Liquid Stuart Medium are not permissible for use with this assay and may produce false negative results.

11. ENTRY OF RESULTS

a. Positive Result: Influenza A and/or Influenza B, or Strep A 2 is Detected.

b. Negative Result: Influenza A and /or Influenza B, or Strep A 2 is Not Detected

c. When both Influenza A and Influenza B are detected, verify by repeating the test & ensure quality controls and the instrument are functioning properly.

d. Additional follow-up testing for Strep A 2 using culture method is required if the result is negative and clinical symptoms persist, or in the event of acute rheumatic fever (ARF) outbreak.

e. Results will automatically be uploaded thru LIS to VISTA/CPRS for performed tests.

f. In the event of contingency plan, results will be documented on a logsheet and faxed or emailed to Ancillary testing Coordinator/ Specialist for manual entry into patient chart via VISTA.

12. NOTIFICATION

None

13. REFERENCES

a. VHA Directive 1106.1, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, http://vaww.lab.med.va.gov/References_Directives_and Regulations_P.asp

b. ID NOW ™ Instrument User Manual, Rev. 09 2020/02

14. APPENDICES

None

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of December 2025. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman
Pathology and Laboratory Medicine Service, Chief

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab: https://www.medialab.com/lms/admin/ad_tab_doc_frameset.aspx?leftdest=todo&oid=44462549&o=3d523f5ddaf473e01ca4a390d42c48e6&docid=1442508&dochash=6973f6026869ac33edd1619d5325ba72&revisionid=2450038&revhash=a042552061c2a60bc57e0615633f51cf