Abbott

ID NOW™

INFLUENZA A & B 2

PACKAGE INSERT

ID NOW™
INFLUENZA A & B 2
PACKAGE INSERT

For use with the ID NOW™ Instrument
For use with nasal or nasopharyngeal specimens
For *in vitro* Use Only
℞ Only

CLIA COMPLEXITY: WAIVED
A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.

Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

INTENDED USE

The ID NOW™ Influenza A & B 2 assay performed on the ID NOW Instrument is a 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 and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. 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.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

SUMMARY and EXPLANATION of the TEST

Influenza is a highly contagious, acute, viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months.[1] Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while Type B infections are usually milder.[1]

Rapid diagnostics with increased sensitivity are essential for the reliable detection of influenza A and B, allowing immediate, effective treatment decisions. Rapid diagnosis of influenza can lead to reduced hospital stays, reduced secondary complications and reduced cost of hospital care, and allow effective implementation of infection control measures.[1, 2]

ID NOW Influenza A & B 2 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swabs and nasopharyngeal swabs (direct and eluted in viral transport media). If the ID NOW Instrument is set to 'Early Detection', a positive result will be displayed for Influenza A or Influenza B immediately upon detection. The ID NOW Instrument has a small footprint and easy to use graphical user interface for convenience within a busy hospital or point-of-care environment. The ID NOW Influenza A & B 2 kit contains all components required to carry out an assay for influenza A and B on the ID NOW Instrument.

PRINCIPLES of the PROCEDURE

ID NOW Influenza A & B 2 is an automated multiplex assay that utilizes isothermal nucleic acid amplification technology for the differential and qualitative detection of influenza A and influenza B viral nucleic acids. It is comprised of a Sample Receiver, containing elution buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument.

The reaction tubes in the Test Base contain the reagents required for amplification of Influenza A and Influenza B, respectively, as well as an internal control. The templates (similar to primers) designed to target Influenza A RNA amplify a unique region of the PB2 segment while the templates designed to amplify Influenza B RNA target a unique region of the PA segment. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, mixing and detection are provided by the instrument, with results automatically reported.

REAGENTS and MATERIALS

Materials Provided

BASE **Test Bases:** Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of Influenza A and B viral RNA.

RCVR **Sample Receivers:** Blue plastic components containing 2.5 mL of elution buffer.

CARTRDG **Transfer Cartridges:** White plastic components used to transfer 2 x 100 µL of sample extract from the Sample Receiver to the Test Base.

Nasal Swabs: Sterile swabs for use with the ID NOW Influenza A & B 2 test.

Positive Control Swab: The positive control swab is coated with inactivated influenza A and B viruses.

Negative Control Swab: The use of a sterile nasal swab ensures appropriate negative results are obtained.

Plastic disposable pipettes capable of delivering 200µl VTM sample

Product Insert

Quick Reference Instructions

Materials Required but not Provided

ID NOW Instrument

Nasopharyngeal Swabs

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
3. To be used in conjunction with the ID NOW Instrument.
4. Performance characteristics of this test have been established with the specimen type listed in the Intended Use section only. The performance of this assay with other specimen types or samples has not been validated.
5. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
6. Proper sample collection, storage and transport are essential for correct results.
7. Leave test pieces sealed in their foil pouches until just before use.
8. Do not tamper with test pieces prior to or after use.
9. Do not use kit past its expiration date.
10. Do not mix components from different kit lots or from other ID NOW assays.
11. Solutions used to make the positive control swab 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.
12. **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.**
13. 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.

14. 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.
15. 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**.
16. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
17. All test pieces are single use items. Do not use with multiple specimens.
18. Performance characteristics for influenza A were established when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
19. 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 Influenza A & B 2 false positive test results.
20. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
21. 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.
22. Visibly bloody samples must not be used with ID NOW Influenza A & B 2.
23. Do not touch the heads of the Control Swabs. Cross contamination with the Positive Control Swabs may occur due to the high sensitivity of the assays run on the instrument.

STORAGE and STABILITY

Store kit at 2-30°C. The ID NOW Influenza A & B 2 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

QUALITY CONTROL

ID NOW Influenza A & B 2 has built-in procedural controls. 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.

Procedural Controls:

ID NOW Influenza A & B 2 contains an internal control that has been designed to control for sample inhibition, amplification 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.

Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW Influenza A & B 2 kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

CONTROL SWAB PROCEDURE

Positive and Negative Controls should be tested following the Run QC Test instructions on the ID NOW Instrument. A Positive Control Swab is included in the kit. Use a sterile swab provided in the kit as the Negative Control Swab. Refer to Quality Control Swab Test Procedure or Instrument User Manual for further details.

Note: *The ID NOW Instrument reports QC results as Pass or Fail. Flu A/B Positive QC pass indicates a positive result for both influenza A and influenza B.*

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

SPECIMEN COLLECTION and HANDLING

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

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 and STORAGE

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

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.

TEST PROCEDURE

The ID NOW Instrument includes an Early Detection feature that allows a multi-target assay to end as soon as a positive result is detected in one of the targets. Please refer to the ID NOW Instrument User Manual for full instructions.

Before testing with ID NOW Influenza A & B 2:

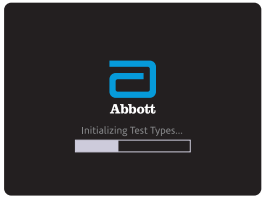
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a pellet is not visible at the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

To Perform a Test:

Step 1

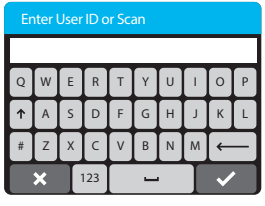
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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

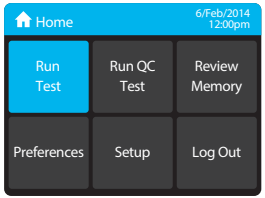
Press '✓' after entry.



To Perform a Test:

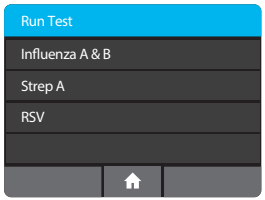
Touch 'Run Test'

This will begin the test process.



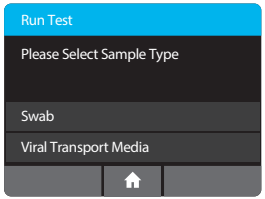
Touch 'Influenza A & B Test'

This starts an Influenza A & B test.



Select Sample Type (if prompted)

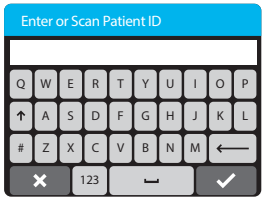
If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.



Enter Patient ID using on screen keyboard or barcode scanner.

Touch '✔'.

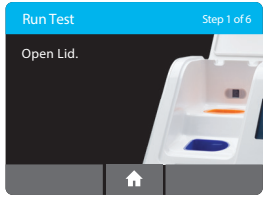
Verify that the ID was entered correctly, then touch '✔' to confirm entry.

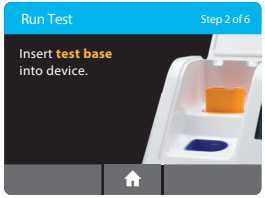


To Perform a Test:

Step 2

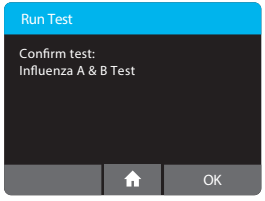
Open the Lid and Insert Orange Test Base into Orange Test Base holder





⚠ **Caution: Do not apply excessive force. Excessive force could damage the instrument.**

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.

To Perform a Test:

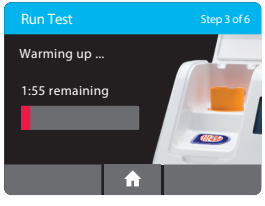
Step 3

⚠ **Caution: Confirm that the Sample Receiver foil pouch indicates Influenza A & B 2 (not another ID NOW assay). Confirm that the foil seal on the Sample Receiver is for the Influenza A & B assay. If not, then remove the Sample Receiver and replace it with a new Sample Receiver for ID NOW Influenza A & B 2.**

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 (Steps 3 through 5). 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.**



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

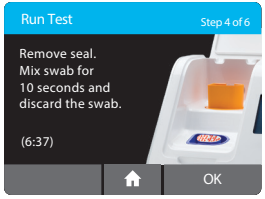
⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.**
DO NOT close the lid or insert the sample until prompted by the instrument.

To Perform a Test:

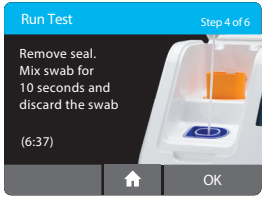
Step 4

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.



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.

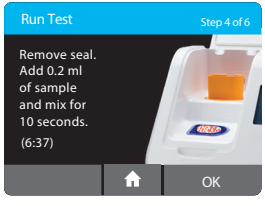


⚠ **Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test 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.**

Discard the swab.
Skip to Step 5a.

Nasal or Nasopharyngeal Swab Eluted in Transport Media Test Procedure

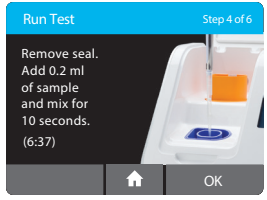
When prompted, remove the foil seal and add 0.2ml of sample to the Sample Receiver using the disposable pipettes provided in the kit.



To Perform a Test:

Vigorously mix the sample in the liquid for 10 seconds. Use the pipette tip to swirl the liquid.

Once the sample is mixed and the pipette is removed, immediately touch 'OK' to proceed. Continue to Step 5a.



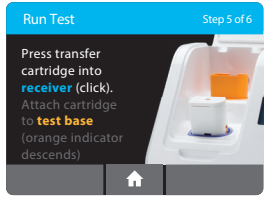
⚠ **Caution: To ensure the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (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.**

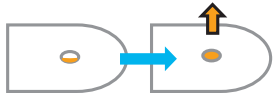
Step 5a

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.





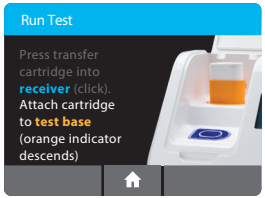
⚠ **Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.**

To Perform a Test:

Step 5b

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.



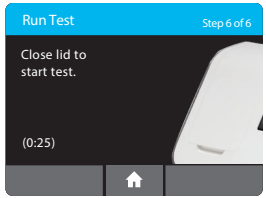
⚠ **Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.**

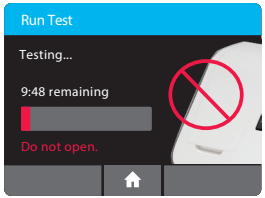
Step 6

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.*



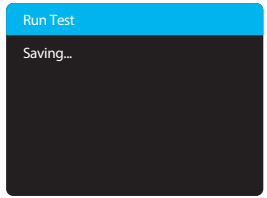


⚠ **Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The 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.**

⚠ **Caution: DO NOT OPEN THE LID. The test will be cancelled and 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.**

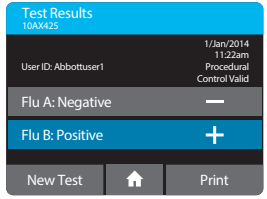
To Perform a Test:

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



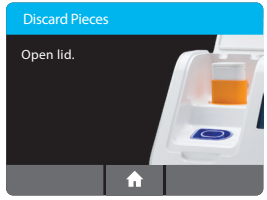
⚠ **Caution: The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.**

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 Print to print test results, press New Test to run another test, Press Home to return to the Home screen

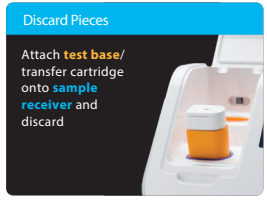
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.



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.**

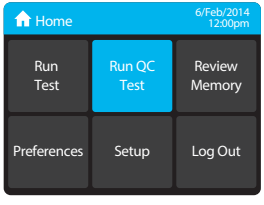
To Perform a Test:

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.

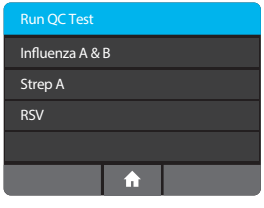
Quality Control Swab Test Procedure

For QC testing, select Run QC Test on the Home screen, and follow the displayed instructions. Refer to Running a QC Test in the ID NOW Instrument User Manual for further details.

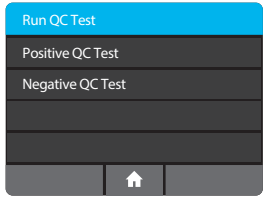
1 **Touch 'Run QC Test'**



2 **Touch 'Influenza A & B'**



3 Select the QC Test to be Run

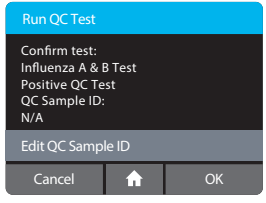


4 Confirm Test

Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.

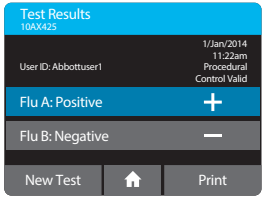
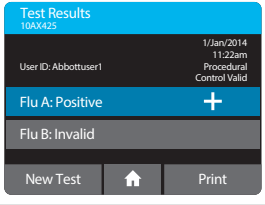
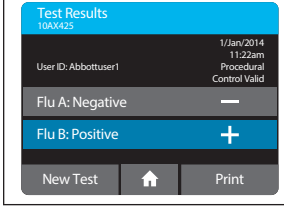
The user has the option to enter an ID for the QC Sample being run.

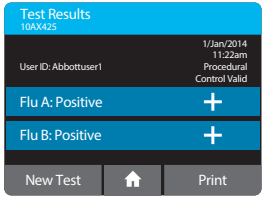
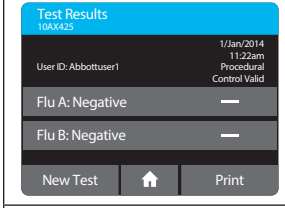
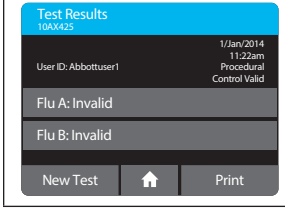
Note: *The QC test is run in the same manner as a Direct Nasal/Nasopharyngeal Swab Patient Test. See the* ***To Perform a Test*** *section above for step by step instructions for direct nasal/nasopharyngeal swab samples.*



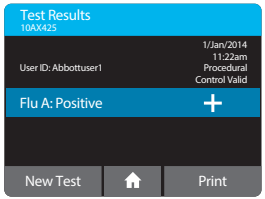
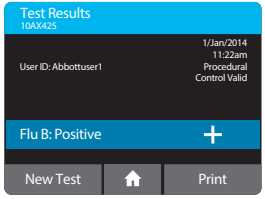
RESULT INTERPRETATION

When the test is complete, the results are clearly displayed on the instrument screen. An individual result for both influenza A and influenza B will be provided.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected; Flu B Viral RNA Not Detected.** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu A Viral RNA Detected; The presence or absence of Flu B Viral RNA cannot be determined.** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu B Viral RNA Detected; Flu A Viral RNA Not Detected.** This result does not rule out co-infections with other pathogens or identify any specific influenza B virus lineage.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected; Flu B Viral RNA Detected.** Dual infections of Flu A and Flu B are rare. Repeat testing with a new specimen. If the result is still dual positive, repeat testing with another method before reporting results. This result does not rule out co-infections with other pathogens or identify any specific influenza A or influenza B virus lineage.
	**Flu A Viral RNA Not Detected; Flu B Viral RNA Not Detected.**
	**The presence or absence of Flu A and Flu B Viral RNAs cannot be determined.** Repeat testing of the sample using new test components. If repeated Flu A and Flu B Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

If the ID NOW Instrument is set to 'Early Detection' a positive result will be displayed for Influenza A or Influenza B immediately upon detection.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected.**
	**Flu B Viral RNA Detected.**

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 re-elute the swab.

LIMITATIONS

- The performance of the ID NOW Influenza A & B 2 was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- ID NOW Influenza A & B 2 performance depends on viral RNA load and may not correlate with cell culture performed on the same specimen. Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply the corresponding virus(es) are infectious, or are the causative agents for clinical symptoms.
- Performance of ID NOW Influenza A & B 2 has not been established for monitoring antiviral treatment of influenza.
- Although this test has been shown to detect A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for the A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses have not been established.
- There is a risk of false negative results due to the presence of sequence variants in the viral targets of the assay. If the virus mutates in the target regions, influenza viruses A or B may not be detected or may be detected less efficiently. Additionally, if the sequence variant occurs in the target sequence recognized by the fluorescently-labeled molecular beacon an invalid assay may result.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may occur if inadequate levels of viruses are present in the specimen.
- False negative results may occur if mucin concentrations of 1% (w/v) or greater are present in the specimen.
- False negative results may occur if Respiratory Syncytial Virus is present as a co-infecting organism.
- Potential interference effects from FluMist™ 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.
- This test is not intended to differentiate Influenza A subtypes or Influenza B lineages. If differentiation of specific influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.

- Negative results do not preclude infection with influenza virus and should not be the sole basis of a patient treatment decision.
- Positive and negative predictive values are highly dependent on prevalence. The assay performance was established during the 2016 to 2017 influenza seasons. The positive and negative predictive values may vary depending on the prevalence and population tested.
- This test has not been evaluated for patients without signs and symptoms of influenza infection.
- The test is a qualitative test and does not provide the quantitative value of detected organism present.
- Cross-reactivity with respiratory tract organisms other than those tested in the Analytical Specificity Study may lead to erroneous results.
- This assay has not been evaluated for immunocompromised individuals.
- This test cannot rule out diseases caused by other bacterial or viral pathogens. The regions selected for amplification are conserved among all known Influenza A and Influenza B subtypes and strains (where sequence data is available from public databases). Laboratory testing has shown that ID NOW Influenza A & B 2 can readily amplify and detect H1N1 (pre-2009 pandemic), H3N2 (variant) and H7N9 (detected in China in 2013) influenza subtypes but the performance of the assay for detection of these subtypes in a clinical setting has not been established due to the lack of clinical samples.

EXPECTED VALUES

The prevalence of influenza varies from year to year, with outbreaks typically occurring during the fall and winter months.[2] The rate of positivity found in influenza testing is dependent on many factors including the method of specimen collection, the test method used, geographic location, and the disease prevalence in specific localities. In the ID NOW Influenza A & B 2 multi center prospective clinical studies (described in the "Clinical Study" section below), a total of 1070 direct nasal or nasopharyngeal swab specimens and 1057 nasal or nasopharyngeal swab specimens eluted in viral transport media were determined to be evaluable. The number and percentage of influenza A and influenza B positive cases per specified age group, as determined by the ID NOW Influenza A & B 2 assay, are presented in the two tables below:

Influenza A Positives by the ID NOW™ Influenza A & B 2 Assay per Age Group

Age Group	Number of Direct Swab Specimens	Number of Influenza A Positives	Influenza A Positivity Rate	Number of Viral Transport Media Specimens	Number of Influenza A Positives	Influenza A Positivity Rate
<1 year	60	6	10.0%	59	7	11.9%
1 to 5 years	184	47	25.5%	177	45	25.4%
6 to 10 years	115	41	35.7%	116	40	34.5%
11 to 15 years	87	30	34.5%	86	28	32.6%
16 to 21 years	86	30	34.9%	84	28	33.3%
>21 to 60 years	460	108	23.5%	457	91	19.9%
>60 years	78	19	24.4%	78	19	24.4%
Total	**1070**	**281**	**26.3%**	**1057**	**258**	**24.4%**

Influenza B Positives by the ID NOW™ Influenza A & B 2 Assay per Age Group

Age Group	Number of Direct Swab Specimens	Number of Influenza B Positives	Influenza B Positivity Rate	Number of Viral Transport Media Specimens	Number of Influenza B Positives	Influenza B Positivity Rate
<1 year	60	4	6.7%	59	4	6.8%
1 to 5 years	184	28	15.2%	177	25	14.1%
6 to 10 years	115	27	23.5%	116	28	24.1%
11 to 15 years	87	20	23.0%	86	18	20.9%
16 to 21 years	86	10	11.6%	84	11	13.1%
>21 to 60 years	460	29	6.3%	457	26	5.7%
>60 years	78	7	9.0%	78	7	9.0%
Total	**1070**	**125**	**11.7%**	**1057**	**119**	**11.3%**

PERFORMANCE CHARACTERISTICS

Clinical Study:

Clinical performance characteristics of ID NOW Influenza A & B 2 were evaluated in a multi-site prospective study during the 2016-2017 respiratory season in the U.S. A total of ten investigational sites throughout the U.S. participated in the study.

In this study, two nasal or nasopharyngeal swabs were collected from one nostril from each subject using standard collection methods. At all sites, one nasal or nasopharyngeal swab was tested directly on ID NOW Influenza A & B 2, according to the test procedure for **Direct Nasal or Nasopharyngeal Swab**. The other nasal or nasopharyngeal swab was eluted in 3 mL of viral transport media (VTM). The samples were processed and tested using the ID NOW Influenza A & B 2 assay according to the test procedure for **Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media**. An FDA-cleared real-time Polymerase Chain Reaction (RT-PCR) test was utilized as the comparator method for this study. All discrepant samples were tested on a different FDA-cleared RT-PCR assay to confirm influenza status.

External control testing, using ID NOW Influenza A & B Positive and Negative Controls, was performed prior to sample testing each day and on each ID NOW Instrument the testing was performed, at all study sites.

A total of 1110 nasal or nasopharyngeal swab specimens were enrolled in this study. Of those, 36 nasal or nasopharyngeal swab specimens did not meet eligibility criteria. A total of 1074 specimens were tested with ID NOW Influenza A & B 2. Patient age and gender distribution for the evaluable specimens is presented in the table below.

Age and Gender Distribution

Age Group (Years)	Female	Male
<1	30	30
1 to 5	80	104
6 to 10	57	61
11 to 15	39	48
16 to 21	48	39
>21 to 60	299	161
>60	44	34
Total	**597**	**477**

Of the 1074 specimens, ID NOW Influenza A & B 2 generated invalid results for 4 direct swab specimens after repeat testing per the product instructions, resulting in a total of 1070 specimens for direct swab performance analysis. ID NOW Influenza A & B 2 generated invalid results invalid results for 11 viral transport media specimens after repeat testing per the product instructions and an additional 6 specimens did not meet eligibility criteria, resulting in a total of 1057 specimens for viral transport media performance analysis.

Compared to the RT-PCR comparator method, the performance of ID NOW Influenza A & B 2 is presented in the tables below.

Direct Nasal or Nasopharyngeal Swab – Performance Obtained for Influenza A with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 – Flu A	Comparator Method		
	Positive	**Negative**	**Total**
Positive	260	21[a]	281
Negative	10[b]	779	789
Total	**270**	**800**	**1070**
Sensitivity: 260/270 96.3% (95%CI: 93.3%-98.2%)			
Specificity: 779/800 97.4% (95%CI: 96.0%-98.4%)			

[a] *Flu A nucleic acid was detected in 6/21 False positive specimens using a second FDA-cleared molecular test*

[b] *Flu A nucleic acid was not detected in 4/10 False negative specimens using a second FDA-cleared molecular test*

Direct Nasal or Nasopharyngeal Swab – Performance Obtained for Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 – Flu B	Comparator Method		
	Positive	**Negative**	**Total**
Positive	97	28[a]	125
Negative	0	945	945
Total	**97**	**973**	**1070**
Sensitivity: 97/97 100% (95%CI: 96.3%-100%)			
Specificity: 945/973 97.1% (95%CI: 95.9%-98.1%)			

[a] *Flu B nucleic acid was detected in 21/28 False positive specimens using a second FDA-cleared molecular test*

Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media – Performance Obtained for Influenza A with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 – Flu A	Comparator Method		
	Positive	**Negative**	**Total**
Positive	246	12[a]	258
Negative	19[b]	780	799
Total	**265**	**792**	**1057**
Sensitivity: 246/265 92.8% (95%CI: 89.0%-95.6%)			
Specificity: 780/792 98.5% (95%CI: 97.4%-99.2%)			

[a] *Flu A nucleic acid was detected in 5/12 False positive specimens using a second FDA-cleared molecular test*

[b] *Flu A nucleic acid was not detected in 6/19 False negative specimens using a second FDA-cleared molecular test*

Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media – Performance Obtained for Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 – Flu B	Comparator Method		
	Positive	**Negative**	**Total**
Positive	97	22[a]	119
Negative	0	938	938
Total	**97**	**960**	**1057**
Sensitivity: 97/97 100% (95%CI: 96.3%-100%)			
Specificity: 938/960 97.7% (95%CI: 96.6%- 98.6%)			

[a] *Flu B nucleic acid was detected in 18/22 False positive specimens using a second FDA-cleared molecular test*

During the prospective clinical study, the initial invalid rate for direct nasal or nasopharyngeal swab samples (before repeat testing per the product instructions) was 0.8% (9/1074) (95% CI: 0.4% to 1.6%). After repeat testing per the product instructions, the invalid rate was 0.4% (4/1074) (95% CI: 0.1% to 1.0%).

The initial invalid rate for swabs eluted in viral transport media was 2.2% (24/1074) (95% CI: 1.5% to 3.2%). After repeat testing per the product instructions, the invalid rate was 1.0% (11/1074) (95% CI: 0.6% to 1.8%).

Performance of ID NOW Influenza A & B 2 for the detection of influenza A and influenza B versus the comparator method in this study is presented in the table below stratified by patient age.

Direct Nasal or Nasopharyngeal Swab – Performance Obtained for Influenza A and Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method – Stratified by Patient Age

	≤ 5 Years of Age (n = 244)		6 - ≤ 21 Years of Age (n = 288)		≥ 22 Years of Age (n = 538)	
Influenza Type	**Sensitivity 95% CI**	**Specificity 95% CI**	**Sensitivity 95% CI**	**Specificity 95% CI**	**Sensitivity 95% CI**	**Specificity 95% CI**
Flu A	100% (52/52) 93.2% - 100%	99.5% (191/192) 97.1% - 100%	95.8% (91/95) 89.6% - 98.8%	94.8% (183/193) 90.7% - 97.5%	95.1% (117/123) 89.7% - 98.2%	97.6% (405/415) 95.6% - 98.8%
Flu B	100% (25/25) 86.3% - 100%	96.8% (212/219) 93.5% - 98.7%	100% (48/48) 92.6% - 100%	96.3% (231/240) 93.0% - 98.3%	100% (24/24) 85.8% - 100%	97.7% (502/514) 96.0% - 98.8%

Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media – Performance Obtained for Influenza A and Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method – Stratified by Patient Age

	≤ 5 Years of Age (n = 236)		6 - ≤ 21 Years of Age (n = 286)		≥ 22 Years of Age (n = 535)	
Influenza Type	**Sensitivity 95% CI**	**Specificity 95% CI**	**Sensitivity 95% CI**	**Specificity 95% CI**	**Sensitivity 95% CI**	**Specificity 95% CI**
Flu A	100% (51/51) 93.0% - 100%	99.5% (184/185) 97.0% - 99.9%	96.8% (90/93) 90.9% - 99.3%	96.9% (187/193) 93.4% - 98.9%	86.8% (105/121) 79.4% - 92.2%	98.8% (409/414) 97.2% - 99.6%
Flu B	100% (24/24) 85.8% - 100%	97.6% (207/212) 94.6% - 99.2%	100% (49/49) 92.7% - 100%	96.6% (229/237) 93.5% - 98.5%	100% (24/24) 85.8% - 100%	98.2% (502/511) 96.7% - 99.2%

ANALYTICAL STUDIES:

A reproducibility study of ID NOW Influenza A & B 2 was conducted by operators from three sites using panels of blind coded specimens containing negative, low positive (at the limit of detection), and moderate positive (above the limit of detection) influenza A and B viral samples.

Virus dilutions were prepared using one influenza A strain and one influenza B strain in natural nasal swab matrix. The concentrations of the viral stocks (in $TCID_{50}$/mL) were determined by standard virologic method prior to inactivation by the vendors. The concentration for each dilution (in genome equivalents/mL) was also assessed using laboratory developed and validated influenza A and influenza B quantitative real-time PCR assays.

Contrived nasal swab specimens were prepared by coating 10 microliters of each virus dilution onto the swab. The contrived swab samples were tested without further elution in viral transport media according to product instructions.

Participants tested each sample multiple times on five different days. The percent agreement with expected results for the influenza A moderate positive and low positive samples was 100% (90/90). The percent agreement with expected results for the influenza B moderate positive and low positive samples were 100% (89/89), 98.9% (89/90), respectfully. All of the true negative samples (89) generated negative test results. There were no significant differences observed within run (replicates tested by one operator), between run (five different days), between sites (three sites), or between operators (nine operators).

The Reproducibility Study site-to-site qualitative results (agreements with expected results) are presented in the table below:

Reproducibility Study Site-To-Site Qualitative Results

Sample Category	SITE						Overall Percent Agreement and 95% CI	
	Site 1		Site 2		Site 3			
	Percent Agreement	Count	Percent Agreement	Count	Percent Agreement	Count		
LP Influenza A	100%	30/30	100%	30/30	100%	29/29	100% (89/89)	(95.9%, 100%)
MP Influenza A	100%	30/30	100%	30/30	100%	30/30	100% (90/90)	(95.9%, 100%)
LP Influenza B	100%	30/30	96.7%	29/30	100%	30/30	98.9% (89/90)	(94.0%, 99.8%)
MP Influenza B	100%	30/30	100%	30/30	100%	29/29	100% (89/89)	(95.9%, 100.0%)
TN	100%	30/30	100%	29/29	100%	30/30	100% (89/89)	(95.9%, 100%)

[1] *Percent Agreement correlates to the percent of negative results.*

Analytical Sensitivity (Limit of Detection)

ID NOW Influenza A & B 2 limit of detection (LOD) in natural nasal swab matrix was determined by evaluating different concentrations of 2 strains of influenza A and 2 strains of influenza B virus in ID NOW Influenza A & B 2. Two strains of influenza A virus representing each of the two common currently or recently circulating influenza A subtypes (i.e., A/H3N2 seasonal, and A/H1N1 pandemic (pdm)) and two strains of influenza B virus representing each of the two influenza B genetic lineages (i.e., Victoria and Yamagata) were included in this study.

Presumed negative natural nasal swab specimens were eluted in UTM. Swab elutes were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Each influenza virus strain was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing. The vendor provided virus strains were re-titered and the concentrations (in $TCID_{50}$/mL) were determined by standard virologic method. The concentration for each dilution (in genome equivalents/µL) was also assessed using laboratory developed and validated influenza A and influenza B quantitative real-time PCR assays.

Contrived nasal swab samples were prepared by coating 10 microliters of each virus dilution onto the swab. The contrived swab samples were tested without further elution in viral transport media according to the test procedure for Direct Nasal or Nasopharyngeal Swab.

An additional LOD study was conducted with contrived swab samples eluted into VTM and tested according to the test procedure for Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media. The LOD for each influenza strain tested was determined using Probit analysis as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The confirmed LODs in natural nasal swab matrix for both direct swab and swab eluted in VTM for each influenza strain tested are presented in the tables below:

Limit of Detection (LOD) Study Results – Natural Nasal Swab Matrix (Direct Swab Testing)

Influenza Strain	Influenza A Subtype or Influenza B Genetic Lineage	LOD ($TCID_{50}$/mL)	LOD ($TCID_{50}$/Swab)*	LOD (Genome Equivalents/mL)	LOD (Genome Equivalents/Swab)*
A/Texas/50/2012	A/H3N2	1.00×10^{-1}	1.00×10^{-3}	1.06×10^{4}	1.06×10^{2}
A/California/7/2009	A/2009 H1N1 pdm	2.00×10^{0}	2.00×10^{-2}	1.60×10^{4}	1.60×10^{2}
B/Brisbane/60/2008	Victoria lineage	5.20×10^{1}	5.20×10^{-1}	6.60×10^{3}	6.60×10^{1}
B/Wisconsin/1/2010	Yamagata lineage	5.01×10^{2}	5.01×10^{0}	1.11×10^{4}	1.11×10^{2}

**Note:* *10 µl of each virus dilution was coated onto a swab*

Limit of Detection (LOD) Study Results – Natural Nasal Swab Matrix (Swab Eluted in VTM Testing)

Influenza Strain	Influenza A Subtype or Influenza B Genetic Lineage	LOD ($TCID_{50}$/mL)	LOD ($TCID_{50}$/Swab)*	LOD (Genome Equivalents/mL)	LOD (Genome Equivalents/Swab)*
A/Texas/50/2012	A/H3N2	1.00×10^{0}	1.00×10^{-2}	2.10×10^{5}	2.10×10^{3}
A/California/7/2009	A/2009 H1N1 pdm	5.00×10^{1}	5.00×10^{-1}	3.83×10^{5}	3.83×10^{3}
B/Brisbane/60/2008	Victoria lineage	1.20×10^{3}	1.20×10^{1}	1.51×10^{5}	1.51×10^{3}
B/Wisconsin/1/2010	Yamagata lineage	9.66×10^{3}	9.66×10^{1}	2.14×10^{5}	2.14×10^{3}

**Note:* *10 µl of each virus dilution was coated onto a swab; each contrived swab was further diluted into 3 mL of UTM*

Analytical Reactivity (Inclusivity)

An analytical reactivity (inclusivity) study was performed to determine whether the ID NOW Influenza A & B 2 assay is able to detect a variety of influenza A and B strains that represent temporal and geographic diversity.

Vendor provided stocks of influenza A and B strains were diluted in natural nasal swab matrix to generate virus dilutions for testing. The concentration (in $TCID_{50}$/mL) for each strain was determined by standard virologic method. The concentration for each dilution (in genome equivalents/mL) was also assessed using laboratory developed and validated influenza A and influenza B quantitative real-time PCR assays.

Contrived swab samples were prepared by coating 10 microliters of virus dilution onto each swab. The contrived swab samples were tested without further elution in viral transport media according to the test procedure for Direct Nasal or Nasopharyngeal Swab.

The starting dilution concentration selected for testing in this study was higher than the established LODs in the Limit of Detection study. Each starting dilution per virus strain was tested in triplicates initially. If initial testing generated at least one negative result, a higher concentration was tested and then diluted 2-fold until negative results were obtained. A concentration level was considered "reactive/positive" in this study if all three replicates generated a positive result for the expected influenza virus.

The ID NOW Influenza A & B 2 assay detected all strains tested at the concentrations indicated in the table below:

Analytical Reactivity Study Results

Influenza Strain	Influenza A Subtype or Influenza B Genetic Lineage	Test Concentration (in $TCID_{50}$ or Genome Equivalents)			
		$TCID_{50}$/mL	$TCID_{50}$/Swab*	Genome Equivalents/mL	Genome Equivalents/Swab*
A/New Caledonia/20/1999	A/H1N1	2.74×10^{4}	2.74×10^{2}	3.00×10^{4}	3.00×10^{2}
A/New Jersey/8/76	A/H1N1	8.62×10^{-1}	8.62×10^{-3}	3.00×10^{4}	3.00×10^{2}
A/Brisbane/59/2007	A/H1N1	2.44×10^{0}	2.44×10^{-2}	3.00×10^{4}	3.00×10^{2}
A/WSN/33	A/H1N1	2.78×10^{2}	2.78×10^{0}	3.00×10^{4}	3.00×10^{2}
A/California/4/2009	A/H1N1	1.26×10^{1}	1.26×10^{-1}	3.00×10^{4}	3.00×10^{2}
A/Maryland/04/2011	A/H1N1	1.55×10^{3}	1.55×10^{1}	3.00×10^{4}	3.00×10^{2}

Influenza Strain	Influenza A Subtype or Influenza B Genetic Lineage	Test Concentration (in $TCID_{50}$ or Genome Equivalents)			
		$TCID_{50}$/mL	$TCID_{50}$/Swab*	Genome Equivalents/mL	Genome Equivalents/Swab*
A/New York/18/2009	A/H1N1	9.08×10^{0}	9.08×10^{-2}	3.00×10^{4}	3.00×10^{2}
A/South Carolina/2/2010	A/H1N1	3.47×10^{1}	3.47×10^{-1}	3.00×10^{4}	3.00×10^{2}
A/Port Chalmers/1/73	A/H3N2	2.02×10^{3}	2.02×10^{1}	3.00×10^{4}	3.00×10^{2}
A/Hong Kong/8/68	A/H3N2	2.16×10^{1}	2.16×10^{-1}	3.00×10^{4}	3.00×10^{2}
A/Aichi/2/68	A/H3N2	3.58×10^{0}	3.58×10^{-2}	3.00×10^{4}	3.00×10^{2}
A/Perth/16/2009	A/H3N2	6.12×10^{2}	6.12×10^{0}	3.00×10^{4}	3.00×10^{2}
A/Victoria/3/75	A/H3N2	9.61×10^{-1}	9.61×10^{-3}	3.00×10^{4}	3.00×10^{2}
A/Wisconsin/67/2005	A/H3N2	1.60×10^{3}	1.60×10^{1}	3.00×10^{4}	3.00×10^{2}
A/Brisbane/10/2007	A/H3N2	5.48×10^{1}	5.48×10^{-1}	3.00×10^{4}	3.00×10^{2}
A/Victoria/361/2011	A/H3N2	6.41×10^{0}	6.41×10^{-2}	3.00×10^{4}	3.00×10^{2}
A/Indiana/10/2011	A/H3N2v	7.02×10^{3}	7.02×10^{1}	3.00×10^{4}	3.00×10^{2}
A/Sichuan/26221/2014 (inactivated)	A/H5N6	N/A	N/A	3.00×10^{4}	3.00×10^{2}
A/Anhui/1/2013 (inactivated)	A/H7N9	N/A	N/A	6.70×10^{4}	6.70×10^{2}
B/Lee/40	Victoria Lineage	1.64×10^{0}	1.64×10^{-2}	2.25×10^{4}	2.25×10^{2}
B/Victoria/504/2000	Victoria Lineage	1.45×10^{2}	1.45×10^{0}	2.25×10^{4}	2.25×10^{2}
B/Nevada/03/2011	Victoria Lineage	3.66×10^{2}	3.66×10^{0}	2.25×10^{4}	2.25×10^{2}
B/Montana/05/2012	Victoria Lineage	2.21×10^{2}	2.21×10^{0}	2.25×10^{4}	2.25×10^{2}
B/Maryland/1/59	Yamagata Lineage	8.42×10^{2}	8.42×10^{0}	2.25×10^{4}	2.25×10^{2}
B/Russia/69	Yamagata Lineage	9.38×10^{2}	9.38×10^{0}	7.23×10^{5}	7.23×10^{3}
B/Bangladesh/3333/2007	Yamagata Lineage	4.64×10^{2}	4.64×10^{0}	2.33×10^{4}	2.33×10^{2}
B/Massachusetts/2/2012	Yamagata Lineage	4.30×10^{2}	4.30×10^{0}	2.25×10^{4}	2.25×10^{2}
B/Malaysia/2506/2004	Yamagata Lineage	3.25×10^{3}	3.25×10^{1}	2.25×10^{4}	2.25×10^{2}
B/Texas/06/2011	Yamagata Lineage	5.33×10^{2}	5.33×10^{0}	2.25×10^{4}	2.25×10^{2}

**Note:* *10 µl of each virus dilution was coated onto a swab*

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of ID NOW Influenza A & B 2, 36 commensal and pathogenic microorganisms (18 bacteria, 17 viruses and 1 yeast) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^3 to 10^{10} cells/mL or CFU/mL (bacteria), 10^4 to 10^8 $TCID_{50}$/mL (viruses), and 10^8 cells/mL (yeast).

Bacteria	Viruses	Yeast
Bordetella pertussis	Adenovirus type 1	*Candida albicans*
Corynebacterium diphtheriae	Adenovirus type 7	
*Escherichia coli**	Human Coronavirus OC43	
Haemophilius influenzae	Echovirus 7	
Klebsiella pneumoniae	Human Coronavirus 229E	
Lactobacillus plantarum	Enterovirus 70	
Legionella pneumophila	Coxsackievirus B4	
*Moraxella/Branhamella catarrhalis**	Human Cytomegalovirus (CMV) (Herpes V)	
Mycobacterium tuberculosis	Human metapneumovirus	
Mycoplasma pneumoniae	Rhinovirus 1A	
Neisseria meningitidis	Measles (Edmonston)	
*Proteus vulgaris**	Mumps (Enders)	
Pseudomonas aeruginosa	Parainfluenza 1	
Staphylococcus aureus	Parainfluenza 2	
Staphylococcus epidermidis	Parainfluenza 3	
Streptococcus pneumoniae	Respiratory Syncytial virus, type B	
Streptococcus salivarius	Epstein Barr Virus	
Streptococcus pyogenes		

** Some cross-reactivity was observed for E. coli concentrations greater than 2.20 x 10^9, Moraxella catarrhalis at concentrations greater than 2.40 x 10^8, and Proteus vulgaris at concentrations greater than 1.50 x 10^8.*

In addition, *in silico* analysis was performed to determine whether there is any significant overlap between ID NOW Influenza A & B 2 target nucleic acid sequence and the genomes of the following upper respiratory tract microorganism. None of the organisms maintained genomic sequence that was significantly similar to the ID NOW Influenza A & B 2 target sequences.

Bacteria	**Viruses**
Bordetella bronchiseptica	Adenovirus 2
Chlamydia pneumoniae	Adenovirus 3
Chlamydia trachomatis	Adenovirus 4
Neisseria gonorrhoae	Adenovirus 5
Neisseria mucosa	Adenovirus 11
Proteus mirabilis	Adenovirus 14
	Adenovirus 31
	Coronavirus NL63
	Coxsackievirus B35
	Echovirus 6
	Echovirus 9
	Echovirus 11
	Enterovirus 71

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with ID NOW Influenza A & B 2 at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Mucin	0.5% w/v
Whole Blood	1% v/v
NeoSynephrine Nasal Spray	20% v/v
Afrin Original Nasal Spray	20% v/v
Ocean Saline Nasal Spray	20% v/v
Chloroseptic Max	20% w/v
Zicam	20% v/v
Beclomethasone	0.068 mg/mL
Budesonide	0.051 mg/mL
Dexamethasone	0.48 mg/mL
Flunisolide	0.04 mg/mL
Fluticasone	0.04 mg/mL
Mometasone	0.04 mg/mL
Mupirocin	4.3 mg/mL
Tobryamycin	1.44 mg/mL
Triamcinolone	0.04 mg/mL
Zanamivir (Relenza)	0.284 mg/mL

Inhibition by other Microorganisms

ID NOW Influenza A & B 2 test performance in the presence of non-influenza respiratory pathogens was evaluated. Vendor provided stocks of influenza A and B strains were diluted in UTM to approximately 3 times the limit of detection. Contrived influenza A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. The following panel of non-influenza viruses were tested at the concentration provided in the table below and was found not to affect test performance.

Virus Panel	Concentration
Adenovirus Type 1	2.95×10^7 $TCID_{50}$/mL
Rhinovirus Type 1A	1.58×10^8 $TCID_{50}$/mL
Respiratory Syncytial Virus, Type B, Strain 18537	3.00×10^3 (PFU/mL)

Inhibition by High Levels of Influenza A and B

ID NOW Influenza A & B 2 test performance in the presence of high levels of influenza A and B was evaluated. Vendor provided stocks of influenza A and B strains were diluted in UTM to approximately 3 times the limit of detection. Contrived influenza A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. To create the co-infection swabs, diluted influenza A (at a concentration approximately 30 times the LOD) was added to the near LOD Flu B swab. Likewise, diluted influenza B (at a concentration approximately 30 times the LOD) was added to the near LOD Flu A swab. No impact on test performance was observed.

Carry-Over Contamination

An analytical carry-over study was performed to demonstrate that when recommended laboratory practices are followed, there is little risk of false positive results caused by carryover or cross-contamination in the ID NOW Influenza A & B 2 test. Vendor provided stocks of influenza A and B strains were diluted in UTM to approximately 30 times the limit of detection. Contrived influenza A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. Testing of the contrived positive swabs was alternated with testing of a negative swab sample for a total of 15 rounds. There were no false positive results obtained.

An additional analytical carry-over study was performed testing contrived positive VTM samples alternated with negative VTM samples following the test procedure for Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media for a total of 15 rounds. There were no false positive results obtained.

CLIA Waiver Studies:

As part of the prospective study (as described in the Performance Characteristics section above), the accuracy of ID NOW Influenza A & B 2 was evaluated when used by operators who had no laboratory experience and who were representative of CLIA waived testing sites (intended users). The study was conducted at ten (10) CLIA waived sites with 35 intended users participating. No training on the use of the test was provided to the operators.

A total of 1110 nasal or nasopharyngeal swab specimens were enrolled in this study. Of those, 31 nasal or nasopharyngeal swab specimens did not meet eligibility criteria. A total of 1079 specimens were tested with ID NOW Influenza A & B 2. Patient age and gender distribution for the evaluable specimens is presented in the table below.

Overall, 1079 nasal or nasopharyngeal swab specimens were tested by intended users at CLIA waived sites with ID NOW Influenza A & B 2, and the results were compared to the results of an FDA-cleared Real-Time reverse transcriptase PCR (RT-PCR) assay, the comparator method for this study. Of the 1079 specimens, ID NOW Influenza A & B 2 generated invalid results for 4 direct swab specimens after repeat testing per the product instructions, resulting in a total of 1075 specimens for direct swab performance analysis. ID NOW Influenza A & B 2 generated invalid results for 11 viral transport media specimens after repeat testing per the product instructions and an additional 6 specimens did not meet eligibility criteria, resulting in a total of 1062 specimens for viral transport media performance analysis.

The performance of ID NOW Influenza A & B 2 compared to PCR for all specimens combined, are presented in the tables below, including the 95% confidence intervals (95% CI).

Direct Nasal or Nasopharyngeal Swab – Performance Obtained for Influenza A with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 - Flu A	Comparator Method		
	Positive	**Negative**	**Total**
Positive	261	21[a]	282
Negative	11[b]	782	793
Total	**272**	**803**	**1075**
Sensitivity: 261/272 96.0% (95%CI: 92.9%-98.0%)			
Specificity: 782/803 97.4% (95%CI: 96.0%-98.4%)			

[a] *Flu A nucleic acid was detected in 6/21 False positive specimens using a second FDA-cleared molecular test*

[b] *Flu A nucleic acid was not detected in 4/11 False negative specimens using a second FDA-cleared molecular test*

Direct Nasal or Nasopharyngeal Swab – Performance Obtained for Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 - Flu B	Comparator Method		
	Positive	**Negative**	**Total**
Positive	97	28[a]	125
Negative	0	950	950
Total	**97**	**978**	**1075**
Sensitivity: 97/97 100% (95%CI: 96.3%-100.0%)			
Specificity: 950/978 97.1% (95%CI: 95.9%-98.1%)			

[a] *Flu B nucleic acid was detected in 21/28 False positive specimens using a second FDA-cleared molecular test*

Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media – Performance Obtained for Influenza A with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 - Flu A	Comparator Method		
	Positive	**Negative**	**Total**
Positive	248	12[a]	260
Negative	19[b]	783	802
Total	**267**	**795**	**1062**
Sensitivity: 248/267 92.9% (95%CI: 89.1%-95.7%)			
Specificity: 783/795 98.5% (95%CI: 97.4%-99.2%)			

[a] *Flu A nucleic acid was detected in 5/12 False positive specimens using a second FDA-cleared molecular test*

[b] *Flu A nucleic acid was not detected in 6/19 False negative specimens using a second FDA-cleared molecular test*

Nasal or Nasopharyngeal Swab Eluted in Viral Transport Media – Performance Obtained for Influenza B with ID NOW™ Influenza A & B 2 against the Comparator Method

ID NOW™ Influenza A & B 2 - Flu B	Comparator Method		
	Positive	**Negative**	**Total**
Positive	97	22[a]	119
Negative	0	943	943
Total	**97**	**965**	**1062**
Sensitivity: 97/97 100% (95%CI: 96.3%-100.0%)			
Specificity: 943/965 97.7% (95%CI: 96.6%- 98.6%)			

[a] *Flu B nucleic acid was detected in 18/22 False positive specimens using a second FDA-cleared molecular test*

During the prospective clinical study, the initial invalid rate for direct nasal or nasopharyngeal swab samples (before repeat testing per the product instructions) was 0.8% (9/1079) (95% CI: 0.4% to 1.6%). After repeat testing per the product instructions, the invalid rate was 0.4% (4/1079) (95% CI: 0.1% to 0.9%).

The initial invalid rate for swabs eluted in viral transport media was 2.2% (24/1079) (95% CI: 1.5% to 3.3%). After repeat testing per the product instructions, the invalid rate was 1.0% (11/1079) (95% CI: 0.6% to 1.8%).

Study with Samples Near the Limit of Detection

A study was conducted to evaluate the performance of ID NOW Influenza A & B 2 with weakly reactive samples when used by untrained users. Randomized blind-coded panels, containing negative, low positive (close to the limit of detection {LOD} or assay cutoff) and moderate positive influenza A and influenza B specimens, were tested with ID NOW Influenza A & B 2 at 3 CLIA waived sites (300 tests in total). Six untrained users at the CLIA waived sites participated in the study. The panel testing was conducted over a minimum of 6 days at each site, and the testing was integrated into the users' daily work flow. The performance of ID NOW Influenza A & B 2 with samples near the assay cutoff was acceptable when used by untrained users, as shown in the table below.

Influenza A and B Testing of Samples near the Assay Cutoff (LOD)

	Direct Swab Method		VTM Method	
	Untrained Users		Untrained Users	
Sample Type	**% Detection**	**95% CI**	**% Detection**	**95% CI**
Flu A Low Positive	98.3% (59/60)	91.1%, 99.7%	100% (60/60)	94.0%, 100%
Flu A Moderate Positive	98.3% (59/60)	91.1%, 99.7%	98.3% (59/60)	91.1%, 99.7%
Flu B Low Positive	98.3% (57/58)	90.9%, 99.7%	100% (60/60)	94.0%, 100%
Flu B Moderate Positive	100% (59/59)	93.9%, 100%	100% (60/60)	94.0%, 100%
True Negative[1]	100% (60/60)	94.0%, 100%	100% (60/60)	94.0%, 100%

[1]Percent Detection correlates to the percentage of negative results.

Using risk analysis as a guide, analytical flex studies were conducted on ID NOW Influenza A & B 2. The testing evaluated numerous sources of potential human errors and environmental factors that could affect the accuracy of results, including those related to sample handling, reagent handling, and extremes of operational conditions. The studies demonstrated that the test is robust to usage variation and environmental factors that may be encountered.

SYMBOLS

 Fragile, handle with care	BASE Test Base	CARTRDG Transfer Cartridge
RCVR Sample Receiver	Rx Only Prescription Only (Applies to US only)	 Caution, consult accompanying documents.

ORDERING and CONTACT INFORMATION

Reorder numbers:

427-000: ID NOW Influenza A & B 2 - 24 Test Kit

425-080: ID NOW Influenza A & B 2 Control Swab Kit

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CE IVD

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INFLUENZA A & B 2

PI

Size:

8.5 in x 5.5 in

Printed Colors

CMYK

Incoming Inspection Colors
(For Reference Only)
Colors below are not used for printing

PMS 2995 U
Primary Blue

PMS 297 U
Light Blue

PMS 303 U
Dark Blue

PN: IN427000
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