Abbott

ID NOW™

RSV

PACKAGE INSERT

ID NOW™ RSV PACKAGE INSERT

For use with the ID NOW™ Instrument
For use with nasopharyngeal specimens
For *in vitro* Use Only
Rx Only

CLIA COMPLEXITY: WAIVED

For Nasopharyngeal Swabs (Tested Directly or after Elution in Viral Transport Media)

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™ RSV 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 of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and 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 diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.

SUMMARY and EXPLANATION of the TEST

Respiratory Syncytial Virus (RSV) is the single most important cause of severe respiratory illness in infants and young children and the major cause of infantile bronchiolitis. It is the most frequent cause of hospitalization of infants and young children in industrialized countries. In the USA alone, 85,000 to 144,000 infants with RSV infections are hospitalized annually, resulting in 20% to 25% of pneumonia cases and up to 70% of bronchiolitis cases in the hospital. Global RSV disease burden is estimated at 64 million cases and 160,000 deaths every year.[1]

RSV disease includes a wide array of symptoms, from rhinitis and otitis media to pneumonia and bronchiolitis. Spread of the virus from contaminated nasal secretions occurs via large respiratory droplets, and close contact with an infected individual or contaminated surface is required for transmission.

RSV is also a significant problem in the elderly, in persons with cardiopulmonary diseases and in immunocompromised individuals. Rates of RSV infection in nursing homes in the USA are approximately 5% to 10% per year with a 2% to 8% case fatality rate, amounting to approximately 10,000 deaths per year among persons >64 years of age.[1]

Rapid diagnostics with increased sensitivity are essential for the reliable detection of RSV, allowing immediate, effective patient management. Rapid accurate diagnosis of RSV can lead to reduced hospital stays and costs, reduction in antimicrobial use, reduced secondary complications and effective implementation of infection control measures.[2]

ID NOW RSV is a rapid (in as little as 13 minutes), instrument-based isothermal test for the qualitative detection of RSV A and RSV B from nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media. 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 RSV kit contains all components required to carry out an assay for RSV on the ID NOW Instrument.

PRINCIPLES of the PROCEDURE

ID NOW RSV utilizes isothermal nucleic acid amplification technology for the qualitative detection of RSV A and RSV 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 RSV A and RSV B, respectively, as well as an internal control. The templates (similar to primers) designed to target RSV A RNA amplify a unique region of the nonstructural gene NS2 while the templates designed to amplify RSV B RNA target the nucleocapsid gene N. 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 as RSV positive, negative or invalid.

REAGENTS and MATERIALS

Materials Provided

Test Bases: BASE	Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of RSV A and RSV B viral RNA.
Sample Receivers: RCVR	Blue plastic components containing 2.5 mL of elution buffer.
Transfer Cartridges: CARTRDG	White plastic components used to transfer 2 x 100 µL of sample extract from the Sample Receiver to the Test Base.
Nasopharyngeal Swabs:	Sterile swabs for use with the ID NOW RSV Test.
Positive Control Swab:	The positive control swab is coated with inactivated RSV A and B viruses.
Negative Control Swab:	The use of a sterile nasopharyngeal swab ensures appropriate negative results are obtained.
Plastic disposable pipettes capable of delivering 200µl VTM sample	
Package Insert	
Quick Reference Instructions	

Materials Required but not Provided

ID NOW Instrument

PRECAUTIONS

1. Federal Law restricts this device to sale by or on the order of a licensed practitioner.
2. To be used in conjunction with the ID NOW Instrument.
3. 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.
4. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
5. Proper sample collection, storage and transport are essential for correct results.
6. Leave test pieces sealed in their foil pouches until just before use. Storage of unpouched test components at temperatures greater than 30°C or at high relative humidity prior to use may result in Invalid or false results.
7. Do not tamper with test pieces prior to or after use.
8. Do not use kit past its expiration date.
9. Do not mix components from different kit lots.
10. 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.
11. **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.**

12. 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.
13. 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.
14. 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.**
15. All test pieces are single use items. Do not use with multiple specimens.
16. 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 RSV false positive test results.
17. 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.
18. 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 RSV 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 RSV 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 RSV contains an internal control that has been designed to control for functionality of the amplification/detection process and reagents. 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 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 RSV 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. RSV Positive QC pass indicates a positive result for both RSV A and RSV 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.

Nasopharyngeal Swab

For optimal performance, use the swab provided in the test kit. Alternatively, sterile rayon, foam, or flocked flexible-shaft NP swabs can be used to collect nasopharyngeal samples.

Calcium alginate and Puritan Purflock® Ultra flocked swabs are not suitable for use in this assay.

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 nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, a direct 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 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 nasopharyngeal swab samples is required, the transport media listed below were tested and are acceptable for use in ID NOW RSV. Elute the swab into 0.5 to 3.0 mL of saline or viral transport media by rotating the swab head in the liquid for 10 - 20 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 24 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. If refrigerated, samples must be warmed to room temperature before testing with ID NOW RSV.

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 (DMEM)
M4 Media
M4-RT Media
M5 Media
M6 Media
Phosphate Buffered Saline
Saline
Tryptose Phosphate Broth
Veal Infusion Broth
Universal Transport Media
Starplex Multitrans Media
Vircell Media

TEST PROCEDURE

Before testing with ID NOW RSV:

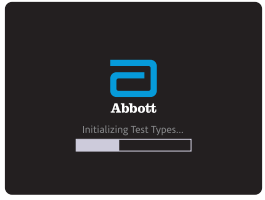
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a pellet is not visible at the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

To Perform a Test:

Step 1

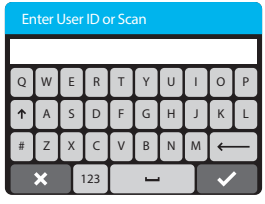
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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.*



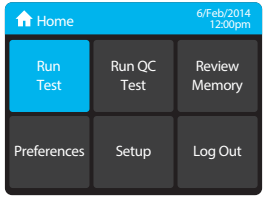
Enter User ID

Press '✓' after entry.



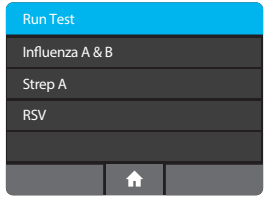
Touch 'Run Test'

This will begin the test process.



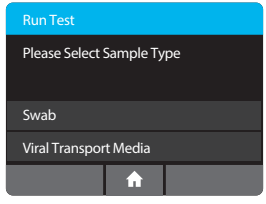
Touch 'RSV'

This starts an RSV test.



Select Sample Type

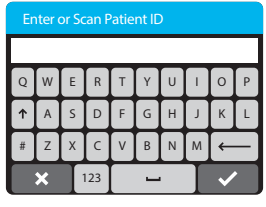
If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.



Enter Patient ID using on screen keyboard or barcode scanner

Touch '✓'.

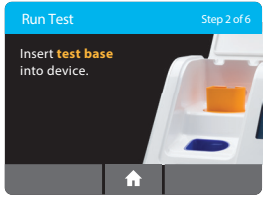
Verify that the ID was entered correctly, then touch '✓' to confirm entry.



Step 2

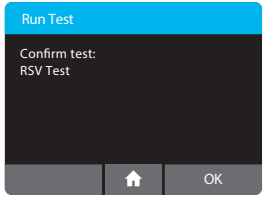
Open the Lid and Insert Orange Test Base into Orange Test Base holder

⚠ **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.



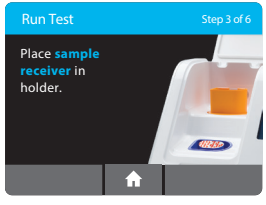
⚠ **Caution: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded.**

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.

Step 3

Insert Blue Sample Receiver into the Blue Sample Receiver holder

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

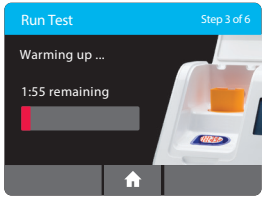


⚠ **Caution: Confirm that the foil seal on the Sample Receiver indicates that it is for use with ID NOW RSV.**
If not, then remove the Sample Receiver and replace it with a new Sample Receiver for ID NOW RSV.

⚠ **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.

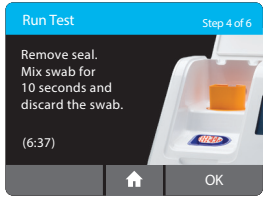
⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT. DO NOT** close the lid or insert the sample until prompted by the instrument.



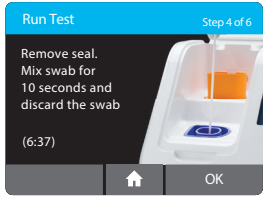
Step 4

Direct 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, **immediately press 'OK' to proceed**.

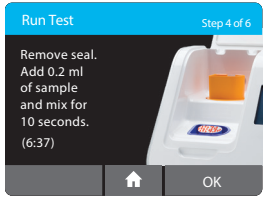


⚠ **Caution: To ensure the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces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

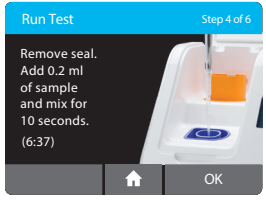
Discard the swab.
Skip to Step 5a.

Nasopharyngeal Swab Eluted in Viral 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.



Vigorously mix the sample in the liquid for 10 seconds. Use the pipette to swirl the liquid. Once the sample is mixed and the pipette is removed, **immediately press 'OK' to proceed.** Continue to Step 5a.

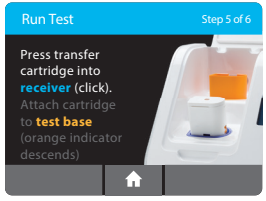


⚠ **Caution: To ensure the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces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

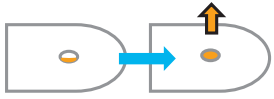
Press the White Transfer Cartridge into the Blue Sample Receiver

Listen for a click.



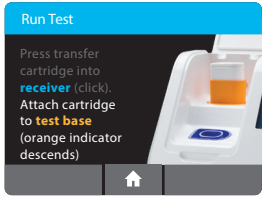
When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.

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



Step 5b

Lift and then connect the Transfer Cartridge to the Test Base

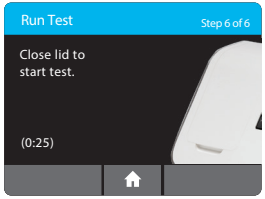


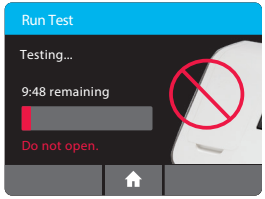
When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.

⚠ **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.





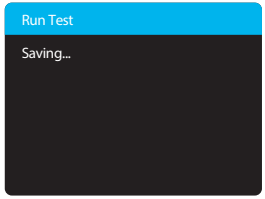
DO NOT OPEN THE LID until the **Test Complete** message appears on the screen.

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.**

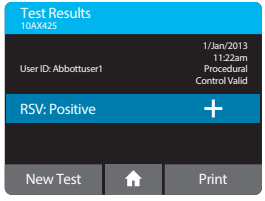
⚠ **Caution: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.**

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



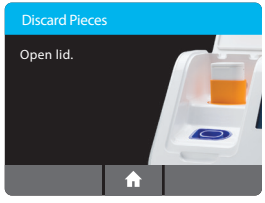
⚠ **Caution: The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.**

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

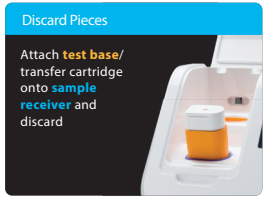
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.



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.



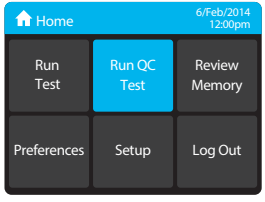
⚠ **Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.**

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.

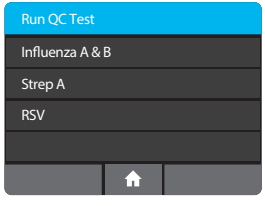
Quality Control Swab Test Procedure

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.

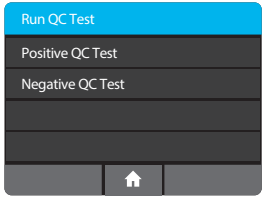
1. Touch 'Run QC Test'



2. Touch 'RSV'

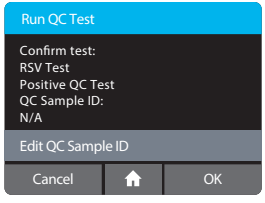


3. Select the QC Test to be Run



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.

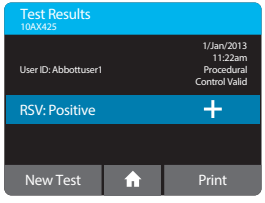
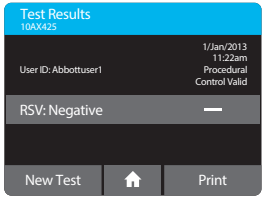
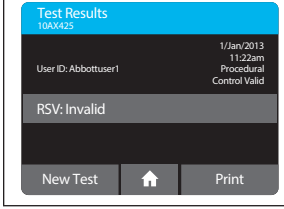


The user has the option to enter an ID for the QC Sample being run.

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

RESULT INTERPRETATION

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

Instrument Display	Interpretation of Results
	**Positive for RSV viral RNA.**
	**Negative for RSV viral RNA.**
	**Invalid.** Immediately repeat testing of the sample following the instructions below.

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. The test will be repeated using the liquid remaining in the Sample Receiver, it is not necessary to collect a new nasopharyngeal swab sample.

LIMITATIONS

- The performance of the ID NOW RSV was evaluated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
- ID NOW RSV 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.
- 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, RSV viruses 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.
- Mucin may interfere with RSV detection at levels greater than 0.0625% w/v.
- This test is not intended to differentiate RSV subtypes. If differentiation of specific RSV subtypes is needed, additional testing, in consultation with state or local public health departments, is required.
- Negative results do not preclude infection with RSV and should not be the sole basis of a patient treatment decision.
- This test has not been evaluated for patients without signs and symptoms of respiratory infection.
- 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.
- The test is a qualitative test and does not provide the quantitative value of detected organism present.
- Positive and negative predictive values are highly dependent on prevalence. The assay performance was established during the 2015 to 2016 respiratory season. The positive and negative predictive values may vary depending on the prevalence and population tested.

EXPECTED VALUES

The prevalence of RSV varies from year to year; the rate of positivity found in RSV testing is dependent on many factors including the method of specimen collection, the test method used, time of year, age of the patient, and the disease prevalence in specific localities. In the ID NOW RSV multi center prospective clinical study (described in the "Clinical Study" section below), a total of 506 nasopharyngeal swab specimens were determined to be evaluable. The number and percentage of RSV positive cases per specified age group, as determined by the ID NOW RSV assay, are presented below:

RSV Positives by the ID NOW™ RSV Assay per Age Group

Age Group (Years)	Number of Nasopharyngeal Swab Specimens	Number of RSV Positives	RSV Positivity Rate
<1	122	58	48%
1 to 5	243	82	34%
6 to 10	58	0	0%
11 to 18	41	1	2%
≥60	42	5	12%
Total	506	146	29%

PERFORMANCE CHARACTERISTICS

Clinical Study:

Clinical performance characteristics of ID NOW RSV were evaluated in a multi-site prospective study during the 2015-2016 respiratory season in the U.S. A total of nine investigational sites throughout the U.S. participated in the study.

In this study, two nasopharyngeal swabs were collected from one nostril from each subject using standard collection methods. At all sites, one nasopharyngeal swab was tested directly on ID NOW RSV, according to the test procedure for **Direct Nasopharyngeal Swab**. The other nasopharyngeal swab was eluted in 3 mL of viral transport media (VTM). The samples were processed and tested using the ID NOW RSV assay according to the test procedure for **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.

External control testing, using ID NOW RSV 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 530 nasopharyngeal swab specimens were enrolled in this study. Of those, 24 specimens did not meet eligibility criteria. A total of 506 nasopharyngeal swab specimens were considered evaluable.

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	56	66
1 to 5	114	129
6 to 10	27	31
11 to 18	19	22
≥60	20	22
Total	236	270

Compared to the RT-PCR comparator method, the performance of ID NOW RSV is presented in the tables below.

Direct Nasopharyngeal Swab – ID NOW™ RSV against the Comparator Method

ID NOW™ RSV	Comparator Method		
	Positive	Negative	Total
Positive	137	7[a]	144
Negative	2	351	353
Total	139	358	497
Sensitivity: 137/139 98.6% (95%CI: 94.9%-99.6%)			
Specificity: 351/358 98.0% (95%CI: 96.0%-99.0%)			

[a] RSV nucleic acid was detected in 6/7 False Positive specimens using an FDA-cleared molecular test

Nasopharyngeal Swab Eluted in Viral Transport Media – ID NOW™ RSV against the Comparator Method

ID NOW™ RSV	Comparator Method		
	Positive	Negative	Total
Positive	138	8[a]	146
Negative	2	353	355
Total	140	361	501
Sensitivity: 138/140 98.6% (95%CI: 94.9%-99.6%)			
Specificity: 353/361 97.8% (95%CI: 95.7%-98.9%)			

[a] RSV nucleic acid was detected in 6/8 False Positive specimens using an FDA-cleared molecular test

During the prospective clinical study, the initial invalid rate for direct nasopharyngeal swab samples (before repeat testing per the product instructions) was 4.1% (21/506) (95% CI: 2.7% to 6.3%). After repeat testing per the product instructions, the invalid rate was 0.8% (4/506) (95% CI: 0.3% to 2.0%).

The initial invalid rate for nasopharyngeal swabs eluted in viral transport media was 2.2% (11/506) (95% CI: 1.2% to 3.9%). After repeat testing per the product instructions, the invalid rate was 0% (0/506) (95% CI: 0.0% to 0.8%).

ANALYTICAL STUDIES:

Reproducibility

A reproducibility study of ID NOW RSV 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) RSV A and B samples.

Participants tested multiple samples of each panel member on five different days. The percent agreement with expected results for the RSV. A moderate positive and low positive samples were 100% (89/89) and 98.9% (89/90), respectfully. The percent agreement with expected result for the RSV B moderate positive and low positive samples were 98.9% (89/90) and 100% (90/90), respectfully. All of the true negative samples (90) 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		
LP[1] RSV A	Percent Agreement	96.7%	100%	100%	98.9% (89/90)	(94.0%, 99.8%)
	Count	29/30	30/30	30/30		
MP[1] RSV A	Percent Agreement	100%	100%	100%	100% (89/89)	(95.9%, 100%)
	Count	29/29	30/30	30/30		
LP[1] RSV B	Percent Agreement	100%	100%	100%	100% (90/90)	(95.9%, 100%)
	Count	30/30	30/30	30/30		
MP[1] RSV B	Percent Agreement	100%	96.7%	100%	98.9% (89/90)	(94.0%, 99.8%)
	Count	30/30	29/30	30/30		
TN[1,2]	Percent Agreement	100%	100%	100%	100% (90/90)	(95.9%, 100%)
	Count	30/30	30/30	30/30		

[1] Low Positive (LP), Moderate Positive (MP), True Negative (TN)
[2] Percent Agreement correlates to the percent of negative results.

Analytical Sensitivity (Limit of Detection)

The limit of detection (LOD) of the ID NOW RSV assay was determined using one characterized strain of RSV A and RSV B.

Presumed negative swab specimens were eluted in UTM. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Each RSV 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/mL) was also assessed using laboratory developed and validated RSV quantitative real-time PCR assays.

Contrived 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 Nasopharyngeal Swab.

Contrived swab samples eluted into VTM were also tested according to the test procedure for Nasopharyngeal Swab Eluted in Viral Transport Media.

The LOD for each RSV strain tested was determined 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 RSV strain tested are presented in the tables below:

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

RSV Strain	LOD ($TCID_{50}$/mL)	LOD (Genome Equivalents/mL)
RSV A/2	5.82×10^2	7.80×10^4
RSV B/9320	6.0×10^1	5.43×10^3

Limit of Detection (LoD) Study Results – Swab Eluted in VTM Testing

RSV Strain	LOD ($TCID_{50}$/mL)	LOD (Genome Equivalents/mL)
RSV A/2	9.15×10^3	1.06×10^6
RSV B/9320	9.64×10^2	1.48×10^5

Analytical Reactivity (Inclusivity)

The reactivity of the ID NOW RSV assay was evaluated with a panel of three (3) RSV strains.

The ID NOW RSV assay detected all strains tested at the concentrations indicated in the table below:

Analytical Reactivity Study Results

Strain	Subtype	Test Concentration (in PFU/mL or Genome Equivalents)		ID NOW™ RSV Result (n=3)
		PFU/mL	Genome Equiva-lents/mL	
A Long	A	9.38×10^{-2}	1.75×10^{3}	Positive
B1	B	1:20,000	2.37×10^{3}	Positive
18537	B	1.00×10^{-1}	1.37×10^{3}	Positive

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of ID NOW RSV, 40 commensal and pathogenic microorganisms (21 bacteria, 18 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

Bordetella pertussis
Corynebacterium diphtheriae
*Escherichia coli**
Haemophilus influenzae
Klebsiella pneumoniae
Neisseria meningitidis
Neisseria sicca
Neisseria subflava
*Proteus vulgaris**
Pseudomonas aeruginosa

Bacteria

Lactobacillus plantarum
Legionella pneumophila
*Moraxella/Branhamella catarrhalis**
Mycobacterium tuberculosis
Mycoplasma pneumoniae
Neisseria gonorrhoeae
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus, Group A
Streptococcus pneumonia
Streptococcus salivarius

Viruses

Adenovirus Type 1
Adenovirus Type 7
Enterovirus/Coxsackievirus B4
Enterovirus Type 70
Epstein Barr Virus
Human Coronavirus 229E
Human Coronavirus OC43
Human Cytomegalovirus (CMV) (Herpes V)
Human Echovirus 7 (Wallace)
Human Metapneumovirus
Influenza A
Influenza B
Measles (Edmonston)
Mumps (Enders)
Parainfluenza 1
Parainfluenza 2
Parainfluenza 3
Rhinovirus type 1A

Yeast

Candida albicans

* Some cross-reactivity was observed for *E. coli* at concentrations greater than 2.75×10^9, *Moraxella catarrhalis* at concentrations greater than 1.50×10^9, and *Proteus vulgaris* at concentrations greater than 4.69×10^8.

In addition, *in silico* analysis was performed to determine whether there is any significant overlap between ID NOW RSV 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 RSV target sequences.

Bacteria	
Bordetella bronchiseptica	*Neisseria mucosa*
Chlamydia pneumonia	*Proteus mirabilis*
Chlamydia trachomatis	

Viruses	
Adenovirus 2	Coronavirus NL63
Adenovirus 3	Coxsackievirus B35
Adenovirus 4	Echovirus 6
Adenovirus 5	Echovirus 9
Adenovirus 11	Echovirus 11
Adenovirus 14	Enterovirus 71
Adenovirus 31	

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 RSV at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Mucin	0.0625%
Whole Blood	1%
NeoSynephrine Cold and Sinus Extra Strength Spray	20%
Afrin PumpMist Original	20%
Ocean Saline	20%
Chloroseptic Max	20%
Zicam Allergy Relief	20%
Beclomethasone	0.068 mg/mL
Budesonide	0.051 mg/mL
Dexamethasone	0.48 mg/mL
Flunisolide	0.04 mg/mL
Fluticasone propionate	0.04 mg/mL
Mometasone furoate	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 RSV test performance in the presence of non-RSV respiratory pathogens was evaluated. Vendor provided stocks of RSV A and B strains were diluted in UTM to approximately 3 times the limit of detection. Contrived RSV A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. The following panel of non-RSV viruses was tested at the concentration provided in the table below and was found not to affect test performance.

Virus Panel	Concentration ($TCID_{50}$/ml)
Adenovirus Type 1	1.58×10^7
Rhinovirus Type 1A	1.58×10^7
Influenza A	5.00×10^6
Influenza B	1.00×10^8

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 RSV test. Vendor provided stocks of RSV A and B strains were diluted in UTM to approximately 30 times the limit of detection. Contrived RSV 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. In addition, testing of contrived positive VTM samples was alternated with negative VTM samples following the test procedure for Nasopharyngeal Swab Eluted in Viral Transport Media for a total of 15 rounds. No false positive results were observed in this study.

CLIA Waiver Studies:

As part of the prospective study (as described in the Performance Characteristics section above), the accuracy of ID NOW RSV 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 nine (9) CLIA waived sites with 28 intended users participating. No training on the use of the test was provided to the operators.

Performance of the ID NOW RSV test when used by intended users at a CLIA waived testing site, is described above in the section titled “Clinical Study”.

A study was conducted to evaluate the performance of ID NOW RSV with weakly reactive samples when used by untrained users. Randomized blind-coded panels, containing negative and low positive (close to the limit of detection {LOD} or assay cutoff) RSV A and B specimens, were tested with ID NOW RSV at 3 CLIA waived sites (63 tests in total). Nine 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 RSV with samples near the assay cutoff was acceptable when used by untrained users, as shown in the table below.

ID NOW™ RSV Testing of Samples near the Assay Cutoff (LOD)

	Untrained Users	
Sample Type	**% Detection**	**95% CI**
RSV A Low Positive	100% (63/63)	94.3%, 100%
RSV B Low Positive	100% (63/63)	94.3%, 100%
True Negative	0% (0/63)	0%, 5.7%

Using risk analysis as a guide, analytical flex studies were conducted on ID NOW RSV. The studies demonstrated that the test is insensitive to stresses of environmental conditions and potential user errors.

SYMBOLS

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

ORDERING and CONTACT INFORMATION

Reorder numbers:

435-000: ID NOW RSV - 24 Test Kit

435-080: ID NOW RSV Control Swab Kit

US +1 877 441 7440
OUS +1 321 441 7200

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

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CE IVD

IN435000 Rev.6 2020/04

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Colors below are not used for printing

PMS 2995 U
Primary Blue

PMS 324 U
Mint

PMS 303 U
Dark Blue

PN: IN435000
Rev: 6

Date of Last Revision:
6.2 2020/04/30