

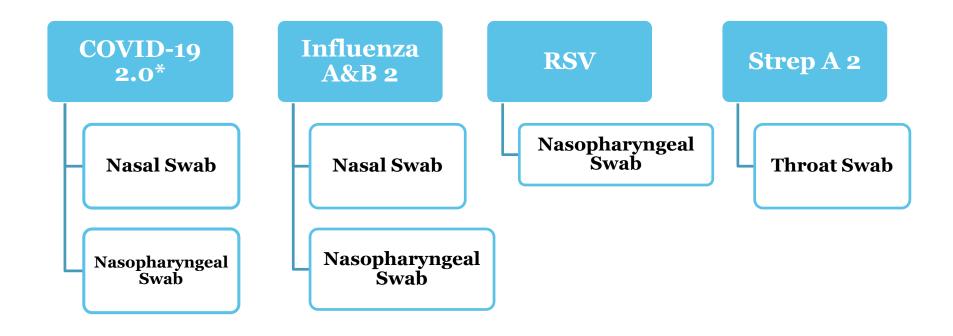
# ID NOW<sup>TM</sup> Sample Collection & Handling

[Insert TC Name]

[Insert TC Title]

[Insert Date]

# ID NOW Assays & Specimen Types



# ID NOW Sample Collection & Handling Best Practices

Use freshly collected specimens for optimal test performance

Follow Standard
Precautions when handling
clinical specimens

Change gloves between sample collection & performing testing

Allow all samples to reach room temperature before testing

Proper sample collection, storage and transport are essential for correct results. Inadequate collection or improper sample handling/storage/ transport may yield erroneous results

# Sample Collection & Handling ID NOW COVID-19 2.0

# ID NOW COVID-19 2.0 Nasal Swab

### **Optimal**

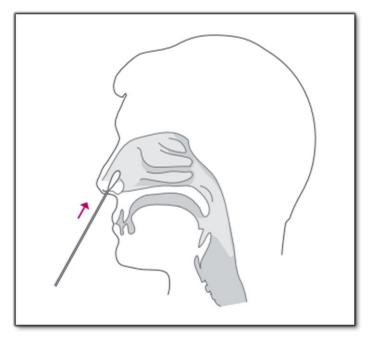
 Swabs provided in the ID NOW COVID-19 2.0 kit



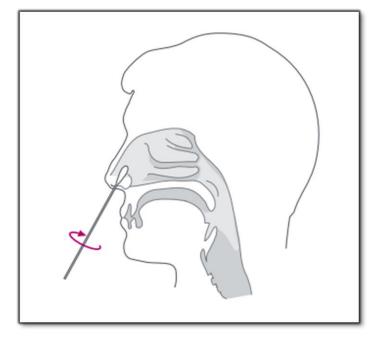
### Acceptable

- Puritan Regular Foam Tip Swabs
- Puritan HydraFlock™ Flock Swabs (Standard Tip)
- Copan Standard Rayon Tip
- MRC Technology, Ltd. Foam Tipped Applicator
- Foamtec Int'l Swab
- Sterile CleanFOAM diagnostic

# ID NOW COVID-19 2.0 Nasal Sample Collection



 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 the nostril

# ID NOW COVID-19 2.0 Nasopharyngeal Swab

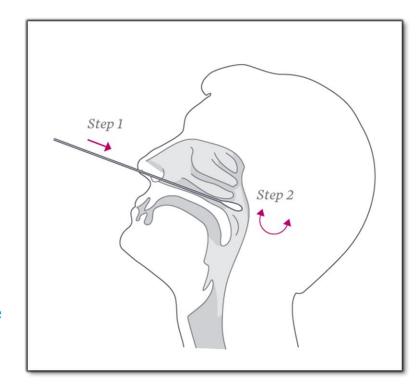
## Acceptable

- Puritan Small Foam Tip HydraFlock™ Flocked swab (mini tip)
- Copan Mini Tip Flocked Swabs



# ID NOW COVID-19 2.0 Nasopharyngeal Sample Collection

- Insert the swab into the nostril exhibiting the most drainage or congestion
- 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, advance the swab into the nasopharynx
  - Distance is halfway of that from the nose to the tip of the ear, about half the length of the swab
  - DO NOT USE FORCE, the swab should travel
  - smoothly with minimal resistance



Leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

# ID NOW COVID-19 2.0 Sample Transport & Storage

For best performance, test direct nasal or nasopharyngeal swabs as soon as possible after collection

## If immediate testing is not possible...

Place the swab in a clean, unused tube, labeled with patient information and capped tightly

Do Not Return the Swab to its Original Packaging

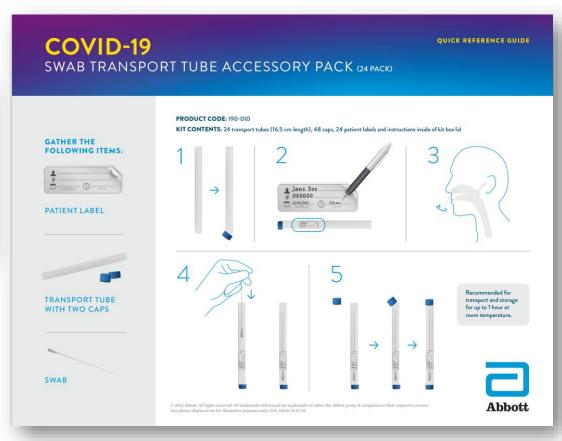
#### **Storage**

Room temperature (15-30°C) for up to 1 hour prior to testing

# ID NOW COVID-19 2.0 Swab Transport Tube Accessory Pack

COVID-19 Swab Transport
 Tube Accessory Pack Overview





# Sample Collection & Handling ID NOW Influenza A&B 2

# ID NOW Influenza A&B 2 Nasal Swab

### **Optimal**

Swabs provided in the ID NOW Influenza A&B 2 kit



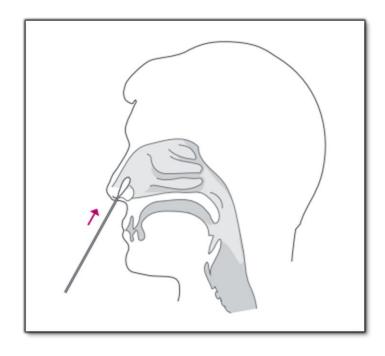
#### Acceptable

- Rayon
- Foam
- HydraFlock® Flocked swab (standard tip)
- HydraFlock® Flocked swab (mini tip)
- Copan Mini Tip Flocked Swab
- Copan Standard Flocked Swab

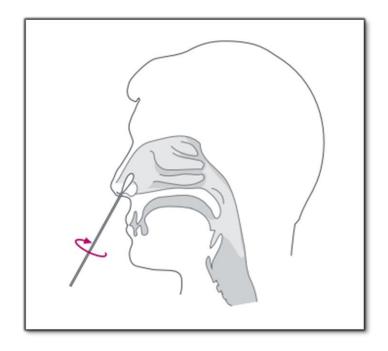
#### **Not Suitable**

- Puritan PurFlock Standard Tip Ultra Flocked Swab
- Puritan PurFlock Mini Tip Ultra Flocked Swab
- Copan Standard Rayon Tip Swab

# ID NOW Influenza A&B 2 Nasal Sample Collection



 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 the nostril

# ID NOW Influenza A&B 2 Nasopharyngeal Swab

### Acceptable

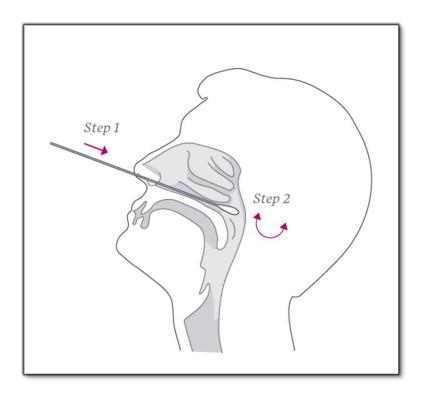
#### Flexible-shaft NP swabs:

- Rayon
- Foam
- Polyester
- Flocked



# ID NOW Influenza A&B 2 Nasopharyngeal Sample Collection

- Insert the swab into the nostril exhibiting the most drainage or congestion
- 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
  - Distance is halfway of that from the nose to the tip of the ear and about half the length of the swab
  - DO NOT USE FORCE, the swab should travel
  - smoothly with minimal resistance



Leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

# ID NOW Influenza A&B 2 Sample Transport & Storage – Direct Swab

Direct nasal or nasopharyngeal swabs should be tested as soon as possible after collection

If immediate testing is not possible...

Direct swabs can be held in its original package



Room temperature (15-30°C) for up to **2 hours** prior to testing

Refrigerated at 2-8°C & tested within **24 hours** from time of collection

# ID NOW Influenza A&B 2 Sample Transport & Storage – Transport Media

#### **Acceptable 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

#### **Not Suitable**

- Tryptose Phosphate Broth
- Brain Heart Infusion Broth
- Veal Infusion Broth
- Wako's E-MEM transport media

# ID NOW Influenza A&B 2 Sample Transport & Storage – Transport Media

#### **Elute the Swab:**

- Within 1 hour of sample collection
- In 0.5 to 3.0 ml of saline or VTM
- By rotating the swab in the liquid for 10 seconds
- Remove the swab and discard

If immediate testing of eluted samples is not possible...



Room temperature (15-30°C) up to **8 hours** prior to testing

Refrigerated at 2-8°C & tested within **72 hours** from time of collection

**Note:** Minimal dilution of the sample is recommended as dilution may result in decreased test sensitivity.

# Sample Collection & Handling ID NOW RSV

# Nasopharyngeal Swab

### **Optimal**

• Swabs provided in the ID NOW RSV kit



#### Acceptable

Flexible-shaft NP swabs:

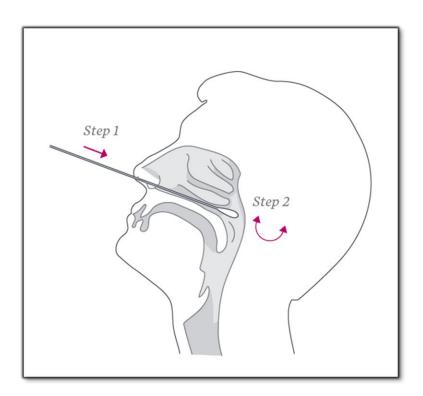
- Rayon
- Foam
- Flocked

#### **Not Suitable**

- Calcium alginate
- Puritan Purflock® Ultra flocked

# Nasopharyngeal Sample Collection

- Insert the swab into the nostril exhibiting the most drainage or congestion
- 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
  - Distance is halfway of that from the nose to the tip of the ear and about half the length of the swab
  - DO NOT USE FORCE, the swab should travel
  - smoothly with minimal resistance



Leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

# Sample Transport & Storage – Direct Swab

Direct nasopharyngeal swabs should be tested as soon as possible after collection

#### If immediate testing is not possible...

Direct swabs can be held in its original package



#### **Storage Time**

Room temperature (15-30°C) for up to **2 hours** prior to testing

Refrigerated at 2-8°C & tested within **24 hours** from time of collection

# ID NOW RSV Sample Transport & Storage – Transport Media

### **Acceptable Transport Media**

- Amie's Media
- Dulbecco's Modified Eagles' Medium (D-MEM)
- M4 Media
- M4-RT Media
- M5 Media
- M6 Media
- Phosphate Buffered Saline
- Saline
- Universal Transport Media
- Tryptose Phosphate Broth
- Veal Infusion Broth
- Starplex Multitrans Media
- Vircell Media

# Sample Transport & Storage – Transport Media

#### **Elute the Swab:**

- Within 1 hour of sample collection
- In 0.5 to 3.0 ml of saline or VTM
- By rotating the swab in the liquid for 10-20 seconds
- Remove the swab and discard

If immediate testing of eluted samples is not possible...



#### **Storage Time**

Room temperature (15-30°C) up to **8 hours** prior to testing

Refrigerated at 2-8°C & tested within **24 hours** from time of collection

**Note:** Minimal dilution of the sample is recommended as dilution may result in decreased test sensitivity.

# Sample Collection & Handling ID NOW Strep A 2

# ID NOW Strep A 2 Throat Swab

### **Optimal**

 Swabs provided in the ID NOW Strep A 2 kit



### Acceptable

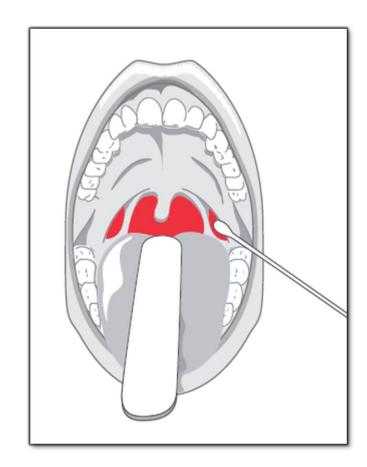
- Foam
- Polyester
- Nylon flocked
- HydraFlock<sup>®</sup>
- BBL™ CultureSwab™ Liquid Amies transport media system

#### **Not Suitable**

- Rayon
- BBL™ CultureSwab™ Liquid Stuart transport media system

# ID NOW Strep A 2 Throat Swab Collection

- Swab the area with a back & forth motion, do not merely touch the area
  - Swabbing is required to remove organisms adhering to the surface of the throat
- Aim for white patches
  - Streptococcal bacteria are frequently found in the white patches in the tonsillar area
- Avoid contact with the lips, teeth, cheek, gums, uvula and tongue
  - Contact with these areas may contaminate the sample
- When using dual swabs, collect bacteria on both sides of the swab head and rub the two swab heads together
  - Rubbing ensure even distribution of the sample



# ID NOW Strep A 2 Transport & Storage

#### Swab specimens should be tested as soon as possible after collection

#### If immediate testing is not possible...

Swab can be held in its original package

Swab can be held in a clean, dry plastic tube or sleeve

#### **Storage Time**

Room temperature (approx. 22°C) up to **72 hours** prior to testing

Refrigerated at 2-8°C for up to **72 hours** prior to testing

BBL<sup>TM</sup> CultureSwab<sup>TM</sup> Liquid Amies transport media system

Swab from media system is used only

#### **Storage Time**

Room temperature (approx. 22°C) for up to **6 hours** prior to testing

Refrigerated at 2-8°C for up to 6 hours prior to testing

# Sample Collection & Handling Summary

Assays	Influenza A&B 2	Strep A 2	RSV	COVID-19 2.0 (*EUA)
Sample Types	<ul><li>Nasal Swab</li><li>NP Swab</li><li>Nasal or NP Swab in VTM</li></ul>	• Throat Swab	NP Swab     NP Swab in VTM	Nasal Swab     NP Swab
Direct Sample Storage	• Room Temp: Up to 2hrs. • 2-8°C: Up to 24 hrs.	• Room Temp or 2-8°C: Up to 72 hrs.	<ul> <li>Room Temp: Up to 2 hrs.</li> <li>2-8°C: Up to 24 hrs.</li> </ul>	<ul> <li>Do Not Return Swab to its Original Packaging</li> <li>If immediate testing is not possible, place the swab in a clean, unused tube, labeled with patient information and capped tightly</li> <li>Room Temp: Up to 1 hr.</li> </ul>
Transport Media Sample Storage	<ul> <li>Room Temp: Up to 8 hrs.</li> <li>2-8°C: Up to 72 hrs.</li> </ul>	<ul> <li>Throat swab in BBL™         CultureSwab™ Liquid         Amies transport         media system</li> <li>Room Temp or 2-8°C:         Up to 6 hrs.</li> </ul>	<ul><li>Room Temp: Up to 8 hrs.</li><li>2-8°C: Up to 24 hrs.</li></ul>	• Not approved



\*ID NOW<sup>TM</sup> COVID-19 2.0 has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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