INTENDED USE:

ID NOW™ is a rapid, instrument-based, molecular in vitro diagnostic test utilizing isothermal nucleic

acid amplification technology for the qualitative detection of the following:

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| **TEST** | **INTENDED USE** | **INTENDED SIGNS & SYMPTOMS** |
| COVID(EUA) | Patients who are suspected of Covid within 7 days of the onset of symptoms |  Respiratory |
| STREP A2 | Detection of Group A strep on patient with signs and symptoms | Pharyngitis |
| FLU A B | Differential diagnosis of FLU A & B in humans with clinical and epidemiological risk factors |  Respiratory |
| RSV | Children <18 years and adults ≥ 60 years with signs and symptoms | Wide array of symptoms from rhinitis and otitis media to respiratory symptoms |

***The items in the following procedure will apply to all tests unless it is assigned to a specific test or tests.***

SUPPLIES:

* ID NOW Instrument
* Nasopharyngeal swabs for COVID-19
* Swab Transport Tube for COVID-19
* ID NOW Test kits for Influenza A/B, COVID-19, RSV, and Strep A
* 10% bleach

KIT STORAGE:

* Store kits at room temperature up to 30°C until the expiration date marked on the outer package and kits.
* Operate the IDNow machine at 15-30°C and 10-80% relative humidity.

QUALITY CONTROL:

* Positive control swabs are provided in each test kit. Handle as though they could transmit disease.
* Negative control swabs: Use the appropriate sterile swab for the corresponding test.

**Frequency of negative and positive quality control:**

* Each new machine prior to patient testing.
* Each new lot/shipment prior to patient testing.
* Each new untrained operator- “At least one level of quality control for each new untrained operator”?

**Quality Control Swab Test Procedure**

1. Scan User ID
2. Touch ‘Run QC Test’
3. Choose the test to run
4. Select Positive or Negative
5. Confirm Test and select OK or Edit QC sample if the information is not correct.
6. Follow the on screen prompts to complete testing.

Note: Enter the lot number as an ID for the QC Sample being run

1. See NOTES in Patient testing section #9 on the following page for precautions
2. CHANGE GLOVES
3. Ensure that both tests pass before testing patients or repeat testing if failures occur.
4. Attach the printouts to the QC worksheet.

SPECIMEN COLLECTION, HANDLING, AND TRANSPORTATION:

* DO NOT PUT SAMPLE IN TRANSPORT MEDIA
* Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.
* For optimal performance use the swab provide in the test kit. Alternate approved swab types are listed below for each test.

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| **TEST** | **COLLECTION METHOD** | **SPECIAL COLLECTION INSTRUCTIONS** | **HANDLING AND TRANSPORTATION** | **APPROVED SWABS** |
| COVID | NP | * Fact sheet MUST be provided to the patient before collection.
 | * Immediately place the swab into a clean transport tube after collection, NOT to the original packaging.
* Test within 1 hour of collection at room temperature
* Discard samples held longer than 1 hour
 | Use sterile, Puritan Small Foam Tip HydraFlock® Flocked swab (mini tip) or Copan Mini Tip Flocked Swabs to collect nasopharyngeal swab samples. |
| STREP A2 | Throat |  | * Can be held in its original package or a clean transport tube
* Test within 72 hours of collection; room temperature
 | Foam, polyester, HydraFlock and nylon flocked throat swabs can be used.  |
| FLU A B | Nasal or NP  | * Collect from the nostril that exhibits the most visible drainage
* Visibly bloody samples must not be used
 | * Can be held in its original package or a clean transport tube
* Test within 2 hours of collection at room temperature or refrigerate and test within 24 hours
* If refrigerated, allow swabs to warm to room temperature before testing
 | Rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs.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. |
| RSV | NP |  | * Test within 2 hours of collection at room temperature or refrigerate and test within 24 hours
 | 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. |

PATIENT TESTING

**Precautions:**

* Leave test pieces sealed in their foil pouches until use
* Do not mix components from different kit lots or other ID NOW assays
* Change gloves between the handling of specimens
* Do not use components that are dropped, damaged, or previously opened
* Ensure your test pieces are for the correct test (pkg 1 and pkg 2)
* Do not touch the test tubes on the bottom of the orange piece
* Follow the step-by-step instructions shown on the instrument screen.

**To Perform a Test:**

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| 1. Wear clean gloves
2. Obtain package 1 and 2 from the kit of the test you intend to perform
3. Touch “Logout” if someone is signed in
4. Use the barcode scanner to scan your ID badge
5. Touch “Run Test”
6. Select the test you intend to perform
7. Scan the Patient ID
8. Verify that the ID was entered correctly, then touch ‘Ok’ to confirm
9. Open the IDNow lid and follow the on-screen prompts

NOTES:1. Confirm that the orange piece has a visible reagent pellet at the bottom of each of the reaction tubes. Do not use if the pellet is not visible
2. If a timeout occurs during the procedure, the test must be re-started using new components
3. If the blue receiver spills, the instrument must be cleaned, and the test must be re-started using new components
4. After mixing the swab, press the swab head against the side of the blue piece to remove excess liquid. CHANGE GLOVES after this step.
5. When the test has completed, connect all 3 pieces, wrap it up in your gloves and discard into the biohazard trash.

RE-TESTING DUE TO AN INVALID RESULT1. Remove the orange and white piece and connect it to a NEW, UNUSED blue piece and dispose in glove
2. Carefully remove the blue receiver from the instrument without spilling the contents and set aside
3. Start a new test
4. Re-insert the used blue piece that was set aside but DO NOT re-mix with the swab.
5. Follow the
6. This procedure should only be performed one time per sample. After that, recollect using a new swab and use all new testing supplies.

RESULT LIMITATIONS AND REPORTING* In general, Negative results do not rule out infection and should not be used as the sole basis for diagnosis treatment or other patient management decisions. If infection is still suspected, further testing should be done with samples sent to Microbiology for testing.
* Except for Strep A, Positive results do not rule out co-infections with other pathogens or specify viral lineage. They also don’t imply that the virus alive or dead or are of a certain subtype. All positive Covid tests are automatically reported to IDPH through Epic.
* Suspected occurrence of false positive or false negative results should be reported to the POC coordinator. As needed, check individual package inserts for the list of limitations regarding false results.

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| **Interfaced****Test** | **Positive** | **Negative** **(Normal Range)** | **Invalid** |
| Covid | Report as Positive  | Report as Negative  | Do not report and repeat test.Usually due to pieces not fully clicked together |
| Strep A | Report as Positive  | Report as Negative  | Do not report and repeat test.Usually due to improper collection  |
| Flu AB | -When A or B turns positive, the machine will stop the test.-Report the Positive from the machine and the other as “Not performed due to early detection of another virus”  | Report as Negative  | Do not report and repeat test.Usually due to inadequate specimen collection. |
| RSV | Report as Positive | Report as Negative  | Do not report and repeat test.Usually due to pieces not fully clicked together |

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ADDITIONAL PRECAUTIONS AND LIMITATIONS: See each individual package insert for a complete list.

DOWNTIME

* Instrument is not functioning correctly:
1. Contact the Lab Clinical Practice Leader
2. Call Abbott Tech Support at 1-855-731-2288
* Results are not posting to Epic:
1. Contact the Lab Clinical Practice Leader or email pathologypointofcareteam@healthcare.uiowa.edu
2. If Epic is available, manually file the test results until the system returns to normal.
3. If Epic is not available, report results verbally to the providers. Results should post again sometime after the system(s) return to normal.

MAINTENANCE

Daily and As Needed throughout the day.

With 10% solution of bleach:

1. Clean exterior of machine
2. Lift the lid and clean the interior avoiding the colored parts. Include the underside of the lid.

**NOTE**: Do not spray the machine directly. Without oversaturating, wet a lint free cloth with bleach.

1. Clean surrounding bench area including the hood.

**REFERENCES:**

* ID NOW Instrument User Manual 3/8/2022 v11.7
* Covid-19 2.0 EUA 05/2022 v07
* Strep A 2 package insert 5/15/2020 v5.3
* Influenza A&B 2 package insert 4/30/2020 v8.2
* RSV package insert 4/30/2020 v6.2

**FORMS:**

Form A: ID NOW Molecular QC Form

Form B: ID NOW Maintenance Form without Hood

Form C: ID NOW Maintenance Form with Hood

Written by: Annie Nimtz-Janssen, Karla Frink Date: 10/17/2022

Revised by: \_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

Approved by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

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| ID NOW MOLECULAR QC FORM

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| 1. **Date ALL Boxes from a shipment with the date it was received. Number the boxes in the shipment** (ie 1 of 6, 2 of 6 etc)
2. **RUN QC WITH EVERY SHIPMENT (Place Printouts on the back of this form)**
* Run both levels of QC on one analyzer. Rotating QC between analyzers with each shipment is recommended
* **Check lot numbers on all boxes in each shipment to make sure they are all the same lot number. Record all lots on QC form for each shipment.**
* \*Enter QC lot number into the IDNOW machine under ‘edit QC sample’:*(if using blank swab for Negative QC enter the lot # on back of the patient swab sheath*)

**Place ‘LOT READY TO USE ‘ labels ON ALL BOXES ONCE QC IS COMPLETED PER SHIPMENT.**

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| **TEST** | **SN# machine** | **Received date** | **# boxes in shipment** | **Control lot # (\*)** | **Control Exp date** | **Kit lot #** | **Kit exp date** | **Expected Result** | **Pass or Fail** | **Date** | **Initials** |
|  |  |  |  |  |  |  |  | **Positive** |  |  |  |
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Reviewed by Lab Director/Designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| MONTH:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ YEAR:\_\_\_\_\_\_\_\_\_\_\_\_UI HEALTHCAREID NOW MOLECULAR MAINTENANCE FORM |
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|  |  |
|  | 1  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
| WORK AREA |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| ANALYZERS |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| AS Needed |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| INITIALS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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 **\*USE ONLY 10% BLEACH TO CLEAN THE ANALYZERS AND WORK AREA DAILY AND AS NEEDED FOR SPILLS.**

**Daily Clean: MUST be done prior to running patients every day!**

**Clean all the white areas on the inside of the analyzer (do not clean the colored portions on the inside), clean the outside of the analyzer and clean the work area in front of the machines.**

**As needed: Clean between patients if you’re running increase volume of flu and seeing more positives.**

**\*\*Write NT-Not tested on days not in use.**

Reviewed by Lab Director/Designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| MONTH: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ YEAR: \_\_\_\_\_\_\_\_\_\_\_\_ID NOW MOLECULAR MAINTENANCE FORM |
| **\*Write NT- (No Tests)** for days that the machines were not used.  |  |
| **DAILY MAINT** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
| (1) HOOD WORK AREA  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| (2) ANALYZERS  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| (3) Clean Before each test |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| (4) UV Light (Hood) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 10% Bleach (weekly) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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**NOTE: Daily Maintenance MUST be done prior to running patients every day**

1. Hood Work Area: Use 10% Bleach with a soft towel or other non-abrasive cloth to clean the work area. (Work area = counter inside and the outside of the clear panel door) **NOTE: Do not use any kind of alcohol product on the surface of the hood.**
2. Analyzers: Use 10% Bleach, clean all the white areas on the inside of the analyzer (do not clean the colored portions on the inside), and clean the outside of the analyzer
3. As Needed:Clean between patients if you experience an increase of positive testing or whenever a spill occurs.
4. UV Light (Hood): At the end of the day, shut the plexiglass front door (light will turn off), then turn the knob all the way to the right. The UV light will come on for a 15-minute decontaminationcycle. *Do not open the door during this cycle or it will shut off*

**UV Light replacement: (1000 hours or 3 months). Currently, we will change the bulbs quarterly. Please document when it is completed in the appropriate month**

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|  | **APRIL** | **JULY** | **OCT** | **JAN** |
| **Date changed** |  |  |  |  |

***Order from Hospital Stores: Hoods with a size of 24” or 36” require item number #167995, while hoods with a length of 48” require #167996.***

Reviewed by Lab Director/Designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_-