Keywords: COVID, COVID-19, LumiraDx, Nasal Swab, SARS-CoV-2, SARS-CoV-2 Antigen Testing, Swab

I. PRINCIPLE/CLINICAL SIGNIFICANCE

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-n-CoV), which has since spread globally, resulting in a pandemic of Coronavirus disease 2019 (COVID-19). COVID-19 is associated with a variety of clinical outcomes, including asymptomatic infection, mild upper respiratory infection, several lower respiratory diseases including pneumonia and respiratory failure, and in some cases, death. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.
The LumiraDx SARS-CoV-2 Ag Test is a single use, rapid microfluidic fluorescence immunoassay test performed on the LumiraDx Instrument for use under the FDA’s Emergency Use Authorization (EUA) only. The device is designed to detect the presence of the nucleocapsid protein antigen directly from SARS-CoV-2 in nasal swab specimens within approximately 12 minutes, without transport media.

SARS-CoV-2 viral antigen is generally detectable in nasal swab specimens during the acute phase of infection. Positive results indicate the presence of the viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

For patients with symptom(s) onset beyond 12 days, negative results should be treated as presumptive. If confirmation is necessary for patient management, a molecular assay should be performed.

### II. ORDER

A physician's order, standard protocol, or order by another health professional authorized to request laboratory tests is required for the LumiraDx SARS-CoV-2 Antigen Test at the point of care. The LumiraDx SARS-CoV-2 Test is authorized for use under FDA Emergency Use Authorization (EUA) only; upon expiration of the EUA or at the discretion of the experts, this test may be discontinued at any time.

### III. SAFETY REQUIREMENTS

Refer to the Quality Assurance Plan for SARS-CoV-2 Point of Care Tests (Appendix A) for additional guidelines.

1. Follow Standard Precautions and CDC hand washing guidelines when performing this test.
2. Proper PPE must be worn at all times when performing testing using the LumiraDx SARS-CoV-2 Test Kit.
3. If specimen collection and testing occur in the same location:
   a. When collecting patient specimens, completing specimen extraction steps, and performing patient testing, the following PPE must be worn at all times:
      i. Two layers of gloves.
      ii. Gown.
      iii. N95 mask and Face Shield.
      iv. (or) PAPR with HEPA Filter.
   b. If QC is performed without patients present, and while reporting results on the patient's chart, the minimum PPE to be worn is:
      i. Single layer of gloves.
      ii. N95 mask or surgical mask, per unit policies.
      iii. Face shield, per unit policies.
4. If specimen collection and testing occur in separate locations:
   a. When collecting patient specimens and completing specimen extraction steps, the following PPE must be worn at all times:
      i. Two layers of gloves.
      ii. Gown.
      iii. N95 mask and Face Shield.
      iv. (or) PAPR with HEPA Filter.
   b. While performing testing (patient and QC), removing test strips from the instrument, and reporting results on the patient's chart, the minimum PPE to be worn is:
      i. Single layer of gloves.
      ii. N95 mask or surgical mask, per unit policies.
      iii. Face shield, per unit policies.
5. All test consumables, including patient swabs and prepared extraction vials, QC vials and material, disposable pipettes used for QC, and used test strips must be considered potentially infectious, handled with care, and disposed of in a JHMI-approved biohazard receptacle.
   a. Empty external Quality Control bottles and gloves are also to be discarded in a JHMI-approved biohazard receptacle.

6. The LumiraDx instrument exterior and testing surface is to be wiped down after each patient and QC test and at the end of the testing day, using an appropriate commercial surface decontamination preparation that has been approved by the Hospital Epidemiology and Infection Control (HEIC) Department.
   a. Refer to Section XV: Maintenance for specific instructions.
### IV. MATERIALS

#### LumiraDx SARS-CoV-2 Antigen Test Kit

<table>
<thead>
<tr>
<th>Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dropper Lids</td>
<td>SAP Item #261730</td>
</tr>
<tr>
<td>Extraction Buffer Vials (48)</td>
<td></td>
</tr>
<tr>
<td>RFID Tag (on Test Strip box)</td>
<td></td>
</tr>
<tr>
<td>LumiraDx Test Strips (48)</td>
<td></td>
</tr>
<tr>
<td>LumiraDx SARS-CoV-2 Ag Test Quick Reference Guide</td>
<td></td>
</tr>
</tbody>
</table>

#### LumiraDx SARS-CoV-2 Antigen Quality Control Kit

<table>
<thead>
<tr>
<th>Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mL vial SARS-CoV-2 Positive Control (2)</td>
<td>SAP Item #261731</td>
</tr>
<tr>
<td>0.5 mL vial SARS-CoV-2 Negative Control (2)</td>
<td></td>
</tr>
<tr>
<td>Transfer Pipettes (24)</td>
<td></td>
</tr>
</tbody>
</table>

#### Equipment

<table>
<thead>
<tr>
<th>Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>LumiraDx Instrument</td>
<td>Point-of-Care Testing Office</td>
</tr>
<tr>
<td>Barcode Scanner (optional)</td>
<td>Point-of-Care Testing Office</td>
</tr>
<tr>
<td>LumiraDx Instrument Base</td>
<td>Point-of-Care Testing Office</td>
</tr>
</tbody>
</table>

#### Additional Supplies

<table>
<thead>
<tr>
<th>Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex-free Disposable Gloves</td>
<td>Central Stores</td>
</tr>
<tr>
<td>N95 Mask</td>
<td>Personal PPE Pack/HEIC</td>
</tr>
<tr>
<td>Gown</td>
<td>Central Stores</td>
</tr>
<tr>
<td>Face Shield</td>
<td>Personal PPE Pack</td>
</tr>
<tr>
<td>PAPR Hood with HEPA Filter</td>
<td>HEIC</td>
</tr>
<tr>
<td>JHMI-Approved Biohazard Waste Container</td>
<td>Central Stores</td>
</tr>
<tr>
<td>HEIC-approved commercial surface decontamination preparation</td>
<td>Central Stores</td>
</tr>
<tr>
<td>Kimwipes</td>
<td>Central Stores</td>
</tr>
<tr>
<td>Sterile Collection Swabs (25)</td>
<td>SAP Item #261733</td>
</tr>
</tbody>
</table>
V. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>LumiraDx SARS-CoV-2 Antigen Test Kit</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's Expiration Date</td>
</tr>
<tr>
<td>LumiraDx SARS-CoV-2 Antigen Quality Controls</td>
<td>Refrigerated (2-8°C)</td>
<td>Unopened Vials: Manufacturer's Expiration Date</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Opened Vials: 30 days, or manufacturer's expiration date, whichever comes first</td>
</tr>
<tr>
<td>LumiraDx Instrument and Base</td>
<td>Room Temperature (15-30°C)</td>
<td>None</td>
</tr>
</tbody>
</table>

1. Per S-RD-REP-00868, the LumiraDx SARS-CoV-2 Antigen Quality Control Kit may be shipped in uncontrolled ambient conditions, between -80°C and 30°C, for up to 14 days without impacting the performance of the product.
   a. NOTE: The effects of shipping on the shelf-life of the product has not yet been tested.

2. Upon opening each LumiraDx SARS-CoV-2 Antigen Test Kit and LumiraDx SARS-CoV-2 Ag QC Kit, the Open Date must be recorded on the outside of the box and QC vials.

3. QC Vials must also be labeled with 30 day expiration date based on open date, and must be kept in the refrigerator when not in use.

4. Do not freeze the contents of the LumiraDx SARS-CoV-2 Test Kit.

5. All test kit contents are single use; do not reuse.

6. Never use LumiraDx SARS-CoV-2 Antigen kit or QC kit contents past their expiration date.

7. A minimum of 2-inches clearance must be maintained at all times on the back and sides of the LumiraDx Instrument for the vents to function properly.
   a. The instrument must be seated in a base at all times, as this provides an additional filter.

8. Do not use the LumiraDx Instrument in direct sunlight.

9. The LumiraDx Instrument door must remain closed at all times when not in use.

10. Store the Test Strips in their original packaging inside the carton.
   a. NOTE: Once removed from their foil pouch, test strips must be used immediately.

11. When stored properly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton.

VI. SPECIMEN TYPE
Each patient test requires collection of a nasal swab sample from both nostrils using one Collection Swab. Only swabs that have been validated for use with the LumiraDx SARS-CoV-2 Antigen test may be used with this test.

VII. SPECIMEN COLLECTION AND HANDLING
Correct specimen collection is paramount for obtaining an accurate test result. Proper PPE (double gloves, gown, N95 mask and face shield, or PAPR hood with HEPA filter) must be worn at all times during Specimen Collection and Handling.

Observed self-collection of NMT swabs is approved, and may be implemented at testing sites, per the discretion of HEIC and POCT leadership.

© Copyright 2023 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University
Nasal Swab Sample:

1. From the LumiraDx SARS-CoV-2 Ag Test Kit, gather one Extraction Vial and one dropper lid.
2. Properly label the Extraction Vial with at least two patient identifiers.
3. Gather one sterile Collection Swab.
4. Tilt the patient's head back 70 degrees.
5. Carefully insert the swab less than 1-inch into the patient's nostril until resistance is met at the Turbinates.
6. Firmly rotate the swab against the nasal wall at least 4 times for 10-15 seconds.
7. Using the same swab, repeat this sampling procedure in the opposite nostril.
8. Remove the foil seal from the top of the Extraction Vial.
9. Place the swab into a properly labeled Extraction Vial.

Specimen Extraction:

1. Label the Extraction Vial with a patient demographic label.
2. Remove the seal or screw cap from the top of the Extraction Vial.
3. Allow the swab to soak in the Extraction Vial for a minimum of 10 seconds.
4. Rotate the swab at least 5 times against the side of the vial.
5. Squeezing the middle of the Extraction Vial, remove the swab and discard in a Biohazard Container.
6. Firmly attach a dropper lid on the Extraction Vial.
   a. NOTE: The extracted sample must be used within 5 hours of preparation when stored at room temperature.
7. Place prepared patient specimen in a double layer of biohazard bags for transport, as needed.
8. Remove the outer layer of gloves, discard in a Biohazard Container, sanitize the base layer of gloves, and place a new second layer of gloves on or doff PPE before proceeding with additional testing or tasks.

Swab Storage:

The swab may not be placed back into the swab packaging sleeve after sample collection. Process the swab in the Extraction Vial as soon as possible following collection.

VIII. PERFORMING QUALITY CONTROL (QC) TESTS

A. The LumiraDx Instrument and SARS-CoV-2 Test Strip has a number of built-in QC functions to ensure the validity of each test run and must be acceptable in order for results to be reported.
   1. The 2D barcode on the strip is read to identify the Lot Expiration date and assess whether Lot Calibration file updates are needed.
   2. The Test Strip has built-in functions that ensure sufficient sample volume has been introduced with each test.
   3. Additional checks ensure the Test Strip has not been damaged or previously used.
   4. The LumiraDx Instrument performs internal electrical and heater operation checks.
      a. If any of the above checks fail, the test run will be rejected and an error message will appear on the instrument touchscreen.
B. Two levels of External Quality Control - Positive and Negative - will be performed:
   1. At least once per week on each test kit and Instrument in use.
      a. At least one level is to be performed on each instrument, with the level of QC (Positive or Negative) tested on each instrument alternated weekly.
         i. NOTE: Take care to ensure both levels of QC are evaluated weekly.
   2. When opening the first box of a new shipment and/or lot number, both levels of QC must be tested before completing patient testing.
   3. As needed when patient results are questionable, or any other issues are suspected or identified.
4. All new operators must complete at least one level of control as part of initial hands-on training prior to testing patient specimens.
5. Both levels of controls must be successfully tested and documented correctly once a year by each operator to demonstrate compliance with competency regulations.

C. Procedure:
1. Prepare materials for testing:
   a. Don all required PPE as indicated in Section III. Safety Requirements.
   b. Verify the LumiraDx SARS-CoV-2 Antigen Test Kit is dated and within the manufacturer’s expiration date.
   c. Verify the LumiraDx SARS-CoV-2 Antigen Quality Control Kit is dated with open date and the vials are dated with the 30-day open expiration date.
   d. Plug the power cord into the LumiraDx Instrument and an electrical outlet, then power on the instrument by pressing the power button.
      i. NOTE: The instrument performs a Self Test each time it is powered on.
      ii. NOTE: If the Instrument is on but the screen is dimmed, tap the screen to wake up the Instrument.
      iii. NOTE: The instrument will shut down automatically after 60 minutes of inactivity if using battery power, or 90 minutes of inactivity if connected to a power source.
   e. Gather two Test Strip foil pouches and the LumiraDx SARS-CoV-2 Ag QC Kit, including the pipettes.
2. Lot Calibration File Installation:
   a. Every new Test Strip Lot has a unique Lot Calibration File that must be installed upon first use.
   b. The LumiraDx Instrument will prompt the operator to install the Lot Calibration File following insertion of a new Test Strip Lot.
   c. Locate the RFID reader by looking for the symbol on the side of the LumiraDx Instrument.
   d. Install the new Lot Calibration File by touching the back of the Test Strip Carton to the symbol.
   e. Once installed, the Instrument will have all information required to process the test.
3. Perform the Test:
   a. Record all applicable information on the LumiraDx SARS-CoV-2 Antigen QC Log (see Appendix B).
   b. Select the "Quality Control" button on the Home Screen.
   c. Select "Quality Control Test".
   d. Following instrument prompts, open the Instrument Door.
   e. Remove the Test Strip from its foil pouch by tearing at the triangle notches and insert in the Instrument.
      i. NOTE: Do not touch the Test Strip sample application area.
      ii. NOTE: Do not touch the test strip contacts.
      iii. NOTE: Testing must be started immediately following removal from the foil pouch.
   f. If a new Test Strip Lot has been inserted, the Instrument will prompt installation of the Lot Calibration File.
      i. NOTE: Follow the on-screen directions.
   g. Confirm the test type is correct (SARS-CoV-2 Ag) and select "Confirm” to proceed.
   h. Select the level of QC to be performed (Positive or Negative).
      i. NOTE: Do not add QC solution to the Test Strip until prompted to do so by the instrument.
      ii. Scan the appropriate QC barcode using the barcode scanner, then select "Next” to continue.
      iii. NOTE: Alternatively, the 16-digit QC lot number from the QC vial may be manually entered using the on-screen keyboard.
   j. Following the strip heating cycle, a 4-minute countdown will appear to allow time for application of the QC solution to the Test Strip.
   k. Once the message for sample application appears, remove the cap from the QC bottle and set aside.
   l. Firmly squeeze the top bulb of the pipette and place the tip well below the surface of the QC solution.
m. Slowly release the bulb to draw up the QC solution into the transfer pipette.
   i. NOTE: Confirm there are no air bubbles in the stem of the pipette.

n. Apply one drop of QC solution to the circular Sample Application Area on the top of the inserted Test Strip.
   i. NOTE: Do not shut the Instrument door until directed to do so.

o. Dispose of the used pipette in a Biohazard Receptacle, and recap the QC vial.

p. Once the QC sample is detected, a confirmation message will display and an audible beep will sound.

q. When prompted, close the Instrument door. This must occur within the indicated countdown, or an error message will display and testing must be repeated.
   i. NOTE: Do not open the lid, unplug, or move the Instrument during testing.
   ii. NOTE: A progress bar will display, indicating remaining time to result.

r. Remove outer layer of gloves, discard in a Biohazard Bin, and clean hands thoroughly. Place a new pair of gloves on before proceeding with any additional testing.

4. Test Completion and Result Documentation:
   a. The Instrument will beep to indicate test completion, and results will display on the screen.
   b. If not already in proper PPE, don all required PPE as indicated in Section III. Safety Requirements.
   c. Record the results from the instrument on the LumiraDx SARS-CoV-2 Antigen QC Log (see Appendix B).
   d. When prompted to do so, open the Instrument door and remove the strip.
   e. Dispose of the used Test Strip in a Biohazard Container.
   f. Decontaminate the working surface and exterior of the analyzer with an appropriate commercial surface decontamination preparation.
      i. NOTE: Take care not to introduce fluid to the inside of the instrument.
   g. Close the Instrument door, then allow to air dry for at least one minute before testing another sample.

D. Corrective Action:
   1. If any QC test fails to give the expected results:
      a. Verify LumiraDx SARS-CoV-2 Antigen Test Kits and LumiraDx SARS-CoV-2 Antigen Quality Control Kits are within their expiration dates and that they have been properly stored.
      b. Ensure proper testing technique is used to repeat testing with the same QC vial and a new Test Strip.
      c. If QC fails a second time, repeat testing with a newly opened and dated QC vial and a new Test Strip.
      d. If QC fails a third time, DO NOT PERFORM ANY PATIENT TESTING. Contact the POCT Office (5-2645 or by sending a CORUS message to "POCT Consult"). You may be directed to contact LumiraDx Technical Support at 1-888-586-4721, option 1.
         i. NOTE: During this time, and in the absence of a backup instrument, urgent patient testing will require that an order be placed and a specimen collected and sent to the Microbiology Laboratory for analysis.
      2. Note any QC failures and corrective actions on the QC log.
IX. PATIENT TEST PROCEDURE

A. Prepare materials for testing:

1. Don required PPE as indicated in Section III. Safety Requirements.
2. Verify that Test Kits are dated, within the manufacturer's expiration date, and QC has been performed and documented successfully on the lot in use within the last week.
3. Plug the power cord into the dock and electrical outlet, and power on the Instrument by pressing the power button.
   a. NOTE: The Instrument performs a Self Test each time it is powered on.
   b. NOTE: If the Instrument is on but the screen is dimmed, tap the touchscreen to wake up the instrument.
   c. NOTE: Automatic shut down will occur following 60 minutes of inactivity if an Instrument is operating via battery power, and following 90 minutes of inactivity for an Instrument connected to a power source.
4. Gather the prepared patient SARS-CoV-2 Extraction Vial and one unopened Test Strip.

B. Specimen Collection and Extraction:

1. Refer to Section VII. Specimen Collection and Handling for step-by-step instructions.

C. Perform the Test:

1. Select "Patient Test" from the Instrument Home Screen.
2. Scan the patient barcode to input the CSN, and manually enter one other identifier, then select "Next" to continue.
3. A "No Matching Patients" warning will populate; confirm the CSN matches the patient barcode, then select "Proceed".
4. When prompted to do so by the instrument, open the Door.
5. Remove a Test Strip from the foil pouch, by carefully tearing the indicated triangles.
   a. NOTE: Testing must be started immediately upon removal from the foil pouch.
6. Following instrument prompts, insert the labeled Test Strip into the Instrument.
   a. NOTE: Do not touch the Test Strip sample application area, or the contacts.
7. If a new Test Strip Lot has been inserted, the Instrument will prompt installation of the Lot Calibration File. Follow the on-screen directions.
   a. NOTE: If this step is required, patient testing must be aborted and QC assessed before proceeding with testing. All new lot numbers must have both levels of QC tested prior to patient testing.
8. Select the appropriate sample type (Nasal Swab) and test type (SARS-CoV-2 Ag), then select "Confirm" to proceed.

9. The instrument will heat the Test Strip to the proper temperature; during this time, gently invert the prepared Extraction Vial 5 times to mix.

10. Apply one large drop of the sample onto the Test Strip Sample Application Area when prompted by the Instrument.
   a. NOTE: This must be completed within 4 minutes of testing temperature being reached.
   b. NOTE: Do not shut the door before prompted to do so by the instrument.

11. Once the sample has been detected, and when prompted to do so by the instrument, close the door to allow for test processing.

12. Place the properly labeled SARS-CoV-2 Antigen Patient Buffer vial in a rack until test results are available.
   a. NOTE: Properly labeled SARS-CoV-2 Buffer vials may be used for a repeat test as needed.

13. Remove gloves, discard in a Biohazard Bin, and sanitize or wash hands prior to proceeding with additional testing.

14. Results are displayed within 12 minutes of sample application.

D. Test Completion and Result Documentation:
1. The instrument will beep to indicate test completion, and results will display on the screen.
2. Don appropriate PPE, as outlined in Section III. Safety Requirements.
3. Record the results from the instrument on the LumiraDx SARS-CoV-2 Antigen Patient Result Log (see Appendix C).
4. When prompted to do so, open the Instrument door, remove the used Test Strip, and dispose in a Biohazard Container.
5. Remove the outer layer of gloves, discard in a biohazard bin, then decontaminate the working surface and exterior of the analyzer with an appropriate commercial surface decontamination preparation that has been approved by the HEIC Department.
   a. NOTE: Take care not to introduce fluid to the inside of the instrument.
6. Close the Instrument door, then allow the instrument to air dry for at least one minute before testing another sample.
7. Remove gloves, discard in a Biohazard Bin, and clean hands thoroughly prior to entering the results on the patient's chart in Epic.
E. Corrective Action:
   1. If a patient test fails to give expected results, or populates an Invalid result or Error code:
      a. Ensure proper testing technique is used to repeat testing with the saved properly labeled SARS-CoV-2 Antigen Patient Buffer vial and a new Test Strip.
      b. If the test fails a second time, there are two potential courses of action:
         i. Recollect a new nasal swab and retest, following the steps above.
         ii. Place the appropriate laboratory order, then collect and transport an NP swab to the Microbiology Laboratory for testing.
      c. Repeated issues may require testing personnel to contact LumiraDx Technical Support, at the direction of the POCT Office.

X. REFERENCE RANGE
   The expected result on the LumiraDx SARS-CoV-2 Antigen Test is Negative(-) for SARS-CoV-2 Ag.

XI. RESULTS INTERPRETATION
   Results will be displayed on the Instrument screen, and must be documented on the appropriate log.

   1. Positive: SARS-CoV-2 Antigen present.
      a. NOTE: This result does not rule out coinfection with other pathogens.
   2. Negative: Negative results are to be treated as presumptive.
      a. NOTE: Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions.
      b. NOTE: Confirmation of negative results with a molecular assay, if necessary for patient management, may be performed.
   3. Invalid: If an issue occurs, a message will be displayed on the Instrument touch-screen.
      a. Alert messages include useful information and are highlighted by an orange banner.
      b. Error messages also include a triangle symbol, as well as an identifying code that may be used for additional troubleshooting.
         i. NOTE: All messages will contain a description of the Instrument status or error and instruction(s) for troubleshooting.

   All test results must be considered in relation to a specific patients' clinical observations, history, and epidemiological information; inconsistent results should be repeated or supplemented with additional test(s). All positive results must be reported to the appropriate public health authorities.

XII. REPORTING RESULTS
   All patient test results must be manually documented on the LumiraDx SARS-CoV-2 Antigen Patient Result Log (Appendix C). This log must then be used to ensure results are properly documented in Epic using the Enter/Edit function. Result documentation on the Patient Result Log and in Epic will be regularly audited by the POCT Office.

   1. Each of the fields is mandatory when completing the Patient Result Log.
      a. Attach a patient label from Epic, or manually record the patient's name and CSN legibly in the appropriate field.
   2. LumiraDx SARS-CoV-2 Antigen is orderable in Epic using test code "POCT SARS COV-2, ANTIGEN, LUMIRADX, NASAL SWAB [POC101217]".
      a. Results will be entered as "Antigen Positive" for Positive results, and "Antigen Negative" for Negative results.
3. Once patient results are entered, they will display under the "Labs" tab in Epic as "POCT SARS COV-2 Antigen, LumiraDx, Nasal Swab".

XIII. LIMITATIONS
1. This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
2. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
3. Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
4. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2, and do not rule out co-infection with other pathogens.
5. Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
   a. A false negative result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected inappropriately. Therefore, a negative test result does not rule out the possibility of SARS-CoV-2 infection.
6. Negative results, from patients with symptom onset beyond twelve days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
7. Test performance was established based on clinical specimen evaluation between June and March 2021. Clinical performance has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation.
   a. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
8. Clinical performance was established on frozen samples and performance may be different with fresh clinical samples.
9. Users should test samples as quickly as possible after sample collection.
10. Swab samples and Extraction buffer must be at room temperature before testing.
11. The amount of antigen in a sample may decrease as the duration of illness increases. Samples collected after 12 days are more likely to be negative compared to RT-PCR.
12. The contents of this kit are for qualitative detection of SARS-CoV-2 antigens from nasal swab and nasopharyngeal samples only.
13. For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 Antigen Test, please visit lumiradx.com or see the IFU.

XIV. PROCEDURAL NOTES
1. The LumiraDx Instrument will perform a Self Test every time it is powered on.
2. The LumiraDx Instrument must remain seated in a LumiraDx Base at all times.
3. Do not open the Test Strip foil pouch until ready for immediate use.
4. Discard and do not use any damaged or dropped Test Strips or other materials.
5. After starting a test, avoid bumping, tilting, or otherwise disturbing the LumiraDx Instrument, as this may cause the test to abort and require retesting.
6. The door on the LumiraDx Instrument must remain closed at all times when not in use, to prevent introduction of dust to the interior of the instrument.
7. The LumiraDx SARS-CoV-2 Antigen Test is a qualitative test.
8. For best results, nasal swabs should be extracted and tested immediately after collection.
9. All prepared SARS-CoV-2 Antigen Extraction vials and used Test Strips must be discarded in a Biohazard Bin after the test is completed.

© Copyright 2023 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University
10. Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
11. The test cannot be visually interpreted; the LumiraDx Instrument must be used to generate results.

XV. MAINTENANCE

Following Completion of Each Test, Quality Control and Patient: Decontaminate the testing surface(s) and the outside of the instrument(s). At least once per day when the instrument(s) are in use, completion must be documented in the appropriate section on the QC, Patient Result, and Swipe Testing logs.

A. Using an appropriate commercial surface decontamination preparation that has been approved by the HEIC Department:
   1. Squeeze the wipe to remove excess liquid.
   2. Gently wipe the following instrument surfaces:
      a. The area around the Test Strip slot.
      b. The exterior of the entire analyzer, including the door.
      c. The instrument touch screen.
         i. NOTE: Do not press the wipe against the open vents, in the test strip slot, or in the USB or power connection ports.
   3. Do not let liquid accumulate near any opening, or otherwise spray or pour solution directly onto the Instrument.
   4. Leave the Instrument "wet" for at least 1 minute.
   5. Once all surfaces have air dried, the instrument is ready to perform another test.

Weekly for the First Month, then As Directed Thereafter: Swipe Testing will be performed to assess compliance with cleanliness guidelines required for accurate SARS-CoV-2 Antigen Testing results, and documented on the LumiraDx SARS-CoV-2 Antigen Swipe Testing Log (see Appendix D).

A. Using a single swab, the exterior of each of the Instrument(s), as well as the testing surface(s) will be swabbed and tested for the presence of SARS-CoV-2 Antigen.
   1. Gather one patient swab, one Extraction Vial, and one dropper lid.
   2. Label the Extraction Vial "Swipe", then remove the foil lid.
   3. Dip one swab into the vial, then thoroughly swab all Instrument(s) and testing surface(s).
   4. Follow the steps as outlined in Section IX. Patient Test Procedure.
      a. NOTE: If a Swipe Test results as Antigen Positive, cease testing and notify the POCT Office immediately.

XVI. TROUBLESHOOTING

In the event of Error Messages, follow troubleshooting guidance provided below or in the available resources. If troubleshooting fails, contact the POCT Office for assistance. Each testing site may directed to contact LumiraDx Technical Support at 1-888-586-4721, option 1, for additional troubleshooting assistance and is responsible for obtaining this assistance independently when directed to do so by the POCT Office.
Most Frequently Seen Errors and Troubleshooting:

<table>
<thead>
<tr>
<th>Error Code</th>
<th>On-Screen Message</th>
<th>Additional Troubleshooting Guidance</th>
</tr>
</thead>
</table>
| 003-3506   | Test Strip Not Detected | • Verify Instrument screen changes from "open door and insert Test Strip" to "insert Test Strip" after the door is opened.  
|            |                         | • Try the same Test Strip in a different instrument if possible. If not possible, try a different Test Strip.  
|            |                         | • Power down the Instrument, wait 30 seconds, then restart and allow Self-Test to complete. |
| 038-3605   | Insufficient Sample Volume | • Repeat test with a new Test Strip.                                           |
| 049-3521   | Test Strip Invalid      | • Repeat test with a Test Strip from a new test kit.  
|            |                         | • Contact Technical Support and provide the Test Strip Lot Number and Test Strip ID Number. |
| 108-1813   | Test Operation Error    | • Onboard control check has failed. Shut down the Instrument, wait 30 seconds, then restart and allow Self-Test to complete.  
|            |                         | • Repeat the test with a new Test Strip.                                      |
| 115-1307   | Instrument Error        | • Contact Technical Support to report this issue.                            |
| 124-1324   | Temperature Issue       | • Move the Instrument to a warmer environment and allow time to warm up.  
|            |                         | • Restarting the Instrument may speed up this process.                        |
| 005-1615   | Temperature Error       | • Ensure Instrument is not subjected to external heat sources, and the ventilation openings are not blocked.  
|            |                         | • Switch off the Instrument and wait for 10 minutes, then restart.  
|            |                         | • If the problem persists, contact Technical Support.                          |
XVII. OPERATOR TRAINING AND COMPETENCY

Testing may only be performed by currently certified staff members who have been trained by a Point-of-Care Coordinator, or a Nurse Educator or designated unit trainer who has undergone appropriate training and observation for training others in SARS-CoV-2 Point-of-Care Tests. Training records must be kept in the employee's personnel file, and a copy sent to the Point-of-Care Testing Office.

Initial training will include the following:

1. Review the policy online.
2. Completion of the MyLearning module and a passing score on the associated quiz.
3. Completion of the Initial Training and Competency Checklist (see Appendix E).
4. Successful performance of at least one level of external controls and/or approved laboratory-prepared control materials (Quality Control).

In order to maintain competency, operators must successfully complete both levels of external control, and a passing score on the MyLearning module quiz once a year. If annual competency requirements are not met by the end of the cycle, retraining must be completed and paperwork submitted to the POCT Office before patient testing will be permitted. The POCT Office follows the fiscal year for competency purposes (July 1-June 30).

XVIII. PROFICIENCY TESTING

Alternate Proficiency Testing will be performed several times a year, in the form of blinded specimens. This will be rotated among all approved testing location.

Any trained operator may be asked to perform the PT specimens, and is expected to treat them the same as a patient test. The LumiraDx SARS-CoV-2 Test Alternate Proficiency Testing assessment form must be completed by the individual testing the specimens (see Appendix F).

XIX. REFERENCES

1. LumiraDx SARS-CoV-2 Antigen Test IFU, SPEC-32311 ART-00570 R7 (revision 02/2022).
4. ICPM IFC023 Infection Control and Prevention: Standard and Isolation Precautions.

XX. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicholas Theodore</td>
<td>06/14/2022</td>
</tr>
<tr>
<td>Ekta Gupta</td>
<td>06/09/2022</td>
</tr>
<tr>
<td>Michael Borowitz</td>
<td>06/17/2022</td>
</tr>
<tr>
<td>William Clarke</td>
<td>06/10/2022</td>
</tr>
</tbody>
</table>

Revision History:
06/22/2022: Order of Appendices C and D revised to match procedure content.