Warning and Precautions:
All kit components can be discarded as biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at https://lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antigen-test. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts and where any component is of animal origin, the source is certified as free from infectious or contagious material – however, should any reagent become exposed it should be treated as potentially infectious.

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform. Intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab and nasopharyngeal swab samples collected from individuals who are suspected of COVID-19 by their healthcare provider within twelve days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Study the LumiraDx Platform User Manual and LumiraDx SARS-CoV-2 Ag Test Strip Product Insert thoroughly before using these Quick Reference Instructions or performing a test. This is not a complete product insert.

Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal or nasopharyngeal samples may be frozen at -80°C and used up to 5 days after freezing. Samples and extraction buffer must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. Do not use any test components beyond its expiration date. Refer to the LumiraDx SARS-CoV-2 Ag Test Strip Product Insert for Sample Collection, Warning and Precautions, and Limitations.

Preventing the sample
Collect a patient swab sample before following steps 1 – 4 of Running the Test. Sample Collection and Handling: Proper sample collection and handling of anterior nasal and nasopharyngeal swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures. Storage and Stability: Store the Test Strips at room temperature – between 2°C and 30°C (36°F and 86°F). When stored correctly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. The dates printed on the Test foil pouch and the Test Strip carton will always be the same.

Cleaning and Disinfecting
Wipe the external surfaces of the LumiraDx Instrument with a soft, slightly damp cloth when it appears visibly dirty. Disinfect the Instrument after each patient test or if contamination is suspected and at least once per day when in use using LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at LumiraDx.com. Use the material until the surface of the Instrument is visibly wet. Allow the surface to remain wet for 1 minute and let air dry. Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.
Running the Test

1. Select Patient Test from the Instrument Home Screen and enter patient details using the Keyboard or Barcode Scanner. See section 10 of the Platform User Manual for instructions on using the Barcode Scanner.

2. Remove the Test Strip from its pouch and hold by gripping only the blue portion. Do not bend the Test Strip or touch any part other than the blue portion.

3. When prompted, open the Instrument door and gently insert the Test Strip as far as it will go. The thick black alignment rib on the Test Strip should be on the left and line up with the black line on the Instrument. Do not apply the sample until prompted. Install the Lot Calibration file if using a new Test Strip Lot for the first time. See section 2.8 of the Platform User Manual.

4. Select the appropriate sample type and confirm the test type.

5. Gently invert the Extraction Vial five times just before applying the sample to the Test Strip.

6. Apply one whole drop of the sample onto the Test Strip Sample Application Area when prompted by the Instrument.

7. Close the door when prompted to continue the test.

8. Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag and the right-hand image shows a negative result for SARS-CoV-2 Ag. Tap Finish to complete testing or tap Comment to leave a comment or to reject the Test, then follow prompts to return to the Home Screen. All test results must be read using the LumiraDx Instrument.

INTERPRETATION OF RESULTS

Positive Test Results:
SARS-CoV-2 antigen present; does not rule out coinfection with other pathogens.

Note: Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals with known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Negative Test Results:
Individuals without symptoms that test negative should be tested again within at least 24 hours and no more than 48 hours between tests. Negative results do not rule out COVID-19. All negative results are presumptive; do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid Results:
If an issue occurs, a message will be displayed on the Instrument touch-screen. Error messages include useful information and are highlighted by an orange banner. Error messages also include a symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.

Example of an error screen:
If the On Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on-screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Quality Controls
To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ag Test Strips, you must use the LumiraDx SARS-CoV-2 Ag Quality Control Pack which are available separately if the LumiraDx Antigen Quality Controls do not perform as expected, do not report patient results. Refer using a new Test Strip – if problems persist contact LumiraDx Customer Services on telephone number 1-888-586-4721.

In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §3581a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use in vitro diagnostics for detection and/or diagnosis of the virus that causes 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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