



LumiraDx SARS-CoV-2 Antigen Test

Authorized for use under FDA's Emergency Use Authorization

Fast Facts

- **Reagent Requirements**

	LumiraDx SARS-CoV-2 Antigen Test Kit	LumiraDx SARS-CoV-2 Antigen QC Kit	LumiraDx Instrument
Storage Temperature	15° - 30°C	2° - 8°C	15° - 30°C
Stability	Manufacturer's expiration date	<i>Unopened:</i> Manufacturer's expiration date <i>Opened:</i> 30 days	No expiration date
Handling Requirements	<ul style="list-style-type: none"> - Record Open Date on each box once opened. - <i>Do not</i> use beyond manufacturer's expiration date. - <i>Do not</i> allow the kit to freeze. 	<ul style="list-style-type: none"> - Record Open Date and expiration date on each vial once opened. - <i>Do not</i> use beyond 30 day open expiration or manufacturer's expiration date. 	<ul style="list-style-type: none"> - 2 inches clearance on back and sides for fans. - <i>Do not</i> use in direct sunlight. - <i>Do not</i> disturb during testing.
Handling Precautions	<ul style="list-style-type: none"> - All kit components are single use. 	<ul style="list-style-type: none"> - QC solutions and used pipettes must be handled as potentially infectious. 	<ul style="list-style-type: none"> - No liquid should enter interior.

- **PPE and Safety Requirements**

- Minimum PPE Requirements -
 - Specimen Collection, Extraction, and Testing steps – patient and QC:
 - *Two layers of gloves, gown, N95 mask, face shield.*
 - Result Recording and Decontamination steps – patient and QC:
 - *Single layer of gloves, N95 mask or surgical mask.*
- Proper Disposal of Consumables –
 - All consumables used for patient and QC testing must be considered potentially infectious and disposed of in the proper Biohazard Receptacle.
- All testing steps prior to Recording Results and Decontamination should be completed behind closed doors, with only one person in the room to limit interruptions and distractions.

- **Testing Procedural Notes**

- *One swab* is to be collected from each patient; the same swab will be used in both nostrils.
 - Insert sterile swab approximately 1 inch into the nostril, then firmly rotate for 10-15 seconds.
 - Using the same swab, repeat this in the other nostril.
- All Extraction Buffer Vials must be labeled with at least two patient identifiers for all testing.
- For best results, nasal swabs should be extracted and extraction buffer preparations tested immediately after collection.
- All prepared SARS-CoV-2 Antigen Extraction vials must be discarded once the test is completed.
- In the event of an Invalid patient test result, repeat the test using the same extraction buffer and a new test strip.
 - In the event of a second failure, place the appropriate order in Epic, collect an NP swab, and send to Microbiology for analysis.
- Epic Test Code: *POC101217*. Results are reported as “Positive” or “Negative”.

- **Decontamination and Maintenance**

- *After Each Test:* Decontaminate testing surface and LumiraDx Instrument surfaces (documented on Maintenance Log once per day).
 - Use hospital-approved disinfectant wipe to wipe all surfaces utilized during testing.
 - Leave LumiraDx Instrument ‘wet’ for at least 1 minute.
 - Once air dry is complete, the next test may be performed.
- *Weekly for the First Month, then Monthly Thereafter:* Swipe Testing (documented on Swipe Testing Log).
 - Swipes of testing surfaces and analyzers tested for presence of SARS-CoV-2 Antigen.

- **Troubleshooting – Most Frequently Observed Error Codes (See Pages 57-61 of LumiraDx Platform User Manual for Full List)**

Error Code	Description	Troubleshooting
Door Open	<i>Door was opened during testing</i>	<ul style="list-style-type: none"> - The instrument door has been opened while running a test so the test cannot be completed. - Dispose of the Test Strip, start a new test and follow the instructions on the display.
Sample Detected	<i>Sample applied too early</i>	<ul style="list-style-type: none"> - Sample has been applied too early so the test cannot be completed. - Dispose of the Test Strip, start a new test and follow the instructions on the display.
Test Timeout	<i>Time exceeded to perform an action. Test has timed out.</i>	<ul style="list-style-type: none"> - An action (for example closing the instrument door) has not been completed within a set time period so the test cannot be completed. - Dispose of the Test Strip, start a new test and follow the instructions on the display.
Sample Error	<i>Insufficient sample volume or Instrument has experienced a problem and cannot complete test</i>	<ul style="list-style-type: none"> - Insufficient sample volume or instrument has experienced a problem and cannot complete a test. - Dispose of the Test Strip, start a new test and follow the instructions on the application of samples in this User Manual. If the problem persists, contact Customer Service.
Instrument Does Not Detect Test Strip	<i>If the Test Strip is not detected and no message is displayed on the touch-screen.</i>	<ul style="list-style-type: none"> - Check that the Test Strip is fully inserted. - Check for damage to the Test Strip. If damaged discard and insert a new Test Strip.
Incorrect date and time	<i>The date and time are incorrect on the instrument screen.</i>	<ul style="list-style-type: none"> - Contact the POCT office for corrections.

- *If for any reason, testing cannot be completed on the LumiraDx SARS-CoV-2 Antigen Test Kits utilizing the LumiraDx Instrument, collect NP swab specimens, place the appropriate orders, and send to Microbiology for testing.*

- **Resources**

- POCT Office available 24/7 for any additional assistance that may be needed.
 - Office Hours: Monday-Friday 7:30-15:30 (CMSC SB207)
 - POCT Office General Phone Line: 5-2645
 - Email POCTGroup@exchange.johnshopkins.edu
 - After Hours use CORUS: Pathology Staff – POCT Consult (covered 24/7)