LumiraDx Instrument cleaning and disinfection procedure

Cleaning and disinfection of the LumiraDx Instrument should follow and be performed according to established site protocols and schedules. It is recommended to clean and disinfect the Instrument with LumiraDx approved disinfecting material at least once per day when the Instrument is in use, unless recommended otherwise for specific tests.

Important Notes:

- When using the direct fingerstick sample application method, it is recommended to disinfect the Instrument with LumiraDx approved disinfecting material after each patient sample or if contamination is suspected.
- Before cleaning and/or disinfecting the Instrument, it is necessary to remove the protective screen cover.
- Excessive liquid may damage the Instrument. Prior to cleaning, it is necessary to manually squeeze any excess liquid from cleaning wipes or cloth. The wipe or cloth should be slightly damp, but not dripping or wet prior to cleaning and/or disinfecting.

Cleaning and disinfection procedure

For cleaning and disinfecting the LumiraDx Instrument, always use LumiraDx approved disinfecting materials. Alcohol wipes alone are not sufficient to disinfect the Instrument.

It is important for the protection of the Instrument that exposure to excess moisture is prevented. All cleaning or disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.

- Using a soft cloth, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, and USB port.
- Allow the instrument to air dry before testing the next specimen. For respiratory samples, disinfectant should remain in contact for at least 1 minute. For blood-based samples, disinfectant should remain in contact for at least 5 minutes.
- Dispose of cleaning and disinfectant materials in accordance with local procedures.

Be careful to minimize the risks of cross-contamination when testing patient specimens, which can cause false positive results. Insufficient cleaning of the workspace, insufficient disinfection of the Instrument, or inappropriate use of protective equipment (for example, failing to change gloves between patients) can increase the risk of cross-contamination between specimens with subsequent false positive results. Consider the CDC guidance at **www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html** for changing gloves and cleaning work area between specimen handling and processing.

Approved disinfectant materials

The following disinfectant formulations have been found by LumiraDx to be compatible for cleaning and disinfection purposes with the LumiraDx Instrument.

- Disinfectants containing sodium hypochlorite between 0.5% and 1.5%.
- Quaternary ammonium compound with didecyldimethylammonium chloride <0.05%, alkyl dimethyl benzyl ammonium chloride <0.03% or a mixture of alkyl C12-C18 dimethyl ethylbenzyl ammonium chloride, alkyl C12-C18 dimethyl benzyl ammonium chloride.

LumiraDx does not recommend the use of products which combine two or more of the above disinfectant formulations.

For more information on finding acceptable products with the above formulations refer to the Environmental Protection Agency (EPA) released List N: Disinfectants for Use Against SARS-CoV-2 (List N) of EPA-registered disinfectant products that have qualified for use against SARS-CoV-2. **https://www.epa.gov/coronavirus/disinfectant-use-and-coronavirus-covid-19**

For product inquiries and technical support please contact LumiraDx Customer Services.

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Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets. Available in the US under FDA Emergency Use Authorization.

Regulatory status of the LumiraDx SARS-CoV-2 Ag Test in the US:
This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories (laboratories certified under CLIA, 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test 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 test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of 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 authorization is terminated or revoked sooner.

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