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 and/or local guidelines. This Technical Bulletin will aim to provide the following:

- General guidance on cleaning
- General guidance on disinfection
- Specific guidance on disinfection based on which type of samples are being tested (blood-based, swab-based, or both)
- A concise list of LumiraDx recommended disinfectant materials

The difference between cleaning and disinfecting:

- **Cleaning** is the physical removal of dirt or other foreign material from the Instrument surface.
- **Disinfecting** is the chemical removal of harmful microorganisms (pathogens) from the Instrument.

General guidance on cleaning the Instrument

- Always wear gloves to clean the Instrument.
- Wipe the external surfaces of the Instrument with a soft cloth that is slightly water dampened, but not wet. **Excessive liquid may damage the Instrument.**
- Dispose of cleaning materials in accordance with local biohazardous waste disposal procedures.

General guidance on disinfecting the Instrument

- Always wear gloves to disinfect the Instrument.
- Before disinfecting the Instrument, it is necessary to remove the protective screen cover.
- It is recommended to disinfect the Instrument with LumiraDx recommended disinfecting material at least once per day when in use or if contamination is suspected, unless recommended otherwise for specific tests. For more information, please refer to the Product Insert for the Test you are running.
- **Excessive liquid may damage the Instrument.** Prior to disinfecting, it is necessary to manually squeeze any excess liquid from disinfecting wipes or cloth. The wipe or cloth should be slightly damp, but not dripping or wet prior to disinfecting.

Disinfection guidance – if only testing blood-based samples

- It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected.
- **Excessive liquid may damage the Instrument.** It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.
- Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens.

Procedure:

1. Using a LumiraDx recommended disinfecting material, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, and USB port.
2. Allow the disinfectant at least **5 minutes** contact time with the Instrument before testing the next sample.
3. Dispose of disinfectant materials in accordance with local biohazardous waste disposal procedures.

Disinfection guidance – if only testing swab-based samples

- It is recommended to disinfect the Instrument at least once per day, or if contamination is suspected.
- **Excessive liquid may damage the Instrument.** It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.

Procedure:

1. Using a LumiraDx recommended disinfecting material, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, and USB port.
2. Allow the disinfectant at least **1 minute** contact time with the Instrument before testing the next sample.
3. Dispose of disinfectant materials in accordance with local biohazardous waste disposal procedures.

Additional guidance – if testing both blood-based & swab-based samples

- If you are testing both blood-based and swab-based samples with your Platform, please follow the above guidance for disinfection based on the most recent sample-type run.

Recommended disinfectant materials for blood-based samples

The following formulations have been found by LumiraDx to be compatible for disinfection purposes with the LumiraDx Instrument when testing blood-based samples.

- 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.

Please note that due to the potential presence of bloodborne pathogens, alcohol-based wipes alone are not suitable for disinfection.

Recommended disinfectant materials for swab-based samples

The following formulations have been found by LumiraDx to be compatible for disinfection purposes with the LumiraDx Instrument when testing swab-based samples.

- 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.

As an alternative, the use of alcohol-based virucidal/bactericidal wipes is acceptable (ethanol or isopropanol based, ≥70 % v/v) as an effective disinfection procedure between swab-based tests (including COVID-19). For blood-based samples we cannot guarantee the effective destruction of any contaminating viruses such as Hepatitis B.

Other notes:

Be careful to minimize the risks of cross-contamination when testing patient samples, 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 samples with subsequent false positive results.

Follow local regulations and guidelines for changing gloves and cleaning work area between sample handling and processing.

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.

The LumiraDx SARS-CoV-2 Ag Test and the LumiraDx SARS-CoV-2 Ab Test have not been cleared or approved by FDA. The LumiraDx SARS-CoV-2 Ag Test has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid protein. The LumiraDx SARS-CoV-2 Ab Test has been authorized by FDA under an EUA only for detecting the presence of total antibodies to SARS-CoV-2. They have not been authorized for use to detect any other viruses or pathogens. The Tests are authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic Tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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