

## GENERAL

**What is nCoV?** nCoV, otherwise known as SARS-CoV-2, is a novel coronavirus that causes COVID-19.

**How can I test for nCoV?** You can either mail your sample in using our sample preservation kit or you can do it yourself using our GeneCount family of products.

**Was the nCoV test developed with real COVID-19 samples?** No. The test development is based on the most current publicly available RNA sequencing information on the virus provided by the US Centre for Disease Control and Prevention (CDC).

**What approvals, validation or accreditation does the nCoV test have?** No specific approvals or accreditation is available. The assay was designed based on the sequences provided by the CDC. In accordance with the CDC disclaimer, while every effort has been made to assure the accuracy of the assay, LuminUltra do not provide any warranty regarding the accuracy of the assay. **All liability on the use of the GeneCount instruments and assays as well as the interpretation of results is assumed by the user.**

**Does the nCoV test have TGA (Therapeutic Goods Approval) approval?** No. The test is STRICTLY for environmental testing for surfaces, air or water cycle (drinking water, wastewater, etc.). CLINICAL OR HUMAN TESTING IS STRICTLY PROHIBITED.

**Will disinfectants or other chemicals cause interferences with sample analysis?** No, disinfectants and other chemicals will be removed during the sample purification process.

**What is the specificity of the assay? What is the likelihood of false positives and negatives?** The assay is highly specific to the nCoV RNA sequences communicated by the CDC. False negatives are highly unlikely, while false positives are unlikely but possible based on the presence of RNA from inactivated viruses. However, this is not a bad thing as even the presence of inactivated viruses indicates that activated viruses were present within the timeframe of hours-days, depending on environmental conditions.

**Will the test detect inactive viruses?** Yes, it will. In fact, the reagents inactivate the virus, making it less hazardous to handle. Detecting inactive viruses in the environment is also beneficial as cleaning should still be completed.

RNA is relatively unstable (unlike DNA) and is destroyed by many disinfectants such as bleach or even sunlight, so if you are detecting viral RNA in a sample then it is a good – but not perfect – indication of the presence of viable virus. The only way to test for true viability would be in a biosafety laboratory using cultured cells which is slow and simply not practical to do on any sort of large-scale basis. Looking for viral RNA using qPCR is the best detection tool available today to rapidly screen for the virus both clinically and in the environment. Even in cases where RNA is detected from potentially inactive virus, the result is still indicative that coronavirus was recently present in the sampling area and that additional cleaning may be warranted. Similarly, not detecting viral RNA would be a strong indication that no nCoV is present or that the cleaning routine is sufficient.

**Does qPCR provide a quantitative value or just presence-absence?** qPCR is fully quantitative, however because nCoV is a pathogen the recommendation is to treat results as positive/negative. There is no acceptable quantity of nCoV.

## Frequently Asked Questions

**What types of samples can be analysed?** Most sample types can be analysed, however, not all GeneCount solutions are available for all sample types. Please contact LuminUltra to learn more.

### SAMPLING

**How is the sample preservation kit used?** The sample preservation kit serves several functions. Importantly, it inactivates the virus and 'freezes' the RNA. Without sample preservation the organisms in the sample can change during transport and storage. The preservation kit also allows the sample to be transported and stored at room temperature – which is increasingly important due to disruptions in carrier logistics

**What are recommended safety precautions for sample collection and testing?** Refer to your public health agency, the World Health Organization or industry organizations (WEF, AWWA, IWA, IAQA, etc) for guidance on safety precautions for workers with the potential for occupational exposure to nCoV. In the United States, OSHA has interim guidance for workers with a lower risk of exposure as well as in increased risk of exposure. Ensure you continuously refer to these guidelines, as they are constantly evolving as new information is gathered. Once a sample has been preserved, the virus will be inactivated and will no longer be viable. Further sample handling for analysis should be done using general laboratory safety protocols and PPE. This will ensure the tester is protected but will also reduce the likelihood of sample contamination.

### MAIL-IN TESTING

**What is the turnaround time for the mail-in service?** The expected turnaround time is 2-3 days.

### INSITU QPCR TESTING

**What equipment is required for testing myself?** LuminUltra Technologies supplies equipment to do the measurement in the form of qPCR instruments and test kits specifically for the testing of novel coronavirus, nCoV. A laptop/PC is also required for software to run the qPCR instrument.

**How long does it take to get results?** Including sample preparation (approx. 10-15 minutes), results will be available in approximately 2 hours. Samples are analysed in batches based on the size of the GeneCount qPCR instrument. For instance, up to 46 samples can be analysed in 2 hours on the GeneCount Q48.

**Is there any special skilled required to perform testing?** The nCoV sample testing requires limited skill for sample preparation and analysis. Instruction sheets are written in plain easy-to-understand English and include a pictorial instruction reference.

**How many samples can I test at one time?** There are 3 instrument offerings available. Q8 instrument can test up to 6 nCoV samples at one time, Q6 instrument can test up to 14 nCoV samples at one time. Q8 and Q16 instruments are portable for use onsite. Q48 instrument can test up to 46 nCoV samples at one time and is ideally suited for fixed or lab dedicated use. For all instruments the remaining two wells are used for positive and negative controls.

**I already have a PCR instrument. Can I use the LuminUltra nCoV test kits with my instrument?** The nCoV assay has been specifically designed and calibrated to GeneCount qPCR instruments. While the assay will work on other qPCR instruments, some work will be required to determine the necessary device settings and analysis parameters. It is not recommended that this be done.

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**Can I use the GeneCount qPCR instrument for other testing?** Yes! LuminUltra has a range of other assays including Legionella, Sulfate-Reducing Prokaryotes, E-Coli and many more.

**Do I need any equipment to take or analyse samples?** Only personal protective equipment (PPE). All necessary supplies and reagent, such as swabs and filters,

Further Questions? Contact us at [nCoVQuestions@luminultra.com](mailto:nCoVQuestions@luminultra.com)