High sensitivity nanoparticle-based COVID-19 RNA extraction kit enabling large volume production

Technology
High performance RNA extraction reagents for efficient COVID-19 testing, containing a novel chemical composition for efficient lysis of virus combined with NTNU-crafted magnetic nanoparticles with optimized high-affinity coating.

Performance
Sensitivity outcompetes current solutions for COVID-19 testing available on the market, demonstrated in patient testing at Norwegian hospitals.

Uniqueness
• Current production volume of 1.5 million tests pr. week, aiming for 5 million tests pr. week by September 2020. Capacity scales up easily
• Implemented in all major Norwegian hospitals for COVID-19 diagnostics since early April
• Compatible with open robotic platforms
• 35 min. extraction time on 96-channel robots
• Enables purification of RNA/DNA from various pathogens and starting materials (i.e. sputum, swab, urine)

Availability
• Actively seeking industry partners for global distribution in order to increase test capacity and ease the burden of the pandemic
• Patent pending

URL
ntnu.edu/ntnu-covid-19-test
**Magnetic bead-based RNA extraction**

After intensive testing for COVID-19, St. Olav’s Hospital was running out of test reagents. To prevent a shortage, a strong and cross-disciplinary team of researchers from NTNU’s Department of Clinical and Molecular Medicine and the Department of Chemical Engineering teamed up to develop an in-house extraction method for SARS-CoV-2 detection. The result is a new and optimized COVID-19 RNA extraction method based on expertise on nucleic acid purification and magnetic bead technology developed at NTNU.

**High sensitivity shown in patient testing**

Results from patient testing at three Norwegian hospitals with 50% patient sample input demonstrates the same or higher sensitivity by extraction of RNA of SARS-CoV-2 as state-of-the-art methods. The reagents are highly flexible and are implemented on several robotic platforms including KingFischer, TECAN, Hamilton and BIOMEK® and is compatible with all PCR master-mix solutions tested. This means that the method can easily be automated on open robotic platforms for high throughput screening.

COVID-19 patient samples analysed by the KingFisherFlexi/NTNU-test showed lower Ct-values than EasyMag/NucliSense, clearly indicating a higher sensitivity for the NTNU-test. The validation contained a 180-case set-up and showed compliance with 177/180 tests (NucliSense & NTNU), corresponding to a qualitatively compliance in 98 % of the cases. The precision of the method is verified by reproducibility and repeatability of CV<10%.
Validation of NTNU test on Hamilton Microlab STAR

COVID-19 patient samples analysed by the Hamilton Microlab STAR/NTNU test showed comparable Ct-values with MagnaPure96. The validation contained a 180-case setup and showed compliance with 175/180 tests (MagnaPure & NTNU), corresponding to a qualitatively compliance in 97% of the cases. The precision of the method is verified by **reproducibility and repeatability of CV<10%**.

**Linearity and sensitivity of the NTNU-test**

Sensitivity of the NTNU-test was analysed with SARS-CoV-2 samples from VIRCELL. The NTNU test showed high sensitivity, detecting samples with 1-3 copies of viral RNA. In addition, the NTNU test showed linearity at low titres of virus, 3-15 copies. Results were consistent with four different production batches (1-4) of magnetic nano-beads, demonstrating the reproducibility of production.