THE LYSIS BUFFER
OPENS THE VIRUS

THE RNA BINDS TO THE
MAGNETIC NANOPARTICLES

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

NTNU
Department of Clinical
and Molecular Medicine

NTNU
Department of Chemical Engineering

URL
ntnu.edu/ntnu-covid-19-test

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

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.

Norwegian University of Science and Technology (NTNU) is the largest university in Norway, with more than 7000 employees and 40.000 students. NTNU is located together with the university hospital **St Olav's Hospital** with 8.000 employees. Both NTNU and St Olav's Hospital have a strong position within medical technology and life science.

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.


P-value = 0,0036
CV < 10%
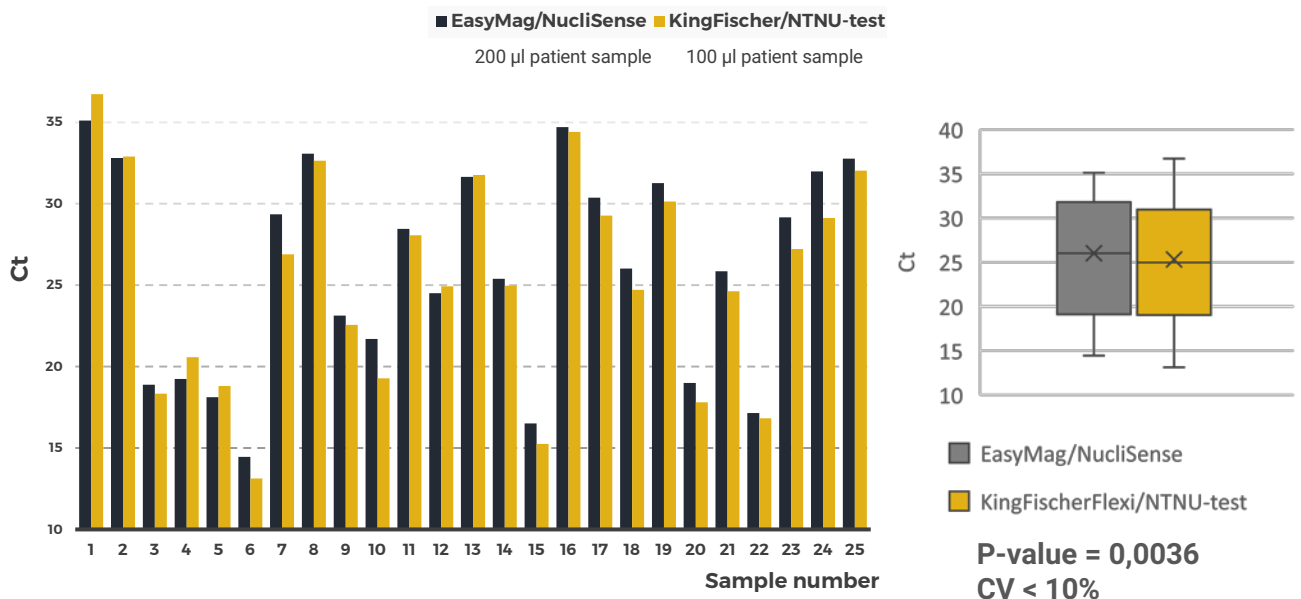
COVID-19 patient samples analysed by the KingFisherFlexi/NTNU-test showed **lower Ct-value**s than EasyMag/NucliSense, clearly indicating a **higher sensitivity for the NTNU-test**. The validation contained a 180-case set-up and showed compliance with 177/180 tests (NucliSense & NTNU), corresponding 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
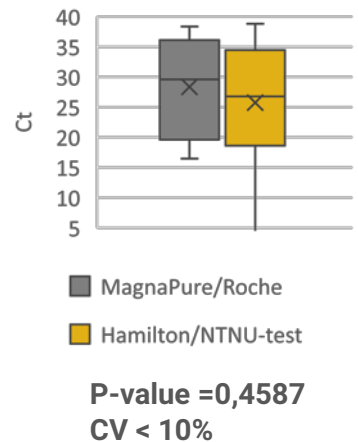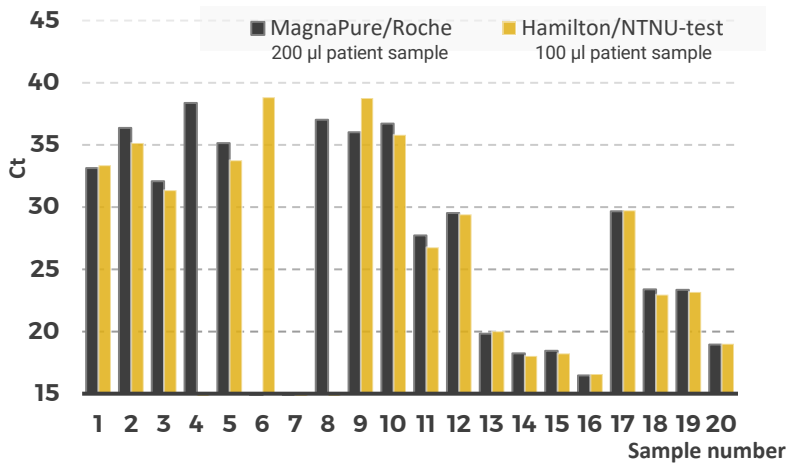
COVID-19 patient samples analysed by the Hamilton Microlab STAR/NTNU test showed comparable Ct-values with MagnaPure96. The validation contained a 180-case setup and showed compliance with 175/180 tests (MagnaPure & NTNU), corresponding to a qualitatively compliance in 97% of the cases. The precision of the method is verified by **reproducibility and repeatability of CV<10%.**

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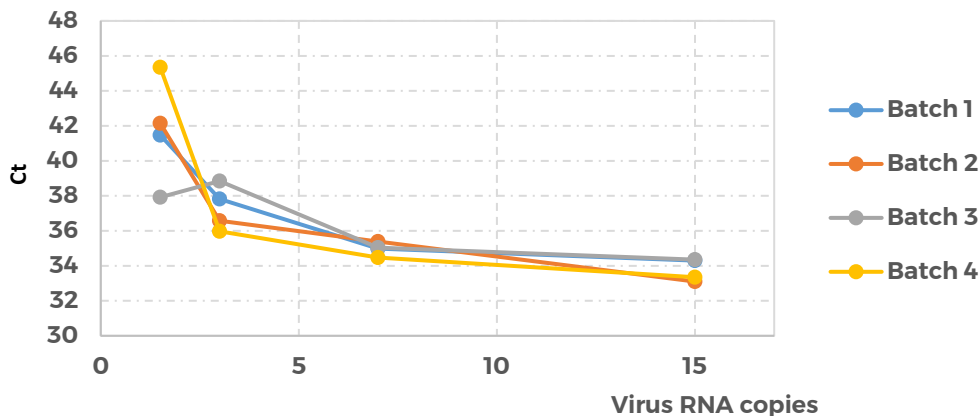
Sensitivity of the NTNU-test was analysed with SARS-CoV-2 samples from VIRCELL. The NTNU test showed high sensitivity, detecting samples with 1-3 copies of viral RNA. In addition, the NTNU test showed linearity at low titres of virus, 3-15 copies. Results were consistent with four different production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

Contact
Tonje S. Steigedal
NTNU Technology Transfer AS
Phone: +47 905 52 334
E-mail: tonje.s.steigedal@ntnu.no

Inventors
Prof. Magnar Bjørås, NTNU
& Team
Post Doc. Sulalit Bandyopadhyay, NTNU
& Team

NTNU
Technology Transfer as