

# ultra-fast PCR Covid-19 test system.

DEMCON LIFE SCIENCES & HEALTH

## CORE COMPETENCIES

1. Thermal management
2. Close collaboration
3. Optical detection
4. Industrial design
5. IVD Certification
6. Project management

During the pandemic, there was an urgent need for large-scale reliable Covid-19 testing on the spot, for example, at airports or entrance gates to crowded events. miDiagnostics, a start-up in nanofluidic processor technology, immediately decided to create a portable, ultra-fast PCR Covid-19 test system. The company was spun out from imec, the world-leading R&D and innovation hub in nanoelectronics and digital technologies, and a research collaboration with the renowned Johns Hopkins

University. Its revolutionary test solution combines the accuracy of a central, lab-based PCR test with the speed of an antigen test, providing the test result within 12 minutes. MiDiagnostics' test system comprises a proprietary silicon chip and reader. The chip is used to support an efficient polymerase chain reaction (PCR). The reader drives the PCR reaction through thermocycling and reads out the disposable assay test cards.



LIFE SCIENCES  
& HEALTH

### **Our challenges**

Demcon life sciences & health had to design the reader in parallel with test-card development and within a very short time frame. Strict thermal and optical requirements concerning the PCR reaction and the detection had been determined, while a tight form factor had been defined for the reader's design. In addition, the usability and suitability of the reader for its purpose had to be optimized, and full traceability of the test results was required.

### **Our solutions**

Driving the PCR reaction required ultra-fast thermocycling temperature profiles. For this, we developed a customized thermal actuator and an advanced control system, drawing on our extensive track record in control for widely varying applications. The design of a 4-channel fluorescence system for the optical detection involved selecting an appropriate light source and suitable optical filters as well as a reliable detector.

We devised the industrial design of the reader to suit the reader's specific application, giving it a robust and appealing, trustworthy medical appearance. The housing was made light-tight to prevent ambient light from interfering with the fluorescence detection. Our design ensured that the device is easy to use,

with only one LED status indicator. It interfaces with a central computer that processes the data and presents the results to the user. We provided for multi-reader connectivity to allow parallel testing. Traceability of test results is enabled by scanning the barcode engraved in each test card; for this, we integrated a barcode scanner in the design. To conclude, we provided the required documentation to our customer for their efficient, successful CE-IVD certification procedure.

### **Our teamwork**

It really was a multi-stakeholder project, with teams from various partners contributing. Following a fast development trajectory, our team engaged in an intensive collaboration with customer teams working on the assay and on disposable development. A team of the contract manufacturer selected for the production of the reader was also integral part of the project team, ensuring manufacturability of the design right from the start. The parallel development of the reader and the test-card required intensive interactions between the teams involved. In addition to the successful ultra-fast PCR Covid-19 test product launch, this project may well have initiated the creation of a generic reader for all kinds of PCR tests. Hereby contributing to the shift of central lab based diagnostics towards point-of-care testing.

**“from concept to certified device within a tight schedule”**

