## Increasing the amplitude of global COVID-19 testing

The scale of the challenge for clinical diagnostics labs around the world quickly became apparent when the SARS-CoV-2 pandemic hit in 2020. Assays to identify the virus were rapidly developed to isolate patients and monitor the spread of the virus but, with shortages of reagents and labware, and the sheer number of samples expected, scaled-up testing was desperately needed. Thermo Fisher Scientific supplies labs with the qPCR equipment that was central to testing, but wanted to do more to support the global efforts, and so set about developing a solution for high throughput screening.

The Genetic Sciences Division of Thermo Fisher Scientific provides an industry-leading portfolio of research products for genetic testing and, prior to the COVID-19 pandemic, focused on supporting scientists working in academic, pharmaceutical and agricultural research. gPCR was a central pillar of the team's capabilities and, with the technique becoming recognized as the gold standard for SARS-CoV-2 identification, the division was called upon to support clinical testing efforts. The first development was the TaqPath™ COVID-19 Combo Kit - for labs to screen for the virus on their existing qPCR machines - and this quickly gained Emergency Use Authorization (EUA) from the FDA. However, customers were asking for more scale and the option to move from testing hundreds of samples a day, to thousands, Elliot Shelton, General Manager, and Robert Balog, Director of R&D. of the division were enlisted to produce a high throughput testing platform to meet this demand, and the Amplitude<sup>™</sup> Solution was born.

Robert explained: "It was mid-April 2020, and I was walking the dogs with my family when I was contacted by the president of the division about a completely new project for the company, a high throughput automated solution that could carry out 10,000 COVID-19 tests a day. We had the EUA for the TaqPath in manual mode as a starting point, and wanted to change as little as possible when automating it so that we could get fast approval. We have tremendous knowledge and experience within the company, and I first turned to colleagues from the Sample Preparation and Analytical Instrumentation groups – who already had experience of automated instruments and cooperative robots – to see what we could build internally. It soon became apparent that we would need outside partners for certain elements of the project."

Elliot added: "We looked at a few different liquid handling options and Tecan consistently came out top on our list of requirements. Despite the restrictions of the pandemic, the company could meet our needs for supply and continuity for a large number of instruments and, in particular, tips and plastics, which was a big issue at the time. However, most importantly, Tecan was the only company to approach us with a true spirit of partnership that would help us meet the challenges we were facing. It quickly rose up the ranks as our clear partner of choice."

Robert continued: "Many of our customers had told us that they didn't have large enough biosafety level 2 (BSL-2) areas to house the complete workflow, and so we designed the Amplitude Solution so that it could be adopted by labs of different sizes and layouts. For that reason, it is based on two Fluent® Automation Workstations - both with Tecan Cavro liquid handling pumps - set up as two distinct platforms. A Fluent 1080 workstation handles live virus in a BSL-2 lab; the instrument processes each sample and dispenses it into four, barcoded 96-well deep well plates in a state where there is no longer any live virus. These plates are then transferred to the second Fluent 780, which can be housed in a standard lab, and combines samples into a single 384-well plate for RNA extraction, qPCR and analysis. A single LIMS system connects both stages, and stores all the sample tracking information from the barcoded plates. The system gives labs a full workflow capacity of 8,000 samples a day."

Developing intuitive software was a key part of the challenge, to ensure that users could easily manage the workflow. Robert explained: "Our colleagues from the Analytical Instrumentation group had previously programmed APIs to interact with Tecan liquid handling platforms and so our proprietary Momentum<sup>™</sup> software was already compatible with Fluent scripts. We then worked with the Tecan team to develop custom scripts and, where possible, integrated Introspect<sup>™</sup> software into the systems, depending on the customers' IT set-ups and firewalls. The software has been able to give us valuable insights into how the systems are working, and the data coming back to us from the field has been really helpful to find high priority issues and start to quickly address any errors."

The first installations of the Amplitude Solution started in September 2020 and the customer response to the system has been overwhelming. 66 Most importantly, Tecan was the only company to approach us with a true spirit of partnership that would help us meet the challenges we were facing. **99** 

Elliot continued: "We went into this not really knowing what the market adoption was going to be, we just saw an unmet need. It was great to see how quickly this system was adopted, and especially how fast we were able to fulfill orders and schedule installations. This was another area where it was fantastic to have Tecan as our partner because, with such unprecedented demand, it was important to be able to coordinate enough field support to successfully install and train users on these machines. Tecan's global presence enabled us to quickly complete installations in all corners of the world."

Elliot concluded: "A year and a half ago, this group was less than 100 people, now we are more than 1,000. Rapid scaling and the collaboration with Tecan has allowed us to support our customers and try to make a difference in combating the pandemic. Moving forward, the intention is to continue to build our presence in this space, and leverage the competencies and infrastructure that we've built as a result of COVID-19. We plan to continue developing and deploying new assays to tackle new disease areas, and really fulfill the promise to our customers that the system isn't just a one-application purchase."

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