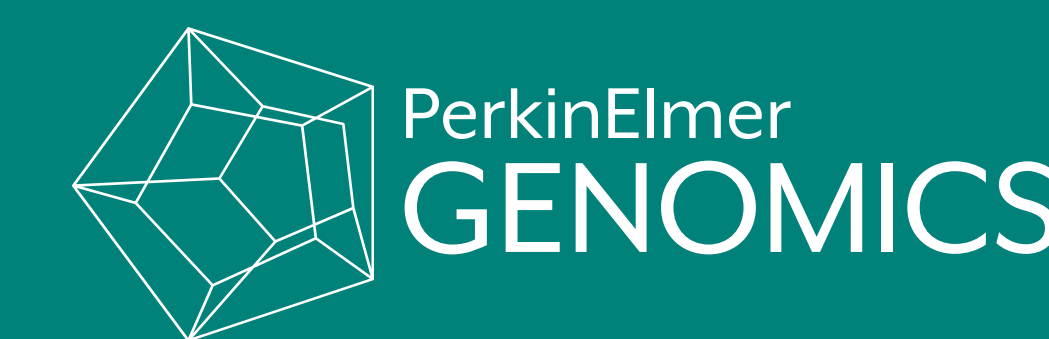


A UNITED FRONT ON TACKLING A PANDEMIC – THE TRUE VALUE OF INDUSTRY AND GOVERNMENT PARTNERSHIPS

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BACKGROUND

The emergence of the SARS-CoV-2 virus, the cause of the COVID-19 pandemic, in late 2019 put every country on high alert and led to major changes in global diagnostic testing capability in infectious disease. From the outset it was apparent that local health authorities were under-prepared and under-staffed to cope with the rapid onset and spread of the disease. Demand for SAR-CoV-2 testing soared, highlighting the limitations of capacity in existing infectious disease laboratories along with requests from governments to support growing testing need. We partnered with U.S. and UK Governments to establish, supply, staff and operate three large-scale, high-throughput SARS-CoV-2 testing facilities. These were ultimately established in Valencia, CA, and in Loughborough and Newport, UK, offering a combined testing of up to 220k samples per day.

The biggest challenge faced globally was the unprecedented scale of testing required and the timeframe to deliver a reliable and sensitive high-throughput assay. The benefits of industry and government partnerships become evident along with having a dedicated supply chain to feed the reagent and consumable needs for high-throughput testing as well as a highly accurate test with a fast turnaround time. Experts from multiple PerkinElmer divisions, including R&D, Genomics, Enterprise, and regional centers were brought into the project, resulting in the establishment of SARS-CoV-2 testing within the three facilities in approximately eight weeks. Clinical testing experts in high-throughput, newborn screening, and rare disease testing, built molecular testing pipelines for the facilities based around the use of real-time polymerase chain reaction assays and sequencing. Laboratories were setup to meet the requirements set by various regulatory and accreditation agencies such as Clinical Laboratory Improvement Amendments, College of American Pathologies, the UK National Health Service validation group and ISO 15189.

SAMPLES PROCESSED

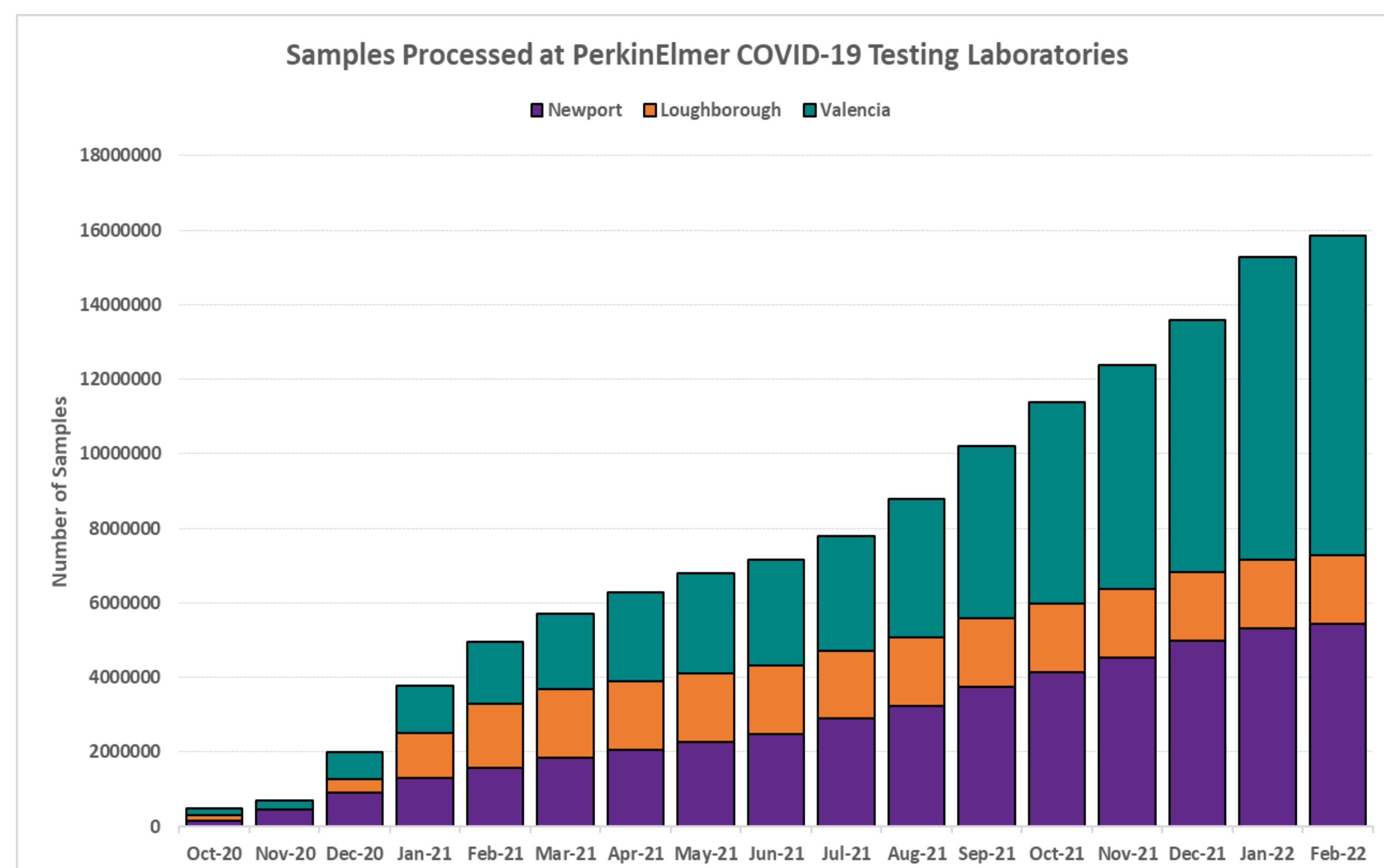


Figure 1: Samples processed at the three PerkinElmer COVID-19 Testing Laboratories between October 2020 and February 2022.

The total number of samples processed in the time span shown is 15,850,471 and the facilities at Newport and Valencia remain active.

IMPLEMENTATION

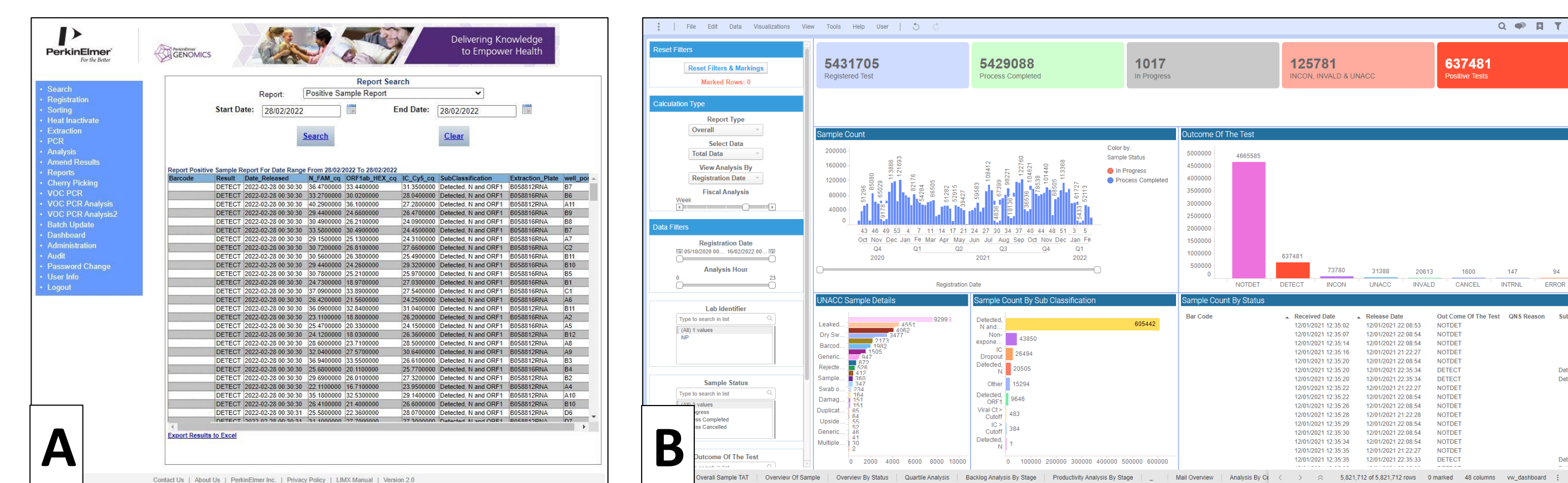


Figure 2: [A] LIM X COVID-19 LIMS Software [B] Spotfire Sample Management Dashboard.

CONCLUSIONS

- By deploying experts from multiple divisions of PerkinElmer with respective Governments in the US and UK, PKI was able to establish and operate three large-scale, high-throughput SARS-CoV-2 testing facilities in less than 8 weeks delivering high-quality real-time PCR and sequencing data with a TAT of <48hrs in the US and <24hrs in the UK.
- To date these facilities have reported results for nearly 16 million SARS-CoV-2 RT-PCR assays. The number of cases is growing globally, and with the emergence of new variants and continual uncertainty about the impact on existing vaccines, there is an ongoing requirement for this scale of testing.
- From the experience of the SARS-CoV-2 global pandemic, the benefits of industry and government collaboration for the public has become much clearer, including:
 - Greater access to large-scale testing operations and governance.
 - Significant reductions in time-to-testing and reporting and the rapid deployment of modern, cutting-edge technology in diagnostic and monitoring programs.
 - Reduced costs to health services from mass-production.
 - High-quality clinical data to drive future diagnostic responses to global pandemics.

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