

Extending and Adapting the Functions of Genetic Laboratories During the COVID-19 Pandemic- Challenges and Successes

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BACKGROUND

Clinical molecular genetics laboratories have expanded rapidly in the last 15 years, incorporating new technologists at an astounding rate that has brought rare disease testing out of research labs and into standard of care medical practice. These laboratories have had to adapt a succession of new technologies and methods of data analysis while building in-house expertise. When the SARS-CoV-2 virus, the cause of COVID-19, emerged in early 2020 and quickly spread across the globe, many areas of the United States (U.S.) when into lockdown. Non-critical healthcare appointments were postponed resulting in a dramatic drop in the number of samples being referred for genetic testing for rare diseases. As large genetics laboratory experienced the resulting drop in volume, the demand for SARS-CoV-2 testing soared. Equipped with expertise in high throughput testing, as well as clinical technologists trained in high-complexity testing, large genetics laboratories stepped in to fill the gap, a measure that kept laboratories running and staff employed. Our expertise in high-throughput high-complexity led from requests to perform testing in our genomics laboratory to building new laboratories in both the U.S. and the United Kingdom (U.K.). These efforts resulted in building three laboratories from an empty space to a functioning, staffed clinical laboratory in approximately eight weeks. Various assays with slightly different designs are available, and the assay used must be best suited to the testing workflow. In the U.S., samples collection is supervised by a healthcare provider. A higher sensitivity assay that does not include an internal human control gene was chosen. In the U.K., home collection is allowed, therefore, an assay that includes a human RNaseP gene control but with lower sensitivity for SARS-CoV-2 was chosen.

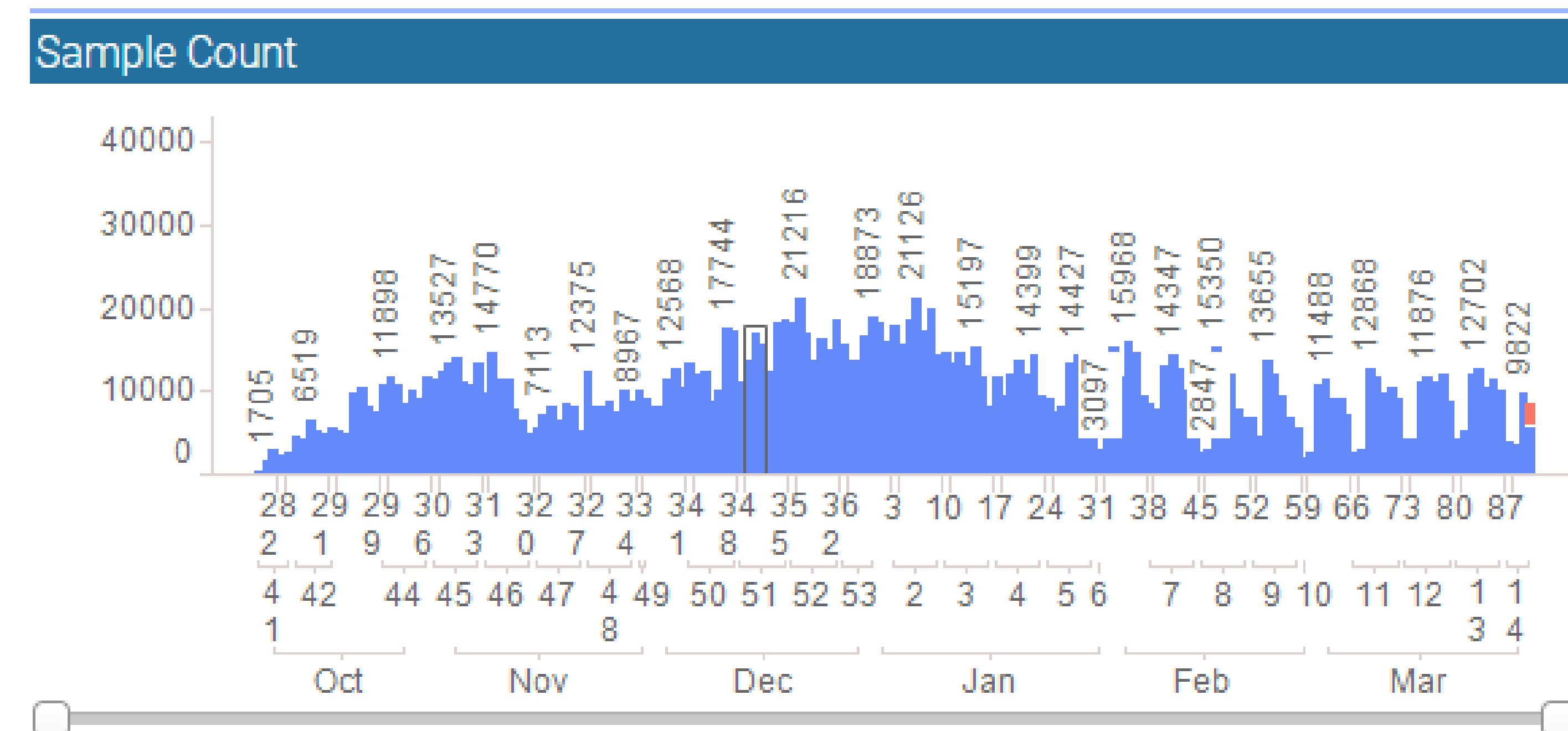
RESULTS

- Across three labs in two countries over 1200 individuals (~550 U.S. and ~700 U.K.) were hired and trained.
- To date, these laboratories have performed nearly 6 million SARS-CoV-2 assays.
- Challenges:
 - Navigating state, federal, and country regulations
 - Rapidly training a large clinical staff while ensuring optimal assay performance.
 - Clinical testing in the U.S. is governed by the Clinical Laboratory Improvement Amendments (CLIA), which provide very specific requirements for personnel, training, proficiency testing and the quality management system.
 - Outside the U.S., laboratory requirements are dictated by accepted best practices and accrediting agencies, rather than specific laws, sometimes making it difficult to know what requirements need to be met.

CONCLUSION

- Given the current global awareness of respiratory virus activity and spread, there is a growing demand for new and expanded testing. Combining SARS-CoV-2 testing with influenza, RSV and potentially other viruses is clinically desirable. Pooling of samples will allow for even greater throughput while reducing the demand for increasingly scarce consumables.
- Our experience with high-throughput sequencing is allowing us to pivot quickly to viral genome sequencing, which is critical to understanding and combating this pandemic.
- Rare metabolic diseases, intellectual disabilities and hereditary cancer syndromes will always still need attention and continuous innovation.
- We will need to learn to balance these activities and continue to support testing needs for these in addition to emerging diseases.

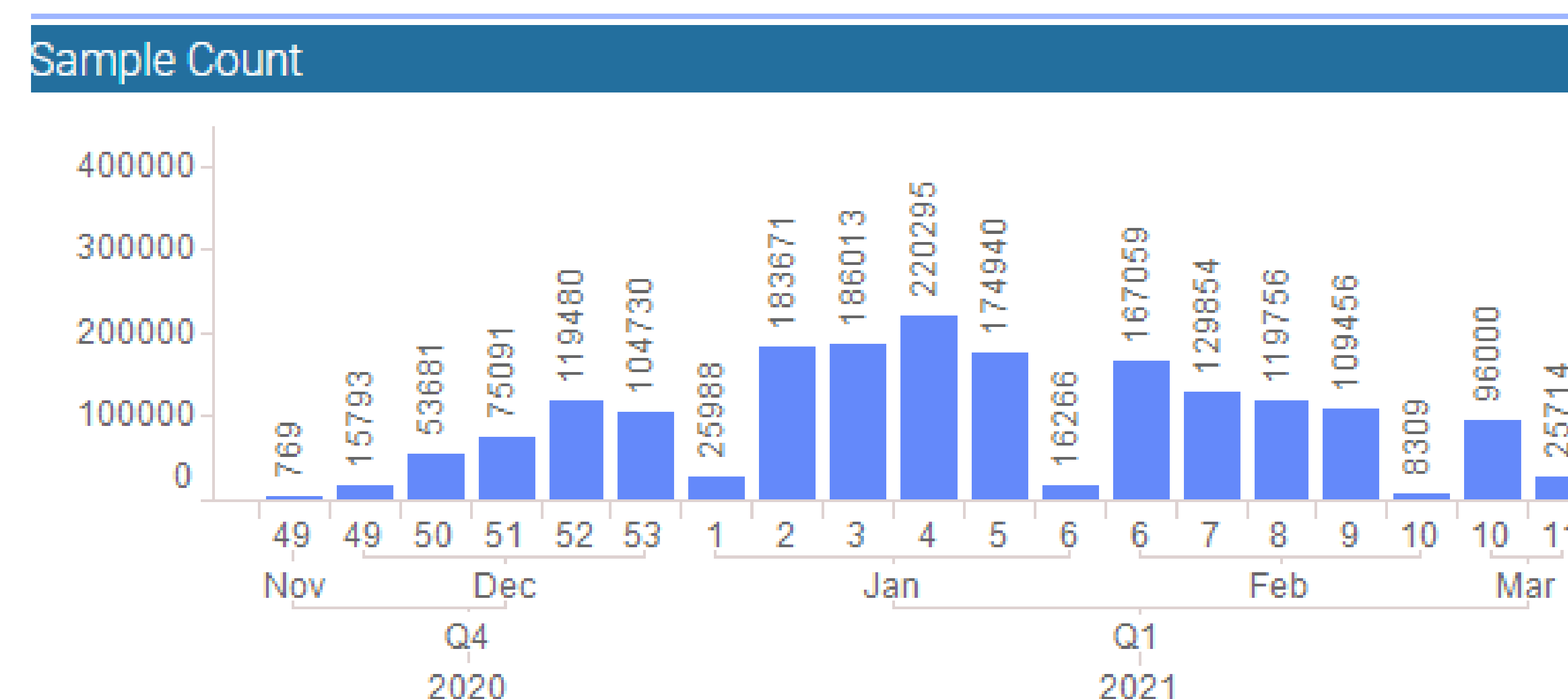
LABORATORY OVERVIEW



- Opened: Oct 5, 2020
- Capacity: 20,000 / day
- Staff: ~250
- Average TAT 14.8 hours
- Average TAT (2021): 10.3 hours

1.8 million tests completed

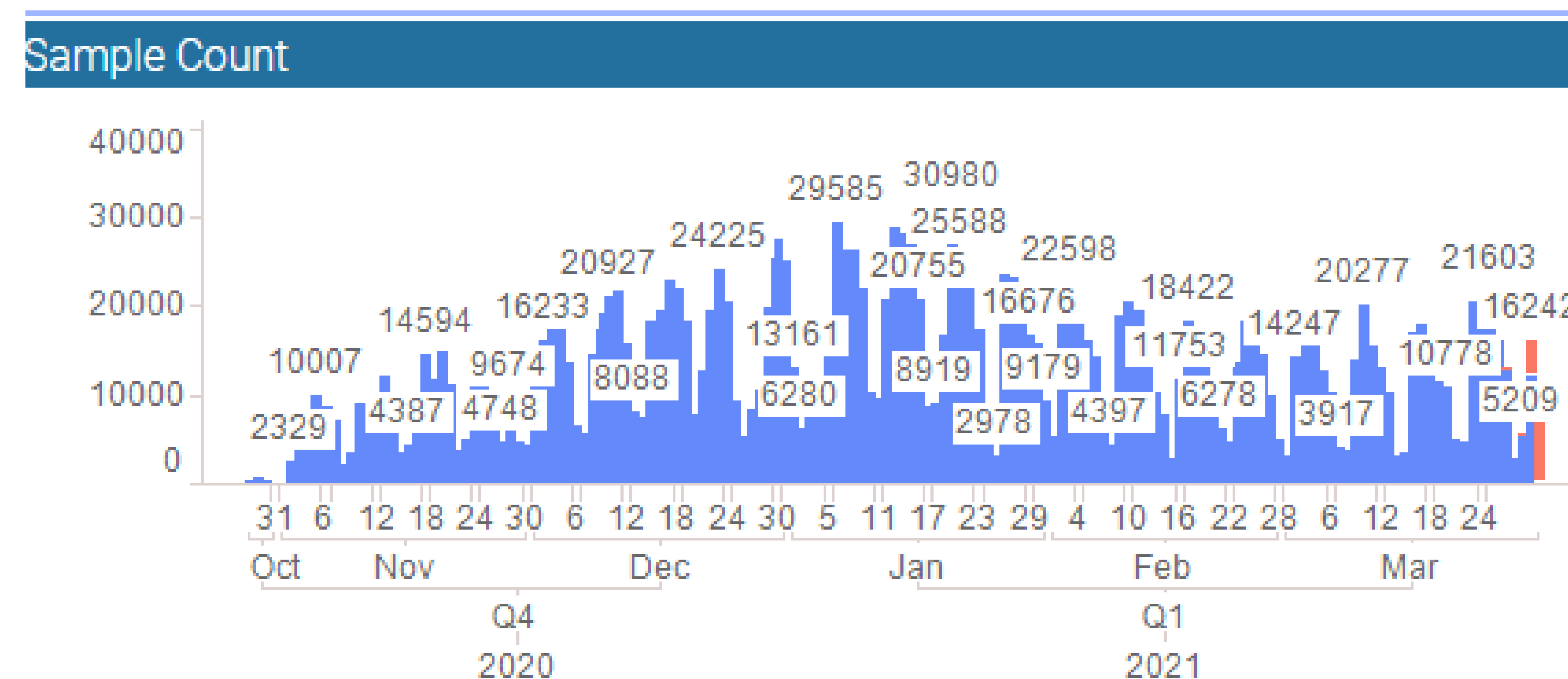
Newport, UK



- Opened: Nov 30, 2020
- Closed Feb 26, 2021
- Capacity: 50,000 / day
- Staff: ~500
- Average TAT 12.6 hours
- Average TAT (2021): 11.7 hours

1.8 million tests completed

Charnwood, UK



- Opened: Oct 28, 2020
- Capacity: 120,000 / day
- Staff: ~500
- Average TAT 25.2 hours
- Average TAT (2021): 15.3 hours

2.0 million tests completed

Valencia, CA