Extending and adapting the functions of genetic laboratories in the continuing COVID pandemic- challenges and successes

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BACKGROUND

As the SARS-CoV-2 virus, the cause of COVID-19, emerged in early 2020 and quickly spread across the globe, clinical molecular genetics laboratories experienced a dramatic drop in samples referred for clinical testing as non-critical healthcare appointments were postponed. Our expertise in high-throughput high-complexity led from requests to perform testing in our genomics laboratory to building new laboratories in both the United Sates (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. In total, these laboratories have employed over 1200 individuals (~550 Valencia, CA, U.S. and ~700 U.K. (Charnwood and Newport)). Initial challenges included navigating state, federal, and country regulations and rapidly training a large clinical staff while ensuring optimal assay performance. As the pandemic continued, unpredictable decreases and surges in case numbers led to uncertainty in program longevity and staffing needs creating operational challenges. The FDA has approved EUAs with a wide range of assay sensitivity, ranging from 20 copies/ ml to several thousand copies/ ml. This wide range of assays used by the laboratories led to some unexpected outcomes. For example, individuals who tested positive the laboratory tested negative by another less sensitive assay, resulting in the perception of discrepant results. Further, vaccinated people testing positive, albeit with indication of a low viral load, was also unexpected. The high sensitivity of the assay with lowest copy detection allows the diagnosis of more individuals than less sensitivity assays, which is critical in stopping the spread of a virus that can be asymptomatic. An approach for cost saving is pooling of samples. When case numbers surge, as occurred with the spread of the SARS-CoV-2 Delta variant, a pooling approach is no longer efficient, therefore, a permanent shift to a pooling approach is not feasible.

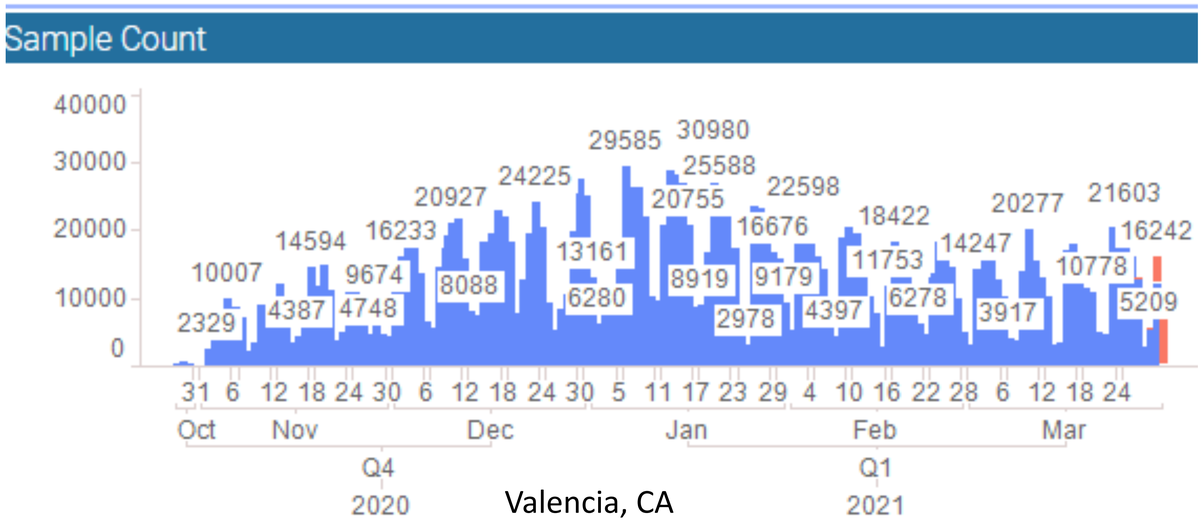
RESULTS

- 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 approximately 16 million SARS-CoV-2 assays, with 2.5 of nearly 9 million Valencia, CA samples performed in the first two months of 2022.
- 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 laboratory operations; Outside the U.S., laboratory requirements are dictated by accepted best practices and accrediting agencies, rather than specific laws.
  - Evolving FDA requirements for Emergency Use Authorization (EUA) for their Laboratory Developed Tests (LDTs) have required laboratories to identify and hire qualified individuals to navigate the assay validation and subsequent assay management requirements
  - Shifting government priorities – Charnwood, UK opened 30Nov2020, closed 26Feb2021
  - Differences in assay sensitivity can result in apparent discrepancies between laboratories
  - Maintaining serge capacity for unpredictable emerging virus strains

CONCLUSION

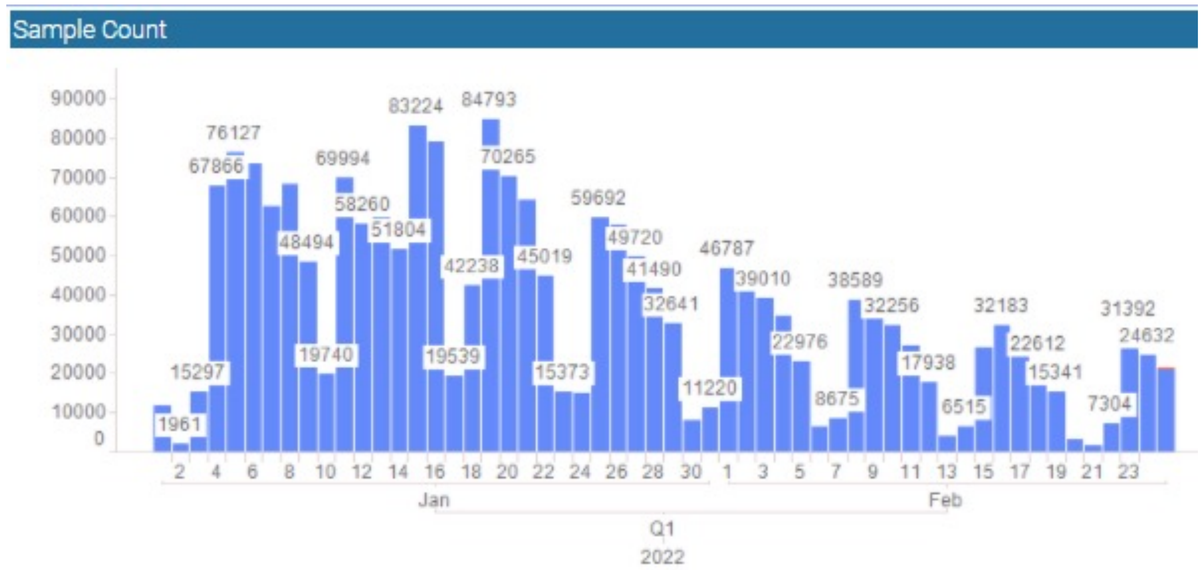
- The demand for COVID testing is likely to remain inconsistent with unpredictable surges
- Our experience with high-throughput sequencing is allowing us to pivot quickly to viral genome sequencing, which is critical to understanding and combating this pandemic.
- Rare metabolic diseases, intellectual disabilities and hereditary cancer syndromes will always still need attention and continuous innovation.

SAMPLES TESTED



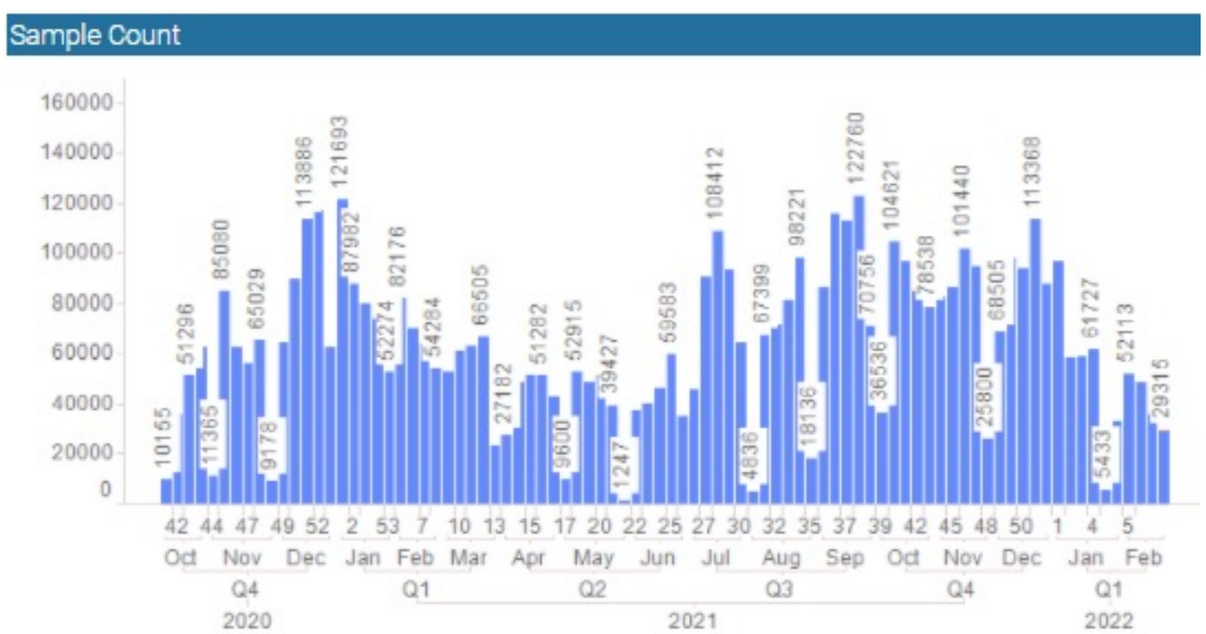
Valencia, CA

Oct 2020 – March 2021: 2 million tested



Valencia, CA

Jan – Feb 2022: 2.5 million tested



Newport, UK

Oct 2020 – Feb 2022: 5.5 million tested