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CASE STUDY

Accelerating the Development of a Rapid Detection NAAT Assay for SARS-CoV2: Overcoming Challenges in In-Silico Sensitivity and Specificity Analysis

Client's Challenge and Goals

The client worked in the area of in-silico sensitivity and specificity analysis of probes and primers for SARS-CoV2 molecular diagnostic assays. Their goal was to obtain the tabular output of gene variants and in-depth variant prevalence information from non-redundant and filtered sequence alignments.

The client was aware of Excelra's specialized knowledge and expertise in the area of in-silico sensitivity and specificity analysis of probes and primers for SARS-CoV2 molecular diagnostic assays. They sought Excelra's services to gain the necessary expertise and support to expedite the development of their rapid detection NAAT assay. This approach would save the client a significant amount of time.

Our Client

A pharma company based out of the EU

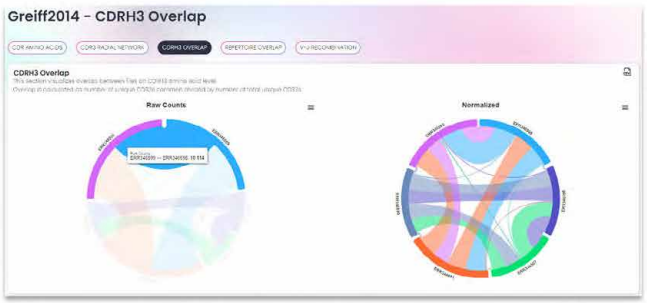
Our Approach

For the faster development of rapid detection NAAT assay, we implemented the following key activities.

We retrieved the SARS-CoV2 multiple sequence alignment from reliable sources such as Nextstrain/Genbank. This allowed us to access a comprehensive dataset for further analysis.

Next, we conducted an in-depth analysis of the prevalence of each variant in the two genes of interest. This analysis helped us identify and prioritize specific variants that could be potentially significant for the client's molecular diagnostic assays.

We needed to ensure the specificity of the primer/probe sequences provided by the client. This involved assessing the sequences for potential binding with the client-provided non-target pathogens. This analysis could minimize the risk of false-positive or cross-reactive results in the diagnostic assays.

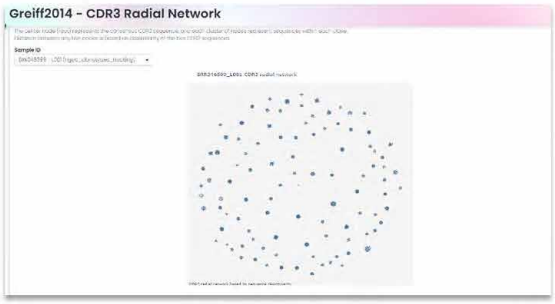


Samples with Shared Domains

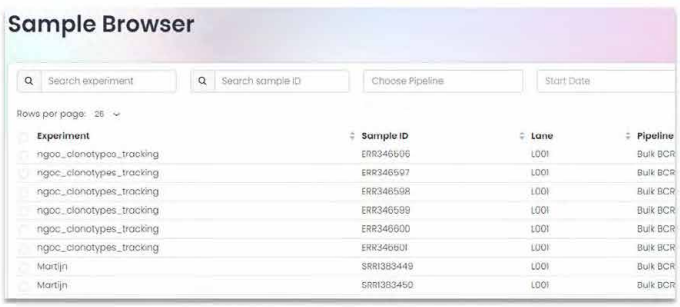
Composition of Amino Acids

V-J Recombination

Sample-wise Shared Clonotypes



Radial Network



Sample Browser

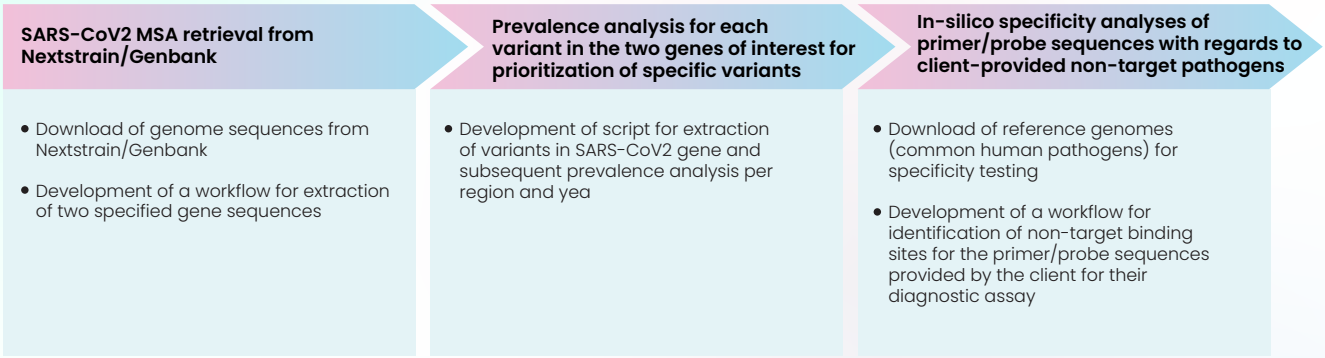
After that, we developed a script specifically designed to extract variants in the SARS-CoV2 gene and perform prevalence analysis based on region and year. This allowed for a comprehensive understanding of variant distribution.

We ensured the client's diagnostic assay would accurately target SARS-CoV2 without cross-reactivity with other pathogens. For this, we downloaded reference genomes of common human pathogens, which were used for specificity testing. Accurately target SARS-CoV2 without cross-reactivity with other pathogens.

We also downloaded genome sequences from Nextstrain/Genbank, which provided a wide range of genetic data for analysis. These sequences were essential for various studies and comparisons.

Lastly, we developed a workflow tailored explicitly for extracting two specified gene sequences. This facilitated identifying and removing the genes of interest, providing vital information for subsequent analyses.

Key Activities



Our Solution

Our solution encompassed script development, reference genome acquisition, workflow creation, and data extraction to ensure an accurate and robust analysis of variants, specificity, and gene sequences for the client's SARS-CoV2 molecular diagnostic assays.

We provided the client with the necessary sequence data by conducting prevalence and in-silico specificity analyses. This holistic approach provided the client with a robust understanding of the variant prevalence and ensured the accuracy and specificity of the primer/probe sequences for their SARS-CoV2 molecular diagnostic assays.

The customer gained an in-depth analysis of variant prevalence and in-silico sensitivity & specificity of probes and primers for SARS-CoV2 molecular diagnostic assays.

Conclusion

Excelra's expertise in in-silico sensitivity and specificity analysis ensured the specificity and sensitivity of the assay, resulting in reliable and accurate detection of SARS-CoV2.

We delivered a comprehensive dataset of gene variants and variant prevalence information, along with specific prioritized variants for the client's molecular diagnostic assays. This allowed the client to make informed decisions on probe and primer selection for their rapid detection NAAT assay.

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