

SARS-CoV-2 NGS Assay – RUO

Highly sensitive solution for viral detection and characterization

KEY HIGHLIGHTS

Highly sensitive detection

- Sensitive detection level as few as 800 viral copies per ml in each specimen

More sequence information

- Coverage of > 99.9% of the genome at 1X or greater post enrichment
- Ability to identify novel viral mutations

Software Analytics

- RUO software analytics report provides variant typing and phylogenetic analysis for epidemiological surveillance

The SARS-CoV-2 NGS Assay - RUO is a highly sensitive nucleic acid hybridization capture-based research-use only assay used for the detection, characterization, and environmental monitoring of the SARS-CoV-2 virus. It utilizes Twist Bioscience's unique ability to rapidly develop virus-specific panels by DNA synthesis, and Biotia's comprehensive data analysis software and reporting capabilities (COVID-DX (v1.0)).

This assay is intended for the qualitative detection of the SARS-CoV-2 virus from nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal wash/aspirates, nasal aspirates, and bronchoalveolar lavage (BAL) specimens for research purposes only. The SARS-CoV-2 NGS Assay enriches for and detects all nucleic acid sequences by hybrid capture target enrichment from the SARS-CoV-2 virus, as opposed to only identifying certain regions. This technology requires a hybridization time of 2 hours, estimating a sensitivity level as few as 800 viral copies per ml in each specimen.

The Biotia COVID-DX (v1.0) software provides a research-oriented report that includes the full sequence of the SARS-CoV-2 virus, enabling improved understanding of mutations, genetic variations, and the evolution of the virus as it is transmitted. FASTQ files (sequencing output) can be generated in laboratories and submitted to Biotia COVID-DX (v1.0), a cloud-based software, to generate research-use only reports. The purchase of each SARS-CoV-2 NGS Assay kit includes credits for COVID-DX (v1.0) bioinformatic analysis of each sample. To receive Biotia analysis credits, simply register through the Biotia User Portal via biotia.io and enter the unique order number emailed to you. These credits provide access to run samples through the report generation component of the software.

RUO Test Report

The research use only (RUO) report is only intended to be used for research and is not intended to guide treatment of patients.

Mutations naturally accumulate over time as a virus spreads through a population. The majority of these mutations do not have an effect on the transmission or pathogenicity of the virus, but a small proportion of these mutations may result in variants with functional differences. The pattern of mutations in a genome can be used to track transmission and spread of the virus and to follow the evolution of the virus over time. As research progresses, genetic variants with functional effects can be identified. Variants in different genes will likely have different functional effects and may contribute to different variants becoming more common in the population. The RUO report of this assay provides detailed information on the variants detected, clade association, and phylogenetic analysis for epidemiological surveillance.

RESULTS SUMMARY

| | | |
|----------------------|------------------|-------------------------------|
| Detected: SARS-CoV-2 | Controls: Passed | Reference Value: Not Detected |
|----------------------|------------------|-------------------------------|

GENETIC VARIANTS DETECTED

| DETECTED | GENE | SITE (BP) | ALTERATION | REFERENCE VALUE |
|----------|--------|--------------------|------------|-----------------|
| + | ORF1ab | 241 | T | Not Detected |
| + | ORF1ab | 478 | T | Not Detected |
| + | ORF1ab | 3,037 | T | Not Detected |
| + | ORF1ab | 14408 ¹ | T | Not Detected |
| + | ORF1ab | 18877 | T | Not Detected |
| + | S | 23403 | G | Not Detected |
| + | 3a | 25563 | T | Not Detected |
| + | 3'UTR | 29759 | C | Not Detected |

| DETAILS | VARIANT LITERATURE NOTES (IF AVAILABLE) | REFERENCES |
|--------------------|---|----------------------|
| ¹ 14408 | Corresponds to P232L, mutation in the RdRp, Orf1ab gene. RdRp enzymes are binding targets for several drugs and studies indicate a mutation may affect drug efficacy. | Pachetti et al. 2020 |

Figure 1. Genetic variants identified. Genetic variants are determined by aligning the test strain to the SARS-CoV-2 reference genome (NC_045512.2) with information on gene location/site, alteration and literature notes if any.

COVERAGE RESULTS: >95% coverage at 5x depth.

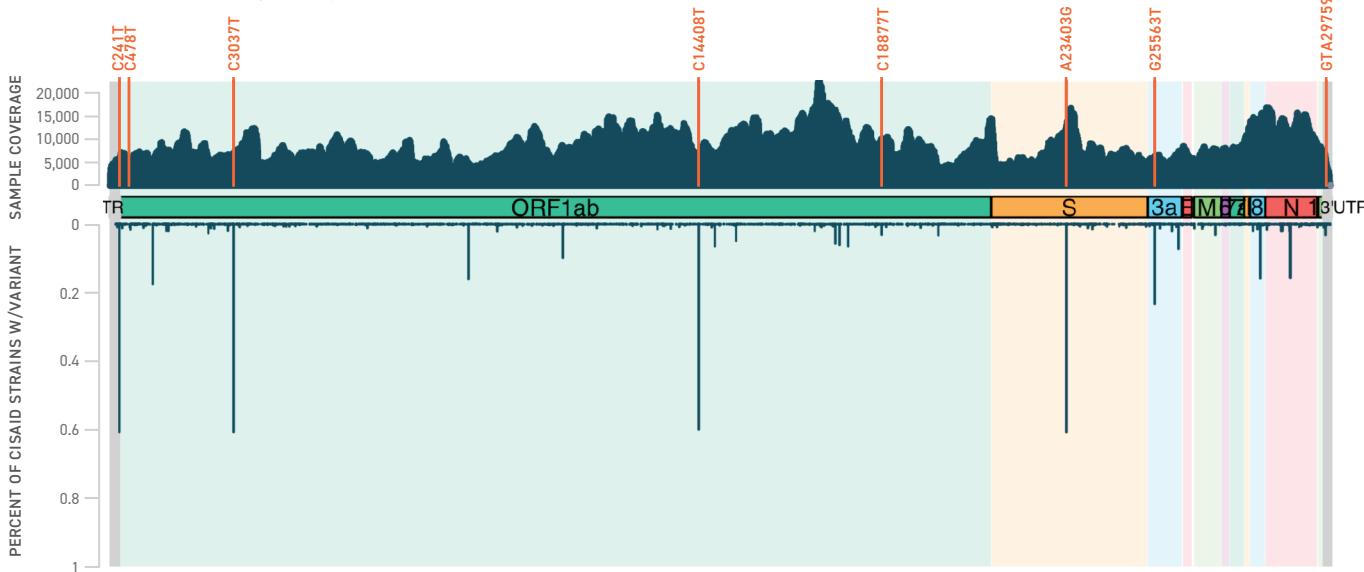


Figure 2. Sequence results mapped across the genome. The percent of the SARS-CoV-2 genome recovered from your test sample, and genetic variants identified compared to the reference genome are indicated. The proportion of known genetic variants of SARS-CoV-2 strains from across the world are shown (bottom).

Clade-Associated Variant Results

Genetic diversity (clades) and variants are determined by aligning the test strain to a reference genome (NC_045512.2) and comparing differences in genetic sequence to a background of 3,365 samples from GISAID (version 24-June-2020), selected to represent global diversity.

Phylogenetic Analysis

Phylogenetic analysis provides information on the origin and diversity of SARS-CoV-2 based on genetic variation. The phylogenetic tree uses a SARS-CoV-2 reference genome to determine which clade in our database the test sample is most closely related to. Ten countries with the highest percentage of tests falling into these clades are listed in the table.

Summary

The **SARS-CoV-2 NGS Assay—RUO** is a highly sensitive hybrid-capture based NGS assay that utilizes tertiary analytics powered by Biotia COVID DX (v1.0) software for complete characterization of SARS-CoV-2. A two-hour hybridization improves workflow throughput and recovering the full virus genome sequences facilitate phylogenetic analysis and enables studies into the lineage and evolution of the SARS-CoV-2 virus. Moreover, the tolerance of the hybrid-capture based method to virus mutations enables successful identification of various mutations. The ability to simultaneously detect and characterize the SARS-CoV-2 virus makes the NGS assay not only a powerful alternative to the limited sequence detection of RT-PCR based methods, but also an invaluable tool for monitoring viral evolution and population-scale surveillance.

| VIRUSES | GENE | SITE (BP) | ALTERATION | RESULTS | REFERENCE VALUE |
|------------|------|-----------|------------|--------------|-----------------|
| SARS-CoV-2 | | | | Detected | Not Detected |
| Clade 19A | nuc | 8782 | C | Not Detected | Not Detected |
| Clade 19A | nuc | 14408 | C | Not Detected | Not Detected |
| Clade 19B | nuc | 8782 | T | Not Detected | Not Detected |
| Clade 19B | nuc | 28144 | C | Not Detected | Not Detected |
| Clade 20A | nuc | 8782 | C | Not Detected | Not Detected |
| Clade 20A | nuc | 14408 | T | Detected | Not Detected |
| Clade 20A | nuc | 23403 | G | Detected | Not Detected |
| Clade 20B | nuc | 8782 | C | Not Detected | Not Detected |
| Clade 20B | nuc | 14408 | T | Not Detected | Not Detected |
| Clade 20B | nuc | 23403 | G | Not Detected | Not Detected |
| Clade 20B | nuc | 28881 | A | Not Detected | Not Detected |
| Clade 20B | nuc | 28882 | A | Not Detected | Not Detected |
| Clade 20C | nuc | 1059 | T | Not Detected | Not Detected |
| Clade 20C | nuc | 8782 | C | Not Detected | Not Detected |
| Clade 20C | nuc | 14408 | T | Not Detected | Not Detected |
| Clade 20C | nuc | 23403 | G | Not Detected | Not Detected |
| Clade 20C | nuc | 25563 | T | Not Detected | Not Detected |

Figure 3. Clade-associated variant results.

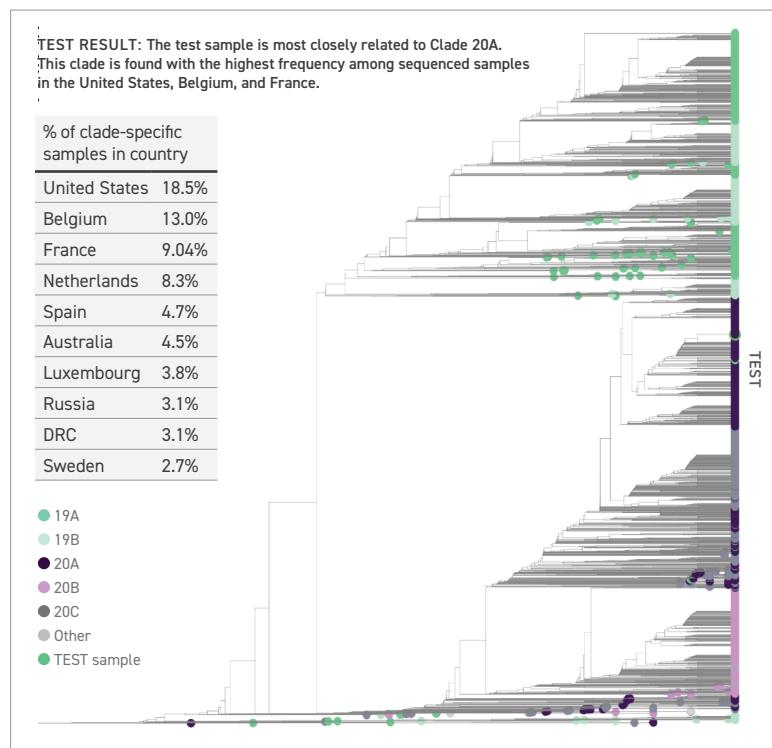


Figure 4. Phylogenetic analysis and surveillance monitoring.

Twist SARS CoV-2 NGS Assay—RUO is a component of the Twist Infectious Disease portfolio of products.

LEARN MORE

twistbioscience.com | biotia.io

sales@twistbioscience.com | customersupport@biotia.io

ORDERING INFORMATION FOR TWIST SARS-COV-2 RESEARCH PANEL + BIOTIA COVID DX (V1.0)—RUO

103564: 2 Reactions, Kit

103566: 12 Reactions, Kit

103567: 96 Reactions, Kit