# Periodic assessment of the general sensitivity of NZYTech molecular tests in response to emerging variants and new genomic information

January 2024 Report

The natural evolution of pathogens implies that new sequence information will become available after the initial design of NZYTech molecular diagnostic kits, which reflects microbial adaptation strategies. As part of post-market surveillance efforts, NZYTech continuously reviews and analyses relevant microbial genomic information to assess whether any emerging mutations overlap established assay designs. In case such an event occurs, NZYTech will release new molecular test versions to retain unparalleled sensitivity and specificity. At least every two months or whenever considered necessary, NZYTech will communicate the outcome of this continuous surveillance effort at www.nzytech.com.

**Diagnosing New Variants Lineages**

Pathogens, in particular viruses, constantly evolve innovative strategies to improve infection efficacy. Variant mutations may reduce the effectiveness of current NZYTech RT-qPCR molecular diagnostic tests that target viruses and bacteria prone to genetic instability. For example, SARS-CoV-2 is paradigmatic in its capacity to genetically adapt to novel environmental constraints, causing, worldwide, emerging concerns about controlling the current COVID-19 pandemic. Thus, through genomic surveillance of SARS-CoV-2, the multiple new Variants of Concern (VOCs) and Variants of Interest (VOIs) that arise independently at multiple locations are verified.

Globally, from 13 October 2023 to 12 January 2024, 248 994 SARS-CoV-2 sequences were shared through GISAID. *Data source: sequences and metadata from GISAID, retrieved on 19 January 2024.*

Currently (January 2024) JN.1 is the dominant circulating VOI (reported by 71 countries), accounting for 65.5% of sequences globally. Its parent lineage, BA.2.86, is stable and accounted for ~7 % of sequences for these last three months. The initial risk evaluation for JN.1 was published on 19 December 2023, with an overall evaluation of low public health risk at the global level based on available evidence.

The other VOIs, XBB.1.5, XBB.1.16 and EG.5, have decreased in global prevalence during the last three-month period, and the same was observed for all VUMs that have shown a decreasing trend over the reporting period.

At this time, WHO is tracking several SARS-CoV-2 variants including:

- Five variants of interest (VOIs): XBB.1.5, XBB.1.16, EG.5, BA.2.86 and JN.1
- Five variants under monitoring (VUMs): DV.7, XBB, XBB.1.9.1, XBB.1.9.2 and XBB.2.3.

With declining rates of testing and sequencing globally, it is increasingly challenging to estimate the severity impact of emerging SARS-CoV-2 variants. There are currently no reported laboratory or epidemiological reports indicating any association between VOIs/VUMs and increased disease severity. *Data source:*

https://www.who.int/publications/m/item/covid-19-epidemiological-update---19-january-2024

**Latest surveillance data**

According to this January report, the molecular NZYTech kits can accurately detect the SARS-CoV-2 virus without being affected by any of the newly identified mutations in the virus genome. The NZYTech SARS-CoV-2 one-step RT-qPCR Kits have been designed to detect SARS-CoV-2 ORF1ab, N, and E genes that are less prone to mutations, even under the current evolving variants. Additionally, the efficacy of current testing devices remains intact as the novel genomic variations do not impair the specificity of all other NZYTech kits.

| **Surveillance History** | |
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| **Date** | **Summary of Revisions** |
| January 31st, 2024 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy. (SARS-CoV-2 JN.1 VOI variant has been included) |
| August 24th, 2023 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy. (Variants of interest XBB.1.5, XBB.1.16, EG.5 and BA.2.86 have been included) |
| July 31st, 2023 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| May 31st, 2023 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| March 31st, 2023 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| January 30th, 2023 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| November 30th, 2022 | Updated in-silico analysis of primer/probe sequences, based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| September 30th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information did not detect mutations that could affect detection efficacy |
| July 28th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information, did not detect mutations that could affect detection efficacy |
| May 30th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information did not detect mutations that could affect detection efficacy |

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| March 29th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information did not detect mutations that could affect detection efficacy |
| January 26th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information did not detect mutations that could affect detection efficacy |
| January 5th, 2022 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic/metagenomic information did not detect mutations that could affect detection efficacy |
| November 29th, 2021 | Updated in-silico analysis of primer/probe sequences based on recent references and genomic information available (SARS-CoV-2 B.1.617.2 and B.1.1.529 variants have been included) |

**Conclusion:**

**None of NZYtech molecular diagnostic tests is impacted by emerging genomic information.**

**References:**


1. COVID-19 Epidemiological update – 19 January 2024. *https://www.who.int/docs/default-source/coronaviruse/situation-reports/20240119_covid-19_epi_update-handover_163.pdfT*
2. Tracking SARS-CoV-2 variants, 30 January 2024. https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/
3. Guidance on the borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices. September 2022. *https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en*