

Oxford Nanopore Diagnostics Frequently asked questions (FAQs) – March 2021

Introduction

Virus genomes constantly change through mutations leading to the emergence of new virus variants, and SARS-CoV-2 is no exception. Research indicates that the SARS-CoV-2 genome gains approximately 1–2 mutations per month¹. Recently, certain variants that have unfolded have accumulated significantly more mutations in short periods of time, causing concern around the globe². Viruses generally acquire mutations over time, giving rise to new variants. Vaccine-induced immunity, however, would likely be the most concerning because once a large proportion of the population is vaccinated, there will be immune pressure that could favour and accelerate emergence of such variants by selecting for “escape mutants”. There is no evidence that this is occurring, and most experts believe escape mutants are unlikely to emerge because of the nature of the virus³.

This FAQ document provides more information about how Oxford Nanopore Diagnostics is monitoring SARS-CoV-2 variants to assess and address any potential changes in the performance of our assays.

What is Oxford Nanopore Diagnostics doing to monitor gene mutations in its assays, and will there be product modifications in the future?

We regularly review post-market reports and database updates as part of our monitoring activities to assess for impact on product performance. To date, there have been no reports of test results being impacted due to virus mutation. Consequently, no adaptations to the test or changes in use are necessary at this time. As part of our Post Market Surveillance (PMS) process we will continue to monitor the landscape and assess any potential impacts of variants on the performance of our assay. Our PMS system provides both proactive and reactive post-market surveillance of the SARS-CoV-2 virus regarding variants of concern (VOC).

What is the sensitivity and specificity of the LamPORE COVID-19 assay?

There is a comprehensive summary of the performance characteristics used to assess analytical and clinical performance of the LamPORE COVID-19 assay in the Instructions for Use. These include limit of detection, reactivity, interfering substances cross-reactivity, and clinical evaluation. These characteristics taken together help to confirm that the test performs as expected. The Instructions for Use are available on the [LamPORE COVID-19 product page](#).

What genes are targeted and why is it important to have three targets in the assay?

The LamPORE COVID-19 assay contains primers that were designed primarily against the Wuhan-Hu-1 strain of SARS-CoV-2, the globally dominant form of causative agent of COVID-19. The LamPORE COVID-19 assay targets regions of three coronavirus genes: neuraminidase (N2), envelope (E1), open reading frame 1a (ORF1a). These target areas are specific to the SARS-CoV-2 virus, reducing the risk of detecting other coronaviruses. At time of writing, the LamPORE COVID-19 assay continues to maintain targeted specificity to 100% of currently available complete genomes for SARS-CoV-2. Being an RNA virus, SARS-CoV-2 is more susceptible to mutations which can impact the efficiency of the assay.

What is the potential impact of the mutations on SARS-CoV-2 diagnostics?

The European Centre for Disease Prevention and Control (ECDC) advise utilising multiple genes for primary detection of SARS-CoV-2 infection⁴. As mentioned above, our assay targets three different regions of the SARS-CoV-2 virus. To date, our ongoing monitoring and surveillance has demonstrated that the performance of the LamPORE COVID-19 assay is unaffected by the known variants.

Who should I contact regarding additional questions?

If you have additional questions or would like to discuss your specific situation, please contact our technical support team at info@oxfordnanopore.com.

References

- ¹ Callaway, E. The coronavirus is mutating — does it matter? *Nature*. 585:7824 (2020).
- ² ECDC. Threat Assessment Brief: Rapid increase of a SARS-CoV-2 variant with multiple spike protein mutations observed in the United Kingdom. Available at: <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom> [Accessed: 23 March 2021]
- ³ CDC. Science Brief: Emerging SARS-CoV-2 Variants. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html> [Accessed: 23 March 2021]
- ⁴ ECDC. Risk related to spread of new SARSCoV-2 variants of concern in the EU/EEA. Available at: <https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-risk-related-to-spread-of-new-SARS-CoV-2-variants-EU-EEA.pdf> [Accessed: 23 March 2021]

Find out more about LamPORE COVID-19 at www.oxfordnanopore.com.