Updated January 2021 – QIAGEN response to the SARS-CoV-2 variants with increased infectivity

It is well established that RNA viruses frequently mutate due to erroneous or ineffective replication of the virus genome[1]. As an RNA virus, Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) lacks a robust proofreading mechanism increasing the likelihood of mutants. Usually these mutations are innocuous, but can sometimes lead to viruses with altered properties or even new strains. During this unprecedented COVID-19 pandemic, data on novel SARS-CoV-2 variants with potentially increased transmissibility (including the SARS-CoV-2 VUI 202012/01 – United Kingdom-variant and the 501Y.V2 – South Africa-variant, among others) is rapidly developing.

To address the possible impact on the genetic variability of SARS-CoV-2, QIAGEN keeps continuous surveillance on the sequences uploaded to public databases (GISAID and GenBank) to assess the effect of the mutations of the SARS-CoV-2 genome. In particular, we periodically perform an in silico analysis on how these mutations could affect the sensitivity of the QIAGEN assays currently used in the fight against COVID-19: QIAstat-Dx® Respiratory SARS-CoV-2 Panel*, NeuMoDx™ SARS-CoV-2 Assay*, and NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Test Strip*.

Specifically, upon the in silico analysis, following our published methodology[2], of the group of variants under investigation (including those listed by European Center for Disease Control)[3] listed on the table below, we can conclude that none of the recorded mutations (captured on GISAID and GenBank) on the listed strains affects the sensitivity of the assays in the QIAGEN products detecting SARS-CoV-2[4].

SARS-CoV-2 Variant	Reported Public Health Impact	Mutations (amino acid change)	Impact on sensitivity of SARS-CoV-2 detection by		
			QIAstat-Dx Respiratory SARS-CoV-2 Panel	NeuMoDx SARS-CoV-2 Assay	NeuMoDx Flu A-B/RSV/ SARS-CoV-2
VOC 202012/01	Report of increased transmissibility from the UK	Deletion (Spike): △69-70, △144,Substitution (Spike): N501Y, A570D, P681H, T716I, S982A, D1118H	No impact	No impact	No impact
501.V2	Report of increased transmissibility from South Africa	Substitution (Spike): D80A, D215G, E484K, N501Y and A701V	No impact	No impact	No impact
Danish Mink Variant	Transmission from mink to humans and community spread confirmed, no changes in transmissibility reported.	Deletion (Spike): Δ69-70 Substitution (Spike):Y453F	No impact	No impact	No impact
Danish Mink Cluster 5	Preliminary report of moderate reduction of neutralization by convalescent sera	Deletion (Spike): Δ69-70 Substitution (Spike): Y453F, I692V, M1229I	No impact	No impact	No impact
Variants with N439K	Reports of minor reduction of neutralization by convalescent sera	Deletion (Spike): Often Δ69-70	No impact	No impact	No impact
Nextstrain Cluster 20A.EU1	Rapid increase in Spain and then the rest of the EU/EEA at the start of the second wave, probably due to random events and travel patterns	Substitution (Spike): A222V	No impact	No impact	No impact
Nextstrain Cluster 20A.EU2	Rapid increase in France at the start of the second wave, probably due to founder effects	Substitution (Spike): S477N (Nucleocapsid): A376T	No impact	No impact	No impact
Variants with D614G	Rapid increase during the early stages of the pandemic in the EU/EEA and then worldwide, probably due to a mix of founder effects and increased transmissibility	Substitution (Spike): D614G	No impact	No impact	No impact
Manaus B.1.1.128 P1 (Brazilian variant)	Emergent lineage in Manaus (Brazil)	Spike L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, H655Y, T1027I6S, D138Y, R190S, K417T, E484K, N501Y, H655Y, T1027I	No impact	No impact	No impact

All of the listed variants above concentrate the highest incidence of genetic variability on the S-gene that encodes for the Spike protein. None of the assays included on the QIAGEN products targets the S-gene to detect SARS-CoV-2.

	QIAstat-Dx Respiratory SARS-CoV-2 Panel	NeuMoDx SARS-CoV-2 Assay	NeuMoDx Flu A-B/RSV/SARS-CoV-2
Genomic regions targeted by the QIAGEN products	E-gene & Orf1ab gene	N- gene & Nsp2 gene	Nsp2 gene

From the onset of the novel coronavirus outbreak, QIAGEN's dedicated global teams have been working around the clock to support the worldwide fight against COVID-19. We will continue with our genetic variation surveillance on a regular basis. Please do not hesitate to reach out to your local QIAstat-Dx or NeuMoDx specialist with questions.

References:

1. Shen Z, et al. Clin Infect Dis 2020
2. Penarrubia L, et al. Int J Infect Dis 2020
3. https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-risk-related-to-spread-of-new-SARS-CoV-2-variants-EU-EEA.pdf
4. Penarrubia L, et al. Int J Infect Dis 2021

* Products and product claims may differ from country to country based on regulations and approvals. Contact your country representative for further details.