Current altona Diagnostics SARS-CoV-2 test kits reactivity analysis (Apr 14, 2024)

Section 1 does focus specifically on the S gene mutations as these are of the highest public concern. Not only due to the possible implications for molecular diagnostic assays but even more so due to potential devastating effects on vaccine efficiency and possible immune evasion of these variants.

Section 2 shows the summarized results from our latest bioinformatical analysis including all newly retrieved sequences collected from different online sources between Mar 11, 2024 to Apr 14, 2024.

Section 1: Variants of concern and other spike mutations

The Omicron viruses account for over 98% of the publicly available sequences since February 2022 and constitute the genetic background from which new SARS-CoV-2 variants will likely emerge, although the emergence of variants derived from previously circulating VOCs or of completely new variants remains possible. Therefore, the Omicron sublineages are independently classified as variants of different public importance. Among those are the variants listed in Table 1:

Table 1: SARS-CoV-2 variants

	WHO Label	PANGOLIN Lineage	Nextstrain clade	Earliest documented samples
Variants of interest (VOIs)	Omicron	XBB.1.5	23A	21-10-2022
	Omicron	XBB.1.16	23B	09-01-2023
	Omicron	EG.5	Not assigned	17-02-2023
	Omicron	BA.2.86	23I	24-07-2023
	Omicron	JN.1	Not assigned	25-08-2023
Variants under monitoring (VUMs)	Currently no VUMs identified.			

None of the mutations contained in the above-mentioned variants does impact the performance of the S gene detection system included in the RealStar®, FlexStar® and AltoStar® kits for detection of SARS-CoV-2.

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Section 2: *In silico* reactivity analysis

Inclusivity data were collected from 11.03.2024 to 14.04.2024 and *in silico* analysis was performed using the newly published sequences and data from the indicated time period (see Table 2).

Table 2: Inclusivity (*In silico* analysis for **67,692** whole genome sequences of SARS-CoV-2 published via GISAID e.V. (www.gisaid.org) and via National Center for biotechnology Information (www.ncbi.nlm.nih.gov) as of Mar 11, 2024 to Apr 14, 2024 for the E gene and the S gene target included in the RealStar®, FlexStar® and AltoStar® kits for detection of SARS-CoV-2.

67692 whole genome sequences (11.03.-14.04.)		**Percentage of sequences showing mismatches**
E gene	Forward Primer	84.35
	Reverse Primer	0.07
	Probe	0.15
S gene	Forward Primer	0.90
	Reverse Primer	0.58
	Probe	0.83

Depending on the mutation frequency and position wet lab experiments in the cause of the post market surveillance activities for the RealStar®, FlexStar® and AltoStar® kits for detection of SARS-CoV-2 were done and so far confirmed that the performance was not affected by such mutations.

Including all previous and this latest data analysis, we have not yet found sequences in the database rendering the respective products for SARS-CoV-2 detection useless or severely diminishing their performance.