Current altona Diagnostics SARS-CoV-2 test kits reactivity analysis (May 22, 2022)

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 April 18, 2022 to May 22, 2022.

Section 1: Variants of concern and other spike mutations

Several SARS-CoV-2 lineages originating from different regions of the world have been described so far. Among those are the variants listed in Table 1:

Table 1: SARS-CoV-2 variants

	WHO Label	PANGOLIN Lineage	GISAID Lineage	Likely Origin
Variants of concern (VOC)	Delta	B.1.617.2 + AY x	G/478K.V1	India
	Omicron*	B.1.1.529	GRA	Multiple countries
Previously circulating VOCs	Alpha	B.1.1.7	GRY	United Kingdom (UK)
	Beta	B.1.351	GH/501Y.V2	South Africa
	Gamma	P1	GR/501Y.V3	Brazil
Previously circulating variants of interest (VOIs)	Epsilon	B.1.427 + B.1.429	GH/452R.V1	California, US
	Zeta	P.2	GR/484K.V2	Brazil
	Eta	B.1.525	G/484K.V3	UK/Nigeria
	Theta	P.3	GR/1092K.V1	Philippines
	Iota	B.1.526	GH/253G.V1	USA
	Kappa	B.1.617.1	G/452R.V3	India
	Lambda	C37	GR/452Q.V1	Peru
	Mu	B.1.621+ B.1.621.1	GH	Colombia
Variants under monitoring (VUMs)	-	B.1.640	GH/490R	Multiple countries

* Includes BA.1, BA.2, BA.3, BA.4, BA.5 as well as BA.1/BA.2 circulating recombinant forms such as XE.

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.

Section 2: *In silico* reactivity analysis

Inclusivity data were collected from 18.04.2022 to 22.05.2022 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 **503,746** 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 April 18, 2022 to May 22, 2022 for the E gene and the S gene target included in the RealStar®, FlexStar® and AltoStar® kits for detection of SARS-CoV-2.

503,746 whole genome sequences (18.04.-22.05.)		Percentage of sequences showing mismatches
E gene	Forward Primer	95.54
	Reverse Primer	0.05
	Probe	0.10
S gene	Forward Primer	0.23
	Reverse Primer	0.14
	Probe	0.27

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.