Current altona Diagnostics SARS-CoV-2 test kits reactivity analysis (Oct 19, 2026)

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 Aug 24, 2026 to Oct 19, 2026.

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	JN.1	24A	25-08-2023
Variants under monitoring (VUMs)	Omicron	PQ.16.1.1	25B	25-03-2024
	Omicron	NB.1.8.1	25B	22-01-2025
	Omicron	XFG	25C	27-01-2025
	Omicron	BA.3.2	Not assigned	22-11-2024

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.

altona Diagnostics GmbH
Mörkenstr. 12
22767 Hamburg
Germany

Tel. +49-40-548 06 76-0
Fax +49-40-548 06 76-10
info@altona-diagnostics.com
www.altona-diagnostics.com

General Manager:
Hans Kuhn, Dr. Sönke Friedrichsen,
Dr. Markus Hess
Commercial Register 10 23 88
VAT ID No.: DE 256 50 20 23

Deutsche Bank AG, Hamburg
IBAN: DE32 2007 0000 0091 1966 00 BIC: DEUT DE HH XXX
Sydbank A/S, Hamburg
IBAN: DE85 2003 0600 1000 5992 70 BIC: SYBK DE 22

Section 2: *In silico* reactivity analysis

Inclusivity data were collected from 24.08.2026 to 19.10.2026 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 **16,473** 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 Aug 24, 2026 to Oct 19, 2026 for the E gene and the S gene target included in the RealStar®, FlexStar® and AltoStar® kits for detection of SARS-CoV-2.

16473 whole genome sequences (24.08.2026-19.10.2026)		**Percentage of sequences showing mismatches**
E gene	Forward Primer	98.68
	Reverse Primer	0.02
	Probe	0.12
S gene	Forward Primer	0.38
	Reverse Primer	2.88
	Probe	15.65

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.