Statement on the detectability of mutant SARS-CoV-2 virus variants with COVID-19 antigen rapid tests from nal von minden GmbH

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Since the outbreak of the SARS-CoV-2 pandemic, various mutations have occurred in this virus, resulting in a large number of variants. The majority of these mutations have no discernible effect on the virus, its infectivity or the course of COVID-19 disease. Recently, however, some virus variants proved to be more infectious and less susceptible to the immune response of both vaccinated and recovered people [1-4]. Those viruses are termed "V*ariants of Concern* (VOC)" and "V*ariants under Investigation* (VUI)", respectively.

These mutants (VOC, VUI) usually show an abundance of characteristic mutations in the spike protein (S-protein), whereas the nucleocapsid protein (N-protein) is usually only affected in isolated cases (see Table 1). Since our COVID-19 antigen rapid tests detect the N-protein of SARS-CoV-2, we can currently assume that mutations of the S-protein have no effect on the detectability of the viruses by COVID-19 antigen rapid tests of nal von minden GmbH.

According to information from the *European Centre for Disease Prevention and Control* (ECDC) [2] and citing a study by *Public Health England* [4, 5], there is no evidence of negative effects of the virus variants B.1.1.7 (VOC-20DEC-01) and B.1.351 (VOC-20DEC-02) on the results of COVID-19 antigen rapid tests. A study by the *Bavarian State Office for Health and Food Safety* (*Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit*, LGL) [7] as well as our previous investigations confirm the detection of these two mutants with identical performance for the nal von minden NADAL COVID-19 antigen rapid test.

Furthermore, our previous laboratory results show that the variants P.1 (VOC-21JAN-02) and B.1.617.1 (VUI-21APR-01) are unrestrictedly detectable with the nal von minden COVID-19 antigen rapid tests. Since the other Indian variants B.1.617.2 (VOC-21APR-02) and B.1.617.3 (VUI-21APR-03) each have only one additional mutation in the nucleoprotein compared to B.1.617.1, we currently assume that our COVID-19 antigen rapid tests will also detect these two mutants. Further studies are already being planned and will be available in the next few weeks.

From a scientific point of view, it can currently be assumed that the virus variants from Great Britain (B.1.1.7), South Africa (B.1.351), Brazil (P.1) and India (B.1.617) can be detected without loss of performance with the nal of minden COVID-19 antigen rapid tests.

Table 1: Mutations in *Variants of Concern* (VOC) and *Variants under Investigation* (VUI) of SARS-CoV-2 [3, 8, 9].

Status	WHO-Nomenklatur	Linie	Bezeichnung	Erstdetektion	Mutationen im S-Protein	Mutationen im N-Protein
VOC	Alpha	B.1.1.7	VOC-20DEC-01 (20I/501Y.V1)	UK	Δ69/70, Δ144, (E484K*), (S494P*), N501Y, A570D, D614G, P681H, T716I, S982A, D1118H (K1191N*)	D3L, R203K, G204R, S235F
VOC	Beta	B.1.351	VOC-20DEC-02 (20H/501.V2)	Südafrika	D80A, D215G, Δ241/242/243, K417N, E484K, N501Y, D614G, A701V	T205I
VOC	Gamma	P.1	VOC-21JAN-02 (20J/501Y.V3)	Japan/ Brasilien	L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, (V1176F*)	P80R, (R203K*), (G204R*)
VOC	Delta	B.1.617.2	VOC-21APR-02 (20A/S:478K)	Indien	T19R, (G142D*), 156del, 157del, R158G, L452R, T478K, D614G, P681R, D950N	D63G, R203M, D377Y, (R385K*)
VOI	Kappa	B.1.617.1	VUI-21APR-01 (20A/S:154K)	Indien	(T95I*), G142D, E154K, L452R, E484Q, D614G, P681R, Q1071H	R203M, D377Y
VOI	n.v.	B.1.617.3	VUI-21APR-03 (20A)	Indien	T19R, G142D, L452R, E484Q, D614G, P681R, D950N	P67S, R203M, D377Y

* Those mutations were only found in some isolates, thus they are not deemed to be “variant-defining mutations”.

Literatur:

[1] Investigation of SARS-CoV-2 variants of concern in England, Technical Briefing 10, 07.05.2021, *Public Health England*.

[2] Risk related to spread of new SARS-CoV-2 variants of concern in the EU/EEA, Rapid Risk Assessment, 29.12.2020, *European Centre for Disease Control and Prevention (ECDC)*.

[3] SARS-CoV-2 Variant Classifications and Definitions, 15.06.2021, *National Center for Immunization and Respiratory Diseases (NCIRD)*.

[4] SARS-CoV-2 variants of concern and variants under investigation in England, Technical briefing 15, 11.06.2021, *Public Health England.*

[5] SARS-CoV-2 lateral flow antigen tests: evaluation of VUI-202012/01, 23.12.2020, *Public Health England*.

[6] SARS-CoV-2 lateral flow antigen tests: evaluation of VOC1 (Kent, UK) and VOC2 (South Africa), 12.02.2021, *Public Health England*.

[7] Jungnick S., Hobmaier B., Mautner L. *et al.*; Bavarian SARS-CoV-2-Public Health Laboratory Team; Bavarian SARS-CoV-Public Health Laboratory Team. Detection of the new SARS-CoV-2 variants of concern B.1.1.7 and B.1.351 in five SARS-CoV-2 rapid antigen tests (RATs), Germany, March 2021. *Euro Surveill*. 2021 Apr;26(16):2100413. doi: 10.2807/1560-7917.ES.2021.26.16.2100413.

[8] https://outbreak.info/situation-reports, reviewed 22.06.2021

[9] https://cov-lineages.org/global_report.html, reviewed 22.06.2021.