nal von minden GmbH rapid test detects the Delta variant

The Delta variant is continuing to spread. “In order to stop it, we need to make sure that we are not transmitting coronavirus to other people,” explains the Federal Ministry of Health, which advises people to get themselves tested. “It is important that the tests can detect the coronavirus mutation. According to a current study by the medical-technology company from Moers (Germany), the nal von minden GmbH rapid test reliably detects the Delta variant. The NADAL COVID-19 antigen test also comes recommended by the Federal Ministry of Health as a means of stemming the pandemic.

“Our rapid test reliably detects the Delta variant” says Tobias Roth, a biochemist at nal von minden GmbH who specialises in virology. This is shown by a current study carried out by the medical-technology company from Moers, Germany. “We had viral proteins from the mutated Delta variant sent to us and then carried various series of tests using our own rapid test. The result is clear: the Delta variant is detected."

“Those who use our rapid test can be sure that it will detect the Delta variant“, says Roland Meißner, CEO at nal von minden GmbH. “As the Delta variant is particularly contagious and very widespread, people need reassurance over the quality of rapid and home-use tests. It was therefore very important to us to closely examine the Delta variant in relation to our coronavirus rapid test."

For the study, nal von minden GmbH generated different dilution series of the nucleocapsid protein (N protein) of the Delta variant. Tobias Roth explains: “Our rapid test uses the so-called nucleocapsid protein as analyte in order to detect a coronavirus infection. This N-protein is also contained within the Delta variant. It acts as a stable shell surrounding the genetic material (RNA) inside the coronavirus. The NADAL test is then used to examine all concentrations of the dilution series in three identical test series (replicates). We can detect the Delta variant just as reliably as the original strain!” In addition, further studies have shown that other previous mutations (referred to by scientists as "Variants of Concern") from Great Britain, South Africa and Brazil (B.1.1.7, B.1.351 and P.1) are also easily recognised.

Therefore, the high quality that characterises the NADAL rapid test also extends to the Delta variant. The diagnostic specificity is over 99.9 percent, whilst the diagnostic sensitivity is 97.56 percent. The specificity indicates whether healthy people who get tested are in fact healthy, while the sensitivity indicates whether sick people are to be identified as such.

A swab obtained from the lower nasal passage is all that is required to carry out a NADAL COVID-19 antigen test. Results are available after 15 minutes.

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Moers
Fon:+49 2841 99820-0
Fax:+49 2841 99820-1

Friedenstraße 32
93053 Regensburg
Deutschland

Regensburg
Fon: +49 941 29010-0
Fax: +49 941 29010-50

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse Regensburg
Kto. 8400 170 73
BLZ 750 500 00
IBAN: DE98 7505 0000 0840 0170 73
BIC: BYLADEM1RBG

info@nal-vonminden.com
www.nal-vonminden.com

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

issued: 2021, June 24th

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-Nomenclature	Lineage	Identifier	First Detection	Mutations in the S-Protein	Mutations in the 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*)
VUI	Kappa	B.1.617.1	VUI-21APR-01 (20A/S:154K)	Indien	(T95I*), G142D, E154K, L452R, E484Q, D614G, P681R, Q1071H	R203M, D377Y
VUI	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".

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