This Document is part of the Technical Documentation File	
Based on:	
DIN EN ISO 14971:	Medical devices – Application of risk management to medical devices, English version of DIN EN ISO 14971:2012
Scope	to identify the hazards associated with this *in vitro* diagnostic (IVD) medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls

Responsible manufacturer:	nal von minden GmbH Carl-Zeiss Str. 12 47445 Moers Germany
Product:	COVID-19 Ag Test Test for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens Format: Cassette Test, single pouched and derived variants (as listed in Annex B8)
Sample Material	human nasal, nasopharyngeal and oropharyngeal specimens* *sample collection with provided swabs; before application to the test cassette, swabs are extracted in the provided buffer
REF (Article#):	For main nal von minden Products*: 243103X-Y e.g. 243103N-20 X-Y = optional extension for different variants (X: optional letter code; Y: optional number code for kit size After number code (Y), REF can be further extended by letter codes. E.g. 243103N-20PB for NADAL® COVID-19 Ag Test kits with specimen collection tubes pre-filled with buffer) *Customer specific variants, brand name variants or variants in language, kit sizes or kit-specific accessories are possible and might have deviating REF (refer to confidential Annex B8 for an overview of available product variants)
Classification: (according to IVDD 98/79/EC)	Other device (all devices except Annex II and self-testing devices)
Product Certification Conformity Assessment Route	IVDD 98/79/EC Annex III
Written by:	Dr. J. Bohne / Dr. P. Jähde
Rev# replaced version **(also refer to History)**	1.0 (2020-09-15)

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1. Risk Analysis / Evaluation according to EN ISO 14971

1.1. Description of product

The NADAL® COVID-19 Ag Test (in the following also referred to as COVID-19 test or test) is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in human nasal, nasopharyngeal and oropharyngeal specimens. This test is intended for use as an aid in the diagnosis of infections with SARS-CoV-2. Note that the concentration of viral nucleoprotein antigens may vary in the course of the disease and might fall below the detection limit of the test. Possible infectiousness of test subjects cannot be ruled out based on negative test results. The NADAL® COVID-19 Ag Test is designed for professional use only.

From test principle, test components, test procedure, result interpretation the test is comparable to typical rapid tests (sandwich immunoassays). Anti-SARS-CoV-2 antibodies are pre-coated onto the test line region 'T'. During testing, the specimen reacts with anti-SARS-CoV-2 antibodies, which are conjugated to coloured particles. The mixture then migrates along the membrane by capillary action and reacts with the anti-SARS-CoV-2 antibodies in the test line region 'T' of the membrane. The presence of a coloured line in the test line region indicates a positive test result. The absence of a coloured line in the test line region indicates a negative result.
Real time stability studies have not been finished yet, because the test is a very recently developed product. Accelerated stability studies indicate that the test is stable if stored at 2-30 °C until the printed expiry date on the pouch. The test must remain in the sealed foil pouches until use.

COVID-19 (Corona Virus Disease) is the infectious disease caused by the recently discovered coronavirus SARS-CoV-2. This new virus was unknown before the disease outbreak in Wuhan, China, in December 2019. The current Gold Standard for the Diagnosis of COVID-19 is the detection of viral RNA via RT-PCR from nasal- and throat swab samples. Due to the very high sensitivity of RT-PCR, the presence of SARS-CoV-2 in patient samples can be shown even before the onset of actual disease symptoms. Antigen rapid tests have a lower sensitivity than PCR due to the lack of analyte

amplification during the detection process. Therefore, rapid tests need higher virus titres, which can take some time to develop and might even stay below the detection limit of rapid tests. Their advantage though is the very short time between sample collection and availability of the test result.

The result of the COVID-19 Ag test might have an influence on decisions about patient care, although currently the impact of antigen rapid test results on patient management is not clear. There is a clear indication that antigen tests should only be used in conjunction with other testing methods e.g. RT-PCR, which remains the gold standard for the detection of SARS-CoV-2 infections especially very early after infection due to its high sensitivity. In addition it is required to take into account the patient history e.g. if there has been a known exposure to SARS-CoV-2 by contact to infected persons. Tests are only an aid in diagnosis. Results must not be used as a sole criterion for a diagnosis. However, it is assumed that rapid antigen test are a useful supportive tool for quickly identifying patients with high virus titre, which can for instance help to initiate quarantine measures faster than with PCR testing alone.
In order to take into account that the test results can depend on the stage of the disease, the intended use section of test gives the information that virus levels might fall below the detection limit of the test over the course of the disease. The intended use section also give a reference to the section LIMITATIONS that includes the following information (Copied from version 7.0, 2021-03-11):

- The COVID-19 Ag Test is for professional *in-vitro* diagnostic use only. It should be used for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in human nasal, nasopharyngeal or oropharyngeal specimens only. Neither the quantitative value nor the rate of increase/decrease in the concentration of SARS-CoV-2 viral nucleoprotein antigens can be determined with this qualitative test.
- The COVID-19 Ag Test only detects the presence of SARS-CoV-2 viral nucleoprotein antigens in specimens and should not be used as the sole criterion for a diagnosis of COVID-19.
- Both viable and non-viable SARS-CoV-2 viruses can be detected using the COVID-19 Ag Test.
- The sections 'Specimen Collection and Preparation' as well as 'Test Procedure' must be followed closely while testing. Failure to follow them may lead to inaccurate test results because the antigen concentration in the swab is highly dependent on the correct procedure.
- As with all diagnostic tests, all results should be interpreted in conjunction with other clinical information available to the physician.
- In the course of SARS-CoV-2 infection, the concentration of viral nucleoprotein antigens may fall below the detection limit of the test.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of a SARS-CoV-2 infection and should be confirmed via molecular assay.
- Positive and negative predictive values are highly dependent on prevalence. The local prevalence should be taken into consideration when interpreting diagnostic test results.
- Positive results do not preclude co-infections with other pathogens (e.g. influenza virus A/B).

This RA will discuss measures that have been introduced to reduce the risk to an acceptable level. In addition, suitability of the tests for the given intended use will be rated on the basis of the available study results.
This will be done with the aid of the tables starting at chapter 1.3.

Tests kits comprise

- NADAL® COVID-19 Ag Test cassettes (generate the test result after sample addition)*
- Sterile swabs**
- Extraction tubes with dropper caps
- Buffer bottles (buffer facilitates flow and antigen extraction)***
- Reagent holder
- 1 package insert (providing detailed instructions how to use the test, the intended use, precautions, limitations, summary about performance studies)

** Test cassettes are also optionally available as versions printed with QR codes*
*** Due to possible supply shortages of COVID-19 related accessory medical products, the swab manufacturer might change.*

**** Different variants exist:*
- Buffer in bottles: Either in 2 bottles (7 mL each) or 1 bottle (10 mL). Both options are sufficient for 20 determinations.)
- Buffer in ampoules: 20 buffer ampoules for single use (400 µL each)
- Specimen collection tubes containing buffer (400 µL each). Here, no additional buffer bottles or ampoules are part of the kit.

A detailed list of provided materials can be found in the respective PIs.

1.2. Estimation of Risks based on Severity of Damage and Probability of Occurrence

DIN EN ISO 14971, Annex D

The risk is estimated with the aid of a risk-diagram (see below). The diagram defines three different areas according to the severity of the expected damage (patient and/or user of the test device) and the probability of the occurrence.

Definition of Severity (S)

DIN EN ISO 14971, Annex D 3

The different grades of the severity of the caused damages can be described in the following way. Severity is usually determined by the parameter of the test (analyte) but also by the contribution that the result of the rapid test will have on the diagnosis.

S1	negligible	no damage, minor damage
S2	minor	damage reversible, damage can be compensated
S3	severe	damage that requires medical treatment but no permanent health threat
S4	very critical	Severe health damage
S5	catastrophic	Losses of Lives

Invalid results **S1**

The user will notice the invalid result and will repeat the testing with a new assay. There might be short delay and minor inconvenience (e.g. new test costs money, or it is necessary to obtain a new sample) but no severe effects for patients' health status are expected.

False positive results **S2/S3**

A positive result of the test will never be seen isolated. It is clearly pointed out in the PI that results must always be interpreted in the clinical context (e.g. patient history, other testing methods like viral RNA detection by RT-PCR, CT imaging of lung). Therefore, it can be strongly assumed that no critical patient management decisions will be done based on the positive result of the antigen test alone. However, a positive result might contribute to decisions about follow-up examinations that will cost money and men power. Positive test result might also have an influence on quarantine decisions for the patients. This will cause a mere inconvenience if the patient stays at home with moderate symptoms. But if the patient is in a hospital, a home for the elderly or in comparable surroundings quarantine measures might generate costs and extra work. In addition, patients might undergo psychological distress thinking they have SARS-CoV-2 infection. All this will most likely be temporary because follow-up tests will reveal that the result was false positive.

Severity of false positive results is rated with S2 regarding patient health but with S3 for the impact that it might have on "institutions".
Please note that it might be necessary to re-rate severity for false positive results in dependence on future recommendations for patient management decisions in relation to antigen rapid tests.

False negative results S3

Also a negative result of the test will never be seen isolated. It is clearly pointed out in the PI that results must always be interpreted in the clinical context (e.g. patient history, other testing methods like viral RNA detection by RT-PCR, CT imaging of lung). The intended use points out that users should be aware that antigen levels might be too low for detection with an immunochromatographic rapid test at all stages of COVID-19. Therefore, RT-PCR remains the more sensitive gold standard for testing in early stages of the disease, and the antigen rapid test can only provide quick supportive information for patients with high viral loads at the time of sample collection. Critical situations might occur if a negative result is falsely interpreted by the user (e.g. doctor's office) to be a 100% guarantee that the patient is not infected with SARS-CoV 2 and will not start additional tests or will not recommend "social isolation" for the patient but send him home without any precautions. In this case, the patient might infect other persons. In addition, the patient might feel too safe and might react too slowly if his symptoms worsen. In this case, there might be a delay in treatment.
We consider these scenarios as extremely unlikely for the following reasons: 1) there are sufficient warnings in the PI that the test is only an aid in diagnosis and that results must never be interpreted isolated. 2) It is hardly imaginable that a patient with typical symptoms matching COVID-19 will not be quarantined until it is clearly confirmed that he does not suffer from the disease. At the moment, antigen rapid tests are not the gold standard for this decision but RT-PCR aiming at the detection of viral RNA. Even without testing there is the recommendation to socially isolate patients who show the respective symptoms or are strongly suspected of being infected with SARS-CoV-2 (e.g. because of close contact to patients diagnosed with COVID-19).
If symptoms are so severe that patients are in hospital it can be strongly assumed that sufficient experience and testing materials are available and that patients will undergo the whole "diagnostic arsenal". It can also be assumed that symptoms of the patient e.g. breathing difficulties will be treated regardless of negative test results.
Severity of false negative results is rated with S3. Although the disease is critical at the moment, the contribution of antigen rapid test results to diagnosis and patient management decisions is most likely only minor. Please note that it might be necessary to re-rate severity for false negative results in dependence on future recommendations for patient management decisions in relation to antigen rapid testing.

Definition of Probabilities (P)

DIN EN ISO 14971, Annex D 3

Probability estimates how frequent a certain event (hazard) is to be expected. The probability of occurrence is determined by the test characteristics, by user mistakes that might occur during normal use but might also be introduced deliberately by the user, and by the chance that the user notices that generated results are false or invalid so that there is no impact on patient's health.
The different grades of probability for the medical product are defined in the following way:

P1	hardly imaginable	Hardly any cases known	1-2 tests/100,000

P2	very unlikely	Very few cases per year	3-9 tests/100,000
P3	unlikely	Several cases per year	1-9 tests/10,000
P4	seldom	Several cases per months	1-9 tests/1,000
P5	probable	May occur during use of the product	1-9 tests/100
P6	frequent	Occurs very frequently during use of the product	1-5 tests/10

Based on the different grades of probability and severity the three areas for risk estimation are defined in the following way:

a) Safe Area (R1): The risk is very low if compared to other risks. Due to the beneficial effects of the medical device it is negligible. The risk is acceptable.
b) ALAP Area (R2): The beneficial effects of the medical device are higher as the risks. The remaining risks cannot be minimized/eliminated further. The risk is acceptable for the moment but the manufacturer must be alert if there are any new /improved ways for risk reduction
c) Unsafe Area (R3): Risks are too high to justify the use of the medical device. The risk is unacceptable.

P6				**Unsafe area**	**(R3)**
P5					
P4		**ALAP**	**area**		
P3			**(R2)**		
P2					
P1	**Safe Area**	**(R1)**			
	S1	**S2**	**S3**	**S4**	**S5**

P: Probability S: Severity R: Risk

Explanation for the definition of the areas:

a) Safe area: As "safe“ area probability P1 (hardly any cases known) and P2 (very unlikely, very few case per year) are defined as long as no severe health damages (S4) or losses of lives (S5) are to be expected. Probability P3 (unlikely, several cases per year) is defined as safe, as long as the expected damages and adverse effects are reversible or only minor. Probability P4 is accepted for this area only if only negligible damages are to be expected.
b) Unsafe area: As „unsafe“ we define conditions that would occur at a very high frequency (probability P6). All possible hazards that may result in severe injuries or health damages belong to the unsafe area, as long as the probability of their appearance is not defined as hardly imaginable or very unlikely (P1, P2). Hazards that may result in death always belong to the unsafe area.
c) ALAP area: This area (risk As Low As Possible) includes all the other combinations (white area of the diagram) that are not defined as safe or as unsafe area. Especially for this area it should be looked if any additional measures for risk reduction can be found.

1.3. Estimation of Risk for the Patient

According to Annex H. 2.5.

For each identified hazard in the following table the residual risk for the patient will be estimated based on the following issues (if applicable)

- likelihood of occurrence
- if applicable measures taken to reduce likelihood of occurrence e.g. temperature sensitive pads during transportation to detect accidental warming up
- rating possibility if a malfunction (especially false/invalid results) could be detected by the user e.g. by application of internal controls
- measures taken to reduce the risks either test immanent features (e.g. leakage control, labelling, packaging etc.) or warnings in PI to prevent false use (unambiguous intended use section, warning in PI not to use results as single basis for diagnosis, limitations section, performance section etc.)

The following tables follow closely the structure of standard DIN EN ISO 14971 and help to identify product characteristics and possible operator errors that might occur (normal use, reasonable foreseeable misuse, abnormal use (intentional misuse)).

Explanations to tables

Possible Hazard	What kind of hazardous situation for the operator and/or the patient might occur if this issue “failed” due to user error and unsuitable product characteristics
S	Grade of severity
P initial	Estimated probability of occurrence without risk reducing measures
Explanation if indicated measures for risk reduction are listed	What is the basis for estimating/rating the hazard What kinds of measures for risk reduction are applied? Is it likely that the user will notice the failure?
Measures sufficient	Are risk reducing measure sufficient (yes) or are there feasible ways for further improvement (no) Especially if the final Risk is higher than R1 re-check if there are further possibilities for risk reduction
P final	Estimated probability of occurrence after introduction of measures for risk reduction
Document	Reference to document where is the information found
Risk	Gives the residual risk according to the defined areas

Notes:
At the moment, there is a high dynamic for COVID-19 regarding recent studies, publications and knowledge about disease progression. Intensive literature research is done in order to see if any new risks can be identified that might make an adjustment of this RA necessary.

Usually non-list A, list B products are rated as products of moderate risk and the Risk Assessment is done with the aid of two forms FO136a (Group Specific Risk Management Report) that covers the general risks of rapid tests for a certain product group (e.g. non-critical infectious disease group). This

document is amended by FO136b (Product-specific Risk Assessment as Amendment of Group-Specific RA), rating risks that only apply to individual products.
Because COVID-19 is a new disease and is rated as pandemic because of high impact on patient health and high contagiousness, FO136b will be completely filled out for this product so that it is not an amendment but a complete Risk Assessment.

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.

1.3.1 Characteristics of medical device that could impact on safety

DIN EN ISO 14971; Appendix C

Appendix C	Qualitative product characteristics	Possible Hazard N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed	Measures sufficient	P final	Document N/A= not appl.	Risk R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
C 2.1	What is the intended use and how is the medical device to be used?	If intended use is not clearly defined, user might use test results in the wrong context and draw false conclusions for diagnosis	S3	P3	Intended Use must be clearly defined to reduce the probability of misuse. Intended use gives information about the detected analytes (SARS-CoV-2 viral nucleoprotein antigens), patient group and that the test is intended to be used as aid in diagnosis only by professional users. A reference to limitations is given. Because even in SARS-CoV-2 infected patients the antigen level might be below the detection limit, this is pointed out in the intended use section. PI provides the required information to the user: *The NADAL® COVID-19 Ag Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in human nasal, nasopharyngeal or oropharyngeal specimens (see section 12 'Limitations'). This test is intended for use as an aid in the diagnosis of infections with SARS-CoV-2. Note that the concentration of viral nucleoprotein antigens may vary in the course of the disease and might fall below the detection limit of the test. Possible infectiousness of test subjects cannot be ruled out based on negative test results. The test procedure is not automated and requires no special training or qualification. The NADAL® COVID-19 Ag Test is designed for professional use only.*	yes	P2	PI TD	R1
C 2.2	Is the medical device intended to be implanted?	N/A			Not implantable, tests are in-vitro diagnostic devices			N/A	N/A
C 2.3	Is the medical device intended to contact the patient or other persons?	Not adequately sterilized means of sample collection might be potentially infectious or might	S3	P4	The device does not come in contact with the patient, since it is an in vitro diagnostic device. Means of sample collection might have contact with the patient and might be part of kit. If they are sterile,	Remains in ALAP, because the use of protective lab	P3	PI	R2

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
		contaminate the collected sample. Chemically hazardous or potentially infectious test components might come into contact with the user during handling			origin is stated in PI and reliability of supplier is ensured. Professional user will come into non-invasive contact during the test procedure. Generally, lab garment (gloves, lab coat etc.) is recommended during the test procedure and especially during the sample collection procedure to avoid contact with kit components and potentially highly infectious samples. Risk from tests is rated lower than from samples. Precautions regarding potentially infectious materials are given in PI.	equipment is ultimately in the responsibility of the user			
C 2.4	What materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Chemically hazardous or potentially infectious test components might come into contact with the user during handling	S3	P3	Tests: Plastic Housing, Plastic Carrier, Cellulose, Glass Fiber, Nitrocellulose, Polyester, Proteins, surfactants, buffer components, salts, carbohydrates, polymers and preservatives. Active ingredients: anti-SARS-CoV-2 antibodies conjugated to coloured particles and anti-SARS-CoV-2 antibodies immobilized in the T-line region of the membrane. All chemicals can be found at very low concentrations on the test strip placed inside the cassette housing. Buffers: Tris buffer with NaCl, proteins and detergent Preservatives sodium azide (0.2 mg/mL) No hazard labelling is required according to Regulation (EC) Nº1272/2008 CLP. Concentrations of potentially hazardous substances e.g. NaN_3 are below exemption threshold. No hazard for user or patient can be identified. Flow of liquid is directed by adsorbent pads, accidental buffer spills are reduced by use of dropper bottles. Even though hazard for operator is low a general warning is included in section Precaution in the PI to treat product as potentially infectious because of material of animal origin. A reference to potentially hazardous substances in tests and buffer is given in section Reagents and Materials supplied. Both will raise user awareness.	yes	P2	TD PI MSDS for kits with hazardous components available on request	R1

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C 2.5	Is energy delivered to or extracted from the patient?	N/A			No energy delivered or extracted from the patient.			NA	N/A
C 2.6	Are substances delivered to or extracted from the patient?	This hazard applies only to kits that include materials for sample collection and only if sample is not released spontaneously. Patients might be injured in course of sample collection. “Quality of sample” might be suboptimal so that false results are obtained	S3	P3	Sample material used for testing is derived from the patient: Some of the test materials are released spontaneously like feces or urine, others are collected with materials that are either part of the kit or are supplied by the user. Usually risk of injury is low e.g. for swab taking. If there is an unusual hazard associated with the supplied materials for sample taking this will be mentioned in the PI. For some kits the “quality of the sample” is very crucial for the result. Therefore for all tests information about suitable sample materials is outlined in PI. If there are patient conditions interfering with result formation this information will be given in PI. If there are unsuitable samples e.g. hemolytic, lipemic etc. this information will also be given.	Yes	P2	PI TD	R1
C 2.7	Are biological materials processed by the medical devices for subsequent re-use, transfusion or transplantation?	N/A			No biological materials are processed for re-use, transfusion or transplantation			NA	N/A
C 2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	N/A			No, the rapid test or reagents are not sterile. There is no direct contact to the patient.			NA	N/A
2.9	Is the medical device intended to be routinely cleaned or disinfected by the user?	N/A			No, rapid tests are for single use. Single Use is clearly stated in PI and on packaging labels.			PI and/or Labels state single use	N/A
C 2.10	Is the medical device intended to modify the patient’s environment?	N/A			No, rapid tests are not intended to modify the patient’s environment.			N/A	N/A

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
C 2.11	Are measurements taken?	Changes in detection limits for the test might lead to false results and contribute to a wrong diagnosis.	S3	P3	Test only provides a qualitative yes-no result. No real measurements are taken. But it is essential that the performance of the test is reliable. Test results must always be interpreted in the context of disease progression and the respective pathogen. Studies prove that Inter-, Intra LOT variability is acceptable (see studies for repeatability and reproducibility) QC procedures ensure that the detection limit of the test remain reliable.	yes	P2	PI and TD LOT-specific Certificate of Analysis available on request	R1
C 2.12	Is the medical device interpretative?	See above If visual interpretation is not done correctly by the user, false results might be the consequence that might have an impact on patient treatment decisions.	S3	P3	Qualitative tests: Visual interpretation of test result over the appearance/non-appearance of the T-line at defined “detection limits”. Results (regardless if obtained in laboratory or near-patient setting) will usually be rated by doctors before any diagnosis regarding the health status is made. The diagnosis of an infection must not be based on an isolated rapid test result The decision what kind of treatment or what kind of quarantine measure is suitable remains in the responsibility of the physician. PI clearly explains how to interpret the test result with pictures for positive, negative and invalid results. On cassette assays areas for control line and test line are marked with either “C” or “T” for easy alignment. There are several warnings in the package insert that it is possible that test results are negative because virus titers can be below the detection limit in some patients.	yes	2	PI and TD LOT-specific Certificate of Analysis available on request	R1
C 2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	N/A			Not applicable: test procedure is done manually and result interpretation is visual. One product variant has QR codes printed on the test cassettes. However, the application of QR codes in context of software systems is not in responsibility of			N/A	N/A

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
					nvm. Users must evaluate suitability of software systems on their own. Therefore, following note is given in section *4. Reagents and Materials Supplied* of the package insert: **Note:** nal von minden COVID-19 Ag test cassettes are also optionally available as versions printed with QR codes. These are indicated by the ending 'QR' after the reference number. The individual QR code allows each individual test cassette to be identified electronically for test result documentation. Suitable software systems must be evaluated by the end user themselves.				
C 2.14	Are there unwanted outputs of energy or substances?	Contact to kit reagents or a leaking of liquids from tests after sample addition might pose a chemical or infectious hazard for the user	S3	P3	No outputs of energy but contact with substances is possible. Risk is reduced by the test design. Liquids are usually provided in dropper bottles or in (pre-filled) sample extraction tubes. Sample transfer is done with the aid of dropper caps. Test are designed in a way that liquid is taken up by adsorbent pads so that unwanted outputs of substances is very unlikely Precautions in PI address safe handling by the user.	yes	P2	PI/TD	R1
C 2.15	Is the medical device susceptible to environmental influences?	Deviations in storage temperature might lead to a deterioration of tests that might lead to false or invalid results. If tests and samples are not brought to room temperature, velocity of detection reaction might be influenced leading to false results. If tests are exposed to humidity outside the pouch for a long time this might affect results (false or invalid)	S3	P3	Yes Storage conditions must be kept Extreme temperatures must be avoided Freezing must be avoided. All this information is given in the PI. Storage temperature is also depicted on packaging labels. Test procedure in PI points out that tests and samples must be brought to room temperature before starting the procedure. If removed from the primary packaging tests should be used without significant delay because they are susceptible to humidity – usually short time exposure is tolerated – respective instructions are given in PI. Moderate short time deviation from highest storage temperature (e.g. short time exposure to 55 °C for several days) are usually tolerated by the rapid tests	Yes	P2	PI and Label TD (Stability Studies)	R1

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
					(robustness) Because of the airtight primary packaging tests are not influenced by low air pressure as it might occur during airfreight.				
C 2.16	Does the device influence the environment?	N/A			No, the device is not meant to influence the environment. Information for safe disposal must be observed (see 2.25)			N/A	N/A
C 2.17	Are there essential consumables or accessories with the medical device?	Buffer is required. If buffer vial misses, the user cannot perform the test. If means of sample application are missing, the user cannot start the test procedure. If he uses alternative methods for sample transfer, the sample volume might deviate. This might have an influence on the test result (e.g. invalid).	S3	P3	Yes, refer to PI sections 4 Reagents and Materials supplied and 5 Additional Materials required Here consumables/accessories that are necessary for sample collection/preparation and test procedure are listed. Therefore the user knows which consumables or accessories are included in each kit. If kit components miss, he will complain at nvm and will get replacement.	Yes	P2	TD and PI	R1
C 2.18	Is maintenance and/or calibration necessary?	N/A			No – the user is not involved in any maintenance or calibration procedures. Calibration of rapid tests to the required detection limit is done during the manufacturing process and is confirmed by QC procedures. LOT-specific Certificates of analysis can be made available to customers if requested.			N/A	N/A
C 2.19	Does the medical device contain software?	N/A			No software is contained in the product. One product variant has QR codes printed on the test cassettes. However, the application of QR codes in context of software systems is not in responsibility of nvm. Users must evaluate suitability of software systems on their own.			N/A	N/A

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
					Therefore, following note is given in section *4. Reagents and Materials Supplied* of the package insert: **Note:** nal von minden COVID-19 Ag test cassettes are also optionally available as versions printed with QR codes. These are indicated by the ending 'QR' after the reference number. The individual QR code allows each individual test cassette to be identified electronically for test result documentation. Suitable software systems must be evaluated by the end user themselves.				
C 2.20	Does the medical device have a restricted shelf-life?	If user uses the test after the expiration date, false results (reduced analytical sensitivity) or invalid results (deterioration of test) might be the consequence.	S3	P3	Yes See C2.15 for storage conditions Expiry given on primary and outer packaging. The kit component with the nearest expiry date will determine the shelf-life of the kit. PI points out under Warnings and Precautions that test must not be used after the expiration date although professional users should be aware that expiration date is essential. So far prediction of shelf-life was done with accelerated stability studies. Real Time Stability studies are still in progress.	yes	P2	PI and label TD (Stability Studies)	R1
C 2.21	Are there any delayed or long-term effects?	N/A			No – assays are for single use.			N/A	N/A
C 2.22	To what mechanical forces will the medical device be subjected?	N/A			None if used according to instructions. Mechanical stress during transport is reduced by suitable packaging. If there are any damages they are usually limited to outer container ("crushed kit boxes") that are noticed by the user. These would most likely not influence the performance.			N/A	N/A
C 2.23	What determines the lifetime of the medical device?	If tests is exposed to conditions that accelerate aging false results might be obtained even if the expiry date is not reached yet.	S3	P3	Aging processes usually caused by environmental stress (also refer to C2.15) Aging might be accelerated if storage conditions are not matched - PI, Label give storage conditions Humidity – if removed from protective primary packaging tests are susceptible to humidity and should be used immediately – this is described in PI	yes	P2	Labels PI TD	R1

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
C 2.24	Is the medical product intended for single use?	False results if user tries to re-use a test. This scenario seems extremely unlikely though.	S3	P2	Yes, tests will not function if re-used because the reagents involved in detection reaction are not longer present in the conjugate pad. Users notice that a test is or has been used when the control line is present. Tests are discarded after use so that an accidental mixing up seems unlikely. New tests must always be removed from the primary packaging. Symbol and/or statement for single use are found on packaging labels and in PI.	yes	P1	PI Label	R1
C 2.25	Is safe decommissioning or disposal of the medical device necessary?	Used test might be potentially infectious because of the sample material. In worst case this might contribute to spread of diseases.	S3	P3	Yes, used devices should be discarded according to local regulations because the devices have been in contact with potentially infectious sample material. User is informed about this in PI.	yes	P2	PI MSDS	R1
C 2.26	Does installation or use of the medical device require special training or special skills?	N/A			If procedures were complicated untrained users might make errors contributing to false results. But for rapid tests this does not apply The information in PI is sufficient for professional users to perform the test – no special training is required. Even laymen can handle these kinds of tests (e.g. pregnancy tests). But because of the detected analytes, the kind of sample material and/or possible diagnostic implications, medical background is required for this test. Furthermore, in accordance with IVDD 98/79/EC Annex III, the test is only made available on the market to professional users, and will therefore not be used for self-testing by lay users.			N/A	N/A
C 2.27	How will information for safe use be provided?	If PI is forgotten in the kit the user cannot use the test. If he tries to use the test nevertheless, false results possible or inadequate diagnostic conclusions drawn from the result	P3	S3	PI will always be provided. If the user has questions, a telephone number and/or e-mail address is given at the end of the user instructions so that she might call to get additional guidance or advice. If PI is forgotten (e.g. packaging mistake) user will notice immediately and will ask nvm for replacement or for sending PI by e-mail. Contact information is also found on outer packaging.	yes	P2	PI	R1

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
C 2.28	Will new manufacturing processes need to be established or introduced?	N/A			Not applicable at the moment. The device is self-containing and is designed for single use only. At the moment there is no need to establish or introduce new manufacturing processes. The quality of the product is checked in various quality control steps in process and end. If processes are introduced that might affect the performance of the test (e.g. new active ingredients like antibodies) a new evaluation of the analytical properties of the device has to be done.			N/A	N/A
C 2.29	Is successful application of the medical device critically dependent on human factors such as the user interface?	PI serves as “user interface” Insufficient information in PI might increase probability of user errors leasing to false results or inadequate diagnostic conclusions drawn from results	S3	P3	PI serves as “user interface”, apart from there are no control interfaces (refer to C 2.27) PI should be read before use. This is clearly stated (symbol) on packaging. PI design is according to the requirements of standard 18113-1 und -2. The use of the device with the aid of the supplied accessories (only if applicable) is clearly depicted in the instructions of the PI. The test result is easy to read. The correct performance of the test is shown by the appearance of the control line that serves as a control for sufficient capillary flow.	yes	P2	PI Label Design of assays	R1
C 2.29.1	Can the user interface design features contribute to use error?	See above	S3	P3	PI according to EU standard (see above) Easy and clear information with a lot of pictures is given in PI Used symbols are explained The design features of the medical device are straight forward and the result easy to interpret. Therefore, it seems unlikely that any use error will occur due to unclear information or design.	yes	P2	PI	R1
C 2.29.2	Is the medical device used in an environment where distractions are commonplace?	Distractions might lead to user mistakes e.g. deviations in incubation times - this increases the probability of false positive	S3	P3	Possible Might lead to reading time deviations as possible user mistake. Importance of timer stressed in PI, usually tolerance time for reading result. PI clearly depicts reading time, visual short instruction	yes	P2	PI	R1

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		results (too long incubation) or false negative results (too short incubation).			also shows reading time. Importance of timer or clock stressed in the PI Awareness of professional user.				
C 2.29.3	Does the medical product have connecting or accessory parts?	N/A (consumables and "loose accessories see C 2.17)			Kit components given in PI (accessories and consumables has already been addressed under C 2.17). The test itself generates the result by itself – there are no connecting or accessory parts needed once the sample has been applied. However, correct sample application and correct reading time are important. For this the user needs the kit components and the additional materials stated in PI Accessories/consumables see C2.17. for rating of risk			N/A	N/A
C 2.29.4	Does the medical product have a control interface?				No			N/A	N/A
C 2.29.5	Does the medical product display information?	User actions that influence C-line and/or T-line appearance (e.g. false reading times, false sample volume) might lead to invalid or false results	3	3	Visual result interpretation over appearance/non-appearance of the T-line (test result line) for qualitative tests. Presence/absence of T-lines gives information if the analyte was detected in the sample material. Test procedure, result interpretation is clearly depicted in the PI usually with a picture to facilitate understanding. Frequently "Visual short instructions" are given as label in the kit box that helps the operator memorize critical steps like sample amount, reading time, result interpretation.	Yes	2	PI	R1
C 2.29.6	Is the medical product controlled by a menu?				No			N/A	N/A
C 2.29.7	Will the medical device be used by persons with special needs?				No- patients for which the assays are suitable cannot be grouped together as persons with special needs in the literally sense.			N/A	N/A
C 2.29.8	Can the user interface be				No – there are no options to switch to different			N/A	N/A

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
	used to initiate user actions?				operation modes.				
C 2.30	Does the medical device use an alarm system?				No			N/A	N/A
C 2.31	In what way(s) might the medical device be deliberately misused?	1) Increased risk of false diagnosis if the test result is not interpreted in the context of all symptoms and available patient information. Tests should be used as an aid in diagnosis but not as only mean of diagnosis. 2) Increased risk of false diagnosis if test is not used according to the intended use but for diagnosing a patient condition for which the test performance has not been approved. 3) Risk that severity of disease or progression of disease is over-/underestimated if the user tries to deduce concentrations from T-line intensities although the test only generates a qualitative result. 4) Use test as screening test also on patients that has not experienced symptoms.	3	3	1) Limitations and Intended Use sections in the PI state correct use. Here it is clearly pointed out that tests are an aid in diagnosis and that a single rapid test result should not be used as sole basis for a diagnosis. 2) Intended use clearly states what the test should be used for. Also the name of the test usually indicates what the test is used for (analyte or analyte abbreviation). If the user deliberately uses the test with a non-approved matrix or for a non-approved purpose it can be strongly assumed that the result will not be used for diagnosis without other tests. 3) Intended use and limitations in the PI state that the result is qualitative. 4) Intended Use clearly states to use the test as aid in diagnosis. Screening is not given as intended use. At the moment, antigen level data about patients without clinical manifestation of infection are rare and only few such patients have been included in the clinical study. Therefore, a general screening is not recommended with this test at the moment. In the future the intended use might be amended for the purpose but only if literature or clinical data demonstrate that antigen levels are sufficiently high. General Operators are aware that reliable test result will only be obtained if they follow the user instructions. Since it is in the interest of the operator to obtain a result it	yes	2	PI	R1

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
					seems unlikely that he/she will use the assay other than for the intended purpose. Since a misuse of the device would bring no obvious benefit for the operator it seems hardly imaginable how the test could be deliberately misused.				
C 2.32	Does the medical device hold data critical for patient care?	Decision for treatment and decisions on patient management (e.g. quarantine, social isolation) might be influenced by the test result.	3	3	Users awareness is raised in the PI that the test is only an aid in diagnosis and that a final diagnosis should not be based on the result of the rapid test. Because result of the test might be obtained faster than laboratory testing results (e.g. if used in a doctor's office) it cannot be ruled out that non-suitable decisions are made which will usually be short-lasting. Because user awareness is raised that false negative results are possible, and that infectiousness of patients cannot be ruled out based on negative results, it can be assumed that in case of symptoms doctors will advise patients to stay at home. At the moment, this is a recommendation for all patients suffering of typical symptoms even if no tests are done.		2	PI	R1
C 2.33	Is the medical product intended to be mobile or portable?	No hazard			Tests are mobile and portable because of the small size. There are no risks related to carrying the tests though. They can be performed virtually in any lab surrounding or doctor's office.			Test immanent	R1
C 2.34	Does the use of the medical device depend on essential performance requirements?	False results if the tests do not meet the performance characteristics	3	3	Yes –it is necessary that the assay shows the required performance that is routinely checked during QC procedures and stated in CoA. Other essential performance requirements are not necessary. It is expected that the user keeps closely to the instruction for use in order to provide optimal conditions for the collection of samples and for the functioning of the test.		2	CoA TD - Manufactur-ing process *	R1

* see Chapter 1.4.

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.

1.3.2. Risk analysis for in vitro diagnostic medical devices

according to DIN EN ISO 14971 / Annex H

Appendix H	Product Characteristics Possible User Errors	Possible Hazard N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed	Measures sufficient	P final	Document N/A= not appl. TD: Technical Docu PI: Product Insert	Risk R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
H.2.1.Identification of Intended Uses									
H 2.1.1 H.2.1.2	General Description and Identification of intended uses	If intended use and intended user are not clearly defined, user might use test results in the wrong context and draw false conclusions for diagnosis	3	3	See C.2.1 Intended Use must be clearly defined to reduce the probability of misuse. Intended use gives information about the detected analytes (viral SARS-CoV-2 nucleoprotein), patient group and that the test is intended to be used as aid in diagnosis only by professional users. A reference to limitations is given. Because the antigen levels might vary during the disease, this is pointed out in the intended use section.	yes	2	PI	R1
H2.2 Identification of possible use errors									
H 2.2.2 Identification of possible use errors by lab personnel (operators)									
	Storage of the device in inappropriate conditions	Exposure to high temperature during storage, use after expiration date after long time storage, delayed testing after removal from primary packaging (exposure to humidity) might lead to invalid results or to false results if performance is affected.	3	3	Measures: Storage conditions clearly defined - Information stated in PI and packaging labels regarding storage temperature PI points out that tests must be stored inside the protective pouch PI points out not to leave tests after expiration date. Expiry is given on labels (primary and kit box). Tolerance of tests e.g. stability frequently is a bit longer than expiry on the pouch, outside the pouch tests are usually stable for several hours (not tested for all tests but PI points out to use within one hour or immediately).	y	2	PI Label TD- A6 Stability Studies	R1
	Use of unsuitable	1) Calibrators not part of	3	3	1) Devices are not calibrated by the user	yes	2	TD (QC	R1

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	calibrator, reagent, control	kits – no hazard 2) Reagents: Kits contain buffer- if they are mixed up false results cannot be ruled out			2) Buffer is included. QC checks are done for test/buffer. Precautions in PI point out not to substitute or mix components from different test kits. It can be assumed though that it would not be critical if reagents are interchanged because formulation is usually not changed so that no significant influence on performance is expected. General PI lists materials that are included into the kit so that the operator would notice if a kit component was missing			procedures) PI	
	Use of unsuitable sample matrix	False results if sample matrix is used that has not been approved of, there might be an unknown effect on test results	3	3	Sample material clearly defined Respective information in PI TD includes clinical study with patient samples to prove that tests function under “real conditions”.	yes	2	PI TD -A7 Performance	R1
	Trial to optimize the procedure in order to improve the performance				Not applicable, procedure straight forward and short, no obvious ways for modifications / optimization			N/A	N/A
	Trying short cuts in test procedure	1) Too short reading time might lead to false negative results (will be discussed later)	3	3	1) Reading time is clearly given in PI and for most tests also in “visual short instructions” General: Test procedure extremely short so it is not expected that the operator will look for short cuts	yes	2	PI	R1
	Negligence of device maintenance	N/A			Does not apply - devices are for single use			N/A	N/A
	Deactivation of safety characteristics or failure when putting them into operation	N/A			Does not apply - no safety characteristics that can be activated			N/A	N/A
	Working under detrimental environmental	1) Sample or test not brought to room temperature –	3	3	1) Temperature – test and samples should be brought to RT before use – Information provided in PI 2) Long time exposure to humidity might affect the	yes	2	PI	R1

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	conditions	temperature might influence velocity of detection reactions – false results 2) Direct exposure of unpacked tests to humidity might affect performance – false results			test after removal from the pouch – therefore tests should be used immediately or, at the latest within one hour for some tests – Information provided in PI				
	User mistakes in 1) sample collection								
	a. Injury of patients during collection procedure	Injury of patient during collection procedure – severity of injury will usually not exceed S3 (reversible damage)	3	3	Usually in responsibility of the professional user if not equipment for sample collection is provided with the kit; if means for sample collection are provided reliability of suppliers is ensured e.g. regarding sterility/quality ; if means of sample collection are sterile the supplier will be given in the PI and on the kit box label according to 93/42/EEC	yes	2	if applicable PI	R1
	b. Suboptimal collection e.g. inadequate location, suboptimal time point etc.	Time point of sample collection is important because antigen levels vary during the disease False negative results possible	3	3	If the "quality" of the sample is influenced by correct location (e.g. pharynx versus nose) or sampling technique respective information is given in the PI Generally PI provides sufficient information for sample collection. For some pathogens numbers vary during the course of infection e.g. levels peak at a certain incubation time and then get lower. For COVID-19, antigen levels are expected to be highest in the early phase of the disease.	yes	2	if applicable PI	
	c. Suboptimal storage of the sample material	Unsuitable storage might lead to degradation of analyte – false negative results	3	3	Suitable storage conditions for the sample materials are described in the PI.	yes	2	if applicable PI	R1
	d. Unsuitable anticoagulant for whole blood or plasma	N/A			No blood used for testing			N/A	N/A
	User mistakes in								

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	2) Sample Preparation								
	a. Suboptimal extraction proce-dure e.g. unsuitable swabs, extraction time of swabs too short	Loss of analyte – false results mainly false negative. If swabs are used that do not come with the kit there might be unknown interferences resulting in false negative or false positive results	3	3	PI gives detailed description of the extraction procedure Suitable swabs are provided with the kit and it seems unlikely that they will not be used by the operator.	Yes	2	PI	R1
	b. Suboptimal preparation of sample e.g. hemolysis	False or invalid results possible either by interferences with the detection reaction, by hindering correct migration or by inadequate background discoloration interfering with visual result interpretation (over-looking of faint lines)	3	3	If there are conditions that might interfere with correct result generation this is pointed out in the PI For swab sample materials, especially the importance of proper sample extraction is shown in the package insert.	yes	2	PI	R1
	c. Wrong volume of buffer	1. Analyte either more concentrated or less concentrated – false results 2. Insufficient extraction of analyte	3	3	1) Buffer frequently comes in bottle(s), ampoules or “pre-filled” in extraction tubes ready to use. If operator gives the buffer from dropper bottles into tubes himself, the number of drops is clearly described in the test procedure 2) Test procedure in PI points out how much buffer/sample should be added. General: Usually dropper bottles are used for liquids to ensure safe handling and easy “measuring” of drops. To obtain completely false results the volume difference must be significant.	Yes	2	PI	R1
	d. Buffers mixed up e.g. use 2x buffer A instead of mixing A and B	N/A			Only one buffer is used for testing			N/A	N/A
	User mistakes in 3) Test Procedure								
	a) Sample								

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
	Application								
	− inadequate sample volume	Suboptimal concentration of analyte resulting in false results	3	3	Detailed description usually in wording and with picture in PI how to transfer the sample. Visual short instructions also provided as label inside kit box. Sample is applied via dropper bottle or caps, which allow easy measurement of sample volume	yes	2	PI Design of accessories provided with the kit	R1
	− Insufficient buffer volume	1. Analyte either more concentrated or less concentrated – false results 2. Invalid results if volume of liquid is too low to complete flow.	3	3	1) Buffer frequently comes “pre-filled” in bottle(s), ampoules or in extraction tubes ready to use so that the drop size is quite defined. Operators are instructed to hold the buffer bottle vertically to ensure reliable drop size 2) Test procedure in PI points out how much buffer should be added. 3) No color change of the C-line if volume is too low. General: Usually dropper bottles or dropper caps are used for liquids to ensure safe handling and easy “measuring” of drops. To obtain completely false results, the volume difference must be significant.	yes	2	PI Design of accessories provided with the kit.	
	− Liquid has access to the reaction field (pipetting drops into the wrong area (cassette)	Invalid results In worst case scenario false result are possible if analyte that has not bound to the coloured conjugate blocks the binding sites in the T-line area	3	3	Detailed description in PI and visual short instructions; no formation of the C-line if liquid does not pass the conjugate pad of the test General: Flooding for cassette assays will be noticed – test set-up makes it unlikely that liquid given to the sample well will not run through the conjugate pad but takes a short-cut via the housing	yes	2	PI Set-up of the test	R1
	− Samples/Tests not brought to room temperature	Velocity of detection reaction might be altered – false results	3	3	PI points out that tests and samples should have room temperature usually at the beginning of the section Test Procedure Warning in precautions that temperatures might affect test results.	yes	2	PI	R1
	− Contamination of the test	Invalid results or false results if contaminant contains the analyte, shows	3	3	Users advised to wear gloves Warning in PI not to touch any critical parts of the test (result area)	yes	2	PI	R1

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		a cross reactivity or interference							
	b) Incubation Time								
	− Too short incubation time	Increased tendency to false negative	3	3	Reading time in wording and with picture in PI. With 15 min reading time is short so that the operator does not become impatient. Professional user will be aware that reading time is essential in order to obtain correct results.	yes	2	PI	R1
	− Too long incubation time	Increased tendency to false positive	3	3	See above	yes	2	PI	R1
	− False incubation time for semiquantitative assays	N/A			Test is a qualitative test and not semiquantitative			N/A	N/A
	c) Result Interpretation								
	− Mixing up of test result line and control line	false results or invalid results	3	3	Detailed description usually in wording and with picture in PI cassette assays has imprint on housing that allows clear identification of C-line (C) and T-line (T)	yes	2	PI set-up of tests	R1
	− Mixing up of test result lines for multiparameter tests with more than one T-line	N/A			The test is a single-parameter test			N/A	N/A
	− Overlooking of faint test result lines	false results but usually mainly around the detection limit	3	3	Usually occurs only close to the detection limit. PI raises user awareness in section result interpretation with the following note: Note: The colour intensity in the test line region (T) may vary depending on the concentration of SARS-CoV-2 viral nucleoprotein antigens in the specimen. Any shade of colour in the test line region (T) should be considered a positive result. Note that this is a qualitative test only and it cannot determine the analyte concentration in the specimen. General: Especially at levels close to the detection limit with	yes	2	PI QC procedures	R1

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					very faint lines, experience shows that there might be differences in the perception between users. Therefore, there are clear specifications during QC which line intensities are rated as “clearly visible”. Line intensities are usually controlled by comparison to colour chart with defined line intensities during QC procedure.				
	– Wrong alignment of colour intensities to colour chart or reference line for semiquantitative rating	N/A			Not a semiquantitative test			N/A	N/A
	d) Other errors								
	– Mistakes in the identification of samples	False results if result is attributed to the wrong patient			See H.2.4.3-12 Hazards due to errors in the identification of samples				
	– Destruction of the device during test procedure or wilful disassembling	Invalid result if the integrity of assembly of components is interrupted (no liquid transfer)	3	1	Awareness of professional user, housing protects the strip inside C-line formation as control for integrity of test assembling	yes	2	Set-up of the test	R1
H 2.2.3. Identification of possible use errors by doctors treating the patient									
H 2.2.3.1	Using result for screening purposes of a population although performance characteristics only suitable for diagnosis of a disease	Diagnosis might not be correct e.g. if screening requires a different cut-off or detection limit.	3	3	So far mostly patients with COVID-19 symptoms have been enrolled in the clinical performance studies. Therefore, the test should only be used as an aid in diagnosis but not for screening. If further studies reveal that the SARS-CoV-2 antigen test can be a useful tool for the identification of symptomless, infected patients, the intended use might be extended. Risk reducing measures are: – Sufficient information in PI (Intended Use, Background. Limitations, Performance Data) – Suitability of the detection limit for the intended	yes	2	PI TD (A7 Performance studies)	R1

Appendix	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard according to Annex H.2.5. N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness to detect false results etc.)	Measures sufficient	P final	Document N/A= not appl.	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
					use has been proven in clinical studies. – QC check that detection limit of the test remains adequate				
H 2.2.3.2	Using result for diagnosis of a disease although performance characteristics only suitable to examine the stage of a disease	Diagnosis might not be correct e.g. if staging of a disease would require a different cut-off or detection limit	3	3	Usually qualitative tests are not used for staging a disease. No conclusions should be drawn from line intensities regarding antigen- or virus concentrations. It is pointed out in the PI, that antigen levels might vary over the course of the disease. Results must be rated in the context of disease progression and symptoms. For both professional/near-patient testing settings, final decisions about diagnosis and/or patient management will be done by a physician.	yes	2	PI TD (A7 Performance studies)	R1
H 2.2.3.3	Using the result of the IVD examination for new clinical intention not approved by the manufacturer		3	3	Intended Use and allowed primary sample material is clearly pointed out in the PI. A new clinical intention seems hardly imaginable except the described “screening” (see above).	yes	2	PI	R1
H.2.2.4.	Identification of possible use errors by patients in self-testing assays	N/A			The test is not sold as self-testing test.			N/A	N/A
H.2.3 Identification of safety characteristics In this section safety characteristics that are determined by the performance of the IVD will be discussed									
H2.3.2	Performance Characteristics of quantitative examination procedures	N/A			Only qualitative results - no exact quantification of analyte concentrations			N/A	N/A
H 2.3.3.	Performance Characteristics of qualitative examination procedures	applicable (see below)							
	Performance Characteristics regarding analytical performance and relative diagnostic performance	False results if performance of a product is not sufficient	3	3	Suitability of the assay was proven in different studies regarding the analytical performance characteristics and the diagnostic performance characteristics with patient material. At least part of this information is given in PI.	yes	2	PI, TD especially Annex A7 CoA	R1

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					All available studies are part of the TD and demonstrated good performance. These include Repeatability and reproducibility study regarding inter and intra- LOT variability Analytical sensitivity (detection limit) Analytical specificity with interference, cross reactivity, specimen type equivalence Diagnostic performance for SARS-CoV-2 nucleoprotein detection: Clinical nasopharyngeal and oropharyngeal swab specimens (C_t values 20-37): Diagnostic sensitivity (C_t 20-37): 80.2% (73.9% - 85.3%)* Overall agreement (C_t 20-37): 96.0% (94.5% - 97.1%)* Diagnostic specificity: >99.9% (99.5% - 100%)* *95% confidence interval Clinical nasopharyngeal and oropharyngeal swab specimens (C_t values 20-30): Diagnostic sensitivity (C_t 20-30): 97.6% (93.1% - 99.2%)* Overall agreement (C_t 20-30): 99.7% (99.0% - 99.9%)* Diagnostic specificity: >99.9% (99.5% - 100%)* *95% confidence interval Clinical nasal swab specimens (C_t values <30): Diagnostic sensitivity (C_t <30): 94.12% (87.64% - 97.81%)* Overall agreement (C_t <30): 97.50% (94.64% - 99.08%)* Diagnostic specificity: >99.9% (97.36% - 100%)* *95% confidence interval In addition, there will be checks that tests are “state of the art” compared to competitor products if sufficient information can be retrieved from competitor PIs/Internet. Postmarket surveillance must find means to rate if the products placed on market match the expected performance claimed in TD, PI. Post market surveillance includes at least complaint analysis, BfARM (or comparable institutions) research etc as			QC procedures PB 06 Complaint Managem. PB07 Postmarket Surveillance and Vigilance	

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					described in PB06 and PB07. Risk reducing measures Performance summarized in PI so that operators gain an impression of the test performance. QC (during manufacturing and final) ensure reliable quality of the product; Certificate of Analysis will be made available to customers on request PB06/PB07				
2.3.4.	Dependability characteristics	No significant negative effect on patients' health condition if the result is delayed because of invalid result But false results (positive/negative) might have an impact on immediate decisions regarding quarantine measures or measures regarding social isolation of patiens	3	3	Delay for a rapid test would usually occur when the generated test result is invalid. In case of invalid results, the test could be repeated within minutes with a new test. Therefore, hazard for the patient is low. For COVID-19, there might also be an impact on quarantine measures / social isolation measures. These will most likely be non-permanent because false results will be clarified by additional testing. Measures: Short test procedure for rapid tests so time of delay would be very short (test immanent) PI points out what to do in case of invalid results. PI points out the possibility of false results and stresses that the test is only an aid in diagnosis and that confirmatory tests are necessary.	yes	2	TD PI	R1
2.3.5.	Ancillary patient information	Negative effect on patient's health conditions if tests are not suitable for certain population groups.	3	3	Tests are not restricted to certain population groups.	yes	2	PI	R1
H.2.4 Identification of known or foreseeable hazards									
H2.4.1.	Possible Hazards to the patient								
	False positive, false negative results	Negative effect on patient's health conditions: Diagnosis of a disease and	3	3	Can be caused by operator mistakes or by test failure due to bad quality of products Operator mistakes minimized by detailed PI and	yes	2	PI TD	R1

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		treatment of the patient might be delayed by false negative results Unnecessary follow-up examinations in case of false positive results			straight forward and easy set-up of devices Reliability of product performance by regular in-process- and final QC. Detailed information about performance studies inform user that there remains a certain probability for false results. Hazard of false positive/false negative results is reduced by the fact that the test results are only an aid in diagnosis and should only be interpreted in the clinical context. Final diagnosis must not be based on the result of a single rapid test. This is clearly pointed out in the PI.			CoA	
	Delayed results	already rated under 2.3.4			see H.2.3.4 If invalid results, new test can be performed with no significant delay				R1
	False information accompanying result	already rated under 2.3.5			see H.2.3.5 Detailed PI with sufficient information regarding assay performance and limitations				R1
H.2.4.2.	Possible hazards in relationship to performance characteristics	Negative effect on patient's health conditions If performance characteristics of a product are not reliable (e.g. detection limit values are not kept) false positive/negative results are possible	3	3	Nal von minden GmbH takes all efforts to guarantee that the products sold meet the described performance characteristics by implying continuous quality controls for all LOTs (see manufacturing process) Before a product is brought to the market studies are done to prove the analytical and the clinical performance of the product Measures: QC in process, final CoA available on request for customers PI usually gives short summary of important studies so that the user gets an impression of the product	yes	2	TD CoA PI	R1
H.2.4.3. Identifying hazards in fault conditions									
H.2.4.3-1 and H.2.4.3-2	Hazards caused by non-homogeneous batches or inconsistencies between batches	Negative effect on patient's health conditions caused by false positive or false negative results	3	3	Respective studies prove that tests are reliable. Three independent LOTs were tested on three days, at three sites and by three operators with defined control materials in 3fold determinations in order to see if	yes	2	TD and/or PI	R1

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					there is significant variability in the result generation between LOTs. To assess variability within LOTs, control samples were tested in 10fold determination with test from one LOT. Results were found to be acceptable. PI includes these study results for information.				
H.2.4.3-3	Hazards caused by non-traceable calibrator value	Negative effect on patient's health conditions caused by false positive or false negative results if calibrator concentrations are not traceable			No calibrators included in kit. Calibration of the rapid test themselves is done during the manufacturing process and is not in the hand of the operator.			N/A	N/A
H.2.4.3-4	Hazards caused by non-exchangeable calibrators				No calibrators included in kit			N/A	N/A
H.2.4.3-5	Hazards caused by non-specificity	Negative effect on patient's health conditions caused by false positive or false negative results	4	3	Cross reactivity or/Interference studies and clinical studies prove reasonable diagnostic specificity. But this kind of testing can never be exhaustive. Therefore, the probability cannot be reduced to safe area. The risk for false results caused by unknown interference, cross reactivity remains in ALAP area. Measure: Studies have been done for possible interfering or cross-reacting substances.	yes	3	TD and/or PI	R2
H.2.4.3-6	Hazards due to sample or reagent carry-over	Negative effect on patient's health conditions caused by false positive or false negative results if operator tries to re-use tests.	3	3	Tests are for single use – this makes sample carry over extremely unlikely Disposable materials for sample transfer - a re-use of these materials seems very unlikely because they are evidently for single use. Measure: PI and packaging always state that tests are for single use.	yes	2	PI Single use	R1
H.2.4.3-7	Hazards due to measurement	N/A Note:			Only qualitative result that is interpreted visually No instruments required for result interpretation or			N/A	N/A

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	imprecision (instrument related)	If tests are suitable for a reader-based result interpretation this will be addressed in a specific RA			test procedure.				
H.2.4.3-8	Hazards caused by stability problems (storage, transport, during use, after first opening pouch)	Invalid test results or Negative effect on patient's health conditions caused by false positive or false negative results if the test performance deteriorates due to stability problems Note: Product-specific amendment necessary if tests require special conditions for storage/transport	3	3	Addressed in stability studies User should keep to information in PI to get best results Expiry date printed on outer and primary packaging Measures: Expiry can be clearly seen from the packaging PI and packaging state storage conditions PI points out not to use expired tests. Primary packaging and included desiccant pillow pack protect the test from humidity so that mainly temperature affects the stability C-line as internal control for severe deterioration of test components. Minor deterioration resulting in changed performance will, however, not be noticed by the operator. Note For this test only accelerated and in-use stability studies are available so far. Real Time stability studies are still ongoing (new product)	yes	2	TD (Annex A6) PI	R1
H.2.4.3-9	Hazards due to unstable reagents	False results if a deteriorated reagent/buffer affects test performance Negative effect on patient's health	3	3	Reagents will be part of stability studies and stored together with the tests - no separate hazard Dropper vials with small opening reduce evaporation in case user forgets to recap bottles. Note: Although Real Time stability studies are not available yet, the buffer formulation is similar to other swab sample viral antigen tests so that similar stability for the buffer is to be expected.	yes	2	TD (Annex A6) PI	R1
H.2.4.3-10	Failure of hardware or software				Not used, test procedure and result interpretation are done manually resp. visually			N/A	N/A

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					One product variant has QR codes printed on the test cassettes. However, the application of QR codes in context of software systems is not in responsibility of nvm. Users must evaluate suitability of software systems on their own. Therefore, following note is given in section 4. Reagents and Materials Supplied of the package insert: **Note:** nal von minden COVID-19 Ag test cassettes are also optionally available as versions printed with QR codes. These are indicated by the ending 'QR' after the reference number. The individual QR code allows each individual test cassette to be identified electronically for test result documentation. Suitable software systems must be evaluated by the end user themselves.				
H.2.4.3-11	Hazards due to packaging failure	In worst case false results – negative effect on patient's health	3	3	Reliable packaging processes during manufacturing Misprints/missing components/ false PI would be noticed by user If pouches are not sealed test might deteriorate because humidity affects essential components for analyte detection. PI points out not to use tests, if pouch is not sealed. In severe cases control line will not appear. Measures: Warning in PI (see above) QC checks for correct sealed pouches Contact given if user finds kit components missing or misprints that cannot be read.	yes	2	PI C-line as control QC checks	R1
H.2.4.3-12	Hazards due to errors in the identification of samples	false results if result is attributed to the wrong patient	4	3	Sufficient space for ID marking provided on cassettes PI instructs the operator in section Test Procedure to label the cassette.: … Label the test cassette with the patient or control identification. General It is the responsibility of the professional user to establish procedures that prevent mixing of patient samples; ID marking should be self-evident for professional users	remains in ALAP cannot be further reduced because it is in responsibility of operator	3	PI Set-up of the test	R2

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H.2.4.3-13	Hazards due to incorrect age or gender	False results if choice of detection limit or analyte is unsuitable for male/female or is age-dependent - possible negative effect on patient's health	3	3	So far no restrictions known. Children frequently develop no or very mild symptoms so that the number of COVID-19 children in the study was very low. But at the moment there is no indication that it would be necessary to exclude patient groups because of age or gender.	yes	2	PI TD	R1
H.2.4.4 Identifying hazards in normal use									
	Hazards due to problems in connection with sample taking, preparation and stability of samples	False results if unsuitable sample material is used or if samples are taken/prepared or stored under suboptimal conditions that influence the presence/concentration of the analyte			Sufficient information about suitable samples and of storage of samples if not used immediately is provided in PI. Collection, preparation (if indicated) and storage of samples has already been rated under H.2.2.2 Identification of possible user errors – sub-issue User mistakes 1) sample collection and 2) sample preparation – no risks were identified leaving area R1				
	Hazards due to an imperfect discrimination between positive and negative samples and/or hazard from imprecise measurement	False results if the test cannot discriminate properly between positive or negative samples.	3	4	Relative diagnostic performance characteristics have been proven in clinical studies. The information is given in the PI so that the user gets an impression of the performance of the test and will not expect 100% correct results. For the COVID-19 test the study results demonstrate good and reliable performance especially for patients with high viral loads (see H 2.3.3). In spite of the good study results users must observe the limitation section stating that false results are possible and emphasizing that diagnosis must never be based on a single rapid test. Tests are only aid in diagnosis.	yes	2	TD and PI	R1
	Hazards due to unexpected influence of other constituents in the sample matrix	False results if there are substances with an unexpected influence on the formation of results	3	3	Analytical specificity studies covered interference and cross reactivity No results were identified that might indicate hazardous situations.	yes	2	TD and/or PI	R1

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	Hazards due to natural heterogeneity of the analyte	False results possible if a mutation or different forms (e.g. complexes with other proteins) of the analyte influence binding to the antibodies used in the detection reaction.	3	3	No data available yet. Clinical study demonstrated a very good correlation. The chosen antigen for the test seems to be well conserved and loss of sensitivity due to mutations seems unlikely. For the moment the risk is rated as R1 but might be re-rated if more clinical data is available.	yes	2	TD	R1
H.2.4.5. Identifying hazardous situations									
H.2.4.5.	Situations leading to false results combined with misuse by the user - using test as confirma-tory instead as aid in diagnosis / final diagnosis only based on test result without clinical context and without additional testing	inadequate quarantine measures/social isolation for patients treatment will be most likely based on symptoms and not on test result	3	4	PI gives sufficient information of intended use / limitations inform user not to expect 100% correct results / by including result of clinical studies user gets an impression of the test performance / tests are for professional users who are aware that clinical judgement is required to diagnose diseases Repeated warning in PI that test is used as an aid in diagnosis and not as sole criterion for diagnosis.	yes	2	PI	R1
H2.4.5.	Test is not used for intended use but for other medical decision e.g. if the user uses the test for detection of the analyte in other sample materials or for another medical application	False test results e.g. if the sample material has not been approved and does not work with the test or if analyte concentrations and thus the detection limit does not match the different application	3	3	Intended Use and suitable sample materials are clearly stated in PI Only professional users – it can be assumed that user would be aware that false results are possible if he tries another medical application	yes	2	PI TD	1
	qualitative test results are used for quantitative application e.g. to monitor disease progression	Possible false conclusions about patient's health and thus inadequate treatment	3	3	It is clearly stated in PI that the test result is only qualitative. It does not seem likely from the test set-up that users will compare T-line intensities from old and more recent tests in order to retrieve quantitative information.	yes	2	PI TD	1

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1.3.3 Risk analysis for biological, chemical and environmental hazards

according to DIN EN ISO 14971 / Annex I

Annex I	Product Characteristics or Possible Errors during Usage that might have an impact on safety	Possible Hazard N/A= not applicable	S	P initial	Explanation if indicated measures for risk reduction are listed (test immanent features, raise of user awareness etc.)	Measures sufficient	P final	Document N/A= not applicable	Risk final R1 =Safe R2= ALAP R3= Unsafe N/A = not appl.
Biological hazards and contributing factors									
Annex I	Tests usually contain materials of animal origin e.g. antibodies or BSA	Materials of animal origin could be potentially infectious for the operator. The patient usually does not come into contact with the test because it is an IVD. Note: If tests contained critical materials a product-specific amendment to this general document must be written to estimate the hazard.	3	3	Usually tests do not contain material of human origin. Materials of animal origin are from reliable suppliers. Although the origin of materials is known and all materials are purified, the total absence of pathogenic agents cannot be guaranteed. Therefore, tests should be handled with the usual precautions e.g. wearing gloves during the test procedure. Accidental leakage of liquids from the test is minimized by the adsorbent pads employed for liquid uptake and by the plastic housing for cassette assays/midstream assays. In the dried state no leakage of materials is to be expected. From the intended use the tests are not to be incorporated at any time – therefore the probability for accidental uptake of materials is very low. Generally the risk from potentially infectious sample material used with the tests is rated significantly higher than the risk from the tests themselves. Precaution section in PI gives sufficient warnings for the user. Professional users handling potentially infectious sample materials are aware that they should use protective lab garment during testing. Used tests must be discarded in accordance with local regulations because of the potentially infectious character of the	yes	2	PI MSDS available on request TD	R1

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					sample material. This is also stated in the PI.				
Chemical Risk									
Annex I	Tests or buffers /solutions provided with the kit might contain hazardous substances	On direct contact with eyes/skin , inhalation or incorporation hazardous substances might affect patient's health. Note If tests contained critical materials in critical concentrations, a product-specific amendment to this general document must be written to estimate the hazard.			Tests and buffers do not contain any hazardous chemicals in concentrations that need to be declared or require labelling with hazard symbols. No relevant danger symbols or labelling requirements of Regulations EG 1272/2008 and (EG) 1907/06 (CLP and REACH) for hazardous substance must be implemented. PI states if kit components contains hazardous substances but also points out that they are below exemption limits . Accidental leakage of liquids from the test is minimized by the adsorbent pads employed for liquid uptake and by the plastic housing. For strips, the grip is covered with laminate foil (front) and the plastic backing plate (back) both are waterproof materials so that contact risk is reduced. In the dried state no leakage of materials is to be expected. Buffers /Reagents are usually provided in dropper bottles that minimize leakage because liquid is only released if pressure is applied. Users are advised to use protective lab garment anyway because they handle potentially infectious materials (see above).	yes		Label, PI, MSDS	R1
Environmental Risks									
	Tests or buffers /solutions provided with the kit might contain hazardous substances	Hazardous substances might pose a risk for the environment Note: If tests contained critical materials in critical concentrations a product-	3	3	For the products no environmental risks are known. Plastic components are not biodegradable so that a release in the environment should be avoided. Chemical risks or biological risks for the environment are not known. If substances are hazardous concentrations are usually very low (< 0.1%). As described, used tests should be disposed of according to local regulations for potentially infectious materials	yes	2	PI, MSDS	R1

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		specific amendment to this general document must be written to estimate the hazard.			because they have been in contact with potentially infectious samples. PI contains information how to discard used tests (see above) MSDS gives further information about disposal. If kit components contained hazardous substances for the environment they would be labeled according to the respective regulations (see chemical risk).				

Component	Potential Consequence/Failure	Risk estimation	Risk Control	Rating of Risk Y= acceptable N= not acceptable

1.4. Production Process

This part of the Risk Assessment rates the production process and addresses the question of the impact of possible failures of test components or kit components and if they would be noticed during the manufacturing process. Please note that this is a general assessment for all rapid tests.

Note: A more detailed (FMEA Failure Mode Effect Analysis) for internal use is available (general FMEA for rapid tests). This table summarizes the most important aspects; confidential data has been excluded from this document.

Component	Potential Consequence/Failure	Risk estimation	Risk Control	Rating of Risk Y= acceptable N= not acceptable
Membrane (quality)	Insufficient chromatography due to disturbed flow rate	Insufficient discoloration – false negative results if faint lines are overlooked Invalid results (incomplete flow)	Membrane from reliable supplier In-process and final QC Usually rapid tests are used as “aid in diagnosis” only	y
Membrane (quality)	Insufficient chromatography due to mechanical damage of membrane	Invalid results (incomplete flow)	Membrane from reliable supplier In-process and final QC	y
Membrane Antibodies or antigens , for this test group usually antigen	No antibody or antigens in test in result line area	False negative results for sandwich immunoassays False positive results for competitive Immunoassays	In-process and final QC Usually rapid tests are used as “aid in diagnosis” only For some tests positive controls in kit for QC by user	y
Reagents C-line formation	No antibody / reagent in control line area	Invalid results	In-process and final QC Invalid result (missing C-line)	y
Conjugate pad	suboptimal contact between conjugate pad and NC membrane	Invalid results	In-process and final QC Invalid result (missing C-line as internal control)	y
Conjugate pad	Colour labelled antibodies/antigens are missing	Invalid results	In-process and final QC Invalid result (missing C-line as internal control)	y
Antibodies/Analyte-conjugates for this test group usually antibody	Antibodies are not functional and do not bind analyte Analyte conjugate is not functional and does not bind antibodies	False negative results for sandwich immunoassays False positive results for competitive Immunoassays	In-process and final QC Usually rapid tests are used as “aid in diagnosis” only For some tests positive controls in kit for QC by user	y
Housing assembly	Back and front of cassette not pressed tightly together	If strip moves up inside the cassette C-line might be invisible and T-line might be mistaken as C-line – so in worst case scenario false negative result obtained by user	Final QC Usually rapid tests are used as “aid in diagnosis” only	y
Pouch, Aluminium foil	Damaged Pouch	Humidity destroys test: invalid, false negative, false positive results possible	Reliable supplier of pouch QC procedures (random controls of pouches) Usually rapid tests are used as “aid in diagnosis” only PI gives warning not to use tests with damaged pouch, User notices damages.	y
Pouch/ Label on kit LOT#	Incorrect LOT# LOT missing LOT nor readable (bad printing)	Traceability no longer ensured	QC procedures (optical check., Procedure of filing of LOT in Office Line) Redundancy of LOT (also printed on outer container)	y

Component	Potential Consequence/Failure	Risk estimation	Risk Control	Rating of Risk Y= acceptable N= not acceptable
Pouch / Label on kit Expiry date	Incorrect expiry date (ED) Missing ED ED not readable	False negative test result possible if wrong expiry date exceeds real expiry date	QC procedures (optical check), when filing LOT + expiry in Office line severe deviations would be noticed Redundancy of ED (also printed on outer container)	y
Pouch / Label on kit Symbols	Symbols for single use, IVD, read user instruction, storage conditions and CE not complete, missing or not readable	User is missing information	QC procedures (optical check) New pouch designs checked before release Redundancy of symbols (PI, outer container) so user can retrieve information elsewhere	y
Desiccant (pouched assays)	Pillow pack not intact SiO_2 balls spilled in pouch	Effect on test not known – most likely test performance would be not influenced adversely, No harm for user	QC-procedures (random control) Reliable supplier of pillow packs	y
Desiccant (pouched assays)	forgotten	Effect on test not known – it can be assumed though that test deteriorates earlier so risk of false negative or invalid results	QC procedures (random controls) At the moment no warning in PI not to use test if desiccant is missing so user might not notice; but as user is professional and uses tests a lot he knows that tests usually contain pillow pack and might notice nevertheless So far not complaints that could be traced back to missing desiccant	y
Package insert	Package insert forgotten	User cannot perform the assay	QC procedures (four eyes principle), product components clearly defined Mistake will be noticed by user and he will complain	y
Package insert	Package insert for wrong product	User cannot perform the assay	QC procedures (four eyes principle), Procedures that ensure correct kit assembly Mistake will be noticed by user and he will complain	
Reagents or buffers	Contamination of liquid	Influence on test performance not known – in worst case test performance might be influenced	QC procedures ; Real time stability studies prove stability Chemicals in solutions do usually not support contaminations and/or solutions might contain low levels of preservatives (frequently sodium azide below exemption limit, < 0.1%) User will notice if solutions are turbid or smelly	y
Reagents or buffers	Missing or insufficient volume	User cannot perform assay In case the buffer comes in individual vials per sample and is directly used for sample dilution/extraction wrong volumes might influence the sensitivity (concentration of analytes) so that false results are possible	Reliable production of buffer ensure correct filling QC procedure in Assembling: Severe deviations in volume would most likely be noticed as well as leaking due to inappropriately closed lids. User will notice if volume is not sufficient for all tests or if vials come with significantly different filling heights or if there has been leaking due to inappropriate closing.	y
Extraction tubes	Missing or insufficient amount	Extraction of swabs not possible	Reliable assembling processes Final QC checks User will notice	y
Dropper caps/tips	Missing or insufficient amount	Sample application not possible	Reliable assembling processes Final QC checks User will notice	y
Disposable pipette	Pipette missing	User cannot perform assay	Reliable assembling processes Final QC checks User will notice	y

Component	Potential Consequence/Failure	Risk estimation	Risk Control	Rating of Risk Y= acceptable N= not acceptable
Disposable pipette	Pipette wrong size	User will use wrong volume	Reliable assembling processes Final QC checks User will notice as volume in µl is also given in PI	y
Lancets	Missing or insufficient amount	Collection of capillary whole blood samples not possible Lancets are added for user convenience and are frequently optional kit components. User can use suitable alternative lancets.	Reliable assembling processes Final QC checks User will notice User might use suitable alternatives – no influence on the test performance is to be expected.	y
Capillaries	Missing or insufficient amount	Sample addition of whole blood samples not possible	Reliable assembling processes Final QC checks User will notice	y
Swabs	Missing or insufficient amount	Collection of swab samples not possible If user uses other swabs made of unsuitable materials results might be influenced (false positive/false negative)	Reliable assembling processes Final QC checks User will notice If indicated PI states what kind of swabs should be used and which swabs are not suitable (e.g swabs with wooden shafts are frequently not recommended)	y
Other kit components e.g. urine collection containers, stool collection paper etc.	Missing or insufficient amount	These kit components are optional and are only supplied for reasons of convenience or to match special customer demands. They do not influence the test performance and can be replaced by the user with suitable alternatives. So users might experience inconvenience when these components are missing but there is no increased risk for false results	Reliable assembling processes Final QC checks User will notice User might use suitable alternatives – no influence on the test performance is to be expected.	y
Manufacturing steps – general				
Production of tests	Tests match not the performance	User obtains false results	The whole manufacturing process is controlled by in process and final QC procedures Acceptance criteria are defined for each QC that would lead to release/rejection of raw materials, semi-finished components etc. See TD for Flow Scheme of Manufacturing process with indicated QC steps Final QC checks performance and kit assembly	y
Assembling of kit	mixing of product	Incorrect kit components e.g. wrong tests, LOT mixed, wrong PI or wrong buffers Missing kit components	Assembling Instructions define which components must be included in kit and how tests (pouches), PI, kit box and kit box label, and other components should look like (four eyes principle) Working Environment (ensure that that no components from other tests are around when starting to assemble kit) Final QC checks performance and kit assembly	y
Storage	Adverse temperature during storage	If temperature exceeded (> 30 °C) during storage test aging might be accelerated and false results might occur	Temperature control in warehouse	y
Transport	Adverse temperature during transport	If temperature exceeded (> 30 °C) during transport test aging might be accelerated and false results might	Efficient transport routes, If long container shipments refrigerated containers are used (REFA)	y

Component	Potential Consequence/Failure	Risk estimation	Risk Control	Rating of Risk Y= acceptable N= not acceptable
		occur	Usually tolerance of assays against short time exposure to higher temperatures (transport stability study)	
Customer related processes	Customer is getting wrong product, product with delay or send to wrong address	Customer will notice right away No hazard for the patient but customer will be upset.	Efficient system to keep track of customer orders. Order confirmation send to the customers	y

2. Results of Risk Analysis, Risk Evaluation

2.1. Summary

The characteristics of the tests were described according to the questions catalogues of standard 14971, possible hazards were described (Risks Analysis), measures to reduce the probability of occurrence were listed (Risk Control, also see 2.2) and remaining risks were rated as R1 =Safe, R2= ALAP and R3= Unsafe (Risk Evaluation).

Risk Assessment covered the following aspects of the product

- Manufacturing process including test production and kit assembly
- Storage
- Transport
- Test characteristics and suitability of the test for the defined intended use
- Possible user mistakes that might occur in normal use
- Possible misuse of the device
- Impacts on patient safety

Two risks were identified in the ALAP Area (R2). They will be further discussed in Chapter 2.4. Final Risk/Benefit Analysis. All other risk were found to be in the Safe Area (R1) with the implemented risk reducing measures.

2.2. Risk Control – solutions to reduce risks

General:
When it was likely that a risk was beyond negligible level and could adversely impact safety and effectiveness, the product design was modified to reduce or minimize the defect. If potential risks could not be corrected through redesign efforts, special controls such as labelling, warnings were provided.
The risks have been minimized to the best knowledge of the manufacturer by applying all possible safety measures.

a) Inherent safety by design

- Test immanent safety control over C-line formation

Severe deterioration of test components e.g. because of suboptimal storage conditions, non-wicking because of disturbed flow or insufficient sample volume will all be detected by the user by the missing C-line. In case of missing C-line the result is invalid and the user is advised to use a new test

- Set-up of test (hardly any problem with leaking liquids)

Flow is directed by test set-up and leaking of liquids (sample and dissolved test materials) is minimized by adsorbent pads that take up the liquid. For cassette assays the test strips are placed inside a plastic housing so a direct contact of the user with the liquid is avoided.

- Labelling of the test

Intended use (analyte or abbreviation of analyte) is stated on the outer container and the primary packaging. These measures ensure that the user will not mix up rapid tests.

- Imprint on cassette depicting C- and T-line (“C”, “T”)

C and T are printed on the housing next to the control line area and the T-line area. This prevents a mixing up of result- and control line and facilitates correct interpretation.

- Design of vials containing liquid or of extraction tubes containing liquid (extraction tubes pre filled with buffer)

Usually vials have dropper caps. This ensures that liquid will stay in the vial even if it is tipped over and avoids pipetting steps that are always prone to accidental spills. In addition, evaporation of the liquid is minimized in case the user forgets to close the vials directly after use.
For extraction tubes with buffer: Extraction tubes are closed by foils (before use) and have dropper caps for carrying out the test procedure. This also ensures that liquid will stay in the vial even if it is tipped over. Extraction tubes pre-filled with buffer further shorten the test procedure avoiding pipetting steps that are always prone to accidental spills.

b) Protective measures in the use of the medical device itself and in the manufacturing process

- Professional user only

Users are professional only – this indicates that they are aware of what they are doing and will take the respective precautions.

- Reliable product components and production processes

Use of reliable materials in the productions process ensures that only tests of good quality enter the market

- Quality control procedures

QC testing is done for each LOT to ensure that only tests with reliable performance will be sold on the market.

c) Information for safety

- Instruction for use with precautions and limitations and detailed information

PI contains precautions for safe test handling of the assay and what situations should be avoided (precautions), information on sample collection and storage, detailed test procedure and result interpretation with pictures and special situations that require attention, a limitation section that emphasises the limitations of the rapid tests, gives critical situations for use. PI also states intended use, gives back ground information, shows test principle and gives summary of studies about test performance. A PI will always be supplied with each kit.

2.3. Effectiveness of Risk Control: Complaint Management / Post Market Surveillance

PB 05 CAPA, PB 06 Complaint Management, PB07 Postmarket Surveillance and Vigilance

Nal von minden GmbH has a complaint management system according to ISO13485.
In regular intervals complaints for the product will be analysed to see if the implemented measures for reducing risks are functional or if there is an accumulation of complaints for certain issue that would make an adjustment necessary.
Complaint Analysis will be done at regular intervals to see if there have been such accumulations.
In addition, market surveillance will include observation of similar products in the market and literature research in order to ensure that the tests are still state of the art (no superior rapid tests on the market e.g. due to a new superior analyte) and to see if there has been re-calls, incidences for similar products for which the identified root-causes might also apply to the nal von minden product.

If new risks for a product are identified during post-market surveillance/complaint analysis the risk assessment or the FMEA will be adjusted accordingly and – if appropriate - CAPAs for risk reduction will be found.
Because the COVID-19 Ag tests are new products, so far no new risk from post market surveillance of complaint analysis have been identified.
It must be noted that the COVID-19 Ag Test is a test for a new parameter and a new disease. There is a high dynamic in publications and recently acquired knowledge about the disease. Re-rating of risks might be required. In addition, complaint analysis and frequently asked questions from customers might reveal "weak spots" in the PI so that adjustment in the future might be required. Ongoing evaluation of test at different locations will show if the described performance matches the factual performance in the market. Here especially data for patients with weak symptoms are of interest.

2.4. Final Risk/Benefit Analysis

The major benefit of the nal von minden COVID-19 Ag rapid test is the generation of fast results with almost no laboratory equipment or expertise. Test are non-invasive and do not employ hazardous materials. Results contribute valuable initial information about the possible presence of SARS-CoV-2 in patient samples. Due to its higher sensitivity, RT-PCR remains the gold standard for diagnosis of infection. Viral RNA detection via RT-PCR is already possible before the onset of symptoms, when antigen levels are still below the detection limit of rapid tests.
If antigen levels in patient samples are sufficiently high, rapid tests might reach similar diagnostic sensitivity as RT-PCR: in the performed clinical study, positive nasopharyngeal and oropharyngeal swab samples with reference PCR C_t values between 20 and 30 were detected with a sensitivity of 97.56%; positive nasal swab specimens with reference PCR C_t values <30 were detected with a sensitivity of 94.12%). If antigen levels in patients are lower though, the sensitivity of the test is strongly reduced and false negative results become much more likely (in the performed clinical study, positive samples with reference PCR C_t values between 20 and 37 were detected with a sensitivity of 80.21%). Therefore, users must always keep in mind that correct positive result generation strongly depends on the antigen titre in the samples, which might change over the course of the disease. Results should always be verified by other diagnostic methods. Especially, no assumptions about the infectiousness of patients should be based on rapid test results alone. Otherwise, potentially infectious patients might be erroneously released as healthy and necessary quarantine measures might not be initiated. This is also pointed out in the package insert.
This risk assessment demonstrates that the majority of residual risks were found to be or could be reduced to an acceptable level (R1). There are three risks that remained in the ALAP area (R2) and could not be further reduced. One of the risks is related to sample identification/correct attribution of results to the patient. The nal von minden tests offer sufficient space to mark tests with patient ID, but it remains in the hands of professional users to establish procedures that prevent mixing up samples. We rate the probability of sample mix-up as a rare event because users are professionals and good laboratory practice can be assumed. However, we do not think that probability is less than P3. P3 combined with S3 leads to R2 (ALAP).
The second risk is unknown influences from the sample matrix on test results. Studies for interference or cross reactivity can never be exhaustive so that nvm rated the probability of false results due to unknown influences with P3. The risk remains in the ALAP area. As nvm has an active complaint management and tries to find root causes for complaints it can be assumed that general problems e.g. from common medication frequently taken by patients suffering from the disease would be identified on the long term. In the clinical study, no false positive results were obtained, indicating a very good specificity. The risk is rated to be acceptable because of the good clinical data

and literature research, if the limitations of the test are kept in mind, but further studies have already been initiated.
The third risk is the contact of the user with potentially highly infectious sample material. The used swab samples might contain sufficient amounts of SARS-CoV-2 to infect the test operator if the samples are not collected and handled correctly. The package insert advises the user to wear appropriate protection equipment during sample collection and testing. Furthermore, the operators are medical professionals who are trained to work with potentially infectious sample materials and will be able to take appropriate protection measures. In addition, the general awareness of the possible high contagiousness of test subjects suspected of a SARS-CoV-2 infection is high, which will most likely add to the proper observance of safety measures. Since following the advice to use protective equipment is ultimately in the responsibility of the user though, the risk could not be further reduced than R2. Therefore, the risk posed by possible infectious sample material stays in the ALAP region.

At the moment, the nvm SARS-CoV-2 antigen test is still rated as “other product” according to IVDD, although the disease leads to severe symptoms especially in certain risk groups and is highly contagious so that it has been rated as pandemic by the WHO.
The overall impact of antigen test results on diagnosis and final patient management decisions (e.g social isolation at home, quarantine) is presumably low because of its lower sensitivity compared to PCR. Users are aware that SARS-CoV-2 nucleoprotein antigens are reliably detected only in patients with high viral loads. At the moment it is not completely known how strongly viral load correlates with strength of disease symptoms and infectiousness. It might be necessary to re-rate severity for false positive results/false negative results depending on future recommendations for patient management decisions in relation to antigen testing.

In conclusion, the rapid test enables the user to quickly detect viral SARS-CoV-2 nucleoprotein antigen in nasal, naso- and oropharyngeal swab samples, given that virus titres in the sample material are sufficiently high. The sample material, the procedure of sample collection and modalities for sample preparation are clearly defined in the PI. The detailed instructions enable the user to avoid mistakes in the sample collection procedure, the assay procedure and the interpretation of results. The result interpretation is accompanied by pictures so that the user can easily understand the PI. In addition, the test set-up is in a way to minimize infection risk from sample material. Respective warnings are also given in the PI.

Analytical and diagnostic performance data show that the assays generated reliable results within LOT and between LOTs and showed good agreement to reference methods with clinical samples especially for high virus titers. The tests are considered safe to be used as an aid in diagnosis. Users must observe the limitations and should keep in mind that results must not be used as sole criterion for a diagnosis and that a negative result does not at any time preclude the possibility of a SARS-CoV-2 infection. Test results should never be seen isolated but always in the clinical context.
If the tests are used according to the intended use as an aid in diagnosis, the benefit from using the assays outweighs the risks from using them. Risks for the patient would mainly occur if false results are obtained, combined with user mistake that tests are not used as an aid in diagnosis but as sole basis for diagnosis with ignoring the clinical context. As the intended use clearly states that the tests are only an aid in diagnosis, the limitation section clearly states the limitations of the assay, and the performance section raises user awareness that no 100% correct results are to be expected, we consider this scenario as unlikely.

According to the quality management system, nal von minden GmbH has an active complaint management so that malfunctions of tests or frequent customer complaints would be noticed and the tests/instructions could be corrected to meet the demands. Newly identified risks either from complaints or from other post market surveillance activities (literature/database researches, customer feedback) will be integrated into the risk analysis. Also wrong estimation of probabilities /severity might lead to a new rating of already identified risks.
As described, this Risk Assessment is based on the currently available study data for the test and on (still limited) knowledge about SARS-CoV-2 infections. Re-rating of hazards and risks might be required in the future. Studies with partners are ongoing that will hopefully demonstrate that the factual performance of the tests in the market matches the performance described in the TD that was used as basis for this risk assessment.

At the moment we do not see any possibility to find solutions to further minimize or reduce risks or to improve the performance of the assays. If used according to the intended use the product seems to be safe and can be sold in markets within and outside Europe after registration on that market.

2.5. Identification of parties who carried out the risk analysis

Risk Analysis written by

2020-09-15

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2021-05-21

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Document History

Product	Revision	Editor	Changes/Reason for Changes	Released (date)
COVID-19 Ag Test (cassette, single pouched) Naso-, oropharyngeal swab	1.0	PhJä/JuBo	Introduction of new Risk Assessment FO136b that is usually only used as amendment to group-specific RAs has been filled out completely in order to match the criticality and contagiousness of the disease. This is a full RA and is valid without a group-specific FO136a form.	2020-09-15
COVID-19 Ag Test (cassette, single pouched) Nasal, naso-, oropharyngeal swab	1.1	PeRu	- Variants of buffer containers and cassette variants with QR code were integrated - Additional sample material: human nasal specimen - Information concerning clinical studies for nasal swabs were added	2021-05-21