

Product Information

243103 NADAL® COVID-19 Ag Test

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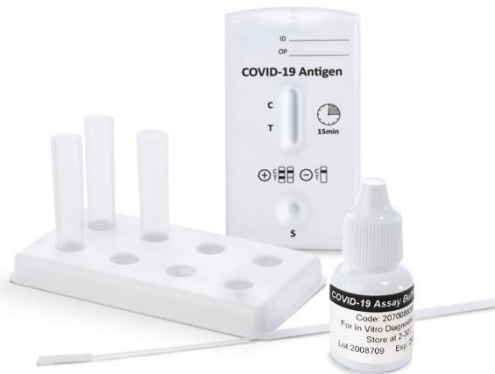
Rapid Tests

Laboratory Diagnostics

Laboratory Service

Consulting & Service

Product	Sample material	Test time	Product code	Stückzahl
COVID-19 Antigen Rapid test for the detection of SARS-CoV-2 nucleoprotein				
NADAL® COVID-19 Ag test cassette	naso- or oropharyngeal swab	15 min	243103N-20	20

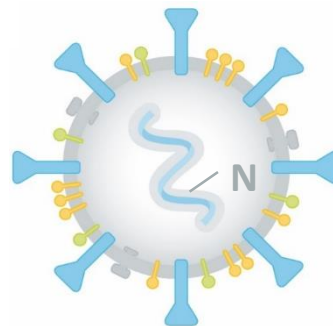


Performance

- ✓ Sensitivity: **97.56 %** (Ct range 20-30)
- ✓ Specificity: **> 99.9 %**

Sales limitations

- ✓ Professional use only

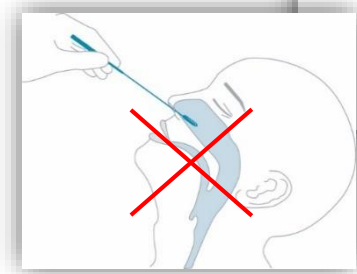
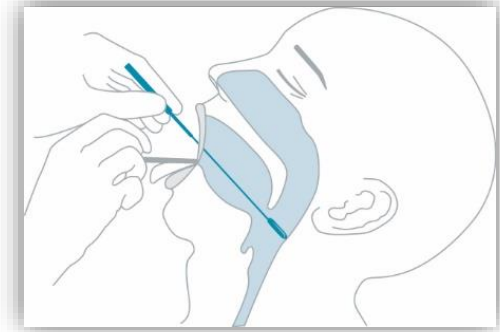
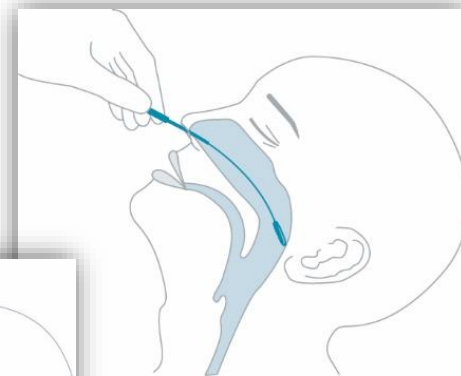
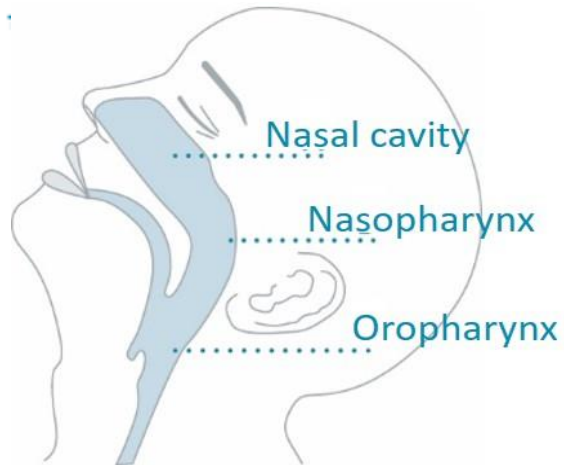


Nucleocapsid protein (N)

- Encases the viral RNA and is involved in replication, transcription and packaging of the viral genome
- Advantage: highly abundant and specific

NADAL[®] COVID-19 Ag Test – Sample collection

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Specimen collection is a critical point – what must be taken into account?

✓ **Sample quality** (slide [3](#))

✓ **Time window**

→ On average up to 8 days after the onset of symptoms, the virus conc. in the upper respiratory tract is highest; thereafter the virus tends to migrate to the lower respiratory tract, i.e. detection by means of a throat swab is becoming increasingly less likely (van Kampen et al., Woelfel et al., Bullard et al.)

✓ **Course of infection**

→ Asymptomatic patients can carry lower viral loads (Chau et al.)

✓ **Viral transport media (VTM) without** denaturing components are compatible

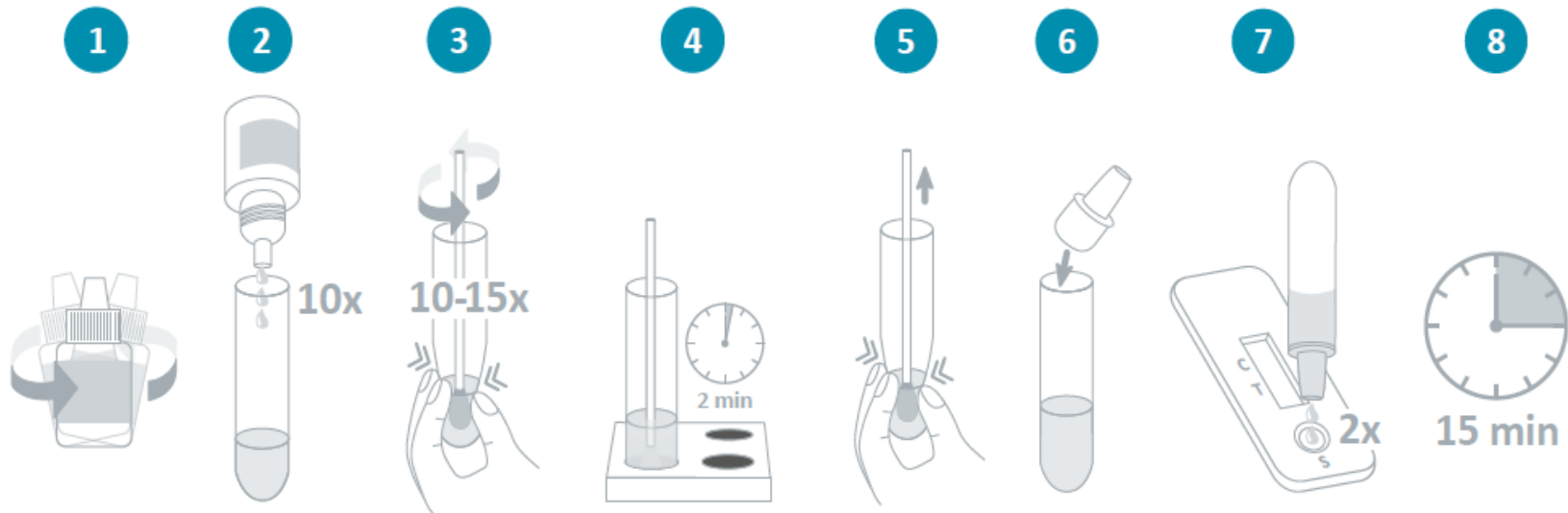
- Denaturing = breaking protein structure
- VTM-N incompatible due to denaturing components, e.g. guanidine salt
- **Use of smallest possible volume (0.5 - max. 1 mL) recommended**
 - high dilutions result in a loss of sensitivity

✓ **Swab tip material**

- Only the swabs included in the test kit can guarantee flawless test performance
 - we advise against the use of swabs other than those supplied in the test kit

NADAL[®] COVID-19 Ag Test – Test procedure

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More detailed information can be found in the instructions for use.

Benefits of using the NADAL[®] COVID-19 Ag Test

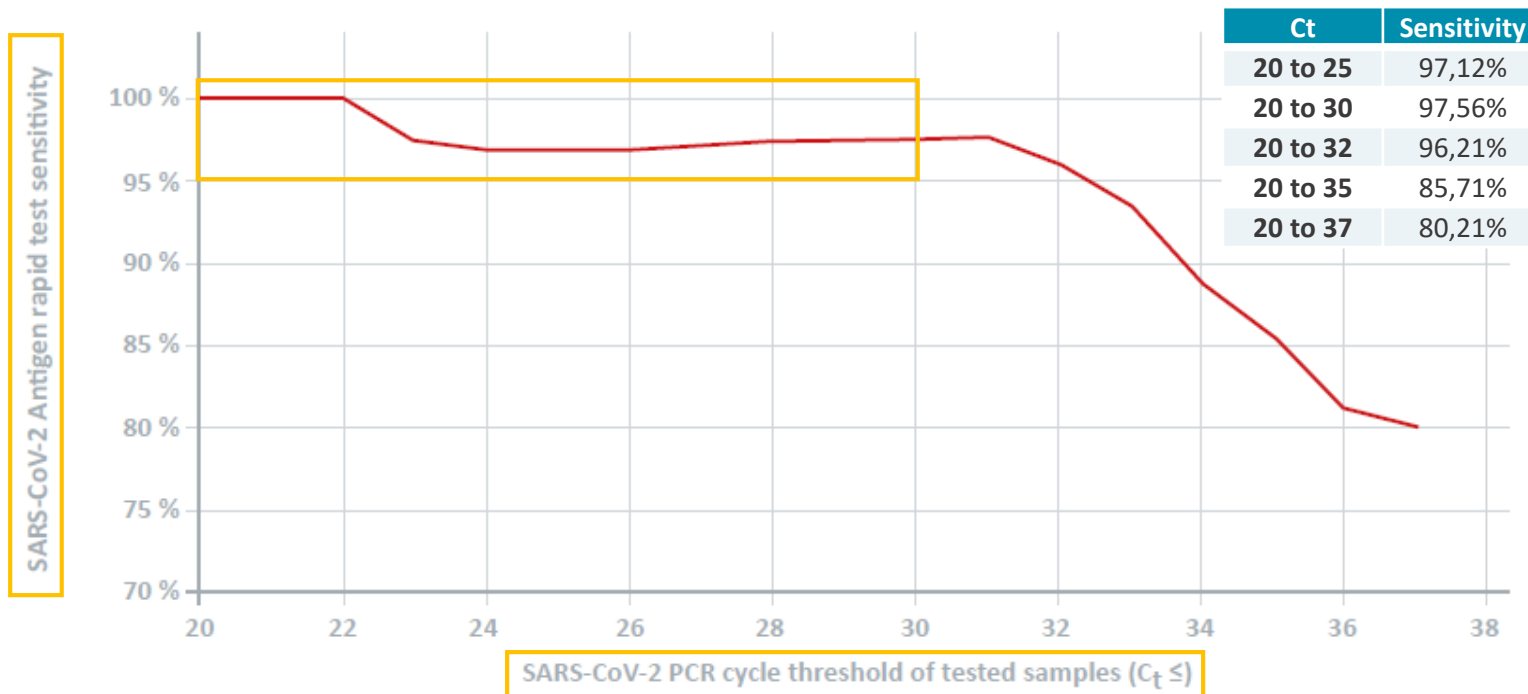
- ✓ Affordable and easy to use – no instrumentation necessary
- ✓ All necessary test components included
- ✓ Compatible with viral transport media (VTM)
- ✓ No cross-reactivity with human pathogenic coronaviruses (like hCoV-229E, -HKU1, -NL63 and -OC43), influenza A/B viruses or other respiratory pathogens

- ✓ Fast and reliable results in just 15 minutes
- ✓ Highly sensitive with high viral loads (Ct range 20-30) (see slides [7](#) & [8](#))
- ✓ Closing a diagnostic gap with antigen testing (see slide [9](#))

Benefits of using the NADAL[®] COVID-19 Ag Test

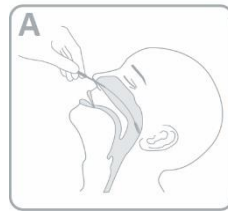
- ✓ Highly sensitive with high viral loads (Ct range 20-30)
- ✓ comparable sensitivity to PCR at Ct values ≤ 30

Sensitivity of antigen test vs. PCR cycle threshold

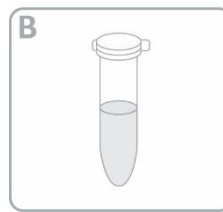


qRT-PCR (quantitative reverse transcription PCR)

✓ qPCR workflow:



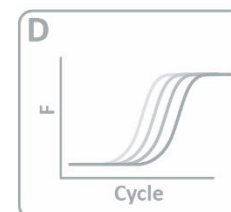
Sample collection



RNA Isolation



qRT-PCR

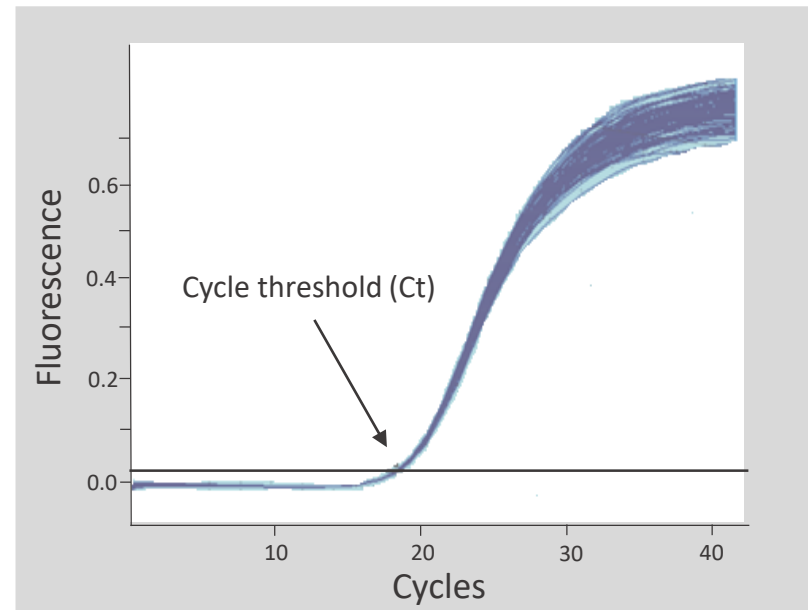


Result interpretation



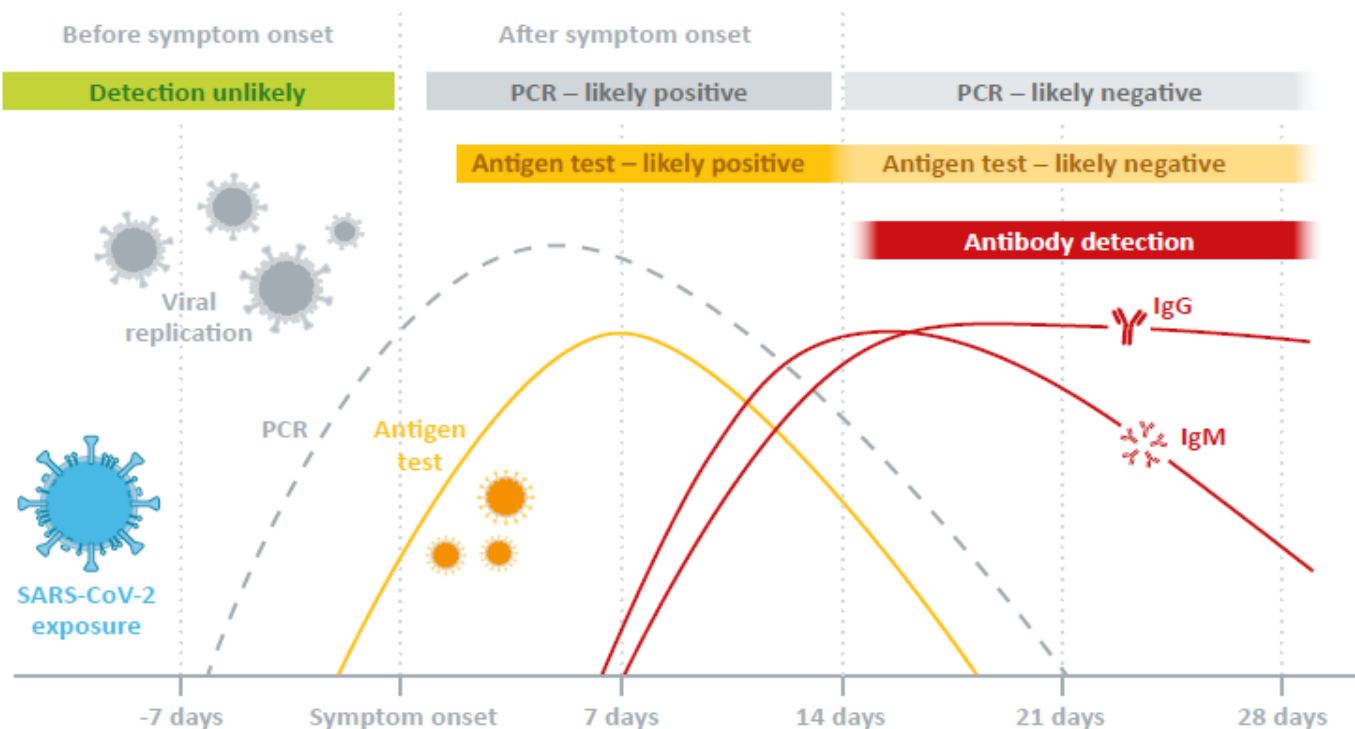
✓ Cycle threshold (Ct):

- the number of cycles required for the fluorescent signal to cross the threshold
 - can be directly correlated to the RNA conc. of the sample
- **The lower the RNA concentration of the sample, the higher the Ct**



Benefits of using the NADAL[®] COVID-19 Ag Test

Test method vs. progression of infection*



*time intervals and rates of viral detection are approximations

- ✓ Closing a diagnostic gap with antigen testing
- ✓ Similar detection windows for Ag detection & PCR

Antigen rapid tests currently on the market

- ✓ **Roche** SARS-CoV-2 Rapid Antigen Test (SD Biosensor)
 - Sensitivity: 96.52 % / specificity: 99.86 %
 - Literature results: Khairat et al. (2020)
 - [Instructions for use](#)

- ✓ **Abbott** Panbio COVID-19 Ag Rapid Test Device
 - Sensitivity: 93.3 % / specificity: 99.4 %
 - [Instructions for use](#)

- ✓ **Rapigen** Biocredit Covid-19 Ag
 - Sensitivity: 92 % / specificity: 98 %
 - Literature results: Khairat et al. (2020), Mak et al. (2020), Weitzel et al. (2020)
 - [Instructions for use](#)

Concluding facts

- ✓ **Applicable for all detection methods, incl. qRT-PCR**: A single negative test does not fully exclude the possibility of COVID-19 infection!
- ✓ **Combining forces is the key, as...**
 - ...“Each category of diagnostic test has its own unique role in the fight against this virus.”
– U.S. Food and Drug Administration
 - NADAL[®] COVID-19 Ag Test benefits (slide [6](#))
 - NADAL[®] COVID-19 Ag Test **sensitivity of 97.56 %** at **Ct value of 20-30** (slide [8](#))
 - Specific marker **nucleocapsid protein** (slide [2](#))

Literatur

Bullard J, Dust K, *et al.* Predicting infectious SARS-CoV-2 from diagnostic samples. *Clin Infect Dis.* 2020 May. doi: [10.1093/cid/ciaa638](https://doi.org/10.1093/cid/ciaa638)

Chau NVV, Thanh Lam V, Thanh Dung N, *et al.* The natural history and transmission potential of asymptomatic SARS-CoV-2 infection. *Clin Infect Dis.* 2020 Jun 4:ciaa711. doi: 10.1093/cid/ciaa711. Epub ahead of print. PMID: 32497212; PMCID: PMC7314145.

Khairat SM, Guindy NEL *et al.* Evaluation of Two Rapid Antigen Tests for Detection of SARS-CoV-2. *J Microbiol Biotechnol*, 2020 Aug, doi: 10.11648/j.ijmb.20200503.18

Mak GCK, Cheng PKC *et al.* Evaluation of rapid antigen test for detection of SARS-CoV-2 virus. *J Clin Virol*, 2020 Aug, <https://doi.org/10.1016/j.jcv.2020.104500>

van Kampen JJA, van de Vijver DAMC, *et al.* Shedding of infectious virus in hospitalized patients with coronavirus disease-2019 (COVID-19): duration and key determinants. *Medrxiv.* 2020 Jun 9. doi: <https://doi.org/10.1101/2020.06.08.20125310>

Weitzel T, Legarraga P *et al.* Head-to-head comparison of four antigen-based rapid detection tests for the diagnosis of SARS-CoV-2 in respiratory samples. (preprint), *bioRxiv*, 2020 May, <https://doi.org/10.1101/2020.05.27.119255>

Woelfel R, Corman VM, *et al.* Virological assessment of hospitalized patients with COVID-2019. *Nature* 2020 Apr. <https://doi.org/10.1038/s41586-020-2196-x>