SARS-CoV-2 Rapid Antigen Test

Testing ready to go when you need to know

The world is relying on faster decisions.

SARS-CoV-2 infections continue to increase. With each day seeing spikes in communities around the world, it is becoming more vital than ever to relieve frontline staff – our heroes in hospitals and clinics. Especially in areas where lab testing is limited or not available, there is an urgent need for decentralized diagnostics that provide fast results ready to go when you need to know.

To control the pandemic, healthcare professionals and patients need to know today whether an infection is present or not.

When our greatest threat is uncertainty, our greatest asset is knowledge.

Covid-19: What we know.[1-7]

Transmission
Person-to-person via respiratory secretions and aerosols

Incubation
Range of 2 – 14 days
(median – 5 days)

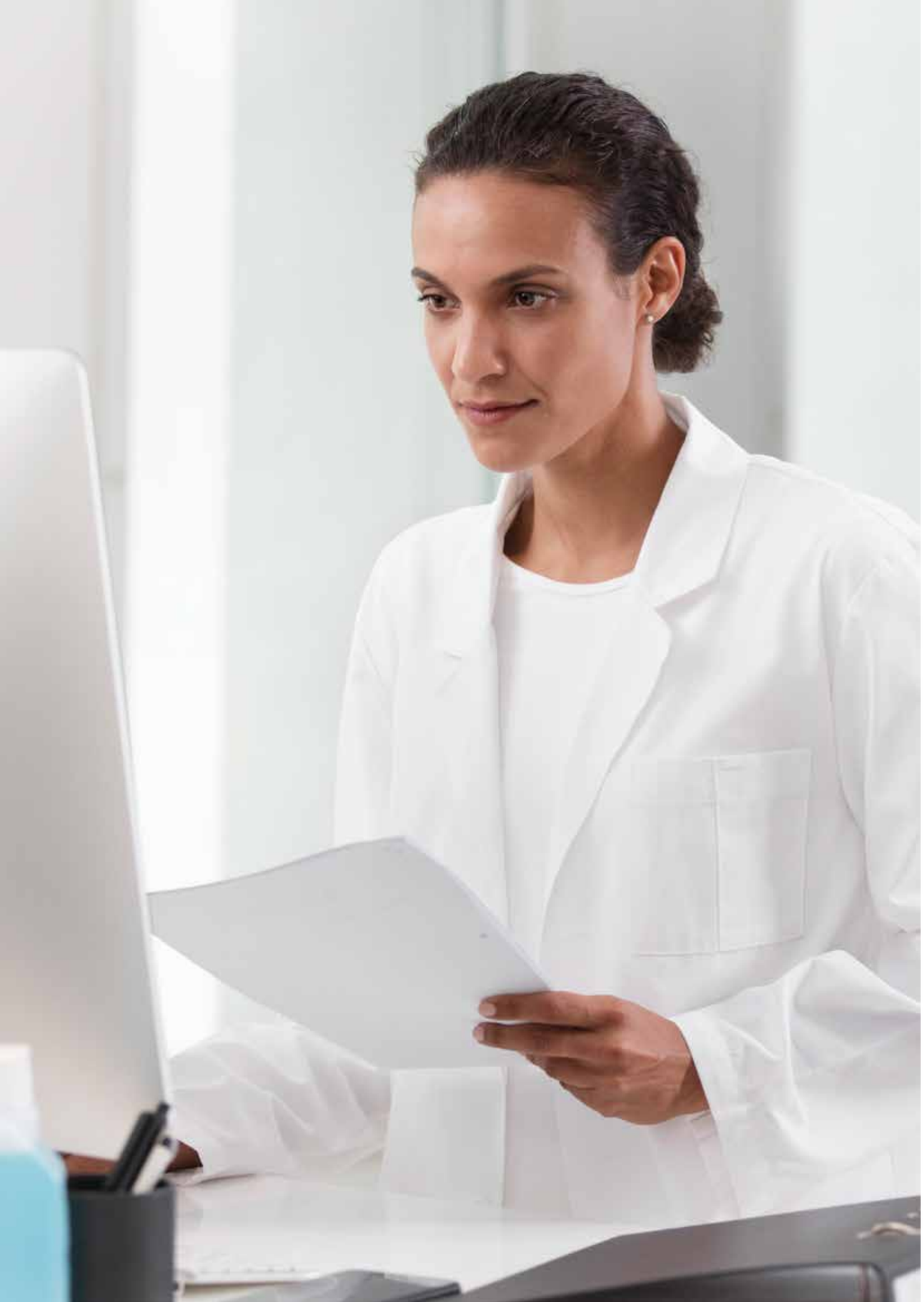
Main symptoms
Fever, respiratory symptoms, abdominal pain, diarrhea, loss of smell/taste, vomiting, headache, myalgia

Clinical presentation
Asymptomatic infection, ranges from mild illness to pneumonia or fatal disease

Clinical progression
Can cause severe respiratory disease, especially in 65+ and multi-morbid patients

Case fatality rate*
Reported mortality rates vary from 0.8 – 15.5 % (average 6.5 %)

** CFR is unreliable during an outbreak*



Time matters.

Direct detection of the virus – through nucleic acid and antigen testing – is essential to contain the virus and make further treatment as well as quarantine decisions.

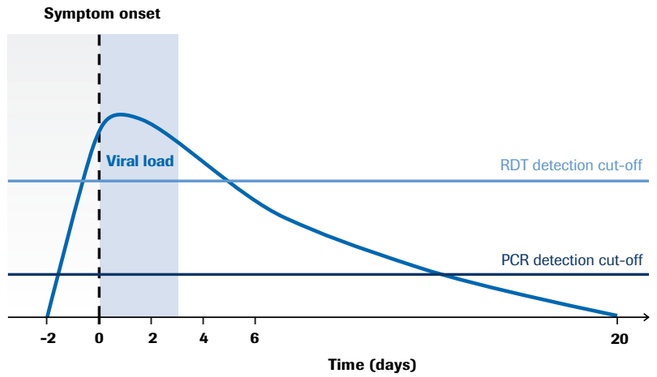
PCR tests are intended for the qualitative detection of SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients.[8]

Rapid antigen tests detect the presence of a specific viral protein. A positive result needs a higher viral load than a PCR test for reliable antigen detection and a high test performance.

Centers for Disease Control and Prevention (CDC) recommend Rapid Antigen Testing as diagnostic testing of Symptomatics or Asymptomatics with recent contact to confirmed case or suspected exposure (e.g. via contract tracing tools). The World Health Organization (WHO) recommends screening of Asymptomatics with suspected exposure or in high-risk environments (institutions, care-homes, schools etc.) where PCR is not immediately available.[5, 9, 10]

Both institutions recommend antigen testing within 5 – 7 days post symptom onset as during that time viral load is highest.[5, 9, 10]

Clinical Sensitivity of a Rapid Test compared to PCR[3]



PCR tests are considered the gold standard due to the highest analytical sensitivity on the market.

However, SARS-CoV-2 rapid antigen tests support tracing of infectious individuals in decentralized locations, especially when lab testing isn't available and time is of the essence.

Fast answers wherever you need them.

In times of uncertainty and increasing patient numbers, the reliable SARS-CoV-2 Rapid Antigen Test provides fast answers, wherever you need them. It is time to expand testing because patients and their communities need to know and rely on quick decisions.

Reliable detection of SARS-CoV-2 specific antigens
The SARS-CoV-2 Rapid Antigen Test provides reliable performance when there is no or limited access to lab testing.

Lab-free testing
Ready to go testing with no infrastructure needed allowing for direct insights and optimized patient workflow.

Fast results, accurate answers
The SARS-CoV-2 Rapid Antigen Test enables rapid and affordable testing to contain further virus spreading after close contact with infected individuals.

With a sample taken from a nasopharyngeal swab the test provides fast, accurate answers in otherwise inaccessible scenarios. At a time of ever growing concern for the safety of communities, healthcare professionals will be able to make fast decisions about the triaging of symptomatic patients for immediate temporary isolation. The SARS-CoV-2 Rapid Antigen Test is a critical tool in supporting the control of the pandemic by providing reliable information.

- **High test quality/performance**
- **No analyzer needed**
- **Fast/direct result while patient is waiting**
- **Easy workflow**

Delivering reliable results at the point of care.

Clinical Performance
The test was found to have a sensitivity of 96.52 % and a specificity of 99.68 %. This was determined from a sample cohort of 426 samples from two independent study centers.*

		PCR		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antigen Test	**Positive**	111	1	112
	Negative	4	310	314
	Total	115	311	426
Sensitivity		96.52 % (111/115, 95 % CI 91.33 – 99.04 %)		
Specificity		99.68 % (310/311, 95 % CI 98.22 – 99.99 %)		

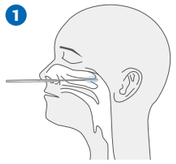
* Reference: SARS-CoV-2 Rapid Antigen Test Product Information V01

Getting fast answers is just a few steps away.

Performing the Roche SARS-CoV-2 Rapid Antigen Test is intuitive and can be implemented in existing processes without the need of additional resources. The test kit can be stored at room temperature. Taking the sample is identical to common nasopharyngeal swab tests and only four simple steps are required to get the result within 15 minutes.

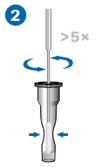
The handling of the Roche SARS-CoV-2 Rapid Antigen Test

1



Insert a sterile swab into the patient's nostril, swab the surface of the posterior nasopharynx. Withdraw the swab from the nasal cavity.

2

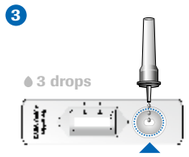


Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

Press the nozzle cap tightly onto the tube.

3



Apply 3 drops of extracted sample to the specimen well of the test device.

4

15 – 30 min

Risk of incorrect results. Do not read the test result after 30 min.

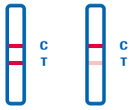
Read the test result at 15 to 30 min.

Understanding the results when you need to know.

Reading and understanding results of the Roche SARS-CoV-2 Rapid Antigen Test is simple.
The control line (C) determines whether the test is valid and a colored test line (T) indicates the detection of antigens specific to SARS-CoV-2. You can read the result within 15 minutes for accurate results.

C Control, test is valid
T Antigens specific to SARS-CoV-2 detected

Positive

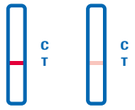


In case of a positive* result, a colored test line T appears in the lower section of the result window. Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.

Negative

In case of a negative** result, only the control line C appears.

Invalid



If no control line C is visible, the test is always invalid.

* *Positive results should not be used as a sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.*

** *A negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA, if necessary for patient management.*

Order information

Test	Quantity per kit	Order No	Cat No
SARS-CoV-2 Rapid Antigen Test English Version	25	09327592190	99COV30D-EN01

References

1 Chen, N. et al. (2020). *Lancet. 395,* 507-13.
2 Holshue, M.L. et al. (2020). *N Engl J Med. 382,* 929-36.
3 Huang, C et al. (2020). *Lancet 395,* 497-506.
4 Wang, D. et al. (2020). *JAMA 323,* 1061-1069.
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6 Wu, J.T. et al (2020). *Lancet 395,* 689-97.
7 https://informationisbeautiful.net/visualizations/covid-19-coronavirus-infographic-datapack.
8 Wölfel, R. et al. (2020). *Virological assessment of hospitalized patients with COVID-2019 581* (7809), 465-469.
9 Criteria to Guide Evaluation and Laboratory Testing for COVID-19. Available at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. Accessed Sept 11, 2020.
10 COVID-19 (Rapid) Antigen Testing Recommendations WHO update September 11th 2020. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=f85a3610-b102-4287-a6df-f3bc0b2e9f7c.

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