

SARS-CoV-2 Ag Rapid Test

Easy and reliable – when it matters most

Your advantages at a glance

- > Patient-friendly – saliva and anterior nasal swabs can be used as sample in addition to the usual swabs
- > User-friendly – all necessary components for each type of sampling included in the kit
- > Reliable – fulfills the valid requirements of the international institutes and has been proven in wide use

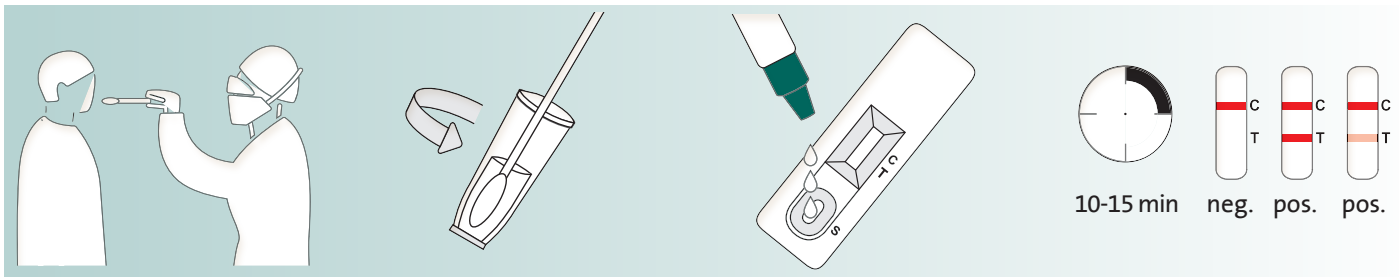


Patient-friendly – just place the swab under the tongue or into the nostrils

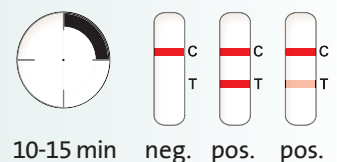


- 1** Painless sample collection
- 2** High sensitivity with saliva¹
- 3** Easy to perform
- 4** Reduced risk of infection¹

User-friendly – easy and time-saving in four steps to the result



- 1.** Place swab under the tongue and let it become completely saturated or sample the nasal walls
- 2.** Fill the extraction buffer into the tube, place the swab into the sample tube and mix it
- 3.** Add three drops from the vial to the test cassette



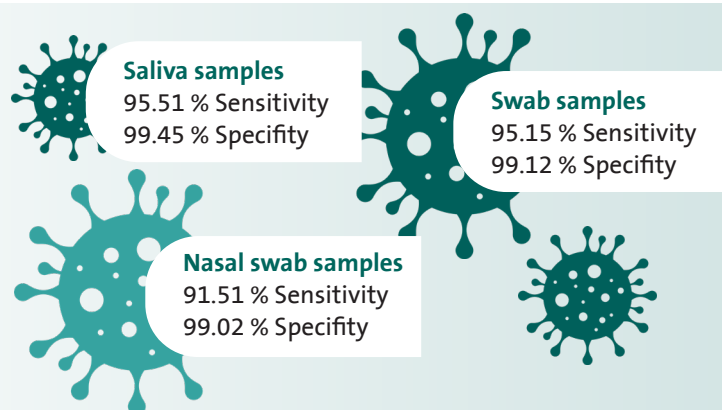
- 4.** Read result

Reliable – meets the valid requirements and has been proven in wide use

Fulfills the requirements regarding sensitivity, specificity and tested patient samples established by well-known institutes worldwide.

Clinical performance²

Sampling	Ct value				Days after onset of symptoms			
	Ct value	No. of samples	RT-PCR results	Antigen test results compared to RT-PCR	Days	No. of samples	RT-PCR results	Antigen test results compared to RT-PCR
Saliva	≤ 30	46	pos	44 46 = 95.65%	≤ 7	89	pos	85 89 = 95.51%
Saliva	≤ 36	157	pos	142 157 = 90.45%	≤ 14	116	pos	107 116 = 92.24%
Saliva	> 40	182	neg	181 182 = 99.45%	> 14	41	pos	35 41 = 85.37%
Swab	≤ 30	107	pos	103 107 = 96.26%	≤ 7	103	pos	98 103 = 95.15%
Swab	≤ 36	185	pos	161 185 = 87.03%	≤ 14	133	pos	122 133 = 91.73%
Swab	> 40	228	neg	226 228 = 99.12%	> 14	52	pos	39 52 = 75.00%
Nasal swab	≤ 30	93	pos	85 93 = 91.40%	≤ 7	106	pos	97 106 = 91.51%
Nasal swab	≤ 36	152	pos	132 152 = 86.84%	≤ 14	131	pos	115 131 = 87.79%
Nasal swab	> 40	205	neg	203 205 = 99.02%	> 14	21	pos	17 21 = 80.95%



Ct value

For PCR, the cycle threshold (Ct-value) is the relevant signal value. It is calculated from the number of replication cycles that are required to generate a fluorescence signal. Lower Ct values indicate a higher virus concentration. A Ct value of < 40 is clinically reported as a PCR positive.³

SARS-CoV-2 Ag Rapid Test REF: LFA0401-25N

- > Colloidal gold immunoassay
- > Sample: Saliva, anterior nasal swabs, nasopharyngeal and oropharyngeal swab specimens
- > Kit size: 25 tests
- > Storage: 2...30°C
- > Shelf life: 18 months
- > CE marked in accordance with Directive 98/79/EC

Kit components

- > 25 test cards with desiccant in a sealed foil pouch
- > 25 sample extraction solution ampoules
- > 25 samples tubes & dripper
- > 25 nasopharyngeal swabs
- > Extraction tube holder
- > Instructions for use

For professional use only

More information about COVID-19 at
www.human.de/covid-19/

¹ Wylie AL. et al. (2020) Saliva or Nasopharyngeal Swab Specimens for Detection of SARS-CoV-2. N Engl J Med 2020; 383:1283-1286
² SARS-CoV-2 Ag Rapid Test. Package insert; article number LFA0401-25N
³ Sethuraman N. et al. (2020) Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 2020;323(22):2249-2251