

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

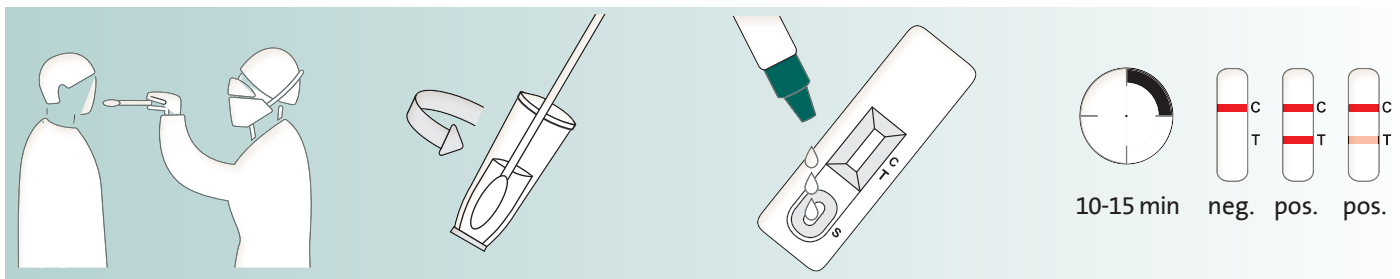


Patient-friendly – just place the swab under the tongue or into the nostrils



- 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

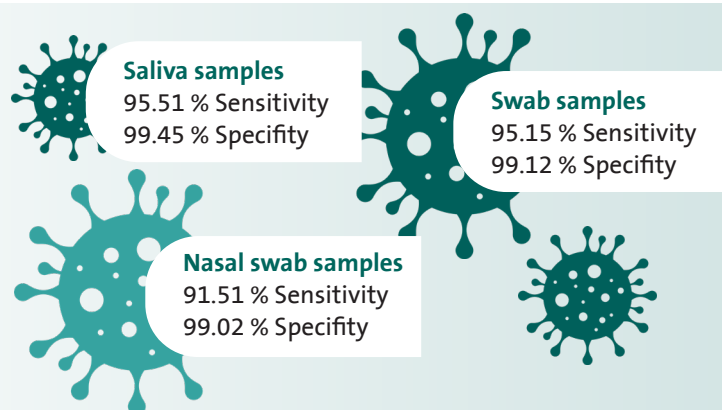
10-15 min neg. pos. pos.

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 | | | |
|------------|----------|----------------|----------------|---|------------------------------|----------------|----------------|---|
| Sample | 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 and 25 oropharyngeal swabs
- > 25 saliva swabs
- > Extraction tube holder
- > Instructions for use

For professional use only

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

¹ Wyllie 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