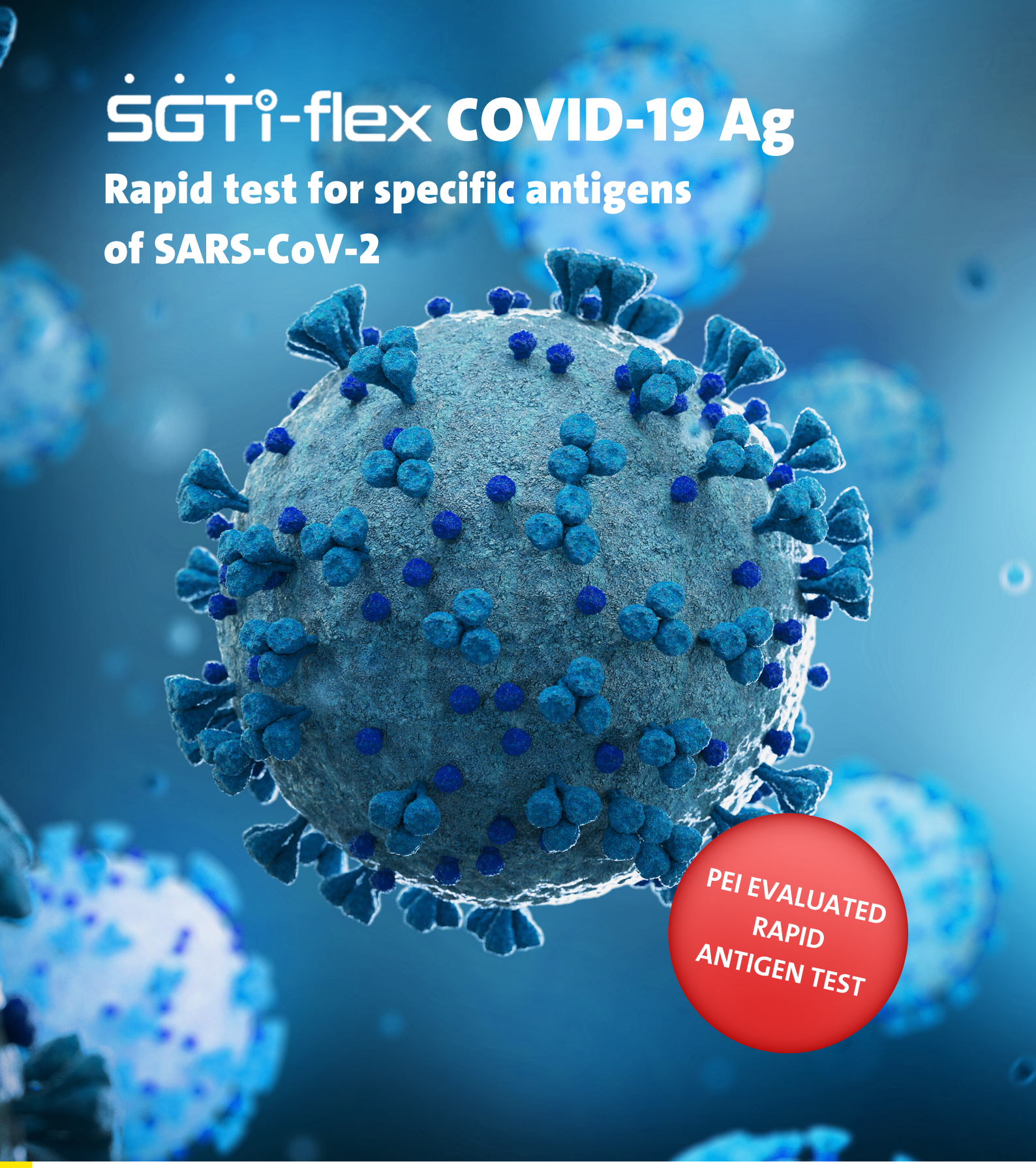
SGTi-flex COVID-19 Ag

Rapid test for specific antigens of SARS-CoV-2



- Qualitative immunochromatographic test
- High sensitivity and specificity
- No cross-reactivity with other viruses or pathogens
- Reliable results after 15 minutes

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Member of IFCC Task Force on COVID-19

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Clinical significance

The rapidly progressing COVID-19 pandemic and the limited laboratory based molecular testing capacities require the availability of fast and easy-to-use tools to allow COVID-19 diagnostics in near-patient settings.

The new SGTi-flex COVID-19 Ag is a cartridge based lateral flow test that provide results within a short time, enable simple and reliable handling without requiring a device. The rapid test increases testing opportunities, particularly in countries that do not have extensive laboratory facilities to implement molecular (polymerase-chain reaction or PCR) tests.

Method

The new SGTi-flex COVID-19 Ag is a one step, rapid gold nanoparticle-based immunochromatographic test for qualitative detection of specific antigens of COVID-19. Measurement can be performed in nasal and nasopharyngeal swab. After the extracted sample is placed in the sample well of the cassette, the antigen in the sample material forms an immunocomplex with the antibody labeled with colloidal gold. This complex moves with the liquid sample and forms a complex with the immobilized capture antibody on the membrane. The resulting reddish colored line is optically interpreted according to the corresponding instructions for use. Results of the immunochromatographic measurements are available after 15 minutes.

Performance characteristics

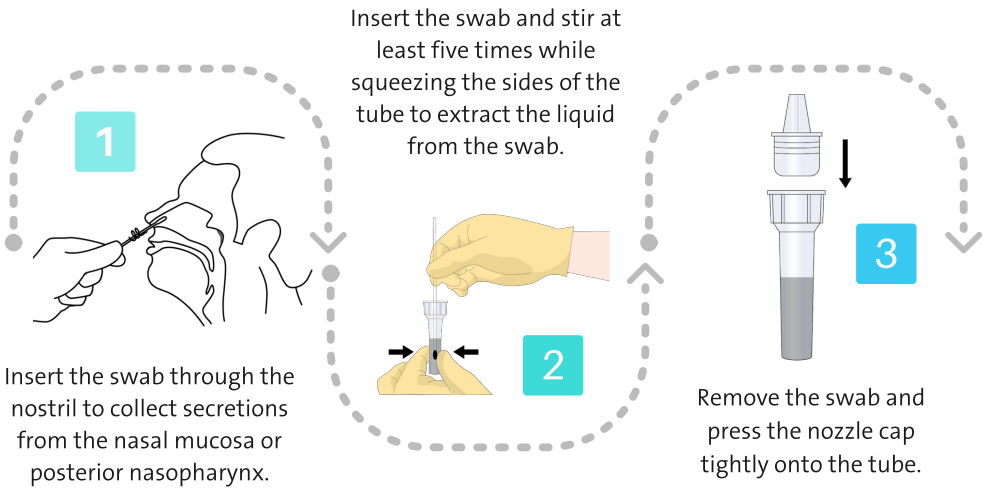
Cross-reactivity	SGTi-flex COVID-19 Ag was tested for potential cross-reactivity using 33 samples containing antibodies to other pathogens and other states of disease (21 other viruses and 12 bacteria). No false positive results were observed with potential cross-reactants.
Specificity and sensitivity*	A total of 243 samples has been tested with the SGTi-flex COVID-19 Ag rapid test. The resulting sensitivity (positive agreement) in the study came up to 95.10% (CI 95%: 90.24%~97.61%), the specificity (negative agreement) was 99% (95% CI : 94.55%~99.82%).
Potential interfering substances	Neither exogenous nor endogenous substances show significant interference with the SGTi-flex COVID-19 Ag rapid test.
Limit of detection	The limit of detection (LoD) of SGTi-flex COVID-19 Ag was determined using dilutions of heat-inactivated SARS-CoV-2 (ATCC, VR-1986HK, 2019nCoV/USAWA1/2020). Based on this test, the LoD was confirmed at $5.3X10^2$ $TCID_{50}$/mL.

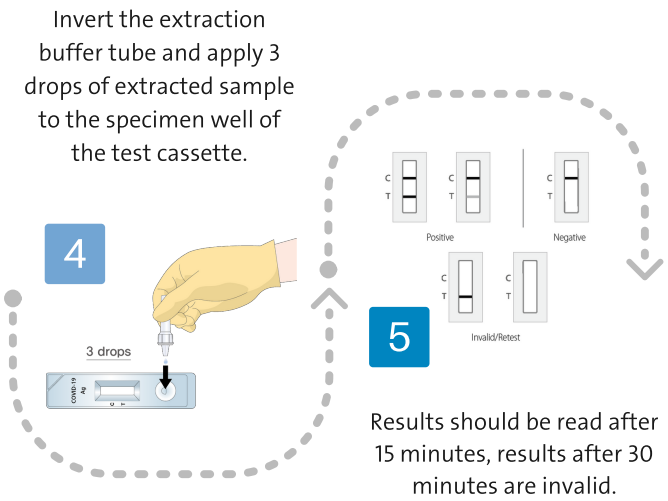
*Shown data for specificity and sensitivity are valid for nasopharyngeal specimen

Benefits of SGTi-flex COVID-19 Ag

- Qualitative detection of SARS-CoV-2 antigens
- One step, gold nanoparticle-based immunochromatographic method
- Suitable for nasal and nasopharyngeal swab
- High sensitivity and specificity
- No cross-reactivity with other viruses or pathogens
- Reliable and fast results - after 15 minutes
- Kit contains all necessary materials
- Separate SGTi-flex COVID-19 Ag Control available (1 positive and 1 negative control)
- Evaluated by Paul-Ehrlich-Institute (PEI)

Test procedure





YouTube video: [SGTi-flex COVID-19 Ag Test - How to Use?]

Order information

CAGT025E0	SGTi-flex COVID-19 Ag	25 tests per kit
60000000256	Nasal sample collection swab	25 pieces (not included in kit)
CAGC001E	SGTi-flex COVID-19 Ag Control	1 positive and 1 negative control

Kit concept

Test cassette	25
Extraction buffer	25 (0,3 mL/tube)
Dropping cap	25
Sample collection swab	25 (nasopharyngeal, included in kit)

- CE marked
- PEI evaluated
- Officially included in the BfArM list (Federal Institute for Drugs and Medical Devices, Germany) of antigen tests for direct detection of SARS-CoV-2

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March 2021