



Convenient

SARS-CoV-2 Antigen

Screening

AMP Rapid Test SARS-CoV-2 Ag Sputum

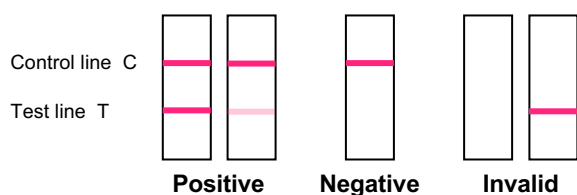
AMP Rapid Test SARS-CoV-2 Ag is a rapid immunochromatographic test for qualitative detection of SARS-CoV-2 antigen in human sputum samples as an aid in quick and efficient diagnosis of Corona Virus Disease 2019 (COVID-19). As the test is detecting SARS-CoV-2 nucleocapsid protein (N-protein) antigen, mutations of the spike protein do not affect the performance of the test.

The test is intended for use by healthcare professionals only, but due to the simplicity of the test procedure and the non-invasive sample collection it is suitable for home testing as well, if permitted by local health authorities. As the result is available within 15 minutes the test is a valuable tool for efficient screening in case of suspected SARS-CoV-2 infection.

Clinical studies evidenced high sensitivity and specificity of the test in comparison with RT-PCR.

AMP Rapid Test SARS-CoV-2 Ag cassettes are packed individually in sealed pouches and are available as single test pack or as a kit of 20 tests. The test kits include a funnel for convenient collection of the sputum sample, sample tube and dropper tip, a pipette, a portion of extraction buffer and a bag for safe disposal of the test including accessories as potentially hazardous waste.

INTERPRETATION OF RESULTS



ORDER INFORMATION:

| Cat.No. | Description | Content | Unit |
|---------|-------------------------------------|--|-----------------|
| RT3950 | AMP Rapid Test SARS-CoV-2 Ag Sputum | test cassette, funnel, sample tube & dropper tip, pipette, buffer, bag (1 each) | 1 cassette |
| RT3951 | AMP Rapid Test SARS-CoV-2 Ag Sputum | sales unit for 10 x RT3950 | 10 x 1 cassette |
| RT3952 | AMP Rapid Test SARS-CoV-2 Ag Sputum | cassette, funnel, sample tube & dropper tip, pipette, buffer, bag, tube holder (20 each) | 20 cassettes |

Illustration of SARS-CoV-2 virion – Source: Center for Disease Control and Prevention, Public Health Image Library (PHIL), ID #23312, Alissa Eckert, MS; Dan Higgins, MAM

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|---------------------------|---|
| Sample: | Sputum |
| Reading time: | 15 to max. 20 minutes |
| Detection limit: | 1.15 x 10 ² TCID ₅₀ /mL |
| Performance: | compared with RT-PCR |
| Test Sensitivity: | 92.2% (95% CI: 86.1% - 96.6%) |
| Test Specificity: | 100.0% (95% CI: 98.5% - 100%) |
| Overall agreement: | 96.7% (95% CI: 94.7% - 98.2%) |

Interferences:

No interferences detected for EDTA blood, anti-viral drugs, antibiotics, anti-bacterial drugs, nasal sprays, nose drops, nasal corticosteroids

Cross-reactivity:

Concentrations of pathogens at which no cross-reactivity was observed are provided in the IFU

Kit composition:

Test cassette, funnel, sample tube & dropper tip, pipette, buffer portion, tube holder (RT3952 only), bag