



Rapid and Efficient

SARS-CoV-2 Antigen

Detection

AMP Rapid Test SARS-CoV-2 Ag

AMP Rapid Test SARS-CoV-2 Ag is a rapid immuno-chromatographic test for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human nasopharyngeal swab samples as an aid in quick and efficient diagnosis of Corona Virus Disease 2019 (COVID-19).

The test is intended for use by healthcare professionals only, but nevertheless is easy to use and does not require any laboratory environment. 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. Potential cross-reactivity was tested with a variety of common pathogens and the concentrations at which no cross-reactivity was observed are provided in the IFU.

AMP Rapid Test SARS-CoV-2 Ag cassettes are packed individually in sealed pouches and are available in 2 different kit sizes of 10 or 25 cassettes. Sterile swabs for collection of nasopharyngeal samples, as well as buffer and tubes for sample extraction are included in the kits.



| | |
|-------------------------|---|
| Sample: | nasopharyngeal swab |
| Reading time: | 15 to max. 20 minutes |
| Detection limit: | 1.15 x 10 ² TCID ₅₀ /mL |
| Performance: | compared with RT-PCR |
| Test Sensitivity: | 97.3% (95% CI: 90.0% - 99.8%) |
| Test Specificity: | 100.0% (95% CI: 96.6% - 100%) |
| Overall agreement: | 98.8% (95% CI: 91.8% - 99.9%) |

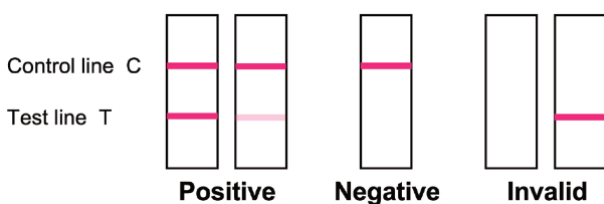
Interferences:

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

Kit composition:

Test cassettes, sterile swabs, extraction buffer, extraction tubes, dropper tips, tube holder

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



ORDER INFORMATION:

| Cat. No. | Description | Sample | Unit |
|----------|------------------------------|---------------------|--------------|
| RT2951 | AMP Rapid Test SARS-CoV-2 Ag | Nasopharyngeal swab | 10 cassettes |
| RT2952 | AMP Rapid Test SARS-CoV-2 Ag | Nasopharyngeal swab | 25 cassettes |

Distributed by:

ImTec
DIAGNOSTICS NV
 Contact: info@imtec.be | +32(0)3-2251139

