VAN OOSTVEEN MEDICAL B.V.
MEDICAL PRODUCTS AND DISPOSABLES

Romed® HOLLAND

REF: COVID-RAPID-AG
Coronavirus Ag Rapid Test Cassette (Swab)

SPECIFICATIONS

2021-02

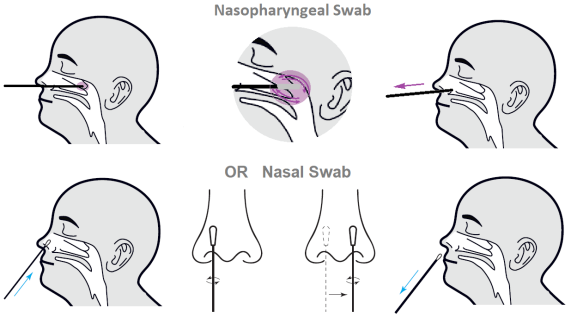
Applicable Directive:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Applicable standards
EN 13612:2003, EN ISO 23640: 2015, EN 62366-1:2015, EN 13532: 2002, EN ISO 13485: 2016, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 18113-4:2011, EN ISO 18113-5:2011, EN 13641: 2002, EN ISO 14971: 2019

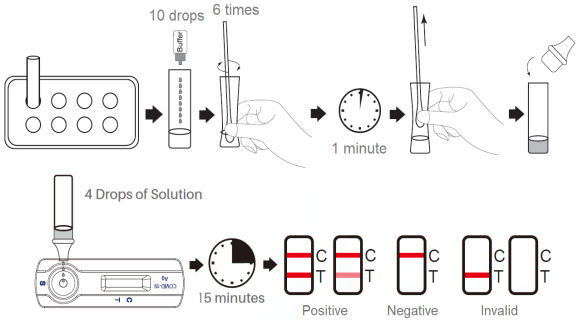
REF	COVID-RAPID-AG
Type	Antigen test
Description	The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab or nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of symptom onset, and asymptomatic individuals. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Negative results from patients with symptom onset beyond ten days should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.
Contained in the packaging	• 20 Test cassettes • 20 Sterile swabs • 20 Extraction tubes and dropper tips • 1 Workstation • 2 Buffers • 1 Package insert
Possible specimen types	nasopharyngeal (NP) swab nasal (N) swab
Test duration	The result should be read in 15 minutes. Do not interpret the result after 20 minutes.
Shelf life	2 years
Storage	2-30°C
Packaging	1 test individually packed, 20 tests in a box, 500 or 1000 tests in an export carton

Easy to follow instructions
(Please read the complete IFU before using the test)

Specimen collection



Sample preparation and test procedure



VAN OOSTVEEN MEDICAL B.V.
MEDICAL PRODUCTS AND DISPOSABLES

Romed® HOLLAND

REF: COVID-RAPID-AG
Coronavirus Ag Rapid Test Cassette (Swab)

SPECIFICATIONS

2021-02

Clinical performance
Romed Coronavirus Ag Rapid Test compared to PCR

	Nasopharingeal Swab	Nasal swab
	119 (+) / 746 (-)	109 (+) / 128 (-)
Specificity	99.60%	100%
Sensitivity	98.32%	97.25%

Cross reactivity
Samples positive for the following organisms were found negative when tested with the Coronavirus Ag Rapid Test Cassette (Swab)

Pathogens	Concentration
Respiratory syncytial virus Type A	5.5×10^{7} PFU/mL
Respiratory syncytial virus Type B	2.8×10^{5} TCID50/mL
Novel influenza A H1N1 virus (2009)	1×10^{6} PFU/mL
Seasonal influenza A H1N1 virus	1×10^{5} PFU/mL
Influenza A H3N2 virus	1×10^{6} PFU/mL
Influenza A H5N1 virus	1×10^{6} PFU/mL
Influenza B Yamagata	1×10^{5} PFU/mL
Influenza B Victoria	1×10^{6} PFU/mL
Rhinovirus	1×10^{6} PFU/mL
Adenovirus 1	1×10^{6} PFU/mL
Adenovirus 2	1×10^{6} PFU/mL
Adenovirus 3	$5\times10^{7.5}$ TCID50/mL
Adenovirus 4	1×10^{6} PFU/mL
Adenovirus 5	1×10^{6} PFU/mL
Adenovirus 7	2.8×10^{6} TCID50/mL
Adenovirus 55	1×10^{6} PFU/mL
EV-A71	1×10^{5} PFU/mL
Mycobacterium tuberculosis	1×10^{3} bacteria/mL
Mumps virus	1×10^{5} PFU/mL
Human coronavirus 229E	1×10^{5} PFU/mL
Human coronavirus OC43	1×10^{5} PFU/mL
Human coronavirus NL63	1×10^{6} PFU/mL
Human coronavirus HKU1	1×10^{6} PFU/mL
Human Metapneumovirus (hMPV)	1×10^{6} PFU/mL
Parainfluenza virus 1	7.3×10^{6} PFU/mL
Parainfluenza virus 2	1×10^{6} PFU/mL
Parainfluenza virus 3	5.8×10^{6} PFU/mL
Parainfluenza virus 4	2.6×10^{6} PFU/mL
Haemophilus influenzae	5.2×10^{6} CFU/mL
Streptococcus pyogenes	3.6×10^{6} CFU/mL
Streptococcus agalactiae	7.9×10^{7} CFU/mL
Streptococcus pneumoniae	4.2×10^{6} CFU/mL
Candida albicans	1×10^{7} CFU/mL
Bordetella pertussis	1×10^{4} bacteria/mL
Mycoplasma pneumoniae	1.2×10^{6} CFU/mL
Chlamydia pneumoniae	2.3×10^{6} IFU/mL
Legionella pneumophila	1×10^{4} bacteria/mL
Pooled human nasal wash	N/A

Interference from substances
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the Romed Coronavirus Ag Rapid Test Cassette (Swab) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Human blood (EDTA anticoagulated)	20% (v/v)
Mucin	5 mg/mL
Oseltamivir phosphate	5 mg/mL
Ribavirin	5 mg/mL
Levofloxacin	5 mg/mL
Azithromycin	5 mg/mL
Meropenem	5 mg/mL
Tobramycin	2 mg/mL
Phenylephrine	20% (v/v)
Oxymetazoline	20% (v/v)
0.9% sodium chloride	20% (v/v)
A natural soothing ALKALOL	20% (v/v)
Beclomethasone	20% (v/v)
Hexadecadrol	20% (v/v)
Flunisolide	20% (v/v)
Triamcinolone	20% (v/v)
Budesonide	20% (v/v)
Mometasone	20% (v/v)
Fluticasone	20% (v/v)
Fluticasone propionate	20% (v/v)