VAN OOSTVEEN MEDICAL B.V.
MEDICAL PRODUCTS AND DISPOSABLES

Romed HOLLAND

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

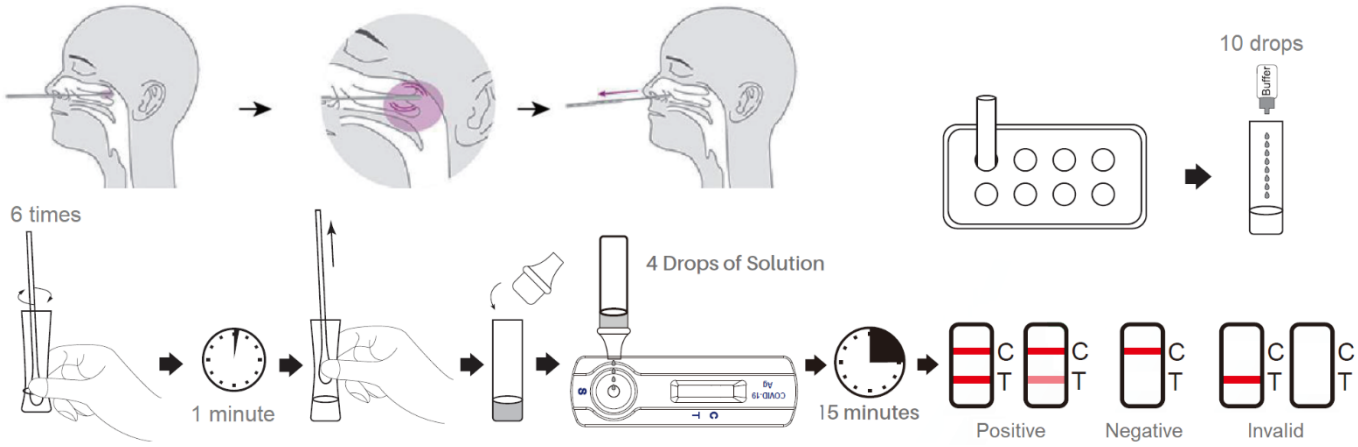
SPECIFICATIONS

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 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN 13975:2003, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016

REF	COVID-RAPID-AG
Type	Antigen test It can show if the body is currently infected
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 nasopharyngeal (NP) swab specimens directly or after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. 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
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)



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Clinical performance

Romed Coronavirus Ag Rapid Test compared to PCR

Below are the test results for 2 studies. Study A was conducted in the US, and has a high confidence interval for the results due to the high number of samples. Study B had a requirement that all the positive samples should be collected within the first 10 days.

	Study A	Study B
	61 (+) / 256 (-)	73 (+) / 130 (-)
Specificity	99.22%	100%
Sensitivity	96.72%	97.3%
Sensitivity Ct<30	Unknown	100%

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 (2019)	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 3	$5\times10^{7.5}$ TCID50/mL
Adenovirus 7	2.8×10^{6} TCID50/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
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 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

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)