Verino® Pro SARS-CoV-2 Ag Rapid Test
Package Insert

REF VCD16-10-041/VCD16-10-043/VCD16-10-044/VCD16-10-045	English

PRINCIPLE AND INTENDED USE

Verino® Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human. The test is for in vitro diagnostic use only. It is for self-testing. It provides only an initial screening test result. More specific alternative diagnosis methods (molecular diagnostic and / or CT) should be performed in order to obtain the confirmation of SARS-CoV-2 infection,The decision about the diagnostic procedure should rest with the physician. This test is intended for home use with self-collected nasal swab samples in individuals aged 16 -69, sampling and testing from anyone under the age of 16 and people over 69 years should be under the guidance of an adult. For people who are not able to perform the test themselves, the test should be conducted by the legal guardians, sick/disabled (Including people with color vision impairment) should be assisted in the test.

The World Health Organisation (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-19. The SARS-CoV-2 virus can cause mild to severe respiratory illness and has spread globally. Cases of severe illness and deaths have been reported. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.

Verino® Pro SARS-CoV-2 Ag Rapid Test is based on immunochromatography technology. Each test device has one line of anti-SARS-CoV-2 antibody on the detection line (T line) and one line of anti-mouse IgG antibody on the quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-SARS-CoV-2 antibody on the detection line. If the specimen contains SARS-CoV-2 antigen, the detection line will appear red indicating the SARS-CoV-2 antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

COMPOSITION

REF No.	VCD16-10-043	VCD16-10-045	VCD16-10-044	VCD16-10-041
Components	1 test/box	3 tests/box	5 tests/box	25 tests/box
test device	1	3	5	25
extraction solution (in the sealed tube)	1	3	5	25
tube tip	1	3	5	25
sterile swab	1	3	5	25
tube stand	1	1	1	1
package insert	1	1	1	1

Materials required but not provided: timer and plastic bag for waste.

Extraction solution composition: Phosphate buffer、Surfactant、BSA

STORAGE AND HANDLING

- Store the test kit in a dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

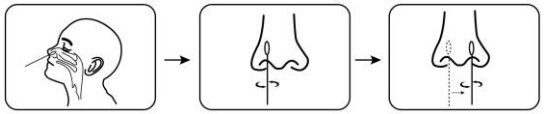
WARNINGS, PRECAUTIONS AND LIMITATIONS

- Results from SARS-CoV-2 antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Should not take any decision of medical relevance without first consulting with the physician.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic and / or CT should be considered to rule out infection in these individuals.
- Positive results may be due to present infection with SARS-coronavirus strains, see “cross-reactivity” for details. Follow-up testing with a molecular diagnostic and / or CT should be considered to confirm the testing result.
- Negative results may occur if the level of antigen in the sample is below the detection limit of the test.
- Inaccurate results may be due to visibly bloody or excessively thick / sticky specimen, insufficient specimen volume or bubbles during applying.
- Do not use swab that is damaged or cannot use.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- For in vitro diagnostic use only, It is for self-testing.
- Keep out of reach of children.
- Use the test device within 60 minutes after opening the foil pouch.
- Do not perform the test in direct sunlight.
- Do not use the test device if it has been exposed to household cleaning products (especially bleach).
- Keep foreign substances away from the test device during the testing process.
- Please take the necessary safety measures (e.g. face mask, gloves) when testing for other people.
- The test equipment used and all parts tested need to be disposed of in accordance with local requirements, and can be placed in a well-sealed bag for disposal as domestic waste.
- Further molecular diagnostic and / or CT is recommended to identify the actual physical situation.
- Do not open the foil pouch of the test device exposing it to the ambient environment until the test device is ready for immediate use.
- Do not use any damaged test device or material.
- Do not reuse the test device.
- Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Do not use test kit beyond the expiration date.
- Only use anterior nasal swab as specimen. Follow the package insert to obtain accurate results.
- Wash hands thoroughly after handling and Wash your hands before sampling and testing.
- This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2 virus.
- The accuracy of the test, depends on the quality of the swab sample-false negative results may be given following poor sampling.
- Any failure to respect the test procedure may negatively impact the performance of the test and/or. invalidate the test result.
- Since the outbreak of the pandemic, the SARS-CoV-2 variant with D614G mutations in the spike protein has replaced the original form in the most regions all over the world. In December 2020, a novel strain of the virus, named ‘VUI-202012/01’, was identified in the England with a set of 17 mutations. Another mutant strain 501Y.V2 of SARS-CoV-2, originally detected in South Africa, shares the same key mutation N501Y. The N501Y mutation locates the receptor-binding domain (RBD) of the spike protein that the virus uses to bind to the human ACE2 receptor, which might be associate with increased transmissibility.
- The nucleocapsid phosphoprotein (N Protein), linking the viral envelope to the viral RNA, plays a central role in the packaging signal RNA recognition and subsequent RNA encapsidation. Based on its vital role in transcription and replication of the virus, the N protein is suggested to be more sensitive for the early detection of infections. SARS-CoV-2 Ag rapid tests produced by VivaChek employ the interaction with antigen sites in N protein. Till now, there is no clear evidence indicating that mutations found in Spike protein can affect the performance of N protein based antigen tests.

SPECIMEN COLLECTION AND HANDLING

1) Specimen collection

Anterior nasal swab specimen
Wash hands with soap and water or use hand sanitizer.It is important to obtain as much secretion as possible. Open swab package at stick end and take swab out. Do not touch the swab head. Insert the sterile swab into one nostril. Make sure the entire tip of the swab is in your nostril (about 1.5 cm). Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).



2) Specimen handling

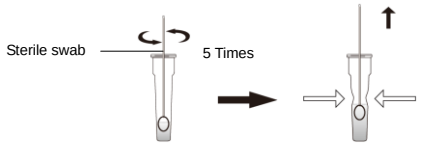
The Specimens should be tested as soon as possible after collection (we recommend to test it within 5 minutes).

TEST PROCEDURE

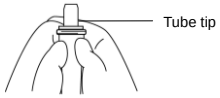
Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

1. Open the extraction solution (in the sealed tube).

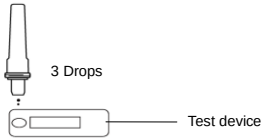
2. Collect specimen refer to **Specimen Collection**.
3. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.



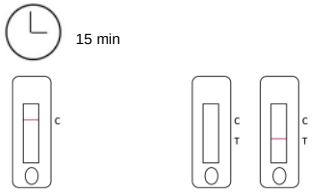
4. Put on the tube tip.



5. Take out a test device from sealed foil pouch and put it on a clean and level surface.
6. Apply 3 drops of the extracted specimen into the specimen well. Please avoid bubbles during applying.



7. Read the test result at 15 minutes. Don't read the result after 20 minutes.

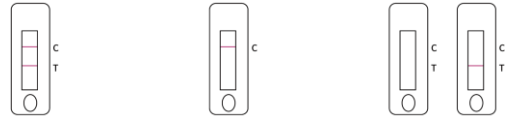


Note:

- *Do not interchange or mix extraction solution from different lots.*
- *Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*

INTERPRETATION OF TEST RESULTS

1. Positive Result:
Both the quality control line C and the detection line T appear. Any shade of color in the test line region (T) should be considered positive.
2. Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.
3. Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.



Positive：Both the quality control line C and the detection line T appear.

Negative：Only the quality control line C appears, with no other line appearing on the detection line.

Invalid：Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not.

Actions to take depending on test result

1.Positive Result:

- There is currently a suspicion of a COVID-19 infection.
- Immediately contact your doctor/family doctor or the local health department.
- Follow local guidelines for self-isolation.
- Have a confirmatory PCR test performed.
- In case of suspicion, immediately contact your doctor/family doctor or the local health department.

2.Negative Result:

- Continue to follow all applicable rules regarding contact with others and protec- tive measures.
- An infection can also be present if the test is negative.
- In case of suspicion, as the coronavirus cannot be precisely detected in all phases of an infection; immediately contact your doctor/family doctor or the local health department.

3.Invalid Result:

- Possibly caused by incorrect testing.
- Repeat the test.
- If the test results are still invalid, immediately contact your doctor/family doctor or the local health department.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained.

PERFORMANCE

1. Limit of Detection

Limit of detection (LoD) per inactivated Virus Culture : 75.5 $TCID_{50}$/mL

The LoD for the Verino® Pro SARS-CoV-2 Ag Rapid Test was established using dilutions of an inactivated virus culture(heat-inactivated SARS-CoV-2 isolate USA-WA1/2020, NR-52281). The starting material was supplied at a concentration of 1.51×10^6 $TCID_{50}$/mL. Studies were designed to estimate the LoD of the assay using anterior nasal swab specimens, the starting material was spiked into a volume of pooled human anterior nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2 to obtain a series of different concentrations.

2. Clinical Sensitivity/Clinical Specificity

A total of 575 specimens were tested using the Verino® Pro SARS-CoV-2 Ag Rapid Test. These anterior nasal swab specimens were obtained from symptomatic subjects. The performance of the Verino® Pro SARS-CoV-2 Ag Rapid Test was compared to a commercialized molecular assay.

Table Summary of sensitivity/specificity of the Verino® Pro SARS-CoV-2 Ag Rapid Test compared to PCR.

Verino® Pro SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	114	0	114
Negative	1	460	461
Total	115	460	575
Sensitivity	99.13% (114/115, 95%CI, 95.24%~99.85%)		
Specificity	>99.99% (460/460, 95%CI, 99.17%~100%)		
Accuracy	99.83% (574/575, 95%CI, 99.02%~99.97%)		

A sensitivity of 99% means that out of 100 only 1 tests are false negative.
A specificity of 99% means that only 1 in 100 tests is false positive.
Sensitivity and specificity together give the accuracy of how many tests are really positive and correctly negative, so 99% means 1 out of 100 tests are false.

CROSS-REACTIVITY AND INTERFERENCE

1. Cross-Reactivity: there was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

1) Cross-reaction with SARS-coronavirus.

Virus	Strain	Concentration
SARS-coronavirus	Urbani	1×10^6 PFU/mL

2) No cross-reaction with potential cross-reactive substances.

Virus/Bacteria/Parasite	Strain	Concentration Range
Influenza A	H1N1	1×10^4~1×10^6 $TCID_{50}$/mL
	H3N2	
	H5N1	
	H7N9	
Influenza B	N/A	
Adenovirus	Type1	
	Type2	
	Type3	
	Type5	
	Type7	
	Type55	
Respiratory syncytial virus	Type A	
	Type B	
Coronavirus	229E	1×10^6 PFU/mL
	OC43	
	NL63	
	HKU1	
MERS-Coronavirus	Florida/USA-2_Saudi Arabia.2014	
Parainfluenza virus	Type1	1×10^4~1×10^6 $TCID_{50}$/mL
	Type2	
	Type3	
	Type4	
Rhinovirus A16	N/A	
Human Metapneumovirus	A1 (IA10-s003)	
Enterovirus	Type 68	
Legionella pneumophila	Bloomington-2	1×10^5 cells/mL
	82A3105	
Mycobacterium tuberculosis	K	
	Erdman	
	HN878	
	CDC1551	
	H37Rv	
Streptococcus pneumonia	475298 [Maryland(D1)6B-17]	
	178[Poland23F-16]	
	262[CIP 104340]	
	Slovakia14-10 [29055]	
Streptococcus pyrogens	Typing stain T1	
Mycoplasma pneumoniae	Mutant22	
	FH strain of Eaton Agent	
	M129-B7	
Chlamydia-longontsteking	AR-39	1×10^6 IFU/mL
Haemophilus influenza	Type b; Eagan	1×10^6~1×10^9 CFU/mL
Candida albicans	CMCC(F)98001	
Bordetella pertussis	A639	
Staphylococcus aureus	NCTC 8325	
Staphylococcus epidermidis	MRSE; RP62A	
Pneumocystis jirovecii	W303-Pji	
Pooled human nasal wash	N/A	14% v/v

2. Endogenous/Exogenous Interference Substances: there was no interference for potential interfering substances listed below.

Potential Interfering Substance		Concentration
Anti-viral drugs	Zanamivir (Infuenza)	5 mg/mL
	Oseltamivir (Infuenza)	10 mg/mL
	Artemether-lumefantrine (Malaria)	50 μM
	Dorxoycline hyclate (Malaria)	70 μM
	Quinine (Malaria)	150 μM
	Lamivudine (Retroviral medication)	1 mg/mL
	Ribavirin (HCV)	1 mg/mL
	Daclatasvir (HCV)	1 mg/mL
Respiratory Specimens	Mucin: bovine submaxillary gland,type I-S	100 μg/mL
	Blood (human), EDTA anticoagulated	5% (v/v)
	Biotin	100 μg/mL
Nasal sprays or drops	Neo-Synephrine (Phenylephrine)	10% (v/v)
	Afrin Nasal Spray (Oxymetazoline)	10% (v/v)
	Saline Nasal Spray	10% (v/v)
Homeopathic allergy relief medicine	Homeopathic Zicam Allergy Relief Nasal Gel	5% (v/v)
	Sodium Cromoglycate	20 mg/mL
	Olopatadine Hydrochloride	10 mg/mL
Anti-inflammatory medication	Acetaminophen	199 μM
	Acetylsalicylic acid	3.62 mM
	Ibuprofen	2.425 mM
Antibiotic	Mupirocin	10 mg/mL
	Tobramycin	5 μg/mL
	Erythromycin	81.6 μM
	Ciprofloxacin	30.2 μM

3. High-dose Hook Effect: cultured SARS-CoV-2 virus was spiked into specimen. No hook-effect was observed at 1.51×10^6 $TCID_{50}$/mL of cultured SARS-CoV-2 virus.

REFERENCES

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INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C~30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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CE 1434
IVD

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