TESTSEALABS®
Rapid Test Kit

COVID-19 Antigen Test Cassette Package insert

CE

In Vitro Diagnostic Use only

Version 1 Effective date: 8/2021

【INTENDED USE】

COVID-19 Antigen Test Cassette employs immunochromatography technology to detect the SARS-CoV-2 antigen in human nasopharyngeal swab、Nasal swab specimen. The Testsea test offers lab-quality results at the point of care. This test is single use only and intended for professional use only.The recommendation to use this test within 7 days of symptom onset, It is supported by the clinical performance assessment

【PRINCIPLE】

The COVID-19 Antigen Test Cassette is a qualitative membrane strip based immunoassay for the detection of SARS-CoV-2 nucleocapsid antigen in human nasopharyngeal swab 、 nasal swab. Nasopharyngealswab 、 Nasal swab specimen requires a sample preparation step in which the sample is eluted into the Extraction buffer. In this test procedure, anti-SARS-CoV-2 nucleocapsid antigen antibody is immobilized in the test line region of the device. After a Nasal swab specimen is placed in the specimen well, it reacts with anti-SARS-CoV-2 nucleocapsid antigen antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-SARS-CoV-2 nucleocapsid antigen antibody

If the specimen contains SARS-CoV-2 nucleocapsid antigen, a coloured line will appear in the test line region indicating a positive result. If the specimen does not contain SARS-CoV-2 nucleocapsid antigen, a coloured line will not appear in this region indicating a negative result. To serve as a procedural control, a coloured line will always appear at the control line region indicating that proper volume to specimen has been added and membrane wicking has occurred

【REACTION SYSTEM】

The test contains anti-COVID-19 antibody as the capture reagent, another anti-COVID-19 antibody as the detection reagent. A Goat anti-Mouse IgG is employed in the control line System

【REAGENTS AND MATERIALS PROVIDED】

Contents name	Description	Quantity
Test device	Foil pouched test device containing one test strip which is encased in plastic device cassette.	20 each
Extraction buffer	Extraction buffer in a sealed tube(contains Casein-Na、Nacl、Proclin-300)	20 each
Extraction tube	A container with extraction buffer	20 each
nasopharyngeal swab or Nasal swab	Sample collection	20 each
Package insert	Instruction for use	1 each
workstation	Put extraction tube	1 each

【MATERIALS REQUIRED BUT NOT PROVIDED】

Timer

【PRECAUTIONS】

1 For professional in vitro diagnostic use only. Do not use after expiration date.

2 Do not eat, drink or smoke in the area where the specimens and kits are handled.

3 Do not re-use any contents in the kit as they are single-use only

4 Handle all specimens as if they contain infectious agents.

5 Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.

6 Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7 Follow standard biosafety guidelines for handling and disposal of potential infective materials.

8 Humidity and temperature can adversely affect results.

9 The test should be performed immediately after the sample is collected. Do not leave the sample at room temperature for more than 1 hours.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30 ℃). The test is stable to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【 SPECIMEN COLLECTION AND PREPARATION 】

1 Specimen collection

Nasopharyngeal swab Specimen collection

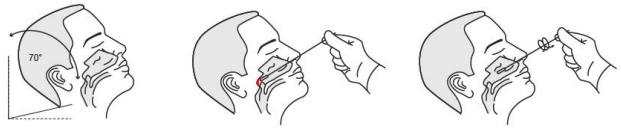
1.Blow their nose to clear nasal passage of excessive mucus.

2.Tilt the patient's head back 70 degrees.

3.Insert swab into the nostril. Swab should reach the surface of posterior nasopharynx. Gently swirl the swab for 5-10 seconds to absorb secretions.

4.Gently remove swab while rotating it.

5.Place the swab into prepared extraction tube

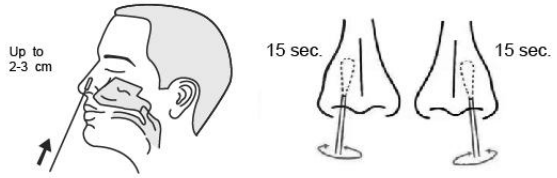


Nasal swab specimen collection

1 Carefully insert the entire swab tip about 2-3 cm into the left nostril. Brush vigorously on the inside of the left nostril at least 5 times or more for at least 15 seconds in a circular motion, take the swab out and insert it into the right nostril about 2.5 cm. Brush vigorously on the inside of the right nostril at least 5 times or more for at least 15 seconds in a circular motion.

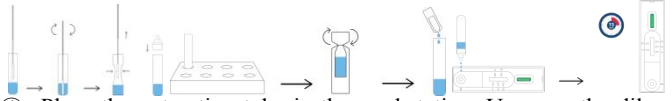
2.Gently remove swab while rotating it.

3.Place the swab into prepared extraction tube



【DIRECTIONS FOR USE】

Allow the test device, specimen, buffer, and/or controls to reach room Allow the test, sample and buffer to reach room temperature 15-30°C (59-86°F) before running.



① Place the extraction tube in the workstation. Unscrew the diluent bottle, open the extraction tube and pour all the extraction buffer into the extraction tube.

② Have the nasopharyngeal or nasal swab carried out by a medically trained person as described.

③ Place the swab in the extraction tube. Rotate the swab for about 10

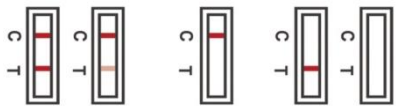
seconds while dripping the head against the inside of the tube to release the antigen in the swab.

④ Remove the swab while pressing the head of the swab against the inside of the extraction tube to expel as much liquid as possible from the swab. Dispose of the swab according to the disposal regulations for biological waste.

⑤ Screw the cap onto the extraction tube and make sure it is firmly in place.

⑥ Place 3 drops of the sample vertically into the sample window of the test cassette. Read the result after 10-15 minutes. Read the result within 20 minutes. Otherwise, a repetition of the test is recommended.

【INTERPRETATION OF RESULTS】



Positive: Two red lines appear. One red line appears in the control zone (C) and one red line in the test zone (T). The test is considered positive if even a faint line appears. The intensity of the test line can vary depending on the concentration of the substances present in the sample.

Negative: Only in the control zone (C) a red line appears, in the test zone (T) no line appears. The negative result indicates that there are no SARS-CoV-2 antigens in the sample or the concentration of the antigens is below the detection limit.

Invalid: No red line appears in the control zone (C). The test is invalid even if there is a line in the test zone (T). Insufficient sample volume or incorrect handling are the most likely reasons for failure. Review the test procedure and repeat the test with a new test cassette

If the problem persists, stop using the test immediately and contact the distributor

【QUALITY CONTROL】

Internal quality control

Internal quality controls are included in the test. The colour line appearing in the control area (C) is an internal positive procedure control which confirms adequate specimen volume and correct procedure technique.

External Control

Control standards are not provided with this kit; however, as a matter of good laboratory practice, it is recommended that positive and negative controls are tested. Users should follow appropriate federal state and local guidelines concerning the frequency of assaying external quality control materials

【LIMITATIONS】

1.This test detects both viable (live) and non-viable, SARS-CoV and COVID-19. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlated with viral culture results performed on the same sample.

2.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

3.The performance of COVID-19 Antigen Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.

4.False negative results may occur if a specimen is improperly collected, transported, or handled.

5.Positive test results do not rule out co-infections with other pathogens.

6.Positive test results do not differentiate between SARS-CoV and COVID-19.

7.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

8.Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

9.If the differentiation of specific COVID-19 viruses and strains was needed, additional testing, in consultation with state or local public health departments is required

【PERFORMANCE CHARACTERISTICS】

1 Clinical Sensitivity and Specificity

For Nasopharyngeal Swab Specimen

The COVID-19 Antigen Test Cassette was compared with a commercial PCR

The patients presenting the COVID-19 like symptoms within seven (7) days of symptom onset at the study sites were enrolled.

A total of 375 nasopharyngeal swab specimens collected, and 125 nasopharyngeal swab positive specimens from individual symptomatic patients （within 7 days of onset were considered evaluate using the for the test without any training provided.

Clinical performance with positive nasopharyngeal swab

within 7 days of symptom onset against the comparator method

		Comparator PCR		Total
		positive	negative	
COVID-19 Antigen Test Cassette	positive	122	4	126
	negative	3	246	249
Total		125	250	375
Positive Percent Agreement (PPA)		96.8%; 95%CI (91.8%~99.0%)		
Negative Percent Agreement (NPA)		98.8%; 95%CI (96.3%~99.8%)		

Positive results broken down by days since symptom onset:

Days post Symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test Cassette
1	3	3	3/3=100%
2	9	9	9/9=100%
3	14	14	14/14=100%
4	17	17	17/17=100%
5	22	22	21/22=95.4%
6	26	26	25/26=96.1%
7	34	34	33/34=97.0%
Total	125	125	122/125=97.6% 95% CI: (94.9%-100%)

Clinical performance with negative nasopharyngeal swab

Number of samples PCR	PCR Negative result	COVID-19 Antigen Test Cassette
250	250	246/250=98.4%
Total	N/A	98.4% :95% CI （96.9% -99.9% ）

The Clinical specificity with Nasopharyngeal Swab negative Specimen is 98.4%:95%CI（96.9%-99.9%）

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For Nasal Swab Specimen

The COVID-19 Antigen Test Cassette was compared with a commercial PCR

The patients presenting the COVID-19 like symptoms within seven (7） days of symptom onset at the study sites were enrolled.

A total of 375 nasal swab specimens collected, and 125 nasal swab positive specimens from individual symptomatic patients （within 7 days of onset were considered evaluate using the for the test without any training provided.

Clinical performance with positive nasal swab

within 7 days of symptom onset against the comparator method

		Comparator PCR		Total
		positive	negative	
COVID-19 Antigen Test Cassette	positive	118	1	119
	negative	7	249	256
Total		125	250	375
Positive Percent Agreement (PPA)		99.2%;95%CI（94.9%~100%)		
Negative Percent Agreement (NPA)		97.2%;95%CI (94.4%~98.8%)		

Positive results broken down by days since symptom onset:

Days post Symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test Cassette
1	3	3	3/3=100%
2	9	9	9/9=100%
3	14	14	14/14=100%
4	17	17	17/17=100%
5	22	22	21/22=95.4%
6	26	26	23/26=88.5%
7	34	34	31/34=91.1%
Total	125	125	118/125=94.4% 95% Cl: (90.7%～98.5%)

EC REP Lotus NL B.V
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Australian Authorised Representative:
PHARMA SOUL PTY LTD
300 Oxford Street, Bondi Junction, NSW 2022
info@pharmasoul.com.au

Clinical performance with negative nasal swab

Number of samples PCR	PCR Negative result	COVID-19 Antigen Test Cassette
250	250	249/250=99.6%
Total	N/A	98.4% :95% Cl （97.5% -99.9%）

The Clinical specificity with Negative nasal swab is 99.6%; 95%Cl: (97.5%-99.9%)

2 limits of detection: We test recombine SARS-CoV-2 protein was diluted with dilution to different concentration , Final confirmation 100pg/ml for SARS-CoV-2 protein is the limits of detection

3 Variability: Test Coefficient of Variation Between lots, within lots, within-day, between-day, within-site, between-site and between-operator

Coefficient of Variation					
Between lots	within lots	within-day	within-site	between-site	between-operator
≦10%	≦10%	≦10%	≦10%	≦10%	≦10%

4. Interfering Substances

The following compounds have been tested using the COVID-19 Antigen Test Cassette and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μl/ml	Oxymetazoline	0.6mg/ml
Mucin	50μg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200μl/ml	Rebetol	4.5μg/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1μg/ml
Mupirocin	12mg/ml		

5 Analytical Specificity （Cross-reactivity and Specificity Testing with Strains)

The COVID-19 Antigen Test Cassette has been tested for other Strain and virus (Table below). The results showed no cross-reactivity.

HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD.
3rd Floor, Building 6,No.8-2 Keji Road,Yuhang District,Hangzhou,China 311100
WEB:www.testsealabs.com

Candida albicans	$1x10^8$org/ml
Staphylococcus epidermidis	$1x10^8$org/ml
Corynebacterium	$1x10^8$org/ml
Streptococcus pneumoniae	$1x10^8$org/ml
Escherichia coli	$1x10^8$org/ml
Streptococcus pygenes	$1x10^8$org/ml
Moraxella catarrhalis	$1x10^8$org/ml
Streptococcus salivarius	$1x10^8$org/ml
Parainfluenza virus 3	$1x10^8$org/ml
Neisseria lactamica	$1x10^8$org/ml
Streptococcus sp group F	$1x10^8$org/ml
Respiratory syncytial virus	$1x10^8$org/ml
Nesseria subflava	$1x10^8$org/ml
Pseudomonas aeruginosa	$1x10^8$org/ml
Arcanobacterium	$1x10^8$org/ml
Influenza A H1N1	$3.16x\ 10_5TCID_{50}$/ml
Influenza A H3N2	$1\ x10^5\ TCID_{50}$/ml
Influenza B	$3.16x\ 10^6TCID_{50}$/ml
Human Rhinovirus 12	$2.81\ x\ 10^4TCID_{50}$/ml
Human Rhinovirus 14	$1.58\ x\ 10^6TCID_{50}$/ml
Human Rhinovirus 16	$8.89\ x\ 10^6TCID_{50}$/ml
Measles	$1.58x\ 10^4\ TCID_{50}$/ml
Mumps	$1.58\ x\ 10^4$TCID50/ml
Parainfluenza virus	$1.58\ x\ 10^7TCID_{50}$/ml
Parainfluenza virus	$1.58\ x\ 10^8\ TCID_{50}$/ml
Respiratory syncytial	$8.89\ x\ 10^4TCID_{50}$/ml
Human coronavirus 229E	$1x10^6TCID_{50}$/ml
MERS	$1.5x10^6TCID_{50}$/ml
Human coronavirus OC 43	$2.45\ x\ 10^6\ LD_{50}$/ml
Human Coronvirus NL63	$1\ x\ 10^{5.07}$ u/ml

6.Hook-Effect:

Test results showed that there was no dose hook effect observed for concentration up to 100ug/ml.

Symbol	Meaning	Symbol	Meaning
IVD	Medical in vitro diagnosis		Storage temperature Limits (4-30°C)
	Manufacturer	Σ	Tests per set
LOT	Batch code		Do not reuse
	Follow the Package insert	EC REP	Authorised Representative in the European Community
	Expiry date	REF	Catalogue number
	Date of manufacture	CE	Standard with 98/79/EC