IVD CE 1434

COV04ST-IFU-001, (Rev. 2)

REF COV04ST

PCL SELF TEST - COVID19 Ag

Instructions for use

Please read the instructions carefully before performing the test. Follow the instructions, and do not modify the process. Strict adherence to the guidelines will avoid inaccurate results and achieve optimal performance of PCL SELF TEST - COVID19 Ag.

Product name

PCL SELF TEST - COVID19 Ag

model name

COV04ST

Intended use

PCL SELF TEST - COVID19 Ag is an in vitro diagnostic medical device based on the immunochromatographic assay (ICA) principle for the qualitative detection of SARS-CoV-2 antigens in human saliva specimens. This test is used to detect antigens of the SARS-CoV-2 virus in people who are symptomatic and asymptomatic. It is intended for non-prescription home use with self-collected saliva specimens directly collected from lay man aged 2 years and older.

Test Principle

PCL SELF TEST – COVID19 Ag detects the N protein (nucleocapsid protein) of SARS-CoV-2. If the sample contains SARS-CoV-2 antigens, these bind to the labelled antibodies to form analyte-labeled antibody complexes. When these complexes reach the test line of the test card, they are retained on the test line by another set of COVID-19 antibodies, which are immobilized on the nitrocellulose membrane. These so-called sandwich complexes appear as a color band on the test line. If the sample does not contain SARS-CoV-2 antigens, no sandwich complexes are formed and no color band appears on the test line.

Kit Components

Materials provided

Component	Description	Unit (Kit)	
		1	2
Test card	Test card with antibody coating and built-in strip (pouch sealed with the desiccant)	1 ea.	2 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, Filled in plastic tube.	500 µL buffer x 1ea	500 µL buffer x 2ea
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	1 ea.	2 ea.
Paper funnel	Funnel-shaped paper cup with a hole in the bottom	1 ea.	2 ea.
IFU	Instruction for use	1 ea	1 ea

Required materials not included

- Timer or stopwatch

Kit storage and stability

- PCL SELF TEST - COVID19 Ag should be stored **at 2-30°C in a dry place**. When stored and handled as directed, the test cards and reagents are stable until expiration date indicated on kit labels.
- Test cards should be used immediately after opening the pouch to avoid prolonged exposure to air.

Instruction for use

Preparation

① Wash your hands thoroughly before the test. It is recommended to wear disposable gloves when using the product.

② Check the kit components and the expiration date written on the pouch. Do NOT use the kit if the expiry date has passed or the packaging is damaged.

③ Open the pouch and peel off the sealing of the extraction buffer tube. Be careful not to splash the liquid out while removing the seal.

④ Insert the tube into the tube holder hole of the kit box. Be careful not to flip the kit box while the tube is fixed.

Sample collection

① Prepare the paper funnel for proper assembly to avoid any leaks during sample collection.

② After taking the extraction buffer tube out of the kit box, plug the tip of the assembled paper funnel into the tube. Be careful not to spill the liquid.

③ Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line (saliva : extraction buffer = 1:1). Be careful not to mix phlegm when collecting saliva.

④ Close the tube with the filter cap. Make sure to close it completely and that the thicker end of the cap is facing down toward the tube.

⑤ Shake the tube up and down 10 times.

⚠ *Do not use stored specimens. Long-term storage may result in a signal decrease*

Assay procedure

⚠ *Reagents should be allowed to stand at room temperature for 20-30 minutes before testing.*
Open the test card pouch just before use.

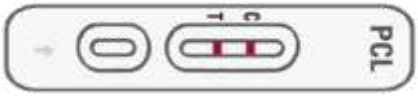
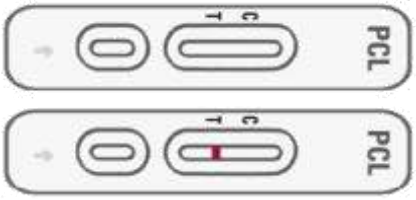
① Take the test card out of its pouch and place it on a flat surface. Add 3 drops of the mixture from the tube to the sample loading well (marked by the letter “S”) of the card.

② Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

⚠ *Reading the test card later than 20 minutes after applying the sample diluent may give inaccurate results.*

Interpretation of results

① Negative	

② Positive	
③ Invalid	

Using the test card can lead to three different results:

① If a single-color band appears in the “C” test region, the result is valid and “non-reactive”, meaning no SARS-CoV-2 antigens could be detected.
This result does not exclude SARS-CoV-2 infection (COVID-19) and sometimes additional tests should be used to exclude this diagnosis with more certainty.
In case of negative results in symptomatic individuals, consulting with a doctor should be advised to help determine the appropriate course of action, taking into account other possible causes of the symptoms (known as differential diagnosis).

② If both color bands appear in “C” and “T” test region, the result is valid and “reactive”, meaning SARS-CoV-2 antigens were detected. Consult a healthcare professional as soon as possible.
This result indicates SARS-CoV-2 infection (COVID-19), and the tested individual should self-isolate and consult a healthcare professional and follow local regulations.

③ If no color band appears or if a single-color band appears near “T” region, the result is invalid. In this case the result cannot be used because the test did not work as intended. Even if the line is faint, the line is considered to exist.

Warnings and precautions

- This product is intended for in vitro diagnostic use.
- This product is intended for single use.
- This product is intended for lay man use.
- The product should be stored at room temperature for at least 20 minutes before use.
- For minors age of 13 and under, guardians must perform from preparation for examination to reading instead.
- This product is a SARS-CoV-2 antigen diagnostic medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- This product may cause false positive result due to an interference reaction when ingesting food or beverages containing vitamin C.
- The low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- If It is difficult to accurately collect samples, proceed with the help of others.
- Do not use beyond the expiration date or damaged products.
- Do not use any other reagents that are not provided in this kit and do not mix components of different lots.
- It is not possible to accurately diagnose SARS-CoV-2 infection only with the result of this product. The user with a positive result should consult with a medical doctor, follow local authorities recommendations, and not take any decision of medical relevance without first consulting their medical practitioner.
- If the concentration of SARS-CoV-2 antigen in the sample is less than the detection limit of the test, or if it is collected or transported improperly, a false negative result may appear. Therefore, the possibility of SARS-CoV-2 infection cannot be eliminated with a negative result.
- This product cannot differentiate between SARS-CoV and SARS-CoV-2 antigens.
- In the early stages of infection, low levels of antigen expression can result in non-reactive results. Sample collected after 7 days from the onset of symptoms may have false negative result.
- This product is intended for infection detection and not for determining infection status.
- If you have a wound or disease in your mouth or nose, be careful not to aggravate the wound.
- Reagents stored or samples collected at lower temperatures should be allowed to come to room temperature (15~25°C) before use.
- Do not suck the samples and reagents.
- Do not smoke, eat, drink, use cosmetic or touch contact lenses while handling the product.
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- The specimen and other components contacted with the sample (e.g. used fragment of the tabletop, timer surface) can be a source of infection even if the test is negative. They should be disinfected. Hands also should be washed or disinfected after and also before the examination.

Performance characteristics

Limit of detection (LoD)

The LoD was determined using limiting dilutions of inactivated SARS-CoV-2 (ZeptoMetrix, #0810587CFHI) in two separate methods.

For LoD screening, positive samples serially diluted 1/2 from $1.15x10^5$ $TCID_{50}$/ml to $2.24x10^2$ $TCID_{50}$/ml.

For confirmation LoD study, 5 points are set as the interval estimated as LoD. Select the lowest concentration marked as positive (≥95%) and one marked negative and proceed to the next test.

As a result of LoD conformation test based on the selected point, the lowest concentration marked positive (≥95%) at 5.62×10^2 $TCID_{50}$/ml for saliva was determined.

- Saliva LoD: 5.62×10^2 $TCID_{50}$/ml

Cross-reactivity/ Microbial interference

Viruses/bacteria listed below were confirmed not to have cross-reactivity or cause interference with PCL SELF TEST - COVID19 Ag.

- Virus (10^5 $TCID_{50}$/mL): Adenovirus type 1, Adenovirus type 7, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43, MERS-CoV, SARS-CoV, Cytomegalovirus, Influenza A H3N2, Influenza A H1N1, Influenza B, Enterovirus type 71, Parainfluenza type 1, Parainfluenza type 2, Parainfluenza type 3, Parainfluenza type 4A, Measles virus, Human Metapneumovirus, RSV type A, RSV type B, Rhinovirus, Epstein Barr virus, Mumps virus and Coronavirus HKU1 (in silico BLAST)
- Bacteria (10^6 CFU/mL): B. pertussis, E. coli, H. influenzae, M. catarrhalis, L. pneumophila, M. pneumoniae, M. tuberculosis, N. meningitidis, P. aeruginosa, S. epidermidis, S. pneumoniae, S. pyogenes, S. salivarius and S. aureus

Endogenous/Exogenous interference

Potential interfering substances listed below were confirmed not to have a response with PCL SELF TEST - COVID19 Ag.

Mucin (4 mg/mL), Human Blood (4%), 4-Acetamidophenol (10 mg/mL), Acetylsalicylic Acid (20 mg/mL), Chlorpheniramine (5 mg/mL), Diphenhydramine (5 mg/mL), Guaiacol glyceryl ether (20 mg/mL), Oxymetazoline (0.05 mg/mL), Phenylephrine (1 mg/mL), Fexofenadine (500 mg/mL), Amantadine (500 mg/mL), Ribavirin (500 mg/mL), Pseudoephedrine HCl (20 mg/mL), Ibuprofen (10 mg/mL), Tamiflu (48 mg/mL), Naso GEL (5%), Chloraseptic (1.5 mg/mL), Cromolyn (15%), Zicam (5%), Homeopathic preparations (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4µg/mL), Mupirocin (10 mg/mL), Fluticasone Propionate (5%), Heparin sodium salt (10%(v/v)), α-Amylase (0.2units/ml), IgA (500ug/ml), Berocca(Bayer) - Vitamin C (25 mg/ml), Listerine (50 % (v/v)), Colgate(Toothpaste) (200 mg/ml), Caffeine (73.5mg/ml), Taurine (500 mg/ml), Sprite (50 % (v/v)), Azelastine (0.01 %(v/v)), Flunisolide (3 mg/ml), Budesonide (0.063 ug/ml), Mometasone Furoate (0.005 ug/ml), Marplus Nasal Spray (10 %(v/v)), Benzalkonium chloride (1 %(v/v)), Neomycin trisulfate salt hydrate (5 mg/ml), Mucosol Tab. (4 ug/ml), Dicode SR Tab. (14.1 ug/ml), Levotro Syr (3 ug/ml), Donghwa elten Tab. (150 ug/ml).

Precision / repeatability study

The Precision / repeatability study, consisting of one negative control and three positive control of each of the saliva specimens, showed consistent results on each panel regardless of lot, operator, testing site and the test date.

Clinical accuracy

The clinical performance of the PCL SELF TEST-COVID19 Ag in saliva specimens were evaluated in comparison to Real-Time PCR results. Saliva samples for COVID-19 were collected from individuals diagnosed as positive or negative by RT-PCR testing.

Positive percent agreement (PPA) is 90.10 % (95% CI: 82.73% - 94.53%) which means 90.10% of positive tested individuals by PCR are positive when tested by this product. Negative percent agreement (NPA) is 99.68 % (95% CI: 98.18% - 99.94%) which means 99.68% of negative tested individuals by PCR are negative when tested by this product.

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	91	1	90.10	99.68
Negative	10	307		
Total	101	308		

Check for Invalid Result

- When your test has experienced an error, you will need to retest with a new test or consult a healthcare professional.
- If you have any questions, please contact us.
  Tel: 82-70-4673-3433
  E-mail: pcl@pclselftest.com
  website: http://pclselftest.com

Key to symbols used

REF	Catalog number	IVD	*In vitro* diagnostics medical device
LOT	Lot number		Consult instructions for use
n	Sufficient for n tests		Do not reuse
2°C 30°C	Store at 2-30℃		Manufacturer
	Expiration Date		Caution
EC REP	European authorized representative	CE 1434	Conformity European (for PCL SELF TEST - COVID19 Ag)
	Do not use if package is damaged		Keep dry
	Protect from sunlight		

PCL, Inc.
701, 99, Digital-ro 9-gil, Geumcheon-gu, Seoul, 08510, Rep. of Korea
Tel: +82-70-4673-3433
Fax: +82-70-4673-3425
Website: www.pclchip.com