IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-1T

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-1T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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
Test card	Test card with antibody coating and built-in strip (pouch sealed)	1 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer x1 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	1 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	1 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

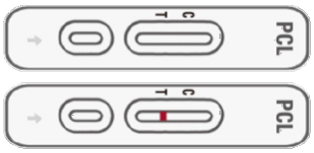
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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

IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-2T

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-2T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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)
		2
Test card	Test card with antibody coating and built-in strip (pouch sealed)	2 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer X2 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	2 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	2 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

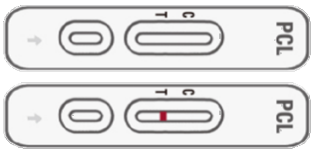
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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

IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-3T

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-3T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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)
		3
Test card	Test card with antibody coating and built-in strip (pouch sealed)	3 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer X3 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	3 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	3 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

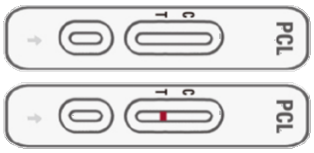
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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

IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-5T

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-5T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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)
		5
Test card	Test card with antibody coating and built-in strip (pouch sealed)	5 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer X5 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	5 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	5 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

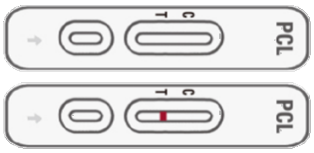
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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

IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-25T

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-25T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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)
		25
Test card	Test card with antibody coating and built-in strip (pouch sealed)	25 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer X25 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	25 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	25 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

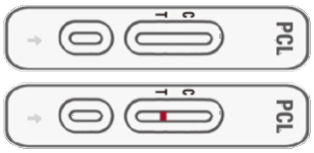
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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

IVD 2℃ 30℃

COV04ST-IFU-001S (Rev. 4)

REF COV04ST-50T

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-50T

Intended Use

PCL SELF TEST-COVID19 Ag is a rapid Immunochromatographic assay (ICA) for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from saliva that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Persons who test positive with the PCL SELF TEST-COVID19 Ag should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The PCL SELF TEST-COVID19 Ag is intended for home use and, as applicable for a lay user testing another person, including self-testing in a non-laboratory setting.

The PCL SELF TEST-COVID19 Ag is only for use under the Interim Order No.3 Respecting the Importation and Sale of Medical Devices for Use in Relations to COVID-19.

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 COVID19 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)
		50
Test card	Test card with antibody coating and built-in strip (pouch sealed)	50 ea.
Extraction buffer tube	Liquid reagent for sample extraction and development, filled in plastic tube.	500 µL buffer X50 ea.
Filter cap	Disposable lid for depositing a certain amount of sample on the test card	50 ea.
Paper cup	Funnel-shaped paper cup with a hole in the bottom	50 ea.
IFU	Instructions for use	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.

Instructions for Use

STEP 1. 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.

STEP 2. Sample Collection

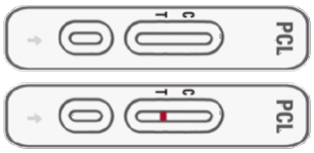
*Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

5. Prepare the funnel to avoid any leaks during sample collection.
   5-1. Place the paper cup so that the tab sticks out from the lower right side.
   5-2. Start by folding the left side of the paper cup inwards following the crease.
   5-3. Fold it in another time in the same direction.
   5-4. Slide the tab into the slit opening across from it.
   5-5. Check to make sure the seal is tight.
   5-6. Lightly press on either side to form a cone.
6. 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.
7. Gather enough saliva in your mouth for 30 seconds and spit it into the tube up to the indicated line. Be careful not to mix phlegm when collecting saliva.
8. 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.
9. Shake the tube up and down 10 times.

STEP 3. Test Preparation & Result Interpretation

10. Take the test card out of its pouch and place it on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card.
11. Verify the test result on the test card ten minutes later. Do not go over 20 minutes to verify the result.

Using the test card can lead to three different results:

Negative	
Positive	
Invalid	

- Negative: If only one band appears on “C”, the test is a valid “negative”, meaning no SARS-CoV-2 antigens were detected. If you show symptoms or if you were in close contact with a SARS-CoV-2 patient, please still refer to medical center for additional PCR testing. For official diagnosis, make sure a qualified medical professional does so on the basis of this test result and more clinical findings including additional testing. Finally, even when the band on the card is faint, it is considered to be valid.
- Positive: If bands appear on both “C” and “T”, the result is a valid “positive”, meaning SARS-CoV-2 antigens were detected. So any faint color lines in the test region (T) should be considered positive. In this case, please refer to the nearest medical center for an official PCR test and appropriate treatment.
- Invalid: If no color band appears or if only one color band appears near the letter “T”, the result is invalid. In this case, please perform another test using a new sample.

Warnings & 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.
- This product is a novel coronavirus antigens diagnosis medical device using the saliva.
- Before testing, read the instruction for use and follow the test procedure.
- the low positive-like results (thin bands) are considered as positive.
- Children are recommended to proceed with saliva test.
- Show the child the test kit and explain what you are going to do.
- Do not use on anyone under 2 years of age.
- 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. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product.
- 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.
- Do not use it if you have a wound or disease in your mouth.
- 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 eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Do not use stored specimens. Long-term storage may result in a signal decrease
- Dispose of all samples and materials used to perform the test must be handled and discarded in accordance with local regulations.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

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 $2.25x10^2$ $TCID_{50}$/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, Herpes Simplex virus-1, 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, S. aureus, C. pneumoniae, P. gingivalis, B. oralis, Nocardia sp., S. mutans, Eikenella sp., C. albicans, and P. jirovecii (in silico BLAST).
- Pooled human nasal wash

Endogenous/Exogenous Interference

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

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

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.

- Saliva specimen

Positive percent agreement, PPA is 90.14 % (95% CI: 80.74% - 95.94%) and negative percent agreement, NPA is 99.61 % (95% CI: 97.86% - 99.99%).

Saliva	RT-PCR*		PPA (%)	NPA (%)
	Positive	Negative		
Positive	64	1	90.14	99.61
Negative	7	257		
Total	71	258		

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
Σ n	Sufficient for n tests		Do not reuse
2℃ 30℃	Store at 2-30℃		Manufacturer
	Expiration Date		Caution

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