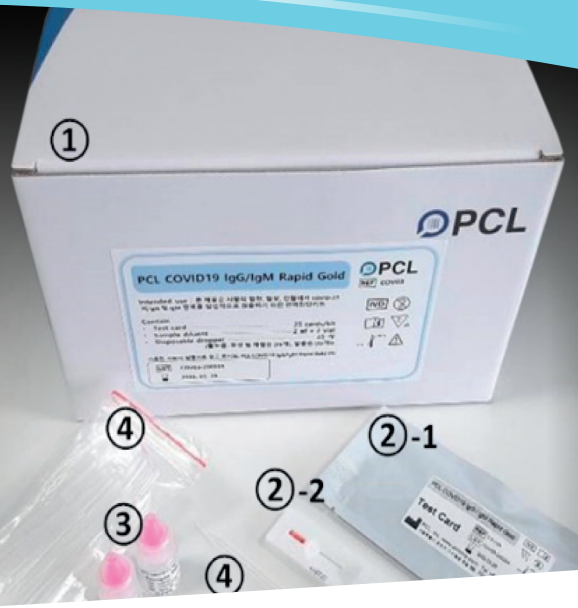
COV03

PCL COVID19 IgG/IgM Rapid Gold

COVID19 Test Kit

Instruction for use



1. Package Box
2-1. Inspection Pouch
2-2. Test Card
3. Buffer for Specimen
4. Dropper

INSTRUCTION FOR USE

Please read the instruction manual carefully before performing the test. Follow the instructions and do not modify the process. Strict adherence to the guidelines will avoid misleading results and achieve optimal performance of PCL COVID19 IgG/IgM Rapid Gold.

PRODUCT NAME

PCL COVID19 IgG/IgM Rapid Gold

INTENDED USE

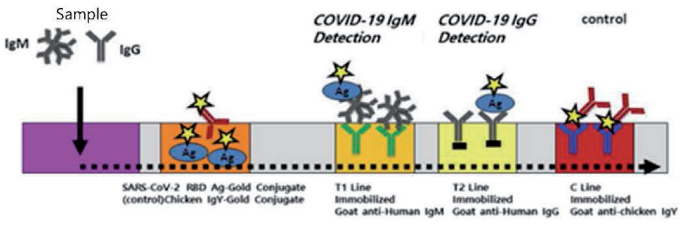
PCL COVID19 IgG/IgM Rapid Gold is an in vitro diagnostic medical device for qualitative detection of IgG and IgM antibodies of COVID19 infection in human serum, plasma, venous blood and capillary blood.

CONCEPT

COVID19 is a respiratory disease caused by a new type of coronavirus (SARS-CoV-2) virus first identified in December 2019 in Wuhan, China [1]. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath, and more. In severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and death. Coronaviruses are a group of viruses that cause symptoms from common cold to more serious illnesses such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV) [2].

PRINCIPLE OF THE PROCEDURE

This product (PCL COVID19 IgG/IgM Rapid Gold) is an in-vitro diagnosis kit that makes use of immunochromatography method that combines antigen-antibody reaction and chromatography for qualitative detection of COVID19 IgG and IgM in human serum, plasma, venous blood, and capillary blood.



KIT COMPONENTS

	Component	Description	Unit
1	Test card	Test card with integrated strips coated with antibodies and antigens (pouch seal)	100 pcs./box
2	Specimen diluent	Liquid reagent for sample dilution and development	8 pcs. 2ml vials/ box.
3	Disposable dropper	Disposable dropper for sucking samples and dropping them on Test card	100 pcs./box
4	User's manual	User's manual	1 pc./box
5	Lancet	Used to puncture the skin in order to dispense the blood	100 pcs./box
6	Alcohol swab	To cleanse the tip of the finger before injection and blood sampling	100 pcs./box

REQUIRED MATERIAL NOT INCLUDED

- Timer or stopwatch.

SAMPLE COLLECTION AND STORAGE METHODS

Capillary: Lancet

① Disinfect the tip of your finger with alcohol before sampling (capillary blood).
② Allow the alcohol to evaporate from the disinfected area, and then pierce the disinfection area with lancet to drain the capillary blood.
③ Collect blood on the skin with the disposable dropper included with the kit.
④ Collected blood should be used for testing immediately after collection.

Venous blood: venipuncture

① Collect blood from a venipuncture in a tube containing anticoagulant.
② Collected blood should be used immediately or within 24 hours when stored at 2~8 ° C.
③ The sample should be at room temperature when tested

Plasma Sample Preparation

① Collect the collected blood in a tube containing anticoagulant and centrifuge the specimen and completely remove the pallets of blood clots and blood clotting components formed.
② Do not use specimens with heavy hemolysis or with high blood fat levels.

Vitrex Medical 19052020 Rev. 002

CTI group

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③ In principle, separated serum should be used immediately. But under inevitable conditions, it should be kept refrigerated or frozen. However, frozen samples cannot be refrozen after thawing.
  • Human serum, plasma, venous blood, and capillary blood can be used for this kit, and the commonly used anticoagulants (heparin, EDTA and sodium citrate) do not affect the test outcomes.

Serum Sample Preparation

① The collected blood is collected in a tube containing no anticoagulant, and left to stand at room temperature for 30 minutes to cause coagulation, followed by centrifugation to separate serum.
② Do not use specimens with heavy hemolysis or suspension or high blood fat levels.
② In principle, separated serum should be used immediately. But under inevitable conditions, it should be refrigerated or frozen. However, frozen samples cannot be refrozen after thawing.

SAMPLE STORAGE

- Samples should be collected in accordance with general clinical guidelines, avoiding hemolysis.
- For plasma or serum samples, store at 2~8°C for use within 5 days after collection. For longer storage, store the samples at - 70°C for no more than 3 months, and the freeze-thaw cycle should not exceed 3 times.
- Whole blood should be used immediately after collection, but under inevitable conditions, they can be stored at 2~ 8°C for up to 3days.
- Do not use samples with hemolysis, lipemia or jaundice
- Make use of air-tight containers with ice for transport of samples.

STORAGE AND STABILITY

- Storage condition: Store at 2 ~ 30°C in dry place.
- Expiry date: 2 months from date of manufacture (indicated on the kit)
- This product should be used immediately after opening the pouch (within 1 hour).

WARNINGS AND PRECAUTIONS

- This product is intended for professional use.
- This product is intended for single use, and should not be reused.
- This product is intended for use with human serum, plasma and whole blood (venous and capillary) samples only.
- Inspections should be performed strictly in accordance with the guidelines.
- Do not use old or damaged products.
- The reagent can be stored at room temperature. Reagents or samples stored at low temperatures should be allowed to come to room temperature before use.
- If clinical samples need to be frozen below -20°C, do not freeze for more than three months and do not exceed three freezethaw cycles.
- Remove the Test card from the pouch and inspect it as soon as possible to avoid prolonged exposure to air. Moisture in the air affects the test results.
- Do not use samples that are left out for too long, or with obvious contamination by visible/odor inspection.
- Follow laboratory test procedures for infectious diseases. Waste after use should be treated as an infectious material and not disposed of randomly.
- suspected and suspected substances.
- The following are related considerations.
  - Wear gloves and handle samples and reagents.
  - Do not suck the sample.
  - Do not smoke, eat, drink, or use cosmetic or touch contact lenses while handling the product.
  - Spilt samples or reagents should be cleaned with disinfectants.
  - Disinfect and dispose of all samples, reagents and potential contaminants in accordance with applicable local regulations.
  - Components of this kit is stable till state expiry date under appropriate handling and storage conditions. Do not use the kit after the expiration date.

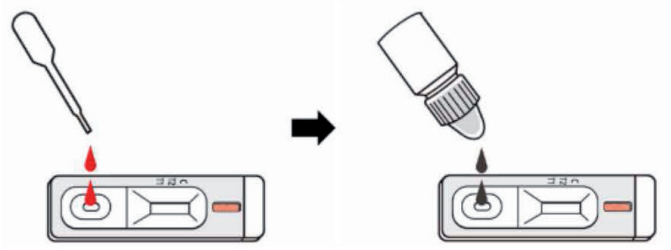
PREPARATION BEFORE USE

Reagent Preparation

- Reagents and frozen/cold samples are allowed to stand at room temperature for 20-30 minutes prior to testing.
- Open the inspection pouch and Test card and place it on a flat surface.
  * Open the inspection pouch just before use. If the pouch is left unused for more than 2 hours after opening, it may cause inaccurate results.

METHOD OF INSPECTION

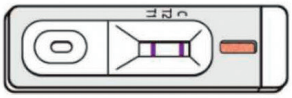
① Open the inspection pouch and place Test card on a flat surface.
② Drop 10 ul of sample into the sample hole of the Test card using a disposable dropper.
② Drop 2-3 drops (60 ul) of sample diluent into the sample hole of the sample device after the sample has been loaded.



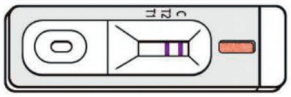
④ Read the results after 10-15 minutes afterwards. Time of result inspection should not be longer than 20 minutes after applying the sample diluent.

RESULT INTERPRETATION

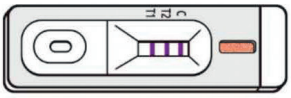
- COVID19 IgM positive: test line (T1), control line (C) red or purple



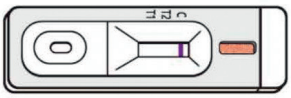
- COVID19 IgG positive: test line (T2), control line (C) red or purple



- COVID19 IgM / IgG co-positive: both test (T1, T2) and control (C) red or purple



- COVID19 IgM / IgG negative: Only control line (C) red or purple



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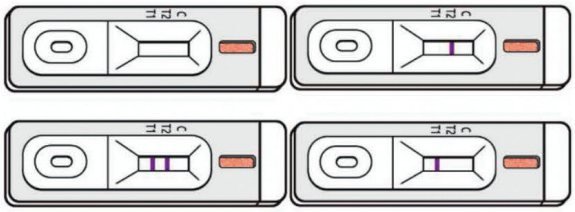
- Invalid: No red or purple band on the control line (C). Retest recommended.



QUALITY CONTROL

- All test results should show a red or purple color band on the control line (C).

LIMIT OF INSPECTION

- The test results of this product should not be considered as absolute, and should not be the sole basis for treatment or patient management. The infection should be confirmed by a specialist along with other experimental results, clinical symptoms, epidemiology and additional clinical data. • In the early stages of infection, low levels of antibody expression can produce negative results.
- Due to limitations of detection methods, negative results cannot entirely rule out the possibility of infection.
- This product can only qualitatively detect COVID19 antibodies in human serum, plasma and whole blood samples, and cannot determine the quantity of specific antibodies in the samples.

PERFORMANCE CHARACTERISTICS

Limit of Detection

In order to set the minimum detection limit of this product, IgG and IgM positive samples were diluted by concentration using 3 lots of products and repeated 20 times for each test. As a result, IgG was set to 1: 20,000 and IgM was set to 1: 10,000.

Cross-reactivity

Substances listed below were confirmed not to have cross-reactivity with PCL COVID19 IgG/IgM Rapid Gold.
- Influenza A IgM, Influenza B IgM, RSV IgM, Parainfluenza IgM, Mycoplasma pneumonae IgM, Chlamydia pneumoniae IgM

Interference response

Substances listed below were confirmed not to have interference response with PCL COVID19 IgG/IgM Rapid Gold.
- Hemoglobin, Bilirubin, Triglycerides, Cholesterol, Rheumatoid Factor, EDTA, Sodium citrate, Heparin sodium

Precision

In order to assure the reproducibility of PCL COVID19 IgG/IgM Rapid Gold, the reproducibility between the lots, the equipment, the operators, and the test sites were evaluated. All of the test delivered the same results for all panels tested, affirming reproducibility of the product.

BIBLIOGRAPHY

1. Wong SK, Li W, Moore MJ, Choe H, Farzan M. A 193-amino acid fragment of the SARS coronavirus S protein efficiently binds angiotensin-converting enzyme 2. J Biol Chem. 2004 Jan 30;279(5):3197-201.
2. Lu et al ., Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Lancet. 2020 Feb 22;395(10224):565-574.

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KEY TO SYMBOL USED

REF	List number	IVD	*In Vitro* Diagnostics Medical Device
LOT	Lot Number		Consult instructions for use
	Do not reuse	30℃ 2℃	Store at 2-30 ℃
	Expiration Date		Manufacturer
		EC REP	European authorized representative