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	<b>Product Name: PCL COVID19 Speedy RT-PCR</b>		Revision date

## SECTION 1 COMPANY AND MATERIAL IDENTIFICATION

### Company Information

- Manufacturer: PCL, Inc.
- Address: #701, 99, Digital-ro 9-gil, Geumcheon-gu, Seoul, 08510, Republic of Korea
- Telephone: +82-70-4673-3433
- Fax: +82-70-4673-3443
- Website: www.pclchip.com
- E-mail: pclchip@pclchip.com

### Product Information

- Name: PCL COVID19 Speedy RT-PCR
- Intended use: The PCL COVID19 Speedy RT-PCR is an in vitro diagnostic (IVD) real-time reverse transcription PCR (RT-PCR) medical device for the qualitative detection of SARS-CoV-2 genes in human nasopharyngeal specimens from individuals who are suspected of COVID-19 by their health care provider. The PCL COVID19 Speedy RT-PCR is intended for use by qualified personnel and trained in the techniques of real-time RT-PCR and in vitro diagnostic procedures. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
  - In vitro diagnostic use only
  - Professional use only

## SECTION 2 PRODUCT COMPOSITION AND CONTROLS

### List of components


	Components	Descriptions
1	Master Mix	Fast Virus 1-Step Master Mix (Sodium azide (< 0.1), Glycerol (20-30%), Dimethyl sulfoxide (5-10%), Gelatin (1-5%))
2	Primer+Probe Mixture	N Primer, N Probe (FAM), E Primer, E Probe (Cy5), IC Primer, IC Probe (HEX), TE buffer
3	Positive Control	Plasmid DNA, TE buffer
4	DW	Diethylpyrocarbonate (DEPC) water
5	IFU	User manual

We recommended handling reagents with caution. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide.

## SECTION 3 HEALTH HAZARDS

This product is not harmful when users follow safe laboratory practices. None of the components within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA) or the European Union (EU) Directives.

- For in vitro diagnostic use only
- **Potential routes of exposure:** No hazardous exposures anticipated under conditions of use as described in other product literature.

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- **Eye:** None
- **Skin:** None
- **Inhalation:** None
- **Ingestion:** None
- **Chronic toxicity:** Unknow
- **Reproductive and developmental Toxicity:** The components of this product are not considered reproductive or developmental toxins.
- **Carcinogenicity:** None of the components of this product is listed by OSHA as a carcinogen
- **Medical Conditions Aggravated by Exposure:** Skin and eye conditions (e.g., dermatitis, conjunctivitis).

#### SECTION 4 FIRST AID MEASURES

- **Eye Contact:** Immediately flush eyes thoroughly with water for at least 15 minutes. If discomfort persists notify medical personnel.
- **Skin Contact:** Immediately wash thoroughly with soap and water for 15 minutes. If discomfort persists notify medical personnel.
- **Inhalation:** Not expected under anticipated conditions of normal use of the reagent. If symptoms are experienced, immediately move to fresh air. If discomfort persists notify medical personnel.
- **Ingestion:** Not expected under anticipated conditions of normal use of the reagent. Drink a moderate amount (8-12 oz.) of water and immediately notify medical personnel. Never give anything by mouth to an unconscious person.
- **Note to physician:** Treat symptomatically.

#### SECTION 5 FIRE FIGHTING MEASURES

- **Unusual Fire and Explosion Hazards:** Not known.
- **Hazardous Combustion Products:** Not known.
- **Extinguishing Media:** Water, carbon dioxide, multipurpose dry chemical, foam.
- **Special Fire Fighting Equipment:** Wear full protective clothing and NIOSH/MSHA-approved positive pressure, self-contained breathing apparatus. Thoroughly wash all equipment after use.

#### SECTION 6 ACCIDENTAL RELEASE MEASURES


- **Personal Precautions:** Take proper precautions to minimize exposure by using appropriate personal protective equipment including gloves, a lab coat and eye protection, and follow good laboratory practices to avoid any and all accidental exposure to workplace materials.
- **Environmental precautions:** No special environmental precautions required.
- **Cleaning up:** Soak up with inert absorbent material.

#### SECTION 7 HANDLING AND STORAGE

- **Handling:** Use personal protective equipment. No special handling advices are necessary.
- **Storage:** Observe all conditions described in the user manual and on the labels.
- **Specific end use:** Professional use only

#### SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

- **Eye Protection:** Wear safety glasses with side shields or full-face shield if eye contact is likely. The choice of protection should be based on the potential for exposure to the eyes.
- **Respiratory Protection:** Inhalation not anticipated in intended use. Respiratory protection not necessary.
- **Skin Protection:** Wear gloves, lab coat, or other protective overgarment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.
- **Engineering Controls:** Provide adequate ventilation and minimize the risk of inhalation of vapors and mists.
- **Other:** Wash hands immediately after handling this material (especially before eating, drinking or smoking).

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## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** Liquid
- **Odor:** Odorless.
- **Boiling Point:** No data
- **Melting Point:** No data
- **Molecular Weight:** No data
- **Flash Point:** No data
- **Auto-flammability:** No data
- **Explosive Properties:** No data
- **Oxidizing Properties:** No data
- **Vapor Pressure (mmHg & temp.):** No data
- **Specific Gravity (H<sub>2</sub>O=1):** No data
- **Solubility in water:** Soluble
- **Partition Coefficient:** No data
- **Percent Volatile (%):** No data
- **Vapor Density (air=1):** No data
- **Evaporation (Butyl Acetate=1):** No data

## SECTION 10 STABILITY AND REACTIVITY

- **Reactivity:** Sodium azide may react with lead and copper plumbing to form highly explosive metal azide.
- **Stability:** Stable under normal conditions of use.
- **Hazardous Decomposition Products:** No data
- **Conditions to Avoid:** No data
- **Materials to Avoid:** No dangerous reaction known under normal use.

## SECTION 11 TOXICOLOGICAL INFORMATION

No toxicological effects under conditions of normal use. See Section 3 for additional information on health hazards.

- **Inhalation:** None
- **Skin (Irritancy and Acute Toxicity):** None
- **Eye (Irritancy and Acute Toxicity):** None
- **Ingestion:** None
- **Chronic Toxicity (Target Organ Effects):** None
- **Carcinogenicity:** None
- **Reproductive and Developmental Toxicity:** None
- **Mutagenicity:** None

## SECTION 12 ECOLOGICAL INFORMATION

No substances known to be hazardous to the environment.


- **Persistence and Degradability:** No data available
- **Aquatic Toxicity:** No data available

## SECTION 13 DISPOSAL CONSIDERATIONS

Dispose of waste materials according to prescribed national and local regulations

## SECTION 14 TRANSPORT INFORMATION

Not regulated in the meaning of transport regulations

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- Land Transport (ADRIRID): Not regulated.
- Air Transport (ICAO/IATA): Not regulated.
- Maritime Transport (IMO-IMDG): Not regulated.
- The product is safe for air/ocean transportation and not regulated by IATA DGR/IMDG

### SECTION 15 REGULATORY INFORMATION

- SARA 313: This product does no regulated by SARA.
- California Proposition 65: This product does not contain any Proposition 65 chemicals.

### SECTION 16 OTHER INFORMATION

The above information is based on data available to us and is correct to the best of our knowledge and belief at the date of publication. Since the information available to us may be insufficient/inadequate, no representation, warranty, or guarantee, expressed or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. As we cannot control the actual method, quantity, or conditions or use, we shall not be liable for any harm caused by handling the reagents as directed herein.