

BEYOND NEW HORIZON  
**CANCERROP**  
Covid-19 Diagnostic Tests

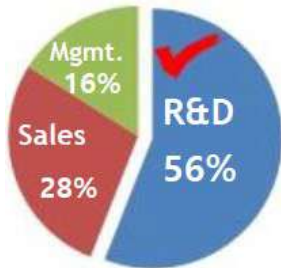


# CANCERROP Profile



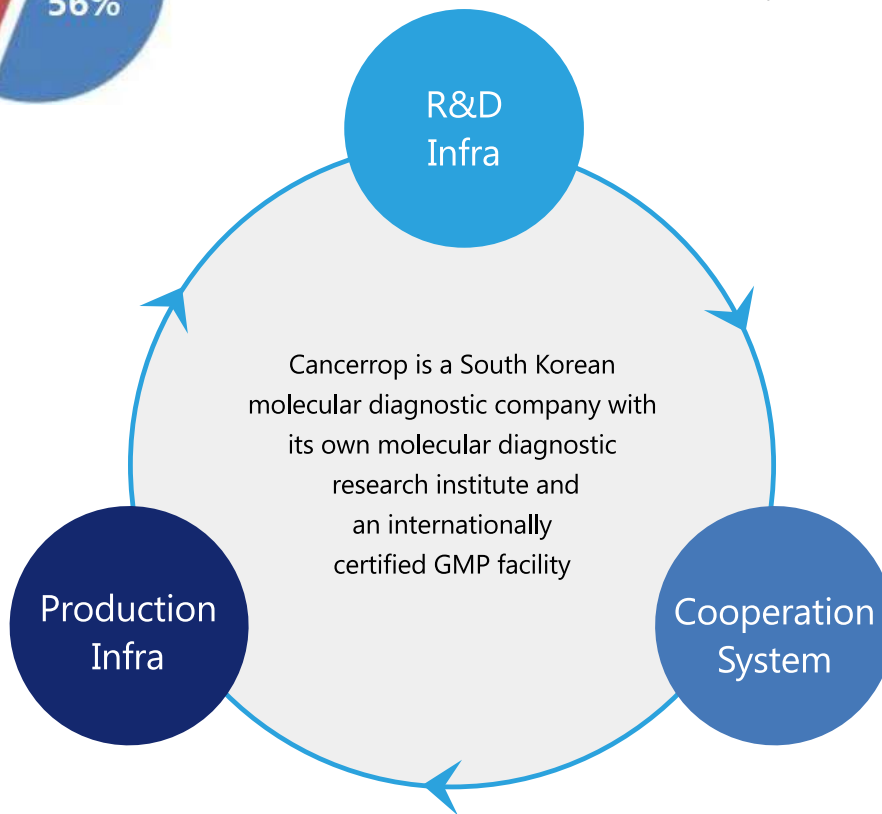
*Own Molecular Diagnostic Research Institute and Research Personnel*

HR Composition



*Quality Management System*

- Korean Standards
  - KGMP, MFDS, Genetics Testing
  - Agency centers of disease control and prevention
- International Standards
  - ISO 9001, ISO 14001, ISO 13485
- EU Standards
  - CE-IVD: BAC Chip, STD PCR Kits



*Largest Production Infrastructure and most Certifications in the Industry*

Scale: 330m<sup>2</sup>  
 Production: 100,000 copies a year  
 Certification: European CE, GMP  
 Other: Class 10,000 clean room, constant temperature and humidity



*Securing Domestic and Overseas Sales Network*

MYONGJI HOSPITAL

BORYUNG  
보령바이오파라다



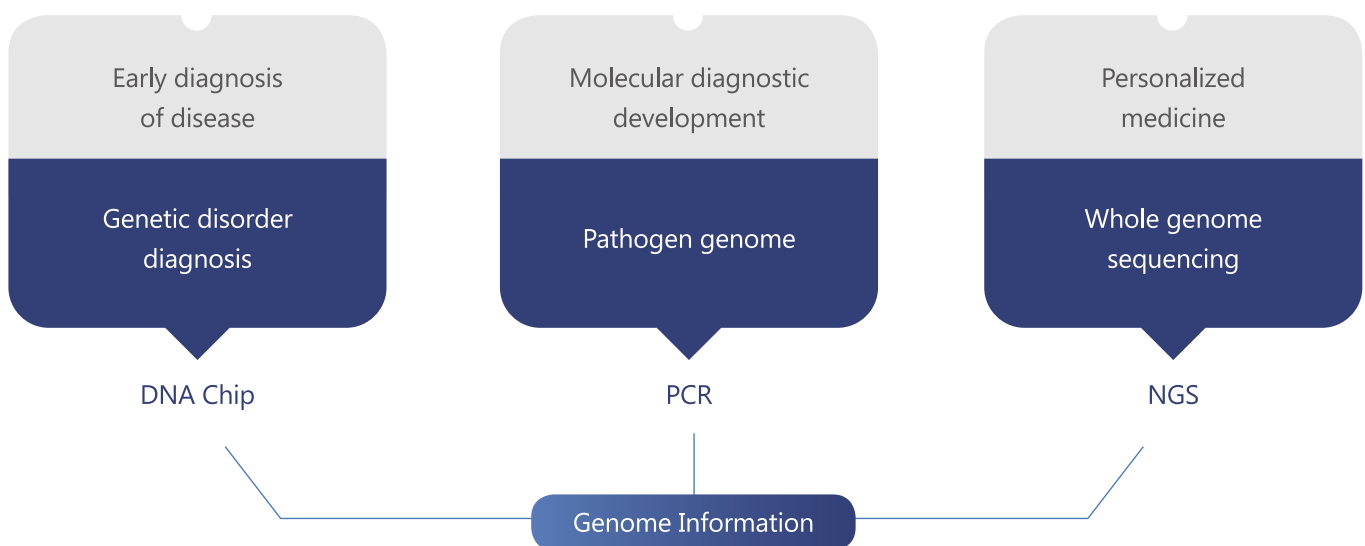
Network of 400



Korean hospitals

Cancerrop is a molecular diagnostic company that provides early diagnosis services and develops new diagnostic technologies

## Leader of Innovative Molecular Diagnostics |



## | Key Success

Successful commercialization of original technology

- 2007 Start of M DNA Chip Diagnosis Service
- 2009 Start of G DNA Chip Diagnosis Service
- 2011 P DNA Chip Kit Development
- 2012 Certification of ISO 9001/14001/13485
- 2013 STD PCR Kit MFDS License Obtained

PCR/DNA Chip technology

- 2001 Establishment of MG Med
- 2006 Registered as Genetic Testing Laboratory
- 2006 Completion of BAC DNA Chip Manufacturing Technology

Laying the foundation for growth by establishing a cooperative system

- 2013 G DNA Chip Technology Transfer Contract with China (Ahngook Pharm)
- 2015 G DNA Chip Technology Transfer Contract with Japan (Boryung Biopharma)
- 2015 G DNA Chip Technology Transfer Contract with US (MacroGen ClinicalLab)
- 2017 Company name changed to CANCERROP  
Expansion of R&C for Precision Medicine
- 2020 **CANCERROP officially launched Q-Sens® COVID-19 RT-PCR Detection Kit (V1, V2) / Q-Sens® COVID-19 IgG/IgM Rapid Kit**

# Q-Sens® COVID-19 Detection Kit V2

## Principle

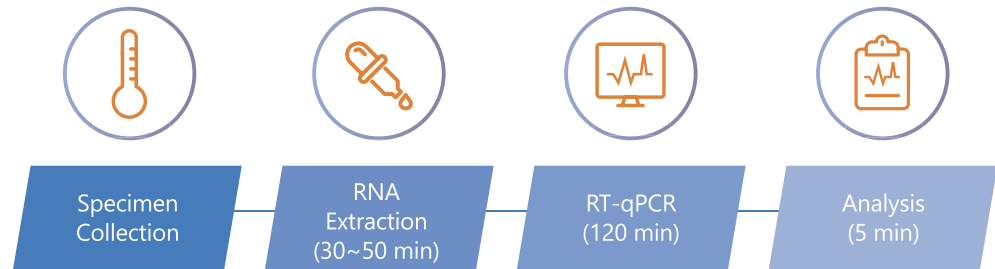
The Q-Sens® COVID-19 Detection Kit V2 is intended for the qualitative detection of SARS-CoV-2 in respiratory specimens such as nasopharyngeal swab, oropharyngeal swab and sputum from patients suspected of COVID-19 infection by their healthcare providers. The Q-Sens® COVID-19 Detection Kit V2 uses real-time reverse transcription polymerase chain reaction (RT-PCR) technology. This product contains enzymes and reaction components required for cDNA synthesis and PCR amplification, so a RT-PCR reaction can be easily performed by one step of adding of RNA template to primer/probe mixture. By using a probe-based multiplex PCR assay, SARS-CoV-2 and Sarbecovirus can be distinguished and diagnosed. The RdRp gene is specific for SARS-CoV-2 whereas the E gene is specific for Sarbecovirus. The internal control is designed to amplify an endogenous human gene and serves as an internal positive control to monitor sample quality, RNA extraction, and RT-PCR run.

## Targets

Target	5' Fluorophore	3' Quencher	Remarks
RdRp gene	FAM	BHQ1	SARS-CoV-2
E gene	HEX*	BHQ1	Sarbecovirus
Internal Control (IC)	Cy5	BHQ2	IC

\* ABI 7500 Fast: JOE or VIC, Bio-Rad CFX96: HEX

## Procedures



## Kit Components



Reagents	Volume (100 Tests)
2X One-Step RT-PCR Mix	2 × 650 µL
5X COVID-19 Primer Mix	520 µL
Positive Control (PC)	100 µL
RNase Free Water	1,000 µL

### Benefits

- Results within 2 hours after RNA extraction
- One-Step Multiplex RT-PCR
- Human Endogenous Internal Control (IC)

### Targets

- RdRp gene & E gene

### Specimens

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

### Packaging & Storage

- 100 Tests/Kit
- Store at below -20°C

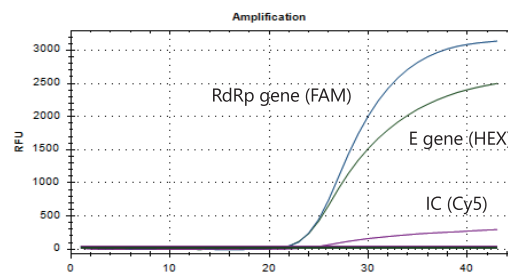
## Clinical Performances

Q-Sens® COVID-19 Detection Kit V2	FDA Approved Comparator Kit	
	Positive	Negative
Positive	70	0
Negative	0	200
Sensitivity	100% (95% CI: 94.8~100%)	
Specificity	100% (95% CI: 98.1~100%)	

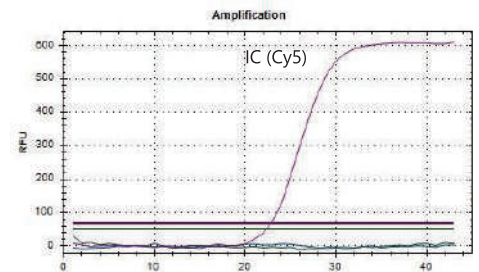
\* Overall Percent Agreement= 100% (95% CI: 98.6~100%) \* Cohen's kappa = 1

## Result and Data

COVID-19 Positive



COVID-19 Negative



- Ct value of targets < 40: Detected (+) - Ct value of targets ≥ 40: Not detected (-)

## Interpretation

Case	RdRp	E	IC	Interpretation
PC	+	+	-	<b>Valid</b>
NC	-	-	-	<b>Valid</b>
1	+	+	+	<b>(COVID-19 Positive)</b> SARS-CoV-2 RNA is detected.
2	-	-	+	<b>(COVID-19 Negative)</b> SARS-CoV-2 RNA is not detected.
3	+/-	+/-	-	<b>(Invalid)</b> Invalid result. Repeat test. If the result is still invalid, a new specimen should be obtained.
4	+	-	+	
5	-	+	+	

## Ordering Information

Cat. No.	Product Name	Size
MGQ005	Q-Sens® COVID-19 Detection Kit V2	100 Tests/Kit
MGI001	Q-Sens® COVID-19 IgG/IgM Rapid Kit	100 Tests/Kit

### Compatibility

- Bio-Rad CFX96 Touch™ Real-time PCR Detection System
- ABI 7500 Fast Real-time PCR Instrument System
- Most of Real-time PCR Instrument Systems

### Certification

- CE-IVD
- MFDS

### References

- Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/index.html> Accessed February 9, 2020.
- Centers for Disease Control and Prevention. Biosafety in Micro-biological and Biomedical laboratories (refer to latest edition). <http://www.cdc.gov/biosafety/publications/>

# Q-Sens® COVID-19 IgG/IgM Rapid Kit

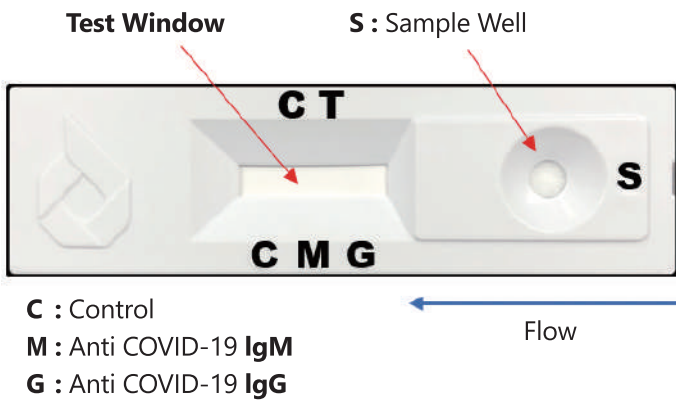
## Principle

The Q-Sens® COVID-19 IgG/IgM Rapid Kit was developed as an immunochromatographic assay to assist diagnosis of disease and immunological conditions by detecting anti-SARS-CoV-2 IgG and IgM antibodies in specimens such as fingerstick whole blood, venous whole blood, serum and plasma.

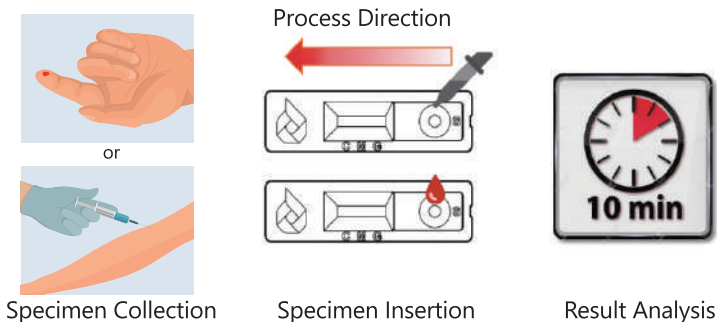
The immunochromatographic assay uses the sandwich method of antigens and antibodies of COVID-19.

The specimen will migrate by capillary action along the membrane, and produce red color on the control line, which is visible to the eye. If a COVID-19 antibody is present, an antigen-antibody complex is formed and shows red color on the test line. The Q-Sens® COVID-19 IgG/IgM Rapid Kit allows for quick results as it requires no additional equipment.

The Q-Sens® COVID-19 IgG/IgM Rapid Kit was developed according to the guidelines of WHO and KCDC.



## Work-Flow



## Benefits and Features

- Quick and easy testing
- Higher reliability than licensed products
- All necessary reagents provided

- Clinical data on patients confirmed by RT-PCR
- Pos 32 } Tested
- Neg 101 }

- Result-Sensitivity 94%

## Product Specification

- Main Characteristics
  - Performance verified by comparison analysis with RT-PCR method
  - Higher reliability than licensed products with 95% total concordance
  - Manufactured in a KGMP facility
  - Excellent sensitivity: Positive detection possible even with 4374x dilution for IgG, and 81x dilution for IgM
  - Accurate results: Results not affected by other interference and cross-response material
  - Rapid reaction: Qualitative detection completed within 10 minutes without additional equipment
  - Store at 2-30°C



# Q-Sens® COVID-19 IgG/IgM Rapid Kit

## Kit Components

Component Parts	Vol. (100 Tests)
Q-Sens® COVID-19 IgG/IgM Rapid Test Card	100 ea/box
10X Specimen Buffer	2.5 ml, 4 ea
Manual	1 ea











## Clinical Performances

	RT-PCR/STANDARD M nCOV Real-time Detection Kit		
		Positive	Negative
Q-Sens® COVID-19 IgG/IgM Rapid Kit	Positive	30	4
	Negative	2	97

## Interpretation

	Interpretation of the Result	Control (C line)	IgG (G Line)	IgM (M Line)
1	SARS-CoV-2 negative	+	-	-
2	SARS-CoV-2 IgM positive	+	-	+
3	SARS-CoV-2 IgG positive	+	+	-
4	SARS-CoV-2 IgM/IgG positive	+	+	+
5	Invalid/Retest	-	+	-
6	Invalid/Retest	-	-	+
7	Invalid/Retest	-	-	-

## Result

Interpretation	Developed Lines
IgM positive	
IgG positive	
IgM/IgG positive	
IgM weak positive	
IgG weak positive	
IgM/IgG weak positive	
Negative	
Invalid/Retest	
	
	



**CANCERROP**  
Beyond New Horizon

[www.cancerrop.com](http://www.cancerrop.com)



BEYOND NEW HORIZON  
**CANCERROP**  
Covid-19 Diagnostic Tests



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