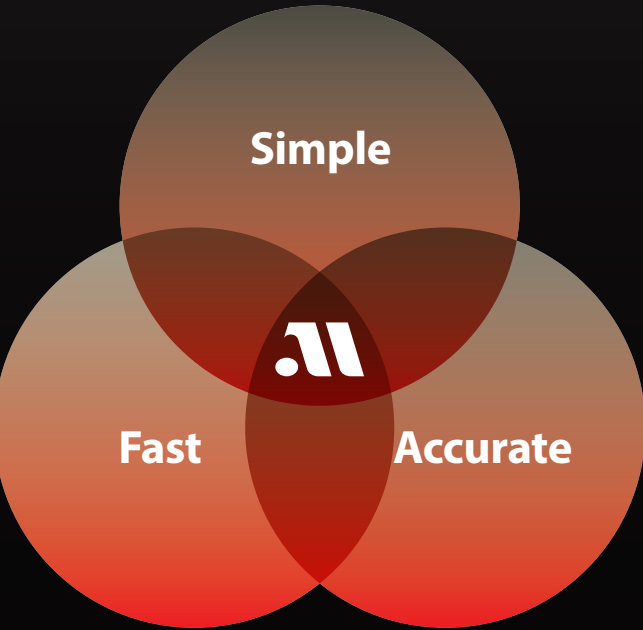


ABOUT US

Beyond MDx  **monitor**

M monitor Inc., founded in 2014, is one of the leading companies with high technologies based on nucleic acid isothermal amplification platform, develops and produces reagents and instruments for molecular diagnosis as well as research field. Our diagnostic products lead the paradigm of diagnosis in accuracy and speed aspects by combining with the advantages of both immuno-chemical diagnosis and molecular diagnostic methods. M monitor is leaping forward as a global molecular diagnosis company based on various product pipelines and innovation.

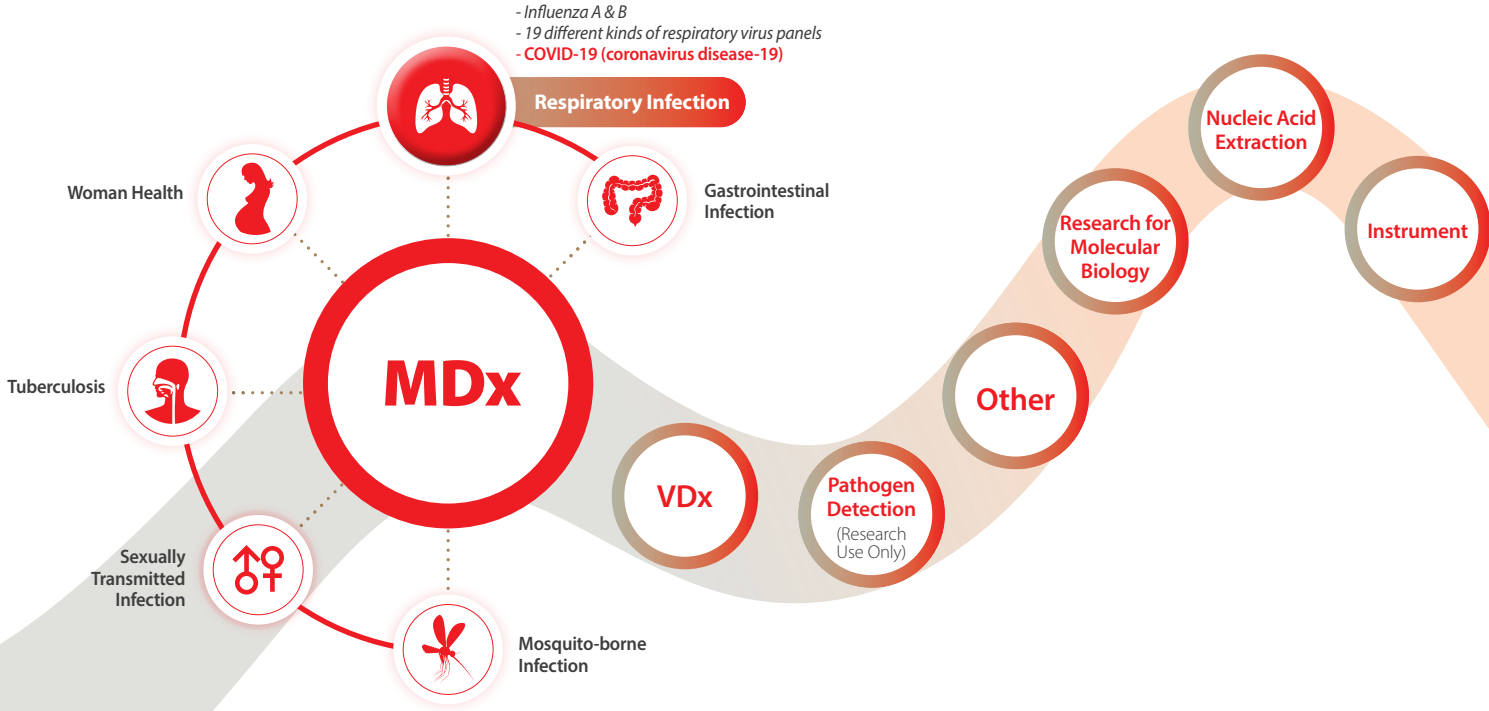
Actualize NEW types of MDx




Molecular diagnosis + Immunochemical diagnosis **NEW PARADIGM**

- Reverse transcriptase and DNA polymerase and the reaction takes place under a **constant temperature**.
- **High specificity** because of designed specific primers to be compatible with the target RNA.

M monitor stands in all areas of Molecular Diagnostics.



ORDERING INFORMATION

Category	Target	Cat. No.	Product	Specimen	Volume
	RdRP gene, N gene	52225	Isopollo® COVID-19 detection kit (colorimetric)	• Nasopharyngeal swab • Oropharyngeal swab • Sputum • Bronchoalveolar lavage	100 Tests
		52226	Isopollo® COVID-19 detection kit (premix) – RdRP gene, N gene		96 Tests
		52227	Isopollo® COVID-19 detection kit (real-time)		100 Tests

EXTRACTION REAGENT (Optional)

Mmaxpress® prep kit HA01

Cat. No 92401

Application Nucleic acid extraction

Specification 13 tests



» Available only for premix and colorimetric type. In case of real-time type, conventional extraction kits are used.

COMPATIBLE INSTRUMENT

MXM-F1

Cat. No 82301

Application Nucleic acid amplification

Specification 150 * 150 * 150 (mm) / 25 wells



MXM-L1

Cat. No 82302


Application Nucleic acid amplification

Specification 130 * 130 * 90 (mm) / 10 wells



» We recommend two kinds of isothermal amplifiers above, however, conventional PCR or real-time PCR instruments are also available if they can be set-up to constant temperature for isothermal reactions.

 **monitor**



- Isopollo® COVID-19 detection kit (real-time)
- Isopollo® COVID-19 detection kit (premix)
- Isopollo® COVID-19 detection kit (colorimetric)

BEYOND CONVENIENCE

Isopollo® **COVID-19** detection kit

A Fast, Efficient and Simple test that all wanted

M monitor introduces a real advance in point-of-care molecular diagnostics of coronavirus that is radically faster, cheaper, and more reliable than the conventional methods.



CORONAVIRUS COVID-19

Within **30** mins, Immediate diagnosis on site

About Coronavirus Disease 2019

Severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) is a virus that causes Chinese Wuhan pneumonia (coronavirus infection) that occurred in December 2019. The World Health Organization (WHO) says it can be transmitted from person to person, but SARS and MERS have reported that, unlike in the absence of symptoms, the new coronavirus is capable of transferring the new coronavirus during the incubation period. New coronaviruses, like SARS and MERS, are spreading to the respiratory tract through droplets.

WHY TO CHOOSE M monitor?

Isopollo® COVID-19 detection kit is for qualitative analysis to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection of clinical specimens of smeared material from human nasopharyngeal and oropharyngeal swab, sputum, and bronchoalveolar lavage by RT-LAMP (Reverse transcription loop-mediated isothermal amplification) and it has high specificity for targeted RNA because 6 primers selectively detect specific RdRp gene and N gene of SARS-CoV-2.

COVID-19 detection kits

Sensitivity

Detection up to 1 pg
Small amount of virus can be detected
*Higher sensitivity as domestic licensed/
temporary permitted product

Rapid

Diagnosis
within 30 mins

POCT

Immediate diagnosis on medical site
(Point-of-Care-Testing)

- **Cost reduction** through simultaneous multiple sample tests
- **99%** of accuracy and **100%** of specificity
- **Accurate** qualitative analysis
- Proper action and infection control through **rapid** diagnosis

Real POCT MDx

Isopollo® COVID-19 detection kit is a diagnostic kit that detects coronavirus based on the newest patent technology (LAMP), and there are three diagnostic kits; real-time type for higher accuracy, premix type for easy to use and colorimetric type for fast confirm the result.

Isopollo® COVID-19 detection kit (real-time)



Isopollo® COVID-19 detection kit (premix)



Isopollo® COVID-19 detection kit (colorimetric)



Sample extraction

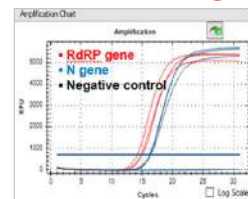


» Conventional RNA extraction kit available.

Reaction time

Amplification condition	Step	Temperature	Time	Cycles
	1	58°C	20 min	40
	2	80°C	2 min	1

Confirm the result using of software



- Positive criterion **Ct value** : within 40 Ct
- Negative criterion **Ct value** : No detection

Characteristic

Type	Real-time	Premix	Colorimetric
Product size (cm)	8.5*7.5*8	16.5*10*11.5 (2pcs/set)	8.5*7.5*8
Reagent type	Individual tube	Ready-to-use reagent	Individual tube
RNA extraction	Conventional extraction kit	Simple and direct extraction kit by M monitor (Mmaxpress® premix kit HA01)	

Sample Extraction Cat. No. 92401, Mmaxpress® prep kit HA01

- Insert Swab with sample into **A tube** and spin it 5~6 times.
- After spinning, replace the lid of the **A tube** with a filter cap and leave at room temperature for 5 minutes.
- Press **A tube** to discard the solution in the tube through the filter cap.
- Repeat the same process as ③ Lock the **B tube**, **C tube** and press the tube to discard the solution of each step through the filter cap.
- Transfer the filter cap from the **C tube** to the **D tube**, lock it. Place the tube upside down and leave for 3 minutes. And transferring the entire Elution buffer solution to a 1.5ml tube.
- Using Pipette and Filter Pipette Tip, 10ml of eluent transferred to 1.5ml tube is used for the reaction

Reaction time

Step	Temperature	Time
1	58°C	30 min
2	80°C	2 min

Confirm the result through visual colorimetric detection

Negative result shows purple color, while positive shows blue.

Color code	Color	Judgement
Blue	Blue	Positive
Purple	Purple	Negative

In case of Premix type,

- Aliquoted Lamp premix
= Primer + Enzyme mix + 2X Reaction Buffer
- Reaction time : 30 min

Example	Judgement
	P : Positive (Blue) N : Negative (Purple)

Comparison of other products

Spec.	real-time	premix / colorimetric
Technology	RT-LAMP	RT-LAMP
Kit size	100 tests / kit	96 tests / kit
Target gene	RdRP, N gene	RdRP, N gene
Sensitivity (%)	> 98%	> 98%
Accuracy (%)	> 99%	> 99%
Reaction time	20 min	30 mins
How to check	PCR performance	Color change
Consumables & device	CFX-96 (Bio-Rad), ABI 7500 / 7500 (Applied Biosystems™)	MXM-L1 *portable small isothermal Amplifier by M monitor

Spec.	A	B	C	D
Technology	Real-time PCR	Real-time PCR	Real-time PCR	Real-time PCR
Kit size	50tests / kit	100tests / kit	100tests / kit	100tests / kit
Target gene	RdRp, E gene	RdRP, E gene, N gene	RdRP, E gene	Orf1a, N gene
Sensitivity (%)	> 98%	> 98%	> 98%	> 98%
Accuracy (%)	> 99%	> 99%	> 99%	> 99%
Reaction time	6 hour	4 hour	2 hour	2 hour
How to check	PCR performance	PCR performance	PCR performance	PCR performance
Consumables & device	CFX-96 (Bio-Rad), ABI 7500 / 7500 (Applied Biosystems™)			

» Korea CDC's Emergency Use Approval (only 4 companies)

We developed three types of COVID-19 diagnostic kits.

Real-time type

Real-time type is similar to a PCR method. It will be more appropriate for places such as large hospitals and laboratories equipped with such experimental equipment.

Premix and colorimetric types

Premix and colorimetric types are easy to diagnose on medical sites. It can be checked the result (infected or not) with simple process without expensive equipment in the field.

*Storage expiration dates

- 6 months (from the date of manufacture)
(+) After opening 50 days

*Product storage condition

- Required refrigeration (-25°C~-15°C)