



Isopollo® COVID-19 detection kit

LAMP based assay system for detection of COVID-19
(Real-time / Premix / Colorimetric)



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Isopollo® COVID-19 detection kit
- *Real-time / Premix / Colorimetric*

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01 Kit Introduction



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

Isopollo® COVID-19 detection kit is a diagnostic kit based on the newest patent technology (LAMP) to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection from extracted RNA 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 genes (RdRP gene and N gene) of SARS-CoV-2.

| Specification | Product | | |
|-------------------------|--|---|---|
| | Isopollo® COVID-19 detection kit (real-time) | Isopollo® COVID-19 detection kit (premix) | Isopollo® COVID-19 detection kit (colorimetric) |
| Detection target | Coronavirus disease (COVID-19) | | |
| Target region | RdRP gene, N gene | | |
| Detection technology | RT-LAMP based assay system for detection of COVID-19 | | |
| RNA extraction | Conventional extraction kit | Simple and direct extraction kit by M monitor (Mmaxpress® prep kit HA 01) | |
| How to check | PCR performance | Immediate check by color change | |
| Compatible instruments* | CFX96™ Real Time PCR System (Bio Rad), ABI 7500 / 7500 Fast Real Time PCR System (Applied Biosystems) *Conventional qPCR system available | Recommended isothermal Amplifier by M monitor (MXM-L1) *Conventional PCR system available | |
| Running time | 22 min | 32 min | 32 min |

01 Kit Introduction



Isopollo® COVID-19 detection kit

▼ Contents of the kit and Quantity



| | Isopollo® COVID-19 detection kit (real-time) | | Isopollo® COVID-19 detection kit (premix) | | Isopollo® COVID-19 detection kit (colorimetric) | |
|-------------------------|---|-----------|---|----------|---|-----------|
| Reagent | 2X Reaction Buffer | 1.25 ml*2 | Lamp premix (CR/CN) | 30 µl*2 | 2X Reaction Buffer | 1.25 ml*2 |
| | Enzyme mix | 200 µl*1 | Control primer* | 40 µl*2 | Enzyme mix | 200 µl*1 |
| | Detection primer (CR) | 200 µl*1 | Control template* | 40 µl*1 | Detection primer (CR) | 200 µl*1 |
| | Detection primer (CN) | 200 µl*1 | Distilled water (DW) | 1.5 ml*1 | Detection primer (CN) | 200 µl*1 |
| | Control primer* | 40 µl*1 | | | Control primer* | 40 µl*1 |
| | Control template* | 40 µl*1 | | | Control template* | 40 µl*1 |
| | Distilled water (DW) | 1.5 ml*1 | | | Distilled water (DW) | 40 µl*1 |
| | | | | | | 1.5 ml*1 |
| | Individual tube | | Ready-to-use reagent | | Individual tube | |
| Volume | 100test/kit | | 96test/kit | | 100test/kit | |
| Retention period | 6 months from the date of manufacture *After opening 50 days | | | | | |

Isopollo® COVID-19 detection kit

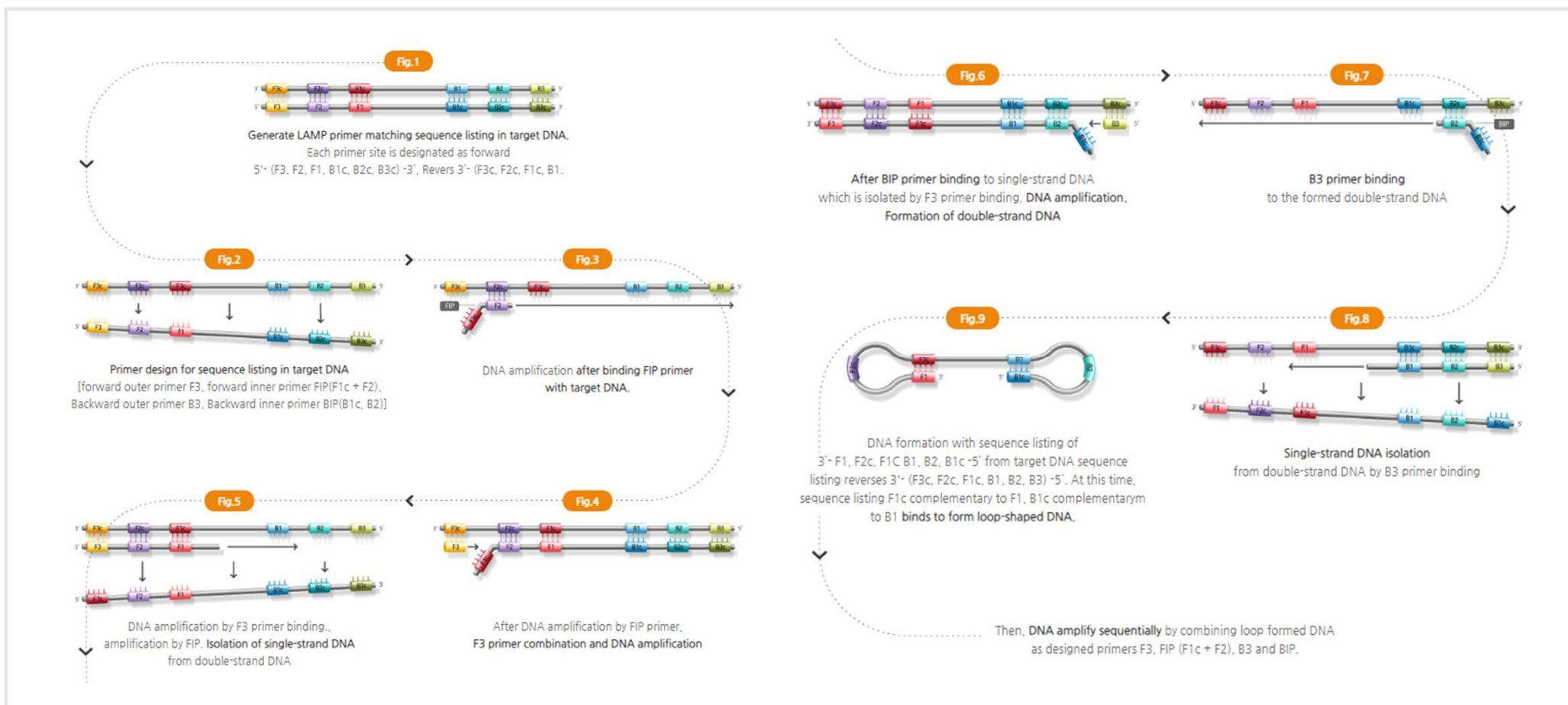


| Isopollo® COVID-19 detection kit (real-time) | Isopollo® COVID-19 detection kit (premix) | Isopollo® COVID-19 detection kit (colorimetric) | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|---|---------|--|---------|-----------|---|------|----------|----|--|------|--------|----------|--|--|------|-------|------|---|------|--------|---|------|-------|
| <p>*Conventional RNA extraction kit available.</p> | <p>SAMPLE EXTRACTION Cat. No. 92401, Mmaxpress® prep kit HA01</p> | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Reaction time</p> <table border="1"> <thead> <tr> <th>Amplification conditions</th> <th>Step</th> <th>Temp.</th> <th>Time</th> <th>Cycles</th> </tr> </thead> <tbody> <tr> <td rowspan="2"></td> <td>1</td> <td>58°C</td> <td>30 sec</td> <td>40</td> </tr> <tr> <td>2</td> <td>80°C</td> <td>2 min</td> <td>1</td> </tr> </tbody> </table> | Amplification conditions | Step | Temp. | Time | Cycles | | 1 | 58°C | 30 sec | 40 | 2 | 80°C | 2 min | 1 | <p>In case of Premix type,</p> <ul style="list-style-type: none"> Aliquoted Lamp premix = Primer + Enzyme mix + 2X Reaction Buffer Reaction time: 20~30 min | <p>Reaction time</p> <table border="1"> <thead> <tr> <th>Step</th> <th>Temp.</th> <th>Time</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>58°C</td> <td>30 min</td> </tr> <tr> <td>2</td> <td>80°C</td> <td>2 min</td> </tr> </tbody> </table> | Step | Temp. | Time | 1 | 58°C | 30 min | 2 | 80°C | 2 min |
| Amplification conditions | Step | Temp. | Time | Cycles | | | | | | | | | | | | | | | | | | | | | |
| | 1 | 58°C | 30 sec | 40 | | | | | | | | | | | | | | | | | | | | | |
| | 2 | 80°C | 2 min | 1 | | | | | | | | | | | | | | | | | | | | | |
| Step | Temp. | Time | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | 58°C | 30 min | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | 80°C | 2 min | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Confirm the result using of software</p> <ul style="list-style-type: none"> Positive criterion Ct value : within 40 Ct Negative criterion Ct value : No detection | <p>Confirm the result through visual colorimetric detection</p> <p>- Immediate check of infection through color change at medical site Negative result shows purple color, while positive shows sky blue.</p> <table border="1"> <thead> <tr> <th>Color code</th> <th>Color</th> <th>Judgement</th> <th>Example</th> <th>Judgement</th> </tr> </thead> <tbody> <tr> <td></td> <td>Blue</td> <td>Positive</td> <td rowspan="2"></td> <td rowspan="2">P: Positive (Blue) N: Negative (Purple)</td> </tr> <tr> <td></td> <td>Purple</td> <td>Negative</td> </tr> </tbody> </table> | Color code | Color | Judgement | Example | Judgement | | Blue | Positive | | P: Positive (Blue) N: Negative (Purple) | | Purple | Negative | | | | | | | | | | | |
| Color code | Color | Judgement | Example | Judgement | | | | | | | | | | | | | | | | | | | | | |
| | Blue | Positive | | P: Positive (Blue) N: Negative (Purple) | | | | | | | | | | | | | | | | | | | | | |
| | Purple | Negative | | | | | | | | | | | | | | | | | | | | | | | |

01 Kit Introduction



Main Technology – LAMP (Loop-mediated isothermal amplification)



Experimental

Result & interpretation

| RdRP | N | Diagnosis |
|------|---|--------------|
| + | + | Infected |
| + | - | Infected |
| - | + | Infected |
| - | - | Not Infected |

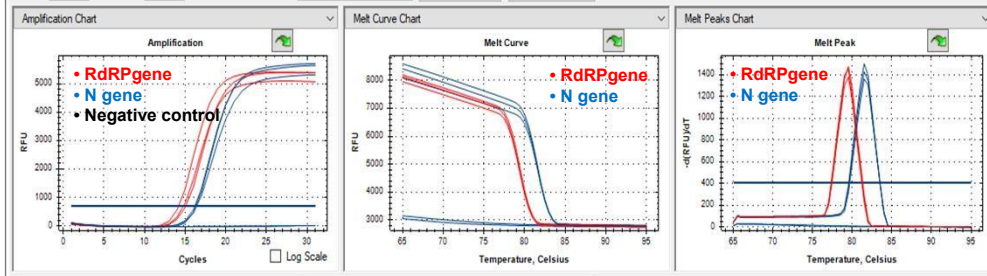
» It is considered that both RdRP and N gene are **positive**.

» Even if only one gene of two genes shows a positive, it is considered to be infected.

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

Confirm the result using of software

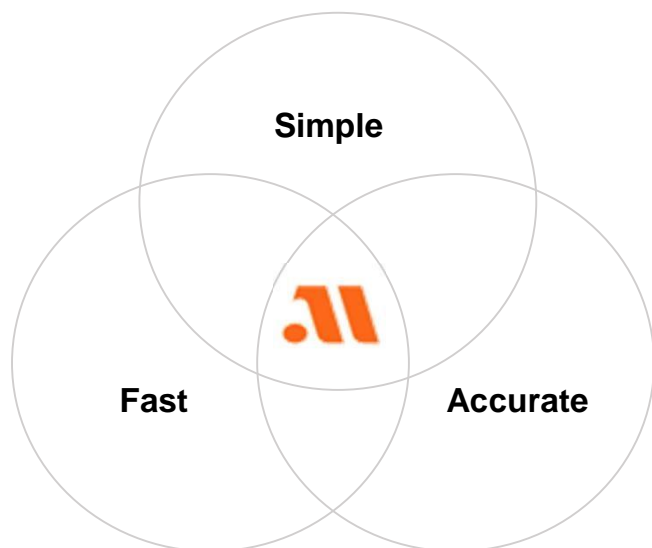
- Positive criterion **Ct value** : within 40 Ct
- Negative criterion **Ct value** : No detection



Characteristic of our products

Why to choose *M monitor*?

Higher specificity than conventional PCR, qualitative detection of RdRP and N gene



| | |
|--------------------|---|
| Rapid | Diagnosis within 1 hour (included extraction process) |
| Sensitivity | Detection up to 1 pg (Small amount of virus can be detected) *Higher sensitivity as domestic licensed/temporary permitted product |
| Accuracy | 99% of accuracy through qualitative analysis and 100% of specificity |
| POCT | Immediate diagnosis on site (Point-of-Care-Testing) |

- ✓ **Cost reduction** through simultaneous multiple sample tests
- ✓ Proper action and infection control through **rapid** diagnosis

01 Kit Introduction



Comparison of other products

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

| Spec. | A | B | C | D |
|---------------------------------|---|----------------------|-----------------|-----------------|
| Technology | Real-time PCR | Real-time PCR | Real-time PCR | Real-time PCR |
| Kit size | 50test/kit | 100test/kit | 100test/kit | 100test/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™) | | | |



| Real-time /Colorimetric | Premix |
|--|---|
| RT-LAMP | RT-LAMP |
| 100test/kit | 96test/kit |
| RdRP, N gene | RdRP, N gene |
| > 98% | > 98% |
| > 99% | > 99% |
| 20 min | 30 min |
| PCR performance | Color change |
| CFX-96 (Bio-Rad), ABI 7500 / 7500 (Applied Biosystems™) | MXM-L1 <small>*portable small isothermal amplifier by M monitor</small> |

M monitor Inc.

M monitor Inc., is one of the leading companies with high technologies based on nucleic acid isothermal amplification platform. 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 diagnosis methods.

| Item | Contents |
|--------------|---------------------|
| Company Name | M monitor |
| Address | , Republic of Korea |
| TEL | +971 562 277 797 |
| CEO | Hyosung Jeon |
| Employee | 24 |
| Foundation | 2014 |
| Homepage | |



02 Manufacturer



Certification List

인증번호(No.) : KTC-A88-0279

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)엠모니터/제 6004 호
M monitor Inc.

■ 대표자 (Representative)
전효성 (Hyo sung Jeon)

■ 업체 소재지 (Company address of Applicant)
대구광역시 달서구 상서공단로11길 62 633호, 222호(호산동, 대구용합알앤디센터)
Room No. 633 and 222, 62, Seongsongangdan-ro 11-gil, Dalseo-gu, Daegu, 42713, South Korea


■ 제조소명 (Name of Manufacturer)
제조사 : (주)엠모니터(Monitor Inc.)
■ 제조소 소재지 (Address of Manufacturer)
대구광역시 달서구 상서공단로11길 62 633호, 222호(호산동, 대구용합알앤디센터)
Room No. 633 and 222, 62, Seongsongangdan-ro 11-gil, Dalseo-gu, Daegu, 42713, South Korea

■ 품목군 (Category)
체외진단 의료기기용 시약류(Reagent for In-Vitro Diagnostic Device)
의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2019. 05. 19
유효기간(Date of Expiration) : 2022. 05. 18

대구지방식품의약품안전청
DAEGU REGIONAL FOOD AND DRUG ADMINISTRATION

한국기계전기전자시험연구원
Korea Testing Certification Institute



Certification of GMP

bsi. By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: M monitor Inc., Room No. 633 and 222, 62, Seongsongangdan-ro, 11-gil, Dalseo-gu, Daegu, 42713, Republic of Korea

Holds Certificate No: **MD 695193**
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:
Design, development and manufacture of In Vitro Reagents for Detecting Helicobacter pylori.

For and on behalf of BSI: *Stewart Brain*
Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-11-23 Effective Date: 2018-11-23
Latest Revision Date: 2018-11-23 Expiry Date: 2021-11-22

Page: 1 of 1

...making excellence a habit!

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated www.bsigroup.com
Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone +44 20 777 4123.
Information and Contact: BSI, Marton Court, Davy Avenue, Welwyn, Herts SG8 9NF, UK. Tel: +44 (0) 200 9000
BSI Assurance UK Limited, registered in England under number 7602023, at 389 Chiswick High Road, London W6 7LU, UK.
A Member of the BSI Group of Companies.

Certification of ISO13485:2016

제 6004 호


의료기기 제조업 허가증

- 업소명 : (주)엠모니터
- 소재지 : 대구광역시 달서구 상서공단로11길 62 633호, 1031호(호산동, 대구용합알앤디센터)
- 대표자(생년월일) : 전효성(1970년 10월 15일)
- 품질책임자(생년월일) : 한형수(1966년 03월 23일)
- 허가조건 :

「의료기기법」 제6조·제15조 및 같은 법 시행규칙 제3조·제29조에 따라 위와 같이 허가합니다.

2018년 03월 07일

대구지방식품의약품안전청



Medical device manufacturing license

www.mt-promed.com

MT Promed Consulting GmbH

Certificate of EU product notification

Herewith we confirm that

MT Promed Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

M monitor Inc.
Room No. 633 and 222, 62, Seongsongangdan-ro11-gil
Dalseo-gu
Daegu 42713
Republic of Korea

MT Promed Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex 1 of this certificate.

05 November 2019

Dr. Michael Rinck
Dr. Michael Rinck
- Managing Director -

Enclosure Annex 1



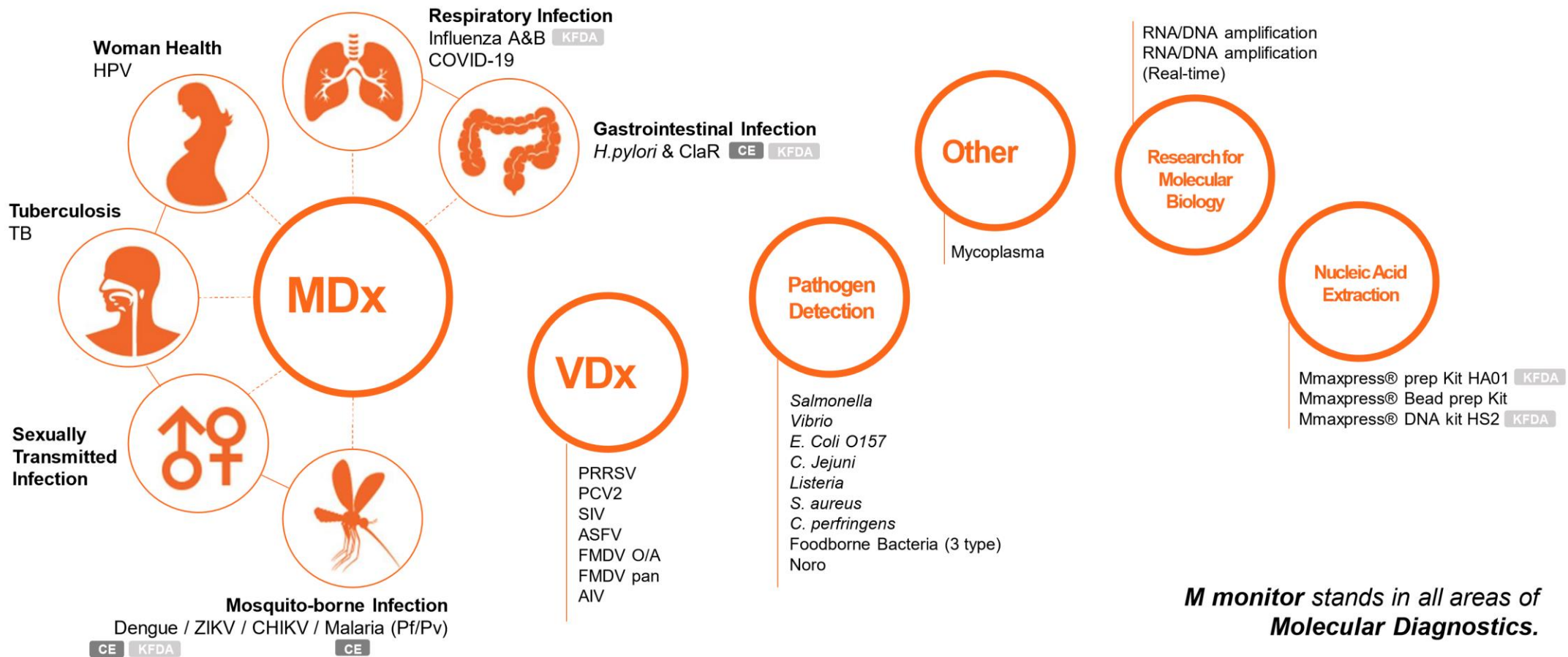
Certification of EU

Certification List

▼ Status of Global Licensing

| | Code | Class | Product Name | Permission / Certification |
|------------------------------|-------------------------------------|--------|---|----------------------------|
| CE-IVD | In Vitro Diagnostic Medical Devices | Others | Isopollo® COVID19 detection kit (real-time) | Complete |
| CE-IVD | In Vitro Diagnostic Medical Devices | Others | Isopollo® COVID19 detection kit (premix) | Complete |
| Free Sale Certificate | In Vitro Diagnostic Medical Devices | Others | Isopollo® COVID19 detection kit (real-time) | Complete |
| Free Sale Certificate | In Vitro Diagnostic Medical Devices | Others | Isopollo® COVID19 detection kit (premix) | Complete |
| CE-IVD | In Vitro Diagnostic Medical Devices | Others | Isopollo® Dengue test kit | Complete |
| CE-IVD | In Vitro Diagnostic Medical Devices | Others | Isopollo® <i>H.Pylori</i> & ClaR | Complete |
| CE-IVD | In Vitro Diagnostic Medical Devices | Others | Isopollo® Malaria (Pf/Pv) detection kit | Complete |
| Peru(DIGEMID) | In Vitro Diagnostic Medical Devices | C | Isopollo® <i>H.Pylori</i> & ClaR | In progress |
| India(CDSCO) | In Vitro Diagnostic Medical Devices | C | Isopollo® Dengue test kit | In progress |
| India(CDSCO) | In Vitro Diagnostic Medical Devices | C | Isopollo® Malaria (Pf/Pv) detection kit | In progress |

Diagnostics Kits Line



M monitor stands in all areas of Molecular Diagnostics.

2.4 M monitor Global activities



RT-LAMP

In the case of general COVID-19 diagnostic kits take about 2 to 6 hours to check the result, while **M monitor uses an innovative technology that can check the result within 1 hour.**

This method is specifically advantageous because it can all be done quickly in **one step**. The sample is mixed with the primers, reverse transcriptase and DNA polymerase and the reaction takes place under a constant temperature. There is no need for expensive thermocycling equipment that is necessary for other methods like PCR, which makes RT-LAMP **very cost effective**. In contrast with conventional PCR and real-time PCR assays, this method is much more efficient while still obtaining a high level of precision. Also, the LAMP method has **High specificity** because of designed specific primers to be compatible with the target RNA.

This diagnostic test product, used to confirm COVID-19 need a diagnostic laboratory, a specialist, a laboratory that can handle clinical samples, and a PCR test equipment (Real-Time qPCR machine) in a large hospital or specialized testing center. **Sensitive and specificity** that only detects COVID-19 are detailed in the product introduction.

*Examination time varies according to the inspection equipment status, experts and proficiency of the hospital.

Frequent Q&A

1) Commercial Prices in other export countries

- Our policy is based on Korea FOB in all countries for export.

*Shipping fee is responsible by the importer.

2) Packaging unit and weight

- Box size (1 kit) : 26cm * 26cm * 27.5cm (6 kg)

*Packing stability evaluation was safe up to 5 days when we shipped in ice pack packaging.

*Packing box size will be change depending on order quantity.

3) Minimum Order Quantity

- MOQ (Minimum Order Quantity) is 50 kits per order.

4) Payment terms

- Buying Immediately : 100% T.T Advance Payment

- Booking in weekly base : 50% Deposit (Basis on Min. 1,000kit) Before 1 ~2week

5) Production Capacity in Manufacturer, Korea

- 30,000 Test / day

6) Product storage condition

- Required refrigeration (-15°C~-20°C)

Frequent Q&A

7) Storage expiration length

- Validity 1 year from date of manufacture (real-time)
- Validity 6 month from date of manufacture (premix)

8) Kit specification

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

- Kit Box Size : 8.5cm * 7.5cm * 8cm
- Kit Unit : 100 Test/kit
- Required Instrument for COVID-19 kit : Conventional PCR Machine
 - a) Bio-Rad, CFX-96 system
 - b) Applied Biosystems™, 7500 Real-Time PCR Instrument System
 - c) Applied Biosystems™, 7500 Fast Real-Time PCR Instrument System

* Isopollo® COVID-19 detection kit (premix/colorimetric)

- Kit Box Size : 16.5cm * 10cm * 11.5cm
- Kit Unit : 96 Test/kit (2pcs/set)
- Required Instrument for COVID-19 kit : portable small isothermal amplifier from M monitor
 - a) M monitor, Inc., MXM-L1 (Nucleic acid amplifier-isothermal condition only)
 - b) M monitor, Inc., MXM-F1 (Nucleic acid amplifier-isothermal condition and end-point PCR is available)

Frequent Q&A

9) Time to extraction result

- You can check the result in about 30 minutes.

10) Specimens

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum
- Bronchoalveolar lavage

Selling Point (only for Sales)

1) Diagnostic Kit Accuracy (More than 99%)

- Sensitivity : Small amount of virus can be detected up to 1 pg using this product.
- Specificity : It has 100% specificity for targeted RNA because 6 primers selectively detect specific genes (RdRP / N gene) of SARS-CoV-2.
- Feature
 - a) Multiple simultaneous detection of specific genes (RdRP / N gene)
 - b) Accurate qualitative analysis
 - *The advantages of both immuno-chemical diagnosis and molecular diagnosis methods.
 - c) Rapid diagnosis of prompt confirm the result and proper action and infection control

2) The efficiency of RT-LAMP diagnosis

- Cost reduction through simultaneous multiple sample tests
- 99% of accuracy and 100% of specificity
- Accurate qualitative analysis
- Proper action and infection control thorough rapid diagnosis
- Positive/Negative control included for clearly check the result

3) Common Use

- Conventional RT-PCR equipment can be used for diagnosis.

Comparison of COVID-19 Test Method

| Spec. | Immune diagnosis | | Molecular Diagnostics (Biochip, Biosense, PCR) | |
|-----------------------------------|---|--|--|---|
| Method of inspection | Antigen Diagnosis | Antibody Diagnosis | PanCorona Virus Test | COVID 19 Detection Test |
| Inspection Equipment | Antigen Diagnostic Kit | Antibody Diagnostic Kit | Real-time PCR | Real-Time RT PCR |
| Pathogen | Corona 19 Detection (Low accuracy / sensitivity) | Corona 19 Detection (Low accuracy / sensitivity) | Whole Corona Virus Detection | Corona19 Detection |
| Accuracy | 50~85% | 50~85% | 80~95% | 95~99% |
| Inspection Difficulty | Low | Low | High (High false positive rate) | Middle |
| Corona19 Diagnostic Method | Put a runny nose or sputum in the kit and check for the presence of N protein of Corona 19 (Not likely to respond within 10 days of onset) | Antibodies (IgG , IgM) to defend against the viral antigens of Corona 19 through the blood Check for infection by presence (Likely not responding within 10 days of onset) | 1) Nucleic Acid Extraction 2) Conventional RT PCR 3) Electrophoresis 4) Transfer CDC at the first positive decision 5) Request for Gene Sequence Analysis 6) Confirmation of final positivity | 1) Nucleic Acid Extraction 2) Real-Time RT-PCR 3) Pathogen Identification 4) Confirmation of Positive Status |
| Diagnostic time | 10~40 mins | 10~40 mins | 1~2 days | 4~6 hours |
| Modification | Easy Kit Development | Easy Kit Development | Sequencing / Genotyping DNA amplification for cloning | - Quantitative Analysis of Gene Expression - Pathogen detection - Virus Quantitative Analysis |
| Feature | Low response early in infection Inadequate for infectious disease confirmation | RT-PCR test required for final confirmation | Complementary measures until development of the diagnostic kit | Specialized Kit for corona19 confirmation (WHO recommended) |

* This information is an unofficial data compiled internally by Medi & Korea to help local distributors understand.



03 Sales Information

Selling Point (only for Sales)

| Cat. No. | Item | Description | Unit | Original Size | Sample Size | Sample Qty |
|----------|------|-------------|------|---------------|-------------|------------|
|----------|------|-------------|------|---------------|-------------|------------|

| | | | | | | |
|-------|--|--|----------|------|-----|-------|
| 52225 | Isopollo® COVID-19 detection kit (colorimetric) | <p>Isothermal amplification-based assay system for detection of COVID-19.</p> <p>- Check for accurate qualitative result within short reaction time and visually confirm through color change.</p> <p>*It can be checked the result (infected or not) with simple process without expensive equipment in the field.</p> | 1 Kit | 100T | 25T | 1 Kit |
| 52226 | Isopollo® COVID-19 detection kit (premix) – RdRP gene, N gene COVID-19 detection kit (premix) consists of 2 boxes (1 set). One is for detection RdRP gene and another is N gene. | <p>Isothermal amplification-based assay system for simultaneous detection of COVID-19 using ready-to-use lamp premix reagent. - Fast and simple checks for infection through color changes on medical site.</p> <p>*It can be checked the result (infected or not) with simple process without expensive equipment in the field.</p> | 1 Kit | 96T | 24T | 1 Kit |
| 52227 | Isopollo® COVID-19 detection kit (real-time) | <p>Real-time LAMP based assay system for detection of COVID-19.</p> <p>- Check for accurate qualitative result within short reaction time of about 20 minutes.</p> <p>*It will be more appropriate for places such as large hospitals and laboratories equipped with experimental equipment.</p> | 1 Kit | 100T | 25T | 1 Kit |
| 92401 | Mmaxpress® prep kit HA01 | Rapid preparation of DNA from nasal swab sample for nucleic acid extraction kit. | 1 Kit | 13T | 13T | 2 Kit |
| 82302 | MXM-F1 | Compatible PCR and Isothermal mode. 25 wells for 0.2ml PCRTubes.8 different MXM-F1 can be controlled by a single laptop. | - | EA | - | - |

| | | | | | | |
|-------|---------------|--|---|----|---|---|
| 82303 | MXM-L1 | Isothermal amplification only. 8 wells for 0.2ml PCR tubes. Compact sized, mobile phone control, and battery pack available for on-site diagnostics. | - | EA | - | - |
|-------|---------------|--|---|----|---|---|



Thank you

