



Pathogen Gene Isothermal Amplification On-site Diagnosis Technology

Technology / Lamp based diagnosis with a POCT-oriented device

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Patent title Novel primer set for MERS Corona virus detection using LAMP and use thereof

Inventor Korea Food Research Institute / Maeng Jinsu and two more

Patent application No. KR 10-2019-0047625 (2019.04.24)

Authority status Registered

Technicality

📌 Technology overview

- A technology related to a kit by which infectious diseases such as MERS and Covid-19 viruses can be quickly diagnosed by using a primer set for a ring-mediated isothermal amplification (LAMP) reaction, a MERS Corona virus detection novel primer set using LAMP for detection using the same, and a use thereof
- A technology which is highly useful in responding to pandemics due to infectious diseases as viruses can be thereby detected immediately, very simply, easily, and quickly on site without expensive equipment

📌 Development background and problem to be solved

- Since PCR, which is the basis of an existing genetic testing method, a change is needed in three temperature steps that are denaturation, annealing, and extension. Thus, a longer reaction time is needed. Also, expensive equipment is required to achieve a temperature cycle, and thus there is a difficulty in terms of field adaptation.
- MERS Corona viruses can be specifically detected by a primer set using LAMP.

📌 Excellence and discrimination of technology

▶ Excellence of technology

- A practical on-site diagnosis and primary inspection in a laboratory are possible with superior economical efficiency (costs up to 1/100) compared to conventional ones.
- The verification of a LAMP gene isothermal amplification technology targeting various Corona viruses and food poisoning viruses has been completed.
- A colorimetric detection method which enables convenient confirmation of results with ensured reliability and simplicity has been developed.
- A self-diagnosis is possible with low-cost equipment, low reaction costs, and a colorimetric detection method which a non-expert can identify on the basis of gene isothermal amplification.

▶ Discrimination of technology

- The technology is a diagnostic technology which can be applied quickly only by producing a primer, when an infectious disease and a variant thereof appear. (An immunodiagnosis takes a long time to develop.)
- The technology is a gene-based rapid diagnostic technology for laboratories and fields and enables detection of variants such as Covid-19.
- Diagnoses can be performed repeatedly multiple times in a rapid diagnosis time (within 30 minutes) and with low costs.
- Rapid repeat diagnostic tests and self-diagnoses are possible in a front-line field and a quarantine area.



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Implementation method

- A primer set for reaction using LAMP is composed of SEQ ID NOs: 1 to 6 for amplifying Nsp1 genes or SEQ ID NOs: 7 to 12 for amplifying Orf5 genes.
- A template including cDNA synthesis with a nucleic acid (RNA) extracted from a separated sample is mixed with a primer set, and a LAMP reaction solution is included, so that the formation of an amplification product according to LAMP during an isothermal amplification reaction at 60-72°C is confirmed. Thus, MERS Corona viruses are detected.

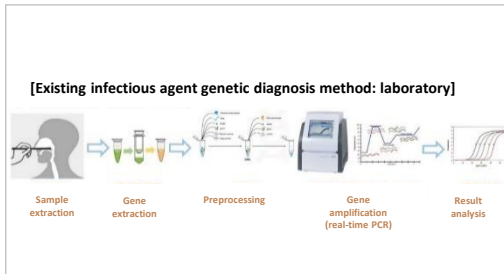


Figure 1 Existing infectious agent genetic diagnosis method: laboratory

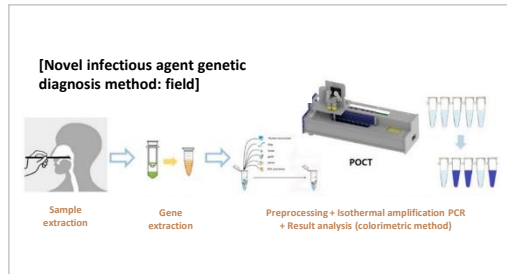


Figure 2 Novel infectious agent genetic diagnosis method: field

Degree of technology completion (TRL)

Degree of technology completion: TRL4 (Lab Scale prototype development stage)

TRL1	TRL2	TRL3	TRL4	TRL5	TRL6	TRL7	TRL8	TRL9
Technical principle presentation	Technology concept setting	Technology concept verification	Lab Scale prototype development	Implementation environment application experiment	Full Scale prototype development	Quasi-commercial product development	Commercial product development	Commercial product implementation

Utilization

Utilization field and applied product

Utilization field

- Field medical facility
- Diagnostic medical device
- Diagnosis of infectious diseases



Figure 1 Laboratory rapid inspection

<Data: Researchers at Johns Hopkins, ENDOCRINOLOGY NETWORK>

Applied product

- Laboratory rapid inspection
- Field diagnosis



Figure 2 Field diagnosis

<Data: Infectious Disease Management Committee >



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Technology trend

- With the emergence of new diseases and the prevalence of infectious diseases, the importance of an early diagnosis has increased. Thus, a medical paradigm is shifting towards diagnoses and prevention. Also, the pace of change is accelerating with the development and convergence of diagnostic and analytical technologies.
- With the recent emergence of Corona viruses and new infectious diseases such as MERS and COVID-19, R&D and application activities for virus diagnosis technologies are expected to be active.
- Recently, in the field of molecular diagnostic equipment, the size of the equipment has been reduced due to MEMS technologies and the like. Also, a digital PCR platform capable of performing linear quantitative detection of a result is applied, and an NGS technology is grafted thereonto. Thus, a rapid and accurate diagnosis can be performed at low costs when detecting pathogens such as bacteria or viruses.
- A LAMP technology among isothermal amplification technologies developed by Eiken, TwistDX, OptiGene, Diagnostics for the Real World, etc. is applied, so that a diagnosis is possible within 60 minutes and the turbidity or fluorescence signal of a solution is diagnosed according to a reaction in real time.

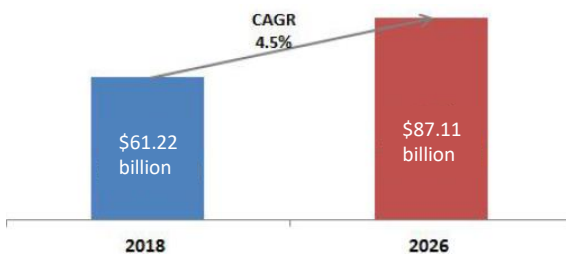
Family patent status

Application nation	Application No. (Application date) / Registration No.	Title of the invention
KOR	KR 10-2019-0047625 (2019.04.24) / KR 10-2133995	Novel primer set for MERS Corona virus detection using LAMP and use thereof

Market prospect

Target market size and prospect

- The global in vitro diagnostic market is expected to grow at a CAGR of 4.5% from USD 61.22 billion in 2018 to USD 87.11 billion in 2026 due to the adoption of new technologies for rapid disease diagnoses.
- The global molecular diagnostic market is expected to grow by 4.7% from 2015 to 2023.
- The molecular diagnostics market in ROK is expected to grow at a CAGR of 14.3% from KRW 174 billion in 2018 to KRW 334.5 billion in 2023.



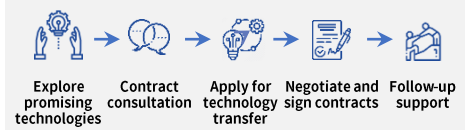
Technology classification (unit: million dollars)	2015	2016	2017	2018	2023	CAGR(%)
Molecular diagnosis	15,102.4	15,962.6	16,656.8	17,507.6	22,034.5	4.7
Immunochemistry	10,096.3	10,591.6	11,119.4	11,684.8	14,869.6	4.7
Field diagnosis (POCT)	6,912.2	7,313.0	7,744.4	8,209.1	10,777.7	5.6
Blood diagnosis	5,292.1	5,547.6	5,820.8	6,113.4	7,664.2	4.6
Clinical microbiological diagnosis	4,212.1	4,405.2	4,611.4	4,831.9	5,987.6	4.4
Organizational diagnosis	4,212.1	4,412.5	4,626.7	4,856.0	6,067.5	4.6
Self blood glucose measurement	3,240.1	3,419.2	3,611.7	3,818.6	4,949.8	5.3

Table Global market trends related to in vitro diagnostic market [million dollars]

<Data: In Vitro Diagnostics/IVD Market, MARKETSDATA, 2018>

Technology transfer query

Technology transfer process



Explore promising technologies → Contract consultation → Apply for technology transfer → Negotiate and sign contracts → Follow-up support

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