



Cell-free-based pathogen field diagnosis technology

Technology / diagnosis technology for the detection of pathogens based on cell-free system



Patent title Cell-free system for diagnosing Middle East respiratory syndrome virus and method for using same

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Patent application No. KR 10-2018-0107086 (2018.09.07)

Authority status Registered

Technicality

Technology overview

- A diagnostic sensor technology using a switch RNA technology which can detect viruses and a cell-free system solution which enables protein expression on paper, glass, or the like
- A technology which enables an easy multiplex operation because, when the genome sequence of a new or mutated virus is revealed, it is possible to rapidly produce a sensor on the basis of sequence information and the technology can be applied to various platforms such as not only paper but also 96 wells and the like

Development background and problem to be solved

- The technology is obtained by fusing a cell-free protein synthesis technology and an RNA diagnostic switch RNA technology to diagnose viruses and bacteria. The technology has the advantage of low costs for pathogen detection. Sensitivity is low compared to PCR, and protein solubilization, refolding, and activation processes should be performed, and thus an execution time is long.

Excellence and discrimination of technology

Excellence of technology

- A switch RNA diagnostic sensor has excellent price competitiveness compared to gene-based diagnostics such as PCR.
- A faster diagnosis time (about 2 hours) compared to an existing diagnosis time (6 hours or 1 day) can be achieved.
- Multiple parts can be simultaneously diagnosed with one diagnosis, and not only a virus diagnosis but also a bacterial identification diagnosis can be applied.

Discrimination of technology

- The technology is suitable for an on-site diagnosis technology because it is possible to build a rapid, low-cost, and non-professional self-diagnosis system.
- An identification diagnosis of pathogenic bacteria can be applied at the time of visiting an emergency room due to an infectious disease such as sepsis.
- The technology helps patients administer appropriate antibiotics.



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Implementation method

- Middle East respiratory syndrome virus-specific RNA is recognized by a ribo-regulator sequence, and the Middle East respiratory syndrome virus-specific RNA includes one or more ribo-regulators selected from SEQ ID NOs: 1-5.
- A vector expresses a ribo-regulator and further includes a reporter gene for detecting the ribo-regulator, and the reporter gene is selected from eGFP, mNeonGreen, Ypet, SYFP, mScarlet-1, mCherry, luciferase, and lacZ.

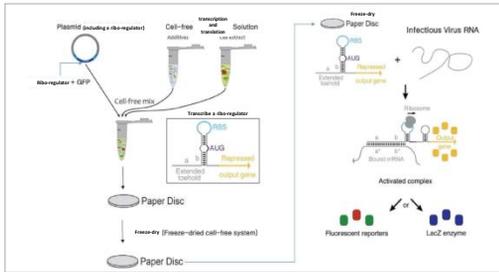


Figure 1 Cell-free system conceptual diagram

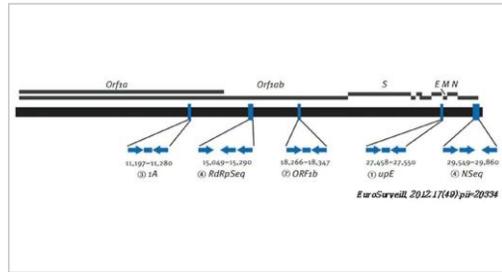


Figure 2 Candidate sites for MERS-CoV diagnosis

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

- Virus diagnosis
- Bacteria identification



Figure 1 Virus field diagnosis

<Data: Z Biotech Inc.>

Applied product

- Virus field diagnosis
- Bacteria identification diagnosis

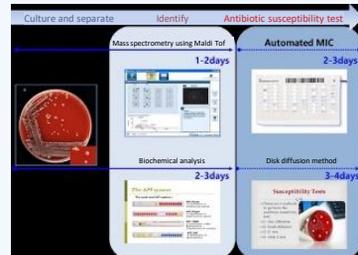


Figure 2 Bacteria identification diagnosis

<Data: Dailyvet>



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Technology trend

- As the introduction of a preventive medical technology is expanding worldwide, government-level initiatives for promoting early diagnosis technologies and services have increased, and the importance of a single cell analysis technology is highlighted.
- A single cell analysis used for a disease diagnosis and monitoring by performing rapid, accurate, and effective tests has recently been actively used in diagnoses and health management, and is being utilized in various diagnostic fields such as genetic analyses, prenatal screening, anticancer drug development, and neurotherapy. Thus, R&D and application activities for single cell analysis technologies are expected to increase.
- Thermo Fisher Scientific of the United States has a technology which utilizes fluorescence imaging for single cell visualization by performing various functions such as cell culture, protein analyses, and multi-channel fluorescence imaging.
- Quiagen N.V. of Germany has a technology which is used for RNA sequencing of single cells, next-generation sequencing (NGS), and library production.

Family patent status

Application nation	Application No. (Application date) / Registration No.	Title of the invention
KOR	KR 10-2019-0073486 (2019.06.20) / KR 10-2222646	Ribo-regulator for diagnosis of foot-and-mouth disease viruses, and use thereof

Market prospect

Target market size and prospect

- The global single cell analysis market accounted for USD 1.7 billion in 2017, and is expected to reach USD 5.9 billion by 2025, growing at a CAGR of 17.6% (2014-2025).
- The comparison of the global market size by region is as follows: North America 36.6% (USD 600 million), Europe 28.4% (USD 470 million), Asia Pacific 17.8% (USD 300 million), Latin America 13.2% (USD 220 million), and Middle East & Africa 3.9% (USD 0.7 billion). The U.S. and Europe account for the majority with more than 70%. However, the market growth rate in the Asia-Pacific region is high, and the market is expected to expand rapidly.

(Unit: million dollars)



Region	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
North America	384	448	521	604	701	811	936	1,079	1,241	1,426	1,634	1,870
Europe	289	340	400	470	551	646	755	881	1,027	1,195	1,388	1,610
Asia Pacific	163	199	243	295	358	433	522	629	756	907	1,086	1,296
Latin America	125	151	182	219	263	316	378	452	539	642	763	905
Middle East & Africa	39	46	55	65	77	90	107	126	148	174	204	239
Total	999	1,184	1,400	1,653	1,949	2,295	2,698	3,167	3,711	4,343	5,074	5,920

Table Global market trends related to the single cell analysis market [million dollars]

<Data: Single Cell Analysis Market(Grand View Research), 2018.4>

Technology transfer query

Technology transfer process

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