

[Reporter Park Ji-hoon's search for unlisted company gems] Orange Biomed's glycated hemoglobin measurement possible with one drop of blood

Reporter Park Ji-hoon parkjh@mk.co.kr

Input: 2025-01-20 18:10:09 correction : 2025-01-20 18:11:47

Targeting the global 500 million diabetic market



Diabetes is a typical chronic disease that affects more than 500 million patients worldwide. In the early stages, there are no clear symptoms, but if left untreated, complications and treatment burdens increase exponentially. Therefore, diabetes management goes beyond simply measuring blood sugar levels every day; a 'glycated hemoglobin (HbA1c)' test that reflects the average blood sugar level over a certain period (2-3 months) is essential. Using the glycated hemoglobin index, blood sugar fluctuations can be identified from a long-term perspective, making it easier for patients or medical staff to establish mid- to long-term treatment

strategies. The problem is that this glycated hemoglobin test has been difficult for ordinary people to access at home due to many limitations, such as hospital visits, blood collection by skilled professionals, and protein reagent management that requires refrigerated distribution and management. Orange Biomed (Representatives Koh Woong-hyun and Park Ye-seul) has come up with an innovative solution that can completely change this existing diagnostic system. The 'OBM rapid A1c' they developed utilizes microfluidics technology, breaking away from the existing method. With just one drop of blood, you can quickly and accurately measure your glycated hemoglobin levels without any reagent preparation or complicated management.



Representatives Koh Woong-hyun and Park Ye-seul

An Orange Biomed official explained, “We achieve high accuracy by observing and analyzing each red blood cell as a single cell within a microfluidic channel.”

You can get tested without going to the hospital

Orange Biomed aims to change the diabetes management paradigm under the mission of 'making it easy and accurate for anyone to measure glycated hemoglobin'. The traditional method of glycated hemoglobin testing required a complex preprocessing process and professional skills because it used a protein quantification method. In addition, there were many limitations such as refrigerated distribution and storage of reagents, periodic instrument zero point adjustment (calibration), and the investment of professional personnel to secure accurate blood volume.

On the other hand, 'OBM rapid A1c' is the world's first to implement advanced microfluidic technology to measure glycated hemoglobin levels without protein reagents. One drop of blood is enough, and accurate measurements are possible without device maintenance. It lowers the high entry barrier of existing testing methods, opening the way for easy use by individual users and primary medical institutions. For general users, the most attractive thing is that they can obtain glycated hemoglobin levels in a few minutes without going to the hospital.

A medical industry insider explained, "If we can check key indicators for diabetes management at any time, it will obviously be of great help in preventing complications and establishing treatment strategies."

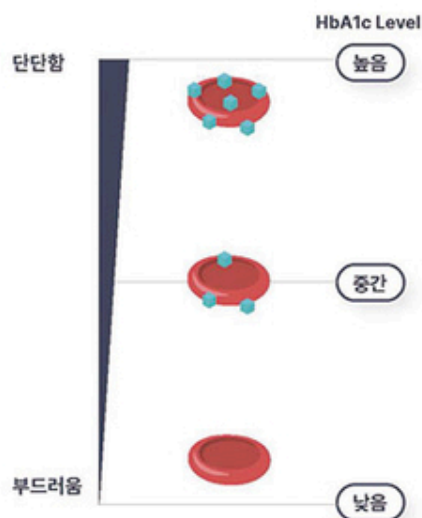
Unlike conventional glycated hemoglobin tests, OBM rapid A1c does not use protein reagents. This means that it is not only free from refrigeration distribution and storage issues, but also does not require difficult maintenance tasks such as periodic zero point adjustment of the equipment itself. Since it does not require elaborate management of blood collection volume, it can be easily used by general users and primary care institutions. Another advantage is that it can reduce dependence on professional manpower and achieve efficiency in terms of test costs and time. This device can shine even more in areas with insufficient medical infrastructure or where there is high demand for remote medical care.

Behind this technology development, excellent human resources are deployed. Orange Biomed was founded in 2021 by five co-founders with master's and doctoral degrees from world-class academic institutions such as Duke University,

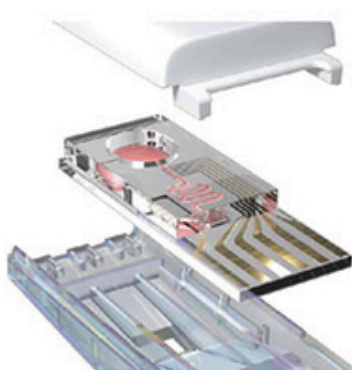
KAIST, and Seoul National University. They combined expertise in various fields such as biotechnology, medical engineering, microfluidic technology, quality control, and production technology. Currently, about eight team members are dedicated to management, research and development, production, and quality control.

KHF Innovation Award and Participation in Global Exhibition

당화혈색소의 생리학적 특징



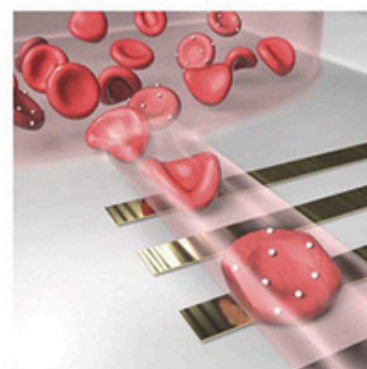
미세 유체 기술



→ 적혈구의 강성 측정

→ 당화혈색소 수치 계산

단일 세포 분석 기법



· 개별 적혈구가 미세유체관을 지날 때 입출구 미세전극에서 전기적 저항 값의 변화를 감지

→ 수 천개 이상의 적혈구 분석

Orange Biomed's innovation is attracting attention both domestically and internationally. In 2024, the company won the 'Innovation Award' for OBM rapid A1c at the 'KHF Innovation Awards' hosted by the Korean Hospital Association. This award is given to companies that have contributed to improving the medical environment with innovative medical industry technologies and services, and the new glycosylated hemoglobin measurement paradigm established by Orange Biomed has been recognized by the domestic medical industry. In addition, Orange Biomed was selected as an innovative startup by the Diabetes Technology Society (DTS) in the United States and was invited to the 'Diabetes Technology Meeting (DTM)' to be held in San Francisco, USA in October 2024. At this event, Orange Biomed presented its latest research results and directly demonstrated OBM rapid A1c, leaving a deep impression on global medical device market players. In addition, it is participating in

the startup park of MEDICA, the world's largest medical device exhibition held in Germany, further expanding its possibilities for advancing into the global market.

Successfully attracted a total investment of 8.1 billion won including Series A

Orange Biomed has achieved the feat of attracting over 8.1 billion won in cumulative investment in just four years since its establishment. In particular, it has secured an additional 3 billion won in the recently completed Series A1 investment round, stably securing the funds necessary for growth.

The funds secured through this investment will be focused on commercializing the product and preparing for US FDA approval. FDA approval is one of the gateways to entering the global medical device market and is a necessary procedure for selling products in the US market. Orange Biomed plans to transform into a company that meets international standards through clinical trials and certification, strengthening the quality management system, and establishing local marketing strategies during this process.

CEO Koh Woong-hyun said, “Thanks to this investment, we will be able to accelerate commercialization and FDA approval,” and “We are thoroughly preparing to enter the U.S. market.”

Targeting the US market, moving towards dominating the global stage

It is no coincidence that Orange Biomed is targeting the US market as its main target. The US is a market with relatively low access to healthcare and high healthcare costs, which creates a high demand for portable medical devices that can diagnose and manage themselves. In particular, the glycated hemoglobin test is becoming increasingly important, as the American Diabetes Association (ADA) has designated it as a top priority for diabetes diagnosis in its 2024 guidelines. Many believe that this will further solidify the demand for simple yet accurate devices such as the 'OBM rapid A1c'.

The company has already established a subsidiary in Seattle, has a team in the U.S., and is working on local market development and FDA approval preparations. In addition, it has confirmed its participation in the 'Eureka Park' of the global IT and home appliance exhibition CES to be held in January 2025, and has completed preparations to reveal its presence in the global market as an innovative healthcare device. As CES Eureka Park is a stage where many global technology innovation startups participate, the partnerships and recognition secured here are expected to be a great help in the U.S. entry strategy.

2025, another year of challenge

In preparation for the future, the company plans to expand its recruitment of talents such as licensing experts, strategy officers, marketing sales directors, and PhD-level researchers by 2025. This is also a stepping stone for a period of global expansion. Now, beyond simply attracting attention for its innovative technology, the company is preparing to implement a corporate operation strategy that will establish and proactively sell the technology in various global markets and increase brand value.

To this end, Orange Biomed plans to raise additional funds by holding a small Series A2 round in early 2025. A company official said, "Once the clinical trials for FDA approval are completed, we will proceed with Series B in earnest and begin building a large-scale mass production system."

In order to enter the US market, establishing a mass production system requires corporate capabilities in various aspects such as quality stabilization, cost reduction, and supply chain management. To this end, Orange Biomed has already gained experience on the international stage through participation in Germany's MEDICA, the US's DTM, and CES Eureka Park, and has laid the foundation for overcoming this complex process by preparing for the FDA approval process.

In the global market, diabetes is not a simple disease, but can be classified as a 'lifestyle management area' that requires continuous management. The number of

diabetes patients is expected to increase in the future due to the increase in average life expectancy, westernized eating habits, and the increase in the obese population. In diseases that require such long-term management, accurate and convenient diagnosis and monitoring technology are emerging as key values. This is why Orange Biomed's OBM rapid A1c is evaluated as precisely targeting this trend.

CEO Park Ye-seul said, "We will open an era in which the 500 million diabetics around the world can use accurate glycated hemoglobin measurements to reduce their fears in preventing complications."

[Reporter Park Ji-hoon]

[This article is from Maeil Kyungjae LUXMEN No. 172 (January 2024)]